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

**Post-Effective Amendment No. 1
to
FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933**

PIERIS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Nevada
(State of Incorporation)

8731
(Primary Standard Industrial
Classification Code Number)

EIN 30-0784346
(IRS Employer
Identification No.)

**255 State Street, 9th Floor
Boston, MA 02109
United States
1-857-246-8794**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

**Stephen S. Yoder
255 State Street, 9th Floor
Boston, MA 02109
United States**

(Name, address, including zip code, and telephone number, including area code, of agent for service)

With copies to:

**William C. Hicks, Esq.
Marc D. Mantell, Esq.
Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.
One Financial Center
Boston, Massachusetts 02111
(617) 542-6000**

Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box. ☒

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the

Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

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 ☒

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

Explanatory Note:

This Post-Effective Amendment No. 1 to the Registration Statement on Form S-1 (File No. 333- 202123) (the “Registration Statement”) of Pieris Pharmaceuticals, Inc. (the “Company”) is being filed pursuant to the undertakings in Item 17 of the Registration Statement to update and supplement the information contained in the Registration Statement as originally declared effective by the U.S. Securities and Exchange Commission (the “SEC”) on May 11, 2015, to (i) include the information contained in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2015 that was filed with the SEC on March 23, 2016 and (ii) to update certain other information in the Registration Statement. This Post-Effective Amendment No. 1 is also being filed to deregister 9,339,765 shares of the Company’s common stock that have been sold under the Registration Statement. For this reason, this Post-Effective Amendment No. 1 only includes 17,982,105 shares of the Company’s common stock registered under the Registration Statement.

No additional securities are being registered under this Post-Effective Amendment No. 1. All applicable registration fees were paid at the time of the original filing of the Registration Statement.

[Table of Contents](#)

The information in this prospectus is not complete and may be changed. The selling stockholders may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED April 14, 2016

PROSPECTUS

PIERIS PHARMACEUTICALS, INC.

17,982,105 Shares of Common Stock

This prospectus relates to the offering and resale by the selling stockholders identified herein of up to 17,982,105 shares of common stock, par value \$0.001 per share, of Pieris Pharmaceuticals, Inc. Of the shares being offered, 17,439,745 are presently issued and outstanding and 542,360 are issuable upon exercise of common stock purchase warrants. These shares include an aggregate of (i) 4,967,202 shares of common stock issued and sold to accredited investors in a private placement offering in a series of closings on December 17, 2014, December 18, 2014 and December 23, 2014, or the Private Placement, (ii) 12,472,543 shares of our common stock issued to former stockholders of Pieris Pharmaceuticals GmbH (formerly known as Pieris AG) in connection with the closing of a share exchange transaction on December 17, 2014, and (iii) 542,360 shares of common stock issuable upon exercise of common stock purchase warrants issued to Northland Securities, Inc. and Katalyst Securities, LLC, as co-exclusive placement agents, or the Placement Agents, and their designees in connection with the Private Placement. All shares of common stock issued in the Private Placement were sold at a purchase price of \$2.00 per share.

The selling stockholders may sell the shares of common stock on any national securities exchange or quotation service on which the securities may be listed or quoted at the time of sale, in the over-the-counter market, in one or more transactions otherwise than on these exchanges or systems, such as privately negotiated transactions, or using a combination of these methods, and at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale, or at negotiated prices. See the disclosure under the heading “Plan of Distribution” elsewhere in this prospectus for more information about how the selling stockholders may sell or otherwise dispose of their shares of common stock hereunder.

The selling stockholders may sell any, all or none of the securities offered by this prospectus and we do not know when or in what amount the selling stockholders may sell their shares of common stock hereunder following the effective date of this registration statement.

We will not receive any proceeds from the sale of our common stock by the selling stockholders in the offering described in this prospectus.

Our common stock is listed on the NASDAQ Capital Market under the symbol “PIRS”. On April 8, 2016, the last reported sale price for our common stock was \$2.35 per share.

Investing in our common stock involves a high degree of risk. Before making any investment in our common stock, you should read and carefully consider the risks described in this prospectus under “[Risk Factors](#)” beginning on page 7 of this prospectus.

You should rely only on the information contained in this prospectus or any prospectus supplement or amendment hereto. We have not authorized anyone to provide you with different information.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

This prospectus is dated _____, 2016

[Table of Contents](#)

TABLE OF CONTENTS

	Page No.
PROSPECTUS SUMMARY	2
RISK FACTORS	7
SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS	39
SELLING STOCKHOLDERS	41
PLAN OF DISTRIBUTION	52
DETERMINATION OF OFFERING PRICE	55
USE OF PROCEEDS	56
DESCRIPTION OF SECURITIES	57
MARKET PRICE OF AND DIVIDENDS ON THE REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS	63
MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	66
BUSINESS	78
MANAGEMENT	114
EXECUTIVE COMPENSATION	119
CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE	128
SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT	133
LEGAL MATTERS	135
EXPERTS	135
WHERE YOU CAN FIND ADDITIONAL INFORMATION	135
INFORMATION NOT REQUIRED IN PROSPECTUS	II-1

[Table of Contents](#)

About This Prospectus

You should rely only on the information that we have provided or incorporated by reference in this prospectus, any applicable prospectus supplement and any related free writing prospectus that we may authorize to be provided to you. We have not authorized anyone to provide you with different information. No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus, any applicable prospectus supplement or any related free writing prospectus that we may authorize to be provided to you. You must not rely on any unauthorized information or representation. This prospectus is an offer to sell only the securities offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. You should assume that the information in this prospectus, any applicable prospectus supplement or any related free writing prospectus is accurate only as of the date on the front of the document and that any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus, any applicable prospectus supplement or any related free writing prospectus, or any sale of a security registered under the registration statement of which this prospectus is a part.

This prospectus contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed, will be filed or will be incorporated by reference as exhibits to the registration statement of which this prospectus is a part, and you may obtain copies of those documents as described below under the heading “Where You Can Find Additional Information.”

As used in this prospectus, 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 GmbH” refers to Pieris Pharmaceuticals GmbH, 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 prospectus have been adjusted to give effect to this forward stock split.

We have registered trademarks for Pieris®, Anticalin® and Pocket Binding®. All other trademarks, trade names and service marks included in this prospectus 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.

[Table of Contents](#)

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 prospectus 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 prospectus 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. \$1.0906 in The City of New York for cable transfers of euro as certified for customs purposes by the Federal Reserve Bank of New York as of December 31, 2015.

PROSPECTUS SUMMARY

This summary does not contain all of the information that should be considered before investing in our common stock. Investors should read the entire prospectus carefully, including the risks related to our business and purchasing our common stock discussed under “Risk Factors” beginning on page 8 of this prospectus, and our financial statements and the accompanying notes beginning on page F-1 of this prospectus.

Our Company

Our Business

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

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

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

Our core Anticalin® technology and platform were developed in Germany, and we have collaboration arrangements with major multinational 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. Furthermore, we established a collaboration with F.Hoffmann—La Roche Ltd. and Hoffmann—La Roche Inc., or Roche in December 2015. 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.

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

For more information regarding our business, see the disclosure under the headings “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business” included elsewhere in this prospectus. For a description of certain risks related to our business, see the disclosure under the heading “Risk Factors” beginning on page 7 of this prospectus.

Corporate History

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 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.

Pieris Pharmaceuticals, Inc. was incorporated under the laws of the State of Nevada on May 24, 2013 with the name “Marika Inc.” On December 17, 2014, Pieris Pharmaceuticals, Inc., Pieris Pharmaceuticals GmbH (“Pieris GmbH”) and the former stockholders of Pieris GmbH entered into an Acquisition Agreement, or the Acquisition Agreement. Pursuant to the Acquisition Agreement, the stockholders of Pieris GmbH contributed all of their equity interests in Pieris GmbH to Pieris in exchange for shares of Pieris common stock, which resulted in Pieris GmbH becoming a wholly owned subsidiary of Pieris, which we refer to as the Acquisition. Prior to the Acquisition, as defined below, Pieris pursued a business of an errand concierge service online marketplace.

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

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

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

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.

Table of Contents

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 GmbH and the holders of Placement Warrants. Pursuant to the terms of the Registration Rights Agreement, we 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 our common stock issued in the Private Placement, as well as an additional 20,000,000 shares of our common stock which we issued to former stockholders of Pieris GmbH 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 registration statement to which this prospectus forms a part was declared effective on May 11, 2015. 1,812,308 of the shares of our common stock which were issued in the Private Placement and 7,527,457 of the shares of our common stock which were issued to former stockholders of Pieris GmbH have already been sold under the registration statement.

If the registration statement ceases to be effective during the required effectiveness period, except as permitted under the Registration Rights Agreement, we 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 we fail 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, we 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, we 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.

On July 6, 2015 we closed a public offering of an aggregate of 9,090,909 shares of our common stock at a purchase price of \$2.75 per share. On July 24, 2015 the underwriters exercised their over-allotment option to purchase 1,211,827 additional shares of our common stock at the public offering price of \$2.75, the sale of which closed on July 28, 2015. Gross proceeds raised by us in the offering, including the exercise of the over-allotment option, were \$28.3 million and net of equity issuance costs are \$25.8 million. We intend to use the net proceeds from the offering to fund research and development, including preclinical and clinical research and development of our drug candidates, working capital and general corporate purposes.

The foregoing description of the Securities Purchase Agreement and the Registration Rights Agreement do not purport to be complete, and are qualified in their entirety by the complete text of those agreements, which are attached as exhibits to this prospectus and incorporated herein by reference.

Risks Associated with Our Business

Our business and ability to execute our business strategy are subject to a number of risks of which you should be aware before you decide to buy our common stock. In particular, you should consider the following risks, which are discussed more fully in the section entitled "Risk Factors" in this prospectus, as well as the other risks described in "Risk Factors."

Table of Contents

- 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 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.
- We are heavily dependent on the successful development of our drug candidates and programs and we cannot be certain that we will receive regulatory approvals or be able to successfully commercialize our products even if we receive regulatory approvals.
- 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.
- We may not be successful in our efforts to build a pipeline of drug candidates.
- 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.
- Clinical drug development involves a lengthy and expensive process with uncertain outcomes; it is very difficult to design and implement; and any of our clinical trials or studies could produce unsuccessful results or fail at any stage in the testing process.
- 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.
- The review processes of regulatory authorities are lengthy, time consuming, expensive and inherently unpredictable. If we are unable to obtain approval for our product 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.
- 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.
- We rely on third parties to conduct 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 will need to grow the size of our organization, and we may experience difficulties in managing any growth we may achieve.
- 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 in our market and our business would be harmed.
- The patent protection covering some of our product candidates may be dependent on third parties, who may not effectively maintain that protection.
- If we are not able to attract and retain highly qualified personnel, we may not be able to successfully implement our business strategy.
- Our share price is expected to be volatile and may be influenced by numerous factors, some of which are beyond our control.

Corporate Information

Solely for purposes of filings with the SEC, the principal contact for Pieris shall be at the principal executive office of Pieris Pharmaceuticals, Inc., located at 255 State Street, 9th Floor, Boston, MA 02109, or under the telephone number (857) 246-8749. Our website address is <http://www.pieris.com>. We have not incorporated by reference into this prospectus the information on our website, and you should not consider it to be a part of this document.

The Offering

This prospectus relates to the resale from time to time by the selling stockholders identified herein of up to 17,982,105 shares of our common stock. We are not offering any shares for sale under the registration statement of which this prospectus is a part.

Common stock outstanding prior to this offering: 39,833,023(1)

Common stock offered by the selling stockholders hereunder: 17,982,105(2)

Common stock to be outstanding after this offering: 39,833,023(3)

Use of Proceeds: We will not receive any proceeds from the sale of our common stock offered by the selling stockholders under this prospectus.

Risk Factors: Investing in our securities involves a high degree of risk and purchasers may lose their entire investment. See the disclosure under the heading "Risk Factors" beginning on page 7 of this prospectus.

NASDAQ Trading Symbol: PIRS

- (1) As of March 20, 2016. Includes (a) 4,967,202 shares of our common stock issued and sold to certain selling stockholders in the Private Placement and (b) 12,472,543 shares of our common stock issued to certain selling stockholders in connection with the Acquisition, all of which are offered for resale by those selling stockholders under the registration statement of which this prospectus is a part.
- (2) Includes (a) 4,967,202 shares of common stock issued and sold to certain selling stockholders in the Private Placement, (b) 12,472,543 shares of our common stock issued to certain selling stockholders in connection with the Acquisition and (c) 542,360 shares of common stock issuable upon exercise of the Placement Warrants.
- (3) Excludes (a) 433,789 shares of common stock reserved for future issuance under the Pieris Pharmaceuticals, Inc. 2014 Employee, Director and Consultant Equity Incentive Plan, or the Pieris Plan, (b) 3,983,711 shares of common stock reserved for future issuance in connection with options to purchase shares of common stock that have been issued to our executive officers, directors, employees and consultants issued under the Pieris Plan, (c) an option to purchase 500,000 shares of common stock issued outside of the Pieris Plan to a newly-hired executive officer that was an inducement option, material to the executive officer entering into employment with the Company in 2015, and (d) an option to purchase 450,000 shares of common stock granted to a newly-hired executive officer in 2015 which is subject to certain restrictions on exercise until the Company's shareholders to approve an increase in the number of shares authorized under the Pieris Plan.

RISK FACTORS

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

Risks Related to Our Business, Financial Position and Capital Requirements

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

We are a clinical-stage biopharmaceutical company. To date, we have not generated any product revenue and are not profitable, and have incurred losses since our inception in August 2000. For the years ended December 31, 2015 and 2014 we reported net loss of \$14.1 and \$9.8 million, respectively. As of December 31, 2015, we had an accumulated deficit of \$79.9 million. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for, our drug candidates and the commercialization of approved products, if any.

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

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

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

We will require additional capital for the further development and commercialization of our drug candidates and may need to raise additional funds sooner than we currently anticipate if we choose to and are able to expand more rapidly than we currently anticipate. Further, we expect our expenses to increase in connection with our ongoing activities, particularly as we advance preclinical development of our 300-Series programs, advance PRS-080 through clinical trials 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.

[Table of Contents](#)

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

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

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

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

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

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

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

- developing our drug candidates using unproven technologies;
- undertaking preclinical development and clinical trials as well as formulating and manufacturing products;
- obtaining the human and financial resources necessary to develop, test, manufacture, commercialize and market our drug candidates;
- engaging corporate partners to assist in developing, testing, manufacturing and marketing our drug candidates;
- continuing to build and maintain an intellectual property portfolio covering our technology and our drug candidates;
- satisfying the requirements of clinical trial protocols, including patient enrollment, establishing and demonstrating the clinical safety and efficacy of our drug candidates and obtaining necessary regulatory approvals;
- achieving acceptance and use by the medical community of our drug candidates after they receive regulatory approvals;

Table of Contents

- 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, however, 54% of our operating expenses and all our revenues come from outside the United States. As such, the financial statements are translated for reporting purposes as follows: (1) asset and liability accounts at year-end rates, (2) income statement accounts at weighted average exchange rates for the year and (3) stockholders' equity accounts at historical rates. Corresponding translation gains or losses are recorded in stockholders' equity.

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

[Table of Contents](#)

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

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

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

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

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

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

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

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

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

[Table of Contents](#)

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

As of December 31, 2015, we had net operating loss carryforwards of approximately \$6.0 million that may be used to reduce our future U.S. federal income tax liabilities, if we become profitable on a federal income tax basis. If unused, these tax loss carryforwards will begin to expire between 2018 and 2035. Our ability to use these loss carryforwards to reduce our future U.S. federal income tax liabilities could also be lost if we were to experience more than a 50% change in ownership within the meaning of Section 382(g) of the Internal Revenue Code of 1986, as amended. If we were to lose the benefits of these loss carryforwards, our future earnings and cash resources would be materially and adversely affected.

As of December 31, 2015, we had net operating loss carryforwards of German corporate income tax of \$5.9 million and net operating loss carryforwards of German corporate trade tax of \$5.7 million that may be used to reduce our future taxable income in our German jurisdiction. Under current German laws, tax loss carryforwards may only be used to offset any relevant later assessment period (calendar year) \$1,090,600 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.

As a result of the ownership change Pieris GmbH experienced from the Acquisition and Private Placement in December 2014, we believe that it is more likely than not that future use of the net operating loss carryforwards that existed prior to the Acquisition may be limited significantly or forfeited entirely. Accordingly, we have written off \$33.9 million and \$22.9 million of corporate income tax loss carryforwards in the German jurisdiction for the 2015 and 2014 periods, respectively. Trade tax loss carryforwards written off in the German jurisdiction were \$33.9 million and \$21.6 million for the 2015 and 2014 periods, respectively.

Additional reorganizational or ownership changes could limit the use of our existing net operating loss carryforwards in any of our jurisdictions or cause us to forfeit additional loss carryforwards in the future.

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

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

We are subject to various laws and regulations in different jurisdictions, and the interpretation and enforcement of laws and regulations are subject to change. We are also subject to different tax regulations in each of the

[Table of Contents](#)

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

Risks Related to the Discovery and Development of Our Drug Candidates

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

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

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

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

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

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

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

We have also entered into license and partnership arrangements, such as with Allergan Inc., or Allergan, Daiichi Sankyo Company Limited, or Daiichi Sankyo, Sanofi Group (formerly Sanofi-Aventis and Sanofi-Pasteur S.A.), or Sanofi, Cadila Healthcare Limited (Zydus Cadila), or Zydus, Strides Arcolab Limited, or Stelis, and F.Hoffmann-La Roche Ltd., or Roche, 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

[Table of Contents](#)

partners have provided information regarding those drug candidates and the related preclinical studies conducted to date, including certain data that is included in this prospectus, we have not received and do not yet have access to comprehensive information regarding those development activities, including the raw data from the studies that have been conducted, information regarding the design, procedural implementation and structure and information regarding the manufacture of the drug candidates used in the studies. Because we have had no input on the development to date of these drug candidates, we may discover that all or certain elements of the trials and studies our partners have performed have not been, or may not in the future be, in compliance with applicable regulatory standards or have otherwise been or may be deficient, and that advancement of the development of these drug candidates on the basis of those trials and studies is not warranted.

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

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

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

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

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

A key element of our strategy is to use and expand our Anticalin® drug platform to build a pipeline of drug candidates to address different targets, and progress those drug candidates through clinical development for the treatment of a variety of different types of diseases. Although our research efforts to date have resulted in identification of a series of targets, we may not be able to develop drug candidates that are safe and effective inhibitors or promoters of all or any of these targets. Even if we are successful in building a product pipeline, the potential drug candidates that we identify may not be suitable for clinical development for a number of reasons, including causing harmful side effects or demonstrating other characteristics that indicate a low likelihood of

[Table of Contents](#)

receiving marketing approval or achieving market acceptance. If our methods of identifying potential drug candidates fail to produce a pipeline of potentially viable drug candidates, then our success as a business will be dependent on the success of fewer potential drug candidates, which introduces risks to our business model and potential limitations to any success we may achieve.

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

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

We completed dosing of healthy volunteers in the clinical Phase Ia trial for PRS-080 in June 2015, and although we are planning to initiate clinical trials for PRS-060 as early as the first quarter of 2017. We may however experience delays in pursuing those or any other clinical trials, and any planned clinical trials may not begin on time, may require redesign, may not enroll sufficient healthy volunteers or patients in a timely manner, and may not be completed on schedule, if at all.

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

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

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

Further, we may also encounter delays if a clinical trial is suspended or terminated by us, by any IRB or Ethics Committee at an institution in which such trials are being conducted, by the Data Safety Monitoring Board, or

Table of Contents

DSMB, for the trial, if applicable, or by the FDA, the European Medicines Agency, or EMA, or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements, inspection of the clinical trial operations or trial site by the FDA, EMA or other regulatory authorities resulting in the imposition of a clinical hold, exposing participants to health risks caused by unforeseen safety issues or adverse side effects, development of previously unseen safety issues, failure to demonstrate a benefit from using a drug candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Therefore, we cannot predict with any certainty the schedule for commencement or completion of any currently ongoing, planned or future clinical trials.

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

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

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

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

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

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

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

The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug products are, and will remain, subject to extensive regulation by the FDA in the United States and by the respective regulatory authorities in other countries, which regulations differ from country to country. We are not permitted to market our

Table of Contents

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

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

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

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

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

[Table of Contents](#)

collaborate may not have the resources to pursue those approvals, and we or they may not be able to obtain any approvals that are pursued. The failure to obtain marketing approval for our drug candidates in foreign jurisdictions could severely limit their potential market and ability to generate revenue.

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

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

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

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

Risks Related to Our Dependence on Third Parties

We rely on third parties to conduct our 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.

[Table of Contents](#)

If our contractors do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to a failure to adhere to our clinical protocols, legal and regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for, or successfully commercialize, the affected drug candidates. In addition, we will be unable to control whether or not they devote sufficient time and resources to our preclinical and clinical programs. These outside contractors may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking such programs ourselves. As a result, our operations and the commercial prospects for the effected drug candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed. These contractors may also have relationships with other commercial entities, some of whom may compete with us. If our contractors assist our competitors to our detriment, our competitive position would be harmed.

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

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

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

- We may be unable to identify manufacturers on acceptable terms, or at all, because the number of potential manufacturers is limited 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.

Table of Contents

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.

[Table of Contents](#)

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

Table of Contents

- 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.

Table of Contents

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, asthma and cancer markets is intense. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, fully integrated pharmaceutical or biotechnology companies, smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, and other public and private research organizations.

There are several third-party drug candidates that could be competitive with drug candidates in our pipeline. Drug candidates interfering with hepcidin function and thus competing with PRS-080 include those that are being developed by Noxxon (NOX-H94), Lilly (LY-2787106, LY-2928057), Ferrumax (FMX-8), ISIS/Xenon (XEN701), and Alnylam (ALN-HPN). Drug candidates interfering with the function of type 2 helper T cells, or Th2, the biological pathway for PRS-060, and thus competing with PRS-060, include those that are being developed by Sanofi/Regeneron (dupilumab), Roche/Genentech (lebrikizumab), Astra-Zeneca (tralokizumab, benralizumab), GSK (mepolizumab) and Teva (reslizumab). Drugs targeting immunomodulatory targets and thus competing with our 300-Series programs include those that are currently marketed by Bristol Myers Squibb (Yervoy/ipilimumab, Opdivo/nivolumab) and Merck (Keytruda/pembrolizumab) and drug candidates are developed by Bristol Myers Squibb (Urelumab / anti-CD137; anti-LAG3; Anti-CD40; Lirilumab/ anti-KIR), Roche / Genentech (MPDL3280A/anti-PDL-1; RG7888 /anti-Ox40), Merck Serono (Avelumab / anti-PDL-1) and AstraZeneca (MEDI4736 / anti-PDL-1; MEDI0680 / anti-PD-1; MEDI6469/ Ox-40; tremelimumab/anti-CTLA-4). Drug candidates targeting cMet and thus competing with PRS-110 include those that are being developed by Roche / Genentech (MetMab), Eli Lilly (LY2875359) and Abbvie (ABT700). For additional information about our third party drug candidates which could be competitive with the drug candidates in our pipeline, see “Business—Competition.”

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

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

- developing drugs;
- undertaking preclinical testing and clinical trials;
- obtaining FDA and other regulatory approvals of drugs;
- prosecuting and enforcing intellectual property rights;

Table of Contents

- formulating and manufacturing drugs; and
- launching, marketing and selling drugs.

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

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

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

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the clinical testing and commercialization of products we develop on our own or with collaborators. We do not currently carry general product liability insurance. We have put in place applicable product liability insurance, covering us as sponsor and the investigators involved in our Phase I clinical trial of PRS-080 in healthy volunteers, in an amount of up to the lesser of €0.5 million (\$0.6 million) per enrolled subject or €10 million (\$12.1 million) for the Phase Ia clinical trial in its entirety. In the future, we will seek to obtain similar insurance coverage with respect to any future clinical trials of our other drug candidates, such as PRS-060 and 300-Series programs, but we may not be able to obtain the levels of coverage desired on acceptable terms, or at all. If we do secure product liability insurance, we may subsequently determine that additional amounts of coverage would be desirable at later stages of clinical development of our drug candidates or upon commencing commercialization of any drug candidate that obtains required approvals, but we may not be able to obtain such additional coverage amounts when needed on acceptable terms, or at all. Unless and until we obtain such insurance, we would be solely responsible for any product liability claims relating to our preclinical and clinical development activities. Further, even after any such insurance coverage is obtained, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by any insurance policies we may then have or that is in excess of the limits of our insurance coverage. We would be required to pay any amounts awarded by a court or negotiated in a settlement that exceed the coverage limitations or that are not covered by any product liability insurance we may obtain, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Risks Related to Our Intellectual Property

If we breach any of the agreements under which we license from third parties the intellectual property rights or commercialization rights to our drug candidates, particularly our license 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.

[Table of Contents](#)

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.

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 23, 2016, we have 38 full-time employees and one part-time employee. 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.

Table of Contents

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

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

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

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

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

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

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

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

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

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

Table of Contents

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

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

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

[Table of Contents](#)

candidates infringes upon one or more claims of these patents. If our activities or drug candidates infringe the patents or other intellectual property rights of third parties, the holders of such intellectual property rights may be able to block our ability to commercialize such drug candidates or practice our methods unless we obtain a license under the intellectual property rights or until any applicable patents expire or are determined to be invalid or unenforceable.

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

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 or practicing competing methods and our ability to generate revenue from any commercialization of the affected drug candidates may suffer.

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

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

[Table of Contents](#)

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

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

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

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

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

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

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

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

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

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

Table of Contents

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

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

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

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

Many of our employees work in Germany and are subject to German employment law. Ideas, developments, discoveries and inventions made by such employees and consultants are subject to the provisions of the German Act on Employees' Inventions (*Gesetz über Arbeitnehmererfindungen*), which regulates the ownership of, and compensation for, inventions made by employees. We face the risk that disputes can occur between us and such employees or ex-employees pertaining to alleged non-adherence to the provisions of this act that may be costly to defend and take up our management's time and efforts whether we prevail or fail in such dispute. In addition, under the German Act on Employees' Inventions, certain employees retained rights to patents they invented or co-invented prior to 2009. Although most of these employees have subsequently assigned their interest in these patents to us, there is a risk that the compensation we 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

Table of Contents

drug discovery and development experience of our drug development team, which we believe is a significant contributor to our competitive advantage, we are dependent on the maintenance and growth of that team with qualified members containing high levels of expertise in specific scientific fields. We currently have 39 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 GmbH are governed by employment contracts which provide certain defined terms for either party to terminate the employment relationship.

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

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

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

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

In contrast, in Germany, there is no analogous doctrine of “employment at will”. By law, German employees must have written employment contracts that reflect the key aspects of the employment relationship. Our relations between German employers and employees are extensively regulated under German labor and employment laws and regulations. German employees 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

Table of Contents

- if a company engages in a mass layoff, which is deemed to occur when the employer intends to dismiss a large percentage of its employees during a one-month period, prior written notification to the German employment office is required.

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

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

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

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

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

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

Risks Related to the Ownership of our Common Stock

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

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

Table of Contents

- 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.

[Table of Contents](#)

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 15c-9 promulgated under 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 15c-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.

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.

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

We are required to comply with Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, subject to certain exceptions. Section 404 of the Sarbanes-Oxley Act requires public companies to conduct an annual review and evaluation of their internal controls and to obtain attestations of the effectiveness of internal controls by independent auditors. However, as discussed in detail below, as an emerging growth company, we are not required to obtain an auditor attestation. As a private company, we were not subject to requirements to establish, and did not establish, internal control over financial reporting and disclosure controls and procedures prior to the

Table of Contents

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 have had material weaknesses in our internal control over financial reporting in the past. Although such weaknesses have been remediated, we cannot assure you that we will be successful in remediating any material weaknesses in our internal control over financial reporting in the future. Any failure to implement and document new and more precise monitoring controls or to implement organizational changes including skillset enhancements through resource changes or education to improve detection and communication of financial misstatements across all levels of the organization could result in additional material weaknesses, result in material misstatements in our financial statements and cause us to fail to meet our reporting obligations, which in turn could cause the trading price of our common stock to decline.

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

Prior to the closing of the Acquisition, we were deemed a “shell company” under applicable SEC rules and regulations because we had no or nominal operations and either no or nominal assets, assets consisting solely of cash and cash equivalents, or assets consisting of any amount of cash and cash equivalents and nominal other assets. Pursuant to Rule 144 promulgated under the Securities Act, sales of the securities of a former shell company, such as us, under that rule are not permitted unless at the time of a proposed sale, we are subject to the reporting requirements of Section 13 or 15(d) of the Exchange Act and have filed all reports and other materials required to be filed by Section 13 or 15(d) of the Exchange Act, as applicable, during the preceding 12 months, other than Form 8-K reports. Additionally, our previous status as a shell company could also limit our use of our securities to pay for any acquisitions we may seek to pursue in the future (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 authorize the issuance of up to 300,000,000 shares of our common stock and up to 10,000,000 shares of preferred stock with the terms, limitations, voting rights, relative rights and preferences and variations of each series that our Board of Directors may determine from time to time. Upon the closings of the private placement of our common stock in December 17, 18 and 23, 2014, we issued an

[Table of Contents](#)

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 thereof and their designees, and in connection with public offering in July 2015 we issued an aggregate of 10,302,736 shares of our common stock. During the year 2015, we issued an aggregate of 245,765 shares of our common stock to consultants in exchange for their services under several contracts. Possible business and financial uses for our authorized capital stock include, without limitation, equity financing, future stock splits, acquiring other companies, businesses or products in exchange for shares of our capital stock, issuing shares of our capital stock to partners or other collaborators in connection with strategic alliances, attracting and retaining employees by the issuance of additional securities under our equity compensation plan, or other transactions and corporate purposes that our Board of Directors deems are in the interests of our company. Additionally, issuances of shares of our capital stock could have the effect of delaying or preventing changes in control or our management. Any future issuances of shares of our capital stock may not be made on favorable terms or at all, they may have rights, preferences and privileges that are superior to those of our common stock, and may have an adverse effect on our business or the trading price of our common stock. The issuance of any additional shares of our common stock will reduce the book value per share and may contribute to a reduction in the market price of the outstanding shares of our common stock. Additionally, any such issuance will reduce the proportionate ownership and voting power of all of our current stockholders.

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

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. As of December 31, 2015, a total of 39,833,023 shares of our common stock were outstanding. Any sales of those shares or any perception in the market that such sales may occur could cause the trading price of our common stock to decline.

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

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

The sale, or availability for sale of our common stock in the public market may adversely affect the prevailing market price of our common stock and may impair our ability to raise additional equity capital. We filed a registration statement with the SEC, to which this prospectus forms a part and which was declared effective on May 11, 2015, to register the resale of 27,321,870 shares of our common stock, which represents all of the shares of our common stock issued and sold in our private placement consummated in December 2014, shares of our common stock issued to former stockholders of Pieris GmbH in connection with the closing of the Acquisition on December 17, 2014, and shares of common stock private placement in December 2014. Such shares represented 69% of our outstanding shares of common stock as of March 23, 2016. The resale registration statement permits the resale of these shares at any time without restriction. The resale of a substantial number of shares of our common stock in the public market could adversely affect the market price for our common stock and make it more difficult for you to sell shares of our common stock at times and prices that you may feel are appropriate. Furthermore, because there are a large number of shares registered pursuant to the resale registration statement, we may continue to offer shares covered by the resale registration statement for a significant period of time, the precise duration of which cannot be predicted. Accordingly, the adverse market and price pressures resulting from an offering pursuant to the resale registration statement may continue for an extended period of time and continued negative pressure on the market price of our common stock could have a material adverse effect on our ability to raise additional equity capital.

Table of Contents

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

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

Pursuant to our 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 4,200,000 shares of our common stock and, as of March 20, 2016, we have granted options to purchase 3,893,711 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 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. See “Description of Capital Stock.”

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

Our Amended and Restated Articles of Incorporation provide that, to the fullest extent permitted by law, and unless we consent to the selection of an alternative forum, the Eighth Judicial District Court of Clark County, Nevada shall be the sole and exclusive forum for any (i) derivative action or proceeding brought in the name or right of the corporation or on its behalf, (ii) action asserting a claim of breach of a fiduciary duty owed by any of our directors,

[Table of Contents](#)

officers, employees or agents to the corporation or any of our stockholders, (iii) any action arising or asserting a claim arising pursuant to any provision of Chapters 78 or 92A of the Nevada Revised Statutes or any provision of our articles of incorporation or bylaws, (iv) any action to interpret, apply, enforce or determine the validity of our articles of incorporation or bylaws or (v) any action asserting a claim governed by the internal affairs doctrine. Our Amended and Restated Articles of Incorporation further provide that any person purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed, to the fullest extent permitted by law, to have notice of and consented to the foregoing provision.

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

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

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

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

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

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

As a public company listed on the NASDAQ Capital Market, and particularly if and after we cease to be an "emerging growth company" or a "smaller reporting company," we will incur significant legal, accounting and other expenses that we did not incur as a private company and that we did not incur prior to the listing of our common stock on the NASDAQ Capital Market including costs associated with public company reporting requirements. In

[Table of Contents](#)

addition, the rules and regulations of the SEC and the NASDAQ Capital Market impose numerous requirements on public companies, including requirements relating to our corporate governance practices and requirements under Section 404 and other provisions of the Sarbanes-Oxley Act, with which we will now need to comply. Further, since we are subject to the Exchange Act, we are required to, among other things, file annual, quarterly and current reports with respect to our business and operating results. Our management and other personnel will need to devote substantial time to gaining expertise regarding operations as a public company and compliance with applicable laws and regulations, and our efforts and initiatives to comply with those requirements could be expensive. The expenses incurred by public companies for reporting and corporate governance purposes have increased dramatically in recent years. We are unable currently to estimate these costs with any degree of certainty.

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

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

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

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

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

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

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements concerning our business, operations and financial performance and condition as well as our plans, objectives and expectations for our business operations and financial performance and condition. Any statements that are not of historical facts may be deemed to be forward-looking statements. You can identify these forward-looking statements by words such as “believes,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “may,” “could,” “might,” “will,” “should,” “aims,” “seeks,” or other similar expressions that convey uncertainty of future events or outcomes. Forward-looking statements appear in a number of places throughout this prospectus and include statements regarding our intentions, beliefs, assumptions, projections, outlook, analyses or current expectations concerning, among other things, our intellectual property position, results of operations, cash needs, spending of the proceeds from this offering, financial condition, liquidity, prospects, growth and strategies, the industry in which we operate and the trends that may affect the industry or us.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics and industry change, and depend on economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. Although we believe that we have a reasonable basis for each forward-looking statement contained in this prospectus, we caution you that forward-looking statements are not guarantees of future performance and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. All of our forward-looking statements are subject to risks and uncertainties that may cause our actual results to differ materially from our expectations.

Actual results could differ materially from our forward-looking statements due to a number of factors, including, without limitation, risks related to:

- the results of our research and development activities, including uncertainties relating to the discovery of potential drug candidates and the preclinical and ongoing or planned clinical testing of our drug candidates;
- the early stage of our drug candidates presently under development;
- our ability to obtain and, if obtained, maintain regulatory approval of our current drug candidates and any of our other future drug candidates;
- our need for substantial additional funds in order to continue our operations and the uncertainty of whether we will be able to obtain the funding we need;
- our future financial performance;
- our ability to retain or hire key scientific or management personnel;
- our ability to protect our intellectual property rights that are valuable to our business, including patent and other intellectual property rights;
- our dependence on third-party manufacturers, suppliers, research organizations, testing laboratories and other potential collaborators;
- our ability to successfully market and sell our drug candidates in the future as needed;
- the size and growth of the potential markets for any of our approved drug candidates, and the rate and degree of market acceptance of any of our approved drug candidates;
- competition in our industry; and
- regulatory developments in the U.S. and foreign countries.

Any forward-looking statements that we make in this prospectus speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this prospectus or to reflect the occurrence of unanticipated events. Comparisons of results for current and any prior periods are not intended to express any future trends or indications of future performance, unless expressed as such, and should only be viewed as historical data. You should, however, review the factors and risks we describe in the reports we will file from time to time with the SEC after the date of this prospectus. See “Where You Can Find More Information.”

[Table of Contents](#)

You should also read carefully the factors described in the “Risk Factors” section of this prospectus and elsewhere to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this prospectus will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified timeframe, or at all.

SELLING STOCKHOLDERS

This prospectus covers the resale from time to time by the selling stockholders identified in the table below of up to an aggregate of 17,982,105 shares of our common stock, which includes (i) 4,967,202 issued and outstanding shares of our common stock issued and sold to investors in the Private Placement, (ii) 12,472,543 shares of our common stock, issued to former stockholders of Pieris GmbH in connection with the closing of the Acquisition, and (iii) 542,360 shares of our common stock issuable to holders of the Placement Warrants pursuant issued in connection with the Private Placement.

Pursuant to the Registration Rights Agreement, we have filed with the SEC the registration statement of which this prospectus forms a part in order to register such resales of our common stock under the Securities Act. We have also agreed to cause this registration statement to become effective and to keep such registration statement effective within and for the time periods set forth in the Registration Rights Agreement. Our failure to satisfy the filing or effectiveness deadlines set forth in the Registration Rights Agreement may subject us to payment of certain monetary penalties pursuant to the terms of the Registration Rights Agreement.

The selling stockholders identified in the table below may from time to time offer and sell under this prospectus any or all of the shares of common stock described under the column “Shares of Common Stock Being Offered in this Offering” in the table below. The table below has been prepared based upon information furnished to us by the selling stockholders as of the dates represented in the footnotes accompanying the table. The selling stockholders identified below may have sold, transferred or otherwise disposed of some or all of their shares since the date on which the information in the following table is presented in transactions exempt from or not subject to the registration requirements of the Securities Act. Information concerning the selling stockholders may change from time to time and, if necessary, we will amend or supplement this prospectus accordingly and as required.

We have been advised, as noted in the footnotes in the table below, that certain of the selling stockholders are broker-dealers, affiliates of a broker-dealer and/or underwriter. Those selling stockholders have informed us that they bought our securities in the ordinary course of business, and that none of these selling stockholders had, at the time of their purchase of our securities, any agreements or understandings, directly or indirectly, with any person to distribute such securities.

The following table and footnote disclosure following the table sets forth the name of each selling stockholder, the nature of any position, office or other material relationship, if any, that the selling stockholder has had within the past three years with us or with any of our predecessors or affiliates, and the number of shares of our common stock beneficially owned by the selling stockholder before this offering. The number of shares reflected are those beneficially owned, as determined under applicable rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under applicable SEC rules, beneficial ownership includes any shares of common stock as to which a person has sole or shared voting power or investment power and any shares of common stock which the person has the right to acquire within 60 days after April 20, 2015 through the exercise of any option, warrant or right or through the conversion of any convertible security. Unless otherwise indicated in the footnotes to the table below and subject to community property laws where applicable, we believe, based on information furnished to us, that each of the selling stockholders named in this table has sole voting and investment power with respect to the shares indicated as beneficially owned.

[Table of Contents](#)

We have assumed that all shares of common stock reflected in the table as being offered in the offering covered by this prospectus will be sold from time to time in this offering. We cannot provide an estimate as to the number of shares of common stock that will be held by the selling stockholders upon termination of the offering covered by this prospectus because the selling stockholders may offer some, all or none of their shares of common stock being offered in the offering.

Selling Stockholder (1)	Broker-Dealer or Broker-Dealer Affiliate	Footnote, if any	Shares of Common Stock Beneficially Owned Before this Offering	Percentage of Common Stock Beneficially Owned Before this Offering (2)	Shares of Common Stock Being Offered in this Offering	Shares of Common Stock Beneficially Owned Upon Completion of this Offering (3)	Percentage of Outstanding Common Stock Beneficially Owned Upon Completion of this Offering (2)(3)
1798 Fundamental Strategies Master Fund Ltd		(4)	1,500,000	5.10%	1,500,000	—	*
Aaron Segal	\$	(5)	40,506	*	17,006	23,500	*
Adolfo and Donna Carmona, JTWROS			50,000	*	50,000	—	*
Alfred J. Difiore Jr.			5,000	*	5,000	—	*
Alice M. and Randall A. Sebring, JTWROS			30,000	*	30,000	—	*
Allan Lipkowitz Revocable Living Trust 8/26/2005		(6)	12,500	*	12,500	—	*
Allen Chase Foundation DBA Eaglebrook School		(7)	15,000	*	15,000	—	*
American Portfolios Financial Services, Inc.	\$	(8)	9,068	*	9,068	—	*
Andre Iseli'			15,000	*	15,000	—	*
Andrew Brenner			20,000	*	20,000	—	*
Anthony Naer			2,000	*	2,000	—	*
Anton and Barbara Bogner, JTWROS			80,000	*	80,000	—	*
Arielle Crothers			5,000	*	5,000	—	*
Barry Cohn	\$	(9)	4,534	*	4,534	—	*
Barry Shemaria			20,000	*	20,000	—	*
Benjamin R. Bowen	\$	(10)	35,000	*	35,000	—	*
Benjamin Schulman			12,500	*	12,500	—	*
BioM AG Munich Biotech Development		(11)	369,540	*	369,540	—	*
BioM Venture Capital GmbH & Co. KG		(12)	281,244	*	281,244	—	*
Boris Shames			4,000	*	4,000	—	*
Brio Capital Master Fund Ltd.		(13)	32,870	*	32,870	—	*
Bruce Rosen			1,800	*	1,800	—	*
Byron C. Hughey			7,500	*	7,500	—	*
Cadila Healthcare Limited		(14)	1,415,539	3.55%	1,415,539	—	*
Carl J. Domino			50,000	*	50,000	—	*
Charles and Beverly Freeland, JTWROS			10,000	*	10,000	—	*
Charles and Diane Medici, JTWROS			12,500	*	12,500	—	*
Choi Family Trust Dated March 15, 2001		(15)	50,000	*	50,000	—	*
Christopher Figoni			12,500	*	12,500	—	*
Christopher James Cozzolino	\$	(16)	2,840	*	2,840	—	*

[Table of Contents](#)

Selling Stockholder (1)	Broker-Dealer or Broker-Dealer Affiliate	Footnote, if any	Shares of Common Stock Beneficially Owned Before this Offering	Percentage of Common Stock Beneficially Owned Before this Offering (2)	Shares of Common Stock Being Offered in this Offering	Shares of Common Stock Beneficially Owned Upon Completion of this Offering (3)	Percentage of Outstanding Common Stock Beneficially Owned Upon Completion of this Offering (2)(3)
Christopher Washburn			12,500	*	12,500	—	*
Claus Schalper		(17)	179,155	*	1,970	177,185	*
Clay Godfrey Lebharr			12,500	*	12,500	—	*
Clayton A. Struve	§	(18)	50,000	*	50,000	—	*
Craig Whited			50,000	*	50,000	—	*
Crossroads Limited Partnership		(19)	50,000	*	50,000	—	*
Currie Family Trust		(20)	20,000	*	20,000	—	*
Daniel Brian Salvas			12,500	*	12,500	—	*
Daryl Squicciarini			25,000	*	25,000	—	*
Dave Rickey & Daughter's Foundation Charitable Trust		(21)	2,000	*	2,000	—	*
David and Susan Stollwerk, JTWROS			12,500	*	12,500	—	*
David Blau			5,000	*	5,000	—	*
David Landskowsky	§	(22)	80,281	*	21,319	58,962	*
Delux Investment Group LLC		(23)	5,000	*	5,000	—	*
Dennis R. DeLoach, Jr.			12,500	*	12,500	—	*
Dennis Reilly			10,500	*	10,500	—	*
Double Add Investments I LLC		(24)	7,500	*	7,500	—	*
Douglas Kohrs			75,000	*	75,000	—	*
Douglas Krasnoff			2,500	*	2,500	—	*
Dr. Karsten Schürle			1,323	*	1,323	—	*
Dr. Steffen Schlehuber			2,632	*	2,632	—	*
Due Mondt Investments, Ltd.		(25)	10,000	*	10,000	—	*
Edward King			36,000	*	36,000	—	*
EFD Capital Inc.		(26)	21,078	*	16,078	5,000	*
Elena Laguta			5,000	*	5,000	—	*
Eliezer Lubitch			8,525	*	8,525	—	*
Eric Rubenstein	§	(27)	87,558	*	24,382	63,176	*
Ethel and Richard Krasnoff, JTWROS			2,500	*	2,500	—	*
FourJr. Investments Ltd.		(28)	25,000	*	25,000	—	*
Gibralt Capital Corporation		(29)	64,038	*	64,038	—	*
Giles Sandvik Giles and Jeanne Sandvik, JTWROS			10,000	*	10,000	—	*
Glen Ackermann			5,000	*	5,000	—	*
Gubbay Investments LLC		(30)	17,500	*	17,500	—	*
H Investment Company, LLC		(31)	50,000	*	50,000	—	*
HFR HE Sphera Global Healthcare Master Trust		(32)	23,550	*	23,550	—	*
Howard and Susan Kalka, JTWROS			25,000	*	25,000	—	*
Howard Stringer		(33)	25,000	*	25,000	—	*
Irwin Gruverman			12,500	*	12,500	—	*

[Table of Contents](#)

Selling Stockholder (1)	Broker-Dealer or Broker-Dealer Affiliate	Footnote, if any	Shares of Common Stock Beneficially Owned Before this Offering	Percentage of Common Stock Beneficially Owned Before this Offering (2)	Shares of Common Stock Being Offered in this Offering	Shares of Common Stock Beneficially Owned Upon Completion of this Offering (3)	Percentage of Outstanding Common Stock Beneficially Owned Upon Completion of this Offering (2)(3)
Jacqueline Cozzolino			7,500	*	7,500	—	*
James and Dorothy Saylor, JTWROS			5,000	*	5,000	—	*
Jay E. Bradbury			12,500	*	12,500	—	*
Jeffrey Paul Peterson	§	(34)	15,000	*	15,000	—	*
Jeffrey Scott and Christine Kellye Rennell, JTWROS			100,000	*	100,000	—	*
Joel L. Hochman Revocable Trust UAD 12/8/1994		(35)	25,000	*	25,000	—	*
John C. Blazier and Fleur A. Christensen, JTWROS			12,500	*	12,500	—	*
John O. Gallant			12,500	*	12,500	—	*
John V. Wagner Jr.			25,000	*	25,000	—	*
Jonathan and Gina Blatt, JTWROS		(36)	25,000	*	25,000	—	*
Jonathan & Gina Blatt Childrens Trust UA 02.20.2002			10,000	*	10,000	—	*
Joseph Codi			12,500	*	12,500	—	*
Joseph O. Manzi			25,000	*	25,000	—	*
Joseph Rubino			12,500	*	12,500	—	*
Kaushal Pandya			5,010	*	5,010	—	*
Kent Tucker Andersen			50,000	*	50,000	—	*
Kevin and Susan Koch, JTWROS			12,500	*	12,500	—	*
Kevin M. Filosa	§	(37)	4,216	*	4,216	—	*
KfW—Kreditanstalt für Wiederaufbau		(38)	299,549	*	299,549	—	*
Kimberly Hanley	§	(39)	629	*	629	—	*
Laurel Walrath			5,000	*	5,000	—	*
Lee Harrison Corbin			50,000	*	50,000	—	*
Lee J. Seidler Revocable Trust Dated April 12, 1990		(40)	25,000	*	25,000	—	*
Linda DelPonte			25,000	*	25,000	—	*
Lindsay Jacobson			50,000	*	50,000	—	*
Lindsey S. McGrandy	§	(41)	464	*	464	—	*
Lisa Ann Torsiello			75,000	*	75,000	—	*
The Bell Family Trust Dated 2/2/95 As Amended		(42)	100,000	*	100,000	—	*
Lynn Zheng			50,000	*	50,000	—	*
Mackie Klingbeil			25,000	*	25,000	—	*
Mahesh N. Ganmukhi			100,000	*	100,000	—	*
Mahipal Ravipati			5,000	*	5,000	—	*
MAPO Beteiligungsgesellschaft mbH		(43)	24,233	*	24,233	—	*
Mark Nicholas Tompkins		(44)	1,958,912	1.92%	548,902	1,410,010	3.54%
Martillo Finance Limited		(45)	56,000	*	56,000	—	*

[Table of Contents](#)

Selling Stockholder (1)	Broker-Dealer or Broker-Dealer Affiliate	Footnote, if any	Shares of Common Stock Beneficially Owned Before this Offering	Percentage of Common Stock Beneficially Owned Before this Offering (2)	Shares of Common Stock Being Offered in this Offering	Shares of Common Stock Beneficially Owned Upon Completion of this Offering (3)	Percentage of Outstanding Common Stock Beneficially Owned Upon Completion of this Offering (2)(3)
Martin J. Junge			12,500	*	12,500	—	*
Matthew Longo			37,000	*	37,000	—	*
Melissa and Andrew Fisher, JTWROS			15,000	*	15,000	—	*
Meryle Evans Family Trust		(46)	15,000	*	15,000	—	*
Michael Crawford			50,000	*	50,000	—	*
Michael J. Pierce			100,000	*	100,000	—	*
Michael Silverman	§	(47)	206,293	*	61,064	145,229	*
Mildred LaMarca			1,000	*	1,000	—	*
Nitin Bhatnagar			9,500	*	9,500	—	*
Noel McGee			5,000	*	5,000	—	*
Northland Securities, Inc.	§	(48)	50,000	*	50,000	—	*
Northlea Partners LLLP		(49)	25,000	*	25,000	—	*
Novo Nordisk A/S		(50)	2,051,802	5.15%	2,051,802	—	*
O. Stuart Chase			10,000	*	10,000	—	*
OrbiMed Private Investments III, LP		(51)	6,698,939	16.82%	6,698,939	—	*
OrbiMed Associates III, LP		(51)	60,681	*	60,681	—	*
Paul Ehrenstein	§	(52)	8,039	*	8,039	—	*
Paul Tompkins			30,000	*	30,000	—	*
Peter C. Gould			12,500	*	12,500	—	*
Peter Figoni			5,000	*	5,000	—	*
Philip C. Kempisty	§	(53)	8,039	*	8,039	—	*
Philip W. Faucette II			12,500	*	12,500	—	*
Prof. Skerra Beteiligungsgesellschaft mbH		(54)	98,891	*	98,891	—	*
Ravi Gutta			40,000	*	40,000	—	*
Richard D. Cohen			25,000	*	25,000	—	*
Richard Pisacano		(55)	5,000	*	5,000	—	*
Richard Salzer and Anca Cretan-Salzer, JTWROS			25,000	*	25,000	—	*
RMR Wealth Management, LLC	§	(56)	9,400	*	9,400	—	*
Robert B. Prag			25,000	*	25,000	—	*
Robert Buckhardt			25,000	*	25,000	—	*
Robert Crosthers	§	(57)	57,862	*	57,862	—	*
Robert David Frankel			12,500	*	12,500	—	*
Robert G. Curtin			12,500	*	12,500	—	*
Robert McGrath			6,000	*	6,000	—	*
Robison Carothers		(58)	10,000	*	10,000	—	*
Roger D. Bozarth			12,500	*	12,500	—	*
Roman Livson	§	(59)	6,496	*	6,496	—	*
Scott Cardone	§	(60)	23,990	*	10,098	13,892	*
Scott Rapfogel			12,500	*	12,500	—	*
Steven and Seena Bernhard, JTWROS							
Steven Bernhard			10,000	*	10,000	—	*
Sphera Global Healthcare Master Fund		(61)	476,450	1.62%	476,450	—	*

[Table of Contents](#)

Selling Stockholder (1)	Broker-Dealer or Broker-Dealer Affiliate	Footnote, if any	Shares of Common Stock Beneficially Owned Before this Offering	Percentage of Common Stock Beneficially Owned Before this Offering (2)	Shares of Common Stock Being Offered in this Offering	Shares of Common Stock Beneficially Owned Upon Completion of this Offering (3)	Percentage of Outstanding Common Stock Beneficially Owned Upon Completion of this Offering (2)(3)
Stanley Rabinovich			50,000	*	50,000	—	*
Stanton J. Rowe			67,500	*	67,500	—	*
Stephen A. DiChiara			12,500	*	12,500	—	*
Stephen Pisacano			5,000	*	5,000	—	*
Stephen Renaud	§	(62)	221,067	*	73,564	147,503	*
Technologie Beteiligungsfonds Bayern II GmbH & Co. KG		(63)	176,166	*	176,166	—	*
The Del Mar Consulting Group, Inc. Retirement Plan Trust		(64)	8,000	*	8,000	—	*
Thomas LaMarca			3,000	*	3,000	—	*
Thomas Norgiel			25,000	*	25,000	—	*
Thomas Zahavi			25,000	*	25,000	—	*
Timothy Hermann	§	(65)	27,689	*	10,603	17,086	*
Todd Harrigan	§	(66)	37,543	*	14,159	23,384	*
TransConnect Unternehmensberatungs- und Beteiligungs AG		(67)	443,491	1.11%	443,491	—	*
Trout Capital, LLC	§	(68)	80,000	*	80,000	—	*
Walter G. Gans			12,500	*	12,500	—	*
William C. Sykes			25,000	*	25,000	—	*
William Crothers			9,000	*	9,000	—	*
William Jeffrey Kadi			75,000	*	75,000	—	*
William Norman Strawbridge			20,000	*	20,000	—	*
Valerie and Leland Zurich, JTWROS			50,000	*	50,000	—	*

* Less than 1%.

§ The selling stockholder is a broker-dealer or an affiliate of a broker-dealer.

(1) All information regarding investors in the Private Placement is provided as of March 11, 2016.

(2) Percentage ownership is based on a denominator equal to the sum of (i) 39,833,029 shares of our common stock outstanding as of March 20, 2016, and (ii) the number of shares of common stock issuable upon exercise or conversion of convertible securities beneficially owned by the applicable selling stockholder.

(3) Assumes that all shares of common stock being registered under the registration statement of which this prospectus forms a part are sold in this offering, and that none of the selling stockholders acquire additional shares of our common stock after the date of this prospectus and prior to completion of this offering.

(4) Lombard Odier Asset Management (USA) Corp. is the investment advisor to the selling stockholder and as such has the power to vote or dispose of the securities held of record by the selling stockholder and may be deemed to beneficially own the securities. Allan Reine is the portfolio manager of Lombard Odier Asset Management (USA) Corp. and as such has the power to vote or dispose of the securities held of record by the selling stockholder and may be deemed to beneficially own the securities. Mr. Reine disclaims beneficial ownership of such securities, except to the extent of his pecuniary interest therein.

(5) Includes 17,006 shares the selling stockholder has the right to acquire through the exercise of a common stock warrant and includes 23,500 shares owned by the selling stockholder that are not being offered in this offering. The selling stockholder is an affiliate of a broker-dealer that acted as a placement agent in the Private Placement.

(6) Allan Lipkowitz, the trustee of the selling stockholder, has the power to vote or dispose of the securities held of record by the selling stockholder and may be deemed to beneficially own those securities. Mr. Lipkowitz disclaims beneficial ownership with respect to such shares, except to the extent of his pecuniary interest therein, if any.

Table of Contents

- (7) O. Stuart Chase, the Headmaster Emeritus of the selling stockholder, has the power to vote or dispose of the securities held of record by the selling stockholder and may be deemed to beneficially own those securities. Mr. Chase disclaims beneficial ownership with respect to such shares, except to the extent of his pecuniary interest therein, if any.
- (8) Includes 9,068 shares the selling stockholder has the right to acquire through the exercise of a common stock warrant. The selling stockholder is a broker-dealer that served as a sub-placement agent in the Private Placement. The selling stockholder is a corporation governed by a board of directors comprised of three directors. The members of the board of directors disclaim beneficial ownership with respect to such shares, except to the extent of their pecuniary interest therein, if any.
- (9) Includes 4,534 shares the selling stockholder has the right to acquire through the exercise of a common stock warrant. The selling stockholder is an affiliate of a broker-dealer that acted as a sub-placement agent in the Private Placement.
- (10) Includes 35,000 shares the selling stockholder has the right to acquire through the exercise of a common stock warrant. The selling stockholder is a managing director of Northland Securities, Inc., which served as placement agent in the Private Placement and received approximately \$170,000 and warrants to purchase approximately 115,000 shares of our common stock, which were allocated to its affiliates, including the selling stockholder.
- (11) Professor Dr. Horst Domdey is the Chief Executive Officer of the selling stockholder has the power to vote or dispose of the securities held of record by the selling stockholder. Professor Dr. Domdey disclaims beneficial ownership of such securities, except to the extent of his pecuniary interest therein.
- (12) Professor Dr. Horst Domdey is the liquidator of the selling stockholder has the power to vote or dispose of the securities held of record by the selling stockholder. Professor Dr. Domdey disclaims beneficial ownership of such securities, except to the extent of his pecuniary interest therein.
- (13) Shaye Hirsch is the director of the selling stockholder and as such has the power to vote or dispose of the securities held of record by the selling stockholder and may be deemed to beneficially own those securities. Mr. Hirsch disclaims beneficial ownership with respect to such shares, except to the extent of his pecuniary interest therein, if any.
- (14) The selling stockholder is a public limited company with limited liability incorporated in India and is governed by a board of directors comprised of seven directors. The members of the board of directors disclaim beneficial ownership with respect to such shares, except to the extent of their pecuniary interest therein, if any.
- (15) Jong Tae Choi is the trustee of the selling stockholder and has the power to vote or dispose of the securities held of record by the selling stockholder and may be deemed to beneficially own those securities. Mr. Choi disclaims beneficial ownership with respect to such shares, except to the extent of his pecuniary interest therein, if any.
- (16) Includes 2,840 shares the selling stockholder has the right to acquire through the exercise of a common stock warrant. The selling stockholder is an affiliate of a broker-dealer that acted as a sub-placement agent in the Private Placement.
- (17) Includes 98,437 shares of our common stock underlying an option held by the selling stockholder and exercisable on or within 60 days following March 20, 2016 that are not being offered in this offering. The selling stockholder was the Chief Financial Officer of Pieris GmbH until December 17, 2014; he is currently the Vice-President of Finance of Pieris and has held this position since December 17, 2014.
- (18) The selling stockholder is an affiliate of a broker-dealer that did not participate in the Private Placement.
- (19) F. Martin Anson, the general partner of the selling stockholder, has the power to vote or dispose of the securities held of record by the selling stockholder and may be deemed to beneficially own those securities. Mr. Anson disclaims beneficial ownership with respect to such shares, except to the extent of his pecuniary interest therein, if any.
- (20) Malcom R. Currie, the trustee of the selling stockholder, has the power to vote or dispose of the securities held of record by the selling stockholder and may be deemed to beneficially own those securities. Mr. Currie disclaims beneficial ownership with respect to such shares, except to the extent of his pecuniary interest therein, if any.
- (21) David M. Rickey, the trustee of the selling stockholder, has the power to vote or dispose of the securities held of record by the selling stockholder and may be deemed to beneficially own those securities. Mr. Rickey disclaims beneficial ownership with respect to such shares, except to the extent of his pecuniary interest therein, if any.

Table of Contents

- (22) Includes 21,319 shares the selling stockholder has the right to acquire through the exercise of a common stock warrant and 58,962 shares owned by the selling stockholder that are not being offered in this offering. The selling stockholder is an affiliate of a broker-dealer that acted as a sub-placement agent in the Private Placement.
- (23) Adam Passaglia, the manager of the selling stockholder, has the power to vote or dispose of the securities held of record by the selling stockholder and may be deemed to beneficially own those securities. Mr. Passaglia disclaims beneficial ownership with respect to such shares, except to the extent of his pecuniary interest therein, if any.
- (24) Adam Passaglia, the manager of the selling stockholder, has the power to vote or dispose of the securities held of record by the selling stockholder and may be deemed to beneficially own those securities. Mr. Passaglia disclaims beneficial ownership with respect to such shares, except to the extent of his pecuniary interest therein, if any.
- (25) Robert S. Beadle, the President of the selling stockholder, has the power to vote or dispose of the securities held of record by the selling stockholder and may be deemed to beneficially own those securities. Mr. Beadle disclaims beneficial ownership with respect to such shares, except to the extent of his pecuniary interest therein, if any.
- (26) Includes 16,078 shares the selling stockholder has the right to acquire through the exercise of a common stock warrant and includes 5,000 shares owned by the selling stockholder that are not being offered in this offering. Barbara J. Glenns, the President of the selling stockholder has the power to vote or dispose of the securities held of record by the selling stockholder and may be deemed to beneficially own those securities. Ms. Glenns disclaims beneficial ownership with respect to such shares, except to the extent of her pecuniary interest therein, if any.
- (27) Includes 24,382 shares the selling stockholder has the right to acquire through the exercise of a common stock warrant and 63,176 shares owned by the selling stockholder that are not being offered in this offering. The selling stockholder is an affiliate of a broker-dealer that acted as a sub-placement agent in the Private Placement.
- (28) Robert D. Burke, the general partner of the selling stockholder, has the power to vote or dispose of the securities held of record by the selling stockholder and may be deemed to beneficially own those securities. Mr. Burke disclaims beneficial ownership with respect to such shares, except to the extent of his pecuniary interest therein, if any.
- (29) Samuel Belzberg, the Chairman and Chief Executive Officer of the selling stockholder, has the power to vote or dispose of the securities held of record by the selling stockholder and may be deemed to beneficially own those securities. Mr. Belzberg disclaims beneficial ownership with respect to such shares, except to the extent of his pecuniary interest therein, if any.
- (30) David Gubbay is the manager of the selling stockholder has the power to vote or dispose of the securities held of record by the selling stockholder and may be deemed to beneficially own those securities. Mr. Grubbay disclaims beneficial ownership with respect to such shares, except to the extent of his pecuniary interest therein, if any.
- (31) Pamela M. Baker is the manager of the selling stockholder has the power to vote or dispose of the securities held of record by the selling stockholder and may be deemed to beneficially own those securities. Ms. Baker disclaims beneficial ownership with respect to such shares, except to the extent of her pecuniary interest therein, if any.
- (32) Sphera Global Healthcare Management LP is in the investment manager of the selling stockholder. Doron Breen is the portfolio manager of Sphera Global Healthcare Management LP and exercises the power to vote or dispose of the securities held of record by the selling stockholder. Mr. Breen disclaims beneficial ownership of such securities, except to the extent of his pecuniary interest therein. The general partner of Sphera Global Healthcare Management LP is Sphera Global Healthcare GP Ltd., a company incorporated in Israel, which has four members on its board of directors. The members of the board of directors disclaim beneficial ownership with respect to such shares, except to the extent of their pecuniary interest therein, if any.
- (33) Includes 1,000 shares owned by the selling stockholder that are not being offered in this offering.
- (34) Includes 15,000 shares the selling stockholder has the right to acquire through the exercise of a common stock warrant. The selling stockholder is the Head of Investment Banking at Northland Securities, Inc., which served as placement agent in the Private Placement and received approximately \$170,000 and warrants to purchase approximately 100,000 shares of our common stock.

Table of Contents

- (35) Joel L. Hochman, the trustee of the selling stockholder, has the power to vote or dispose of the securities held of record by the selling stockholder and may be deemed to beneficially own those securities. Mr. Hochman disclaims beneficial ownership with respect to such shares, except to the extent of his pecuniary interest therein, if any.
- (36) Henry Joshua Blatt, the trustee of the selling stockholder, has the power to vote or dispose of the securities held of record by the selling stockholder and may be deemed to beneficially own those securities. Mr. Blatt disclaims beneficial ownership with respect to such shares, except to the extent of his pecuniary interest therein, if any.
- (37) Includes 4,216 shares the selling stockholder has the right to acquire through the exercise of a common stock warrant. The selling stockholder is an affiliate of a broker-dealer that acted as a sub-placement agent in the Private Placement.
- (38) The selling stockholder is a public-law institution organized under the laws of the Federal Republic of Germany and is owned by the Federal Republic of Germany and by the 16 German states. Petra Röttcher, Vice President, and Markus Danhausen, Senior Investment Manager, have the power to vote or dispose of the securities held of record by the selling stockholder. Certain other persons affiliated with the selling stockholder may also have the power to vote or dispose of the securities held of record by the selling stockholder. No decision may be made by any of these individuals acting alone and each person with such authority disclaims beneficial ownership with respect to such shares, except to the extent of his or her pecuniary interest therein, if any.
- (39) Includes 629 shares the selling stockholder has the right to acquire through the exercise of a common stock warrant. The selling stockholder is an affiliate of a broker-dealer that acted as a sub-placement agent in the Private Placement.
- (40) Lee J. Seidler, the trustee of the selling stockholder, has the power to vote or dispose of the securities held of record by the selling stockholder and may be deemed to beneficially own those securities. Mr. Seidler disclaims beneficial ownership with respect to such shares, except to the extent of his pecuniary interest therein, if any.
- (41) Includes 464 shares the selling stockholder has the right to acquire through the exercise of a common stock warrant. The selling stockholder is an affiliate of a broker-dealer that acted as a sub-placement agent in the Private Placement.
- (42) Lon E. Bell, the trustee of the selling stockholder, has the power to vote or dispose of the securities held of record by the selling stockholder and may be deemed to beneficially own those securities. Mr. Bell disclaims beneficial ownership with respect to such shares, except to the extent of his pecuniary interest therein, if any.
- (43) Dr. Martin Pöhlchen is the managing director of the selling stockholder has the power to vote or dispose of the securities held of record by the selling stockholder. Dr. Pöhlchen disclaims beneficial ownership of such securities, except to the extent of his pecuniary interest therein.
- (44) Includes 1,410,010 shares owned by the selling stockholder that are not being offered in this offering.
- (45) WT Director Limited is the controlling entity of the selling stockholder. Each of Paul Conway and Du Preez Vermeulen, authorized signatories of WT Director Limited, has the power to vote or dispose of the securities held of record by the selling stockholder and may be deemed to beneficially own those securities. Messrs. Conway and Vermeulen disclaim beneficial ownership of such securities, except to the extent of his pecuniary interest therein.
- (46) Steven Evans, the trustee of the selling stockholder, has the power to vote or dispose of the securities held of record by the selling stockholder and may be deemed to beneficially own those securities. Mr. Evans disclaims beneficial ownership with respect to such shares, except to the extent of his pecuniary interest therein, if any.
- (47) Includes 61,064 shares the selling stockholder has the right to acquire through the exercise of a common stock warrant. The selling stockholder is an affiliate of a broker-dealer that acted as a placement agent in the Private Placement.
- (48) Includes 50,000 shares the selling stockholder has the right to acquire through the exercise of a common stock warrant. The selling stockholder is a broker-dealer who served as placement agent in the Private Placement and received approximately \$170,000 and warrants to purchase approximately 100,000 shares of our common stock, 50,000 of which were allocated to its affiliates. The selling stockholder is a corporation governed by a board of directors comprised of three directors. The members of the board of directors disclaim beneficial ownership with respect to such shares, except to the extent of their pecuniary interest therein, if any.

Table of Contents

- (49) John Abeles, the manager of the general partner of the selling stockholder, has the power to vote or dispose of the securities held of record by the selling stockholder and may be deemed to beneficially own those securities. Mr. Abeles disclaims beneficial ownership with respect to such shares, except to the extent of his pecuniary interest therein, if any.
- (50) The selling stockholder is a corporation governed by a board of directors comprised of 11 directors. The members of the board of directors disclaim beneficial ownership with respect to such shares, except to the extent of their pecuniary interest therein, if any.
- (51) OrbiMed Capital GP III LLC, or GP III, is the sole general partner of OrbiMed Private Investments III, LP and, as such, may be deemed to indirectly beneficially own the shares held by OrbiMed Private Investments III, LP. OrbiMed Advisors LLC, or OrbiMed, is the general partner of OrbiMed Associates III, LP and the sole managing member of GP III and, as such, OrbiMed may be deemed to indirectly beneficially own the shares held by OrbiMed Private Investments III, LP and OrbiMed Associates III, LP. Samuel D. Isaly is the managing member of, and owner of a controlling interest in, OrbiMed. Accordingly, OrbiMed and Mr. Isaly may be deemed to have voting and investment power over the shares held by OrbiMed Private Investments III, LP and OrbiMed Associates III, LP. GP III, OrbiMed and Mr. Isaly disclaim beneficial ownership with respect to such shares, except to the extent of their pecuniary interest therein, if any. Chau Khuong is an employee of OrbiMed Advisors LLC and is its designee to the Company's Board of Directors pursuant to an agreement between the Company and investment funds affiliated with OrbiMed. Mr. Khuong replaced Michael Sheffery, a former Member of OrbiMed Advisors LLC, on the Company's Board in 2014.
- (52) Includes 8,039 shares the selling stockholder has the right to acquire through the exercise of a common stock warrant. The selling stockholder is the president of Katalyst Securities, LLC, which served as placement agent in the Private Placement and which received approximately \$491,000 and warrants to purchase approximately 245,630 shares of our common stock, which were allocated to its affiliates, including the selling stockholder.
- (53) Includes 8,039 shares the selling stockholder has the right to acquire through the exercise of a common stock warrant. The selling stockholder is an owner of 50% of Katalyst Securities, LLC, which served as placement agent in the Private Placement and which received approximately \$491,000 and warrants to purchase approximately 245,630 shares of our common stock, which were allocated to its affiliates, including the selling stockholder.
- (54) Prof. Dr. Arne Skerra has the power to vote or dispose of the securities held of record by the selling stockholder and may be deemed to beneficially own those securities. Prof. Dr. Skerra is a former member of the advisory board of Pieris GmbH and currently serves as a consultant to Pieris.
- (55) Includes 5,000 shares the selling stockholder has the right to acquire through the exercise of a common stock warrant. The selling stockholder is an affiliate of a broker-dealer that acted as a placement agent in the Private Placement.
- (56) Includes 9,400 shares the selling stockholder has the right to acquire through the exercise of a common stock warrant. The selling stockholder is a registered investment advisory firm, which utilizes a broker-dealer that acted as a placement agent in the Private Placement for broker-dealer services. Philip Rabinovich, the managing member and principal shareholder of the selling stockholder, has the power to vote or dispose of the securities held of record by the selling stockholder and may be deemed to beneficially own those securities; he is also a registered representative of a sub-placement agent in the Private Placement.
- (57) Includes 57,862 shares the selling stockholder has the right to acquire through the exercise of a common stock warrant. The selling stockholder is an affiliate of a broker-dealer that acted as a sub-placement agent in the Private Placement.
- (58) Includes 10,000 shares the selling stockholder has the right to acquire through the exercise of a common stock warrant. The selling stockholder is an affiliate of a broker-dealer that acted as a placement agent in the Private Placement.
- (59) Includes 6,496 shares the selling stockholder has the right to acquire through the exercise of a common stock warrant. The selling stockholder is an affiliate of a broker-dealer that acted as a placement agent in the Private Placement.
- (60) Includes 10,098 shares the selling stockholder has the right to acquire through the exercise of a common stock warrant and includes 13,892 shares owned by the selling stockholder that are not being offered in this offering. The selling stockholder is an affiliate of a broker-dealer that acted as a sub-placement agent in the Private Placement.

Table of Contents

- (61) The selling stockholder is a corporation with a four-member board of directors; the selling stockholder has delegated investment discretion to Sphera Global Healthcare Management LP (“Sphera LP”), which serves as the investment manager of the selling stockholder. Doron Breen is the portfolio manager of Sphera LP and exercises the power to vote or dispose of the securities held of record by the selling stockholder. Mr. Breen disclaims beneficial ownership of such securities, except to the extent of his pecuniary interest therein. The general partner of Sphera LP is Sphera Global Healthcare GP Ltd., a company incorporated in Israel, which has four members on its board of directors.
- (62) Includes 61,064 shares the selling stockholder has the right to acquire through the exercise of a common stock warrant, 12,500 shares that were purchased by the selling stockholder in the Private Placement and 147,503 shares owned by the selling stockholder that are not being offered in this offering. The selling stockholder is an affiliate of a broker-dealer that acted as a placement agent in the Private Placement.
- (63) The general partner of the selling stockholder is Technologie Beteiligungsfonds Bayern Verwaltungs GmbH (“TBBV”), a limited liability company. The managing directors of TBBV are Roman Huber and Dr. Georg Ried and the authorized officers of TBBV are Monika Steger, Klaus Löschner and Rosi Keimerl. Both managing directors acting together or one managing director and one authorized officer acting together have the power to vote or dispose of the securities held of record by the selling stockholder. Each of the managing directors and the authorized officers disclaims beneficial ownership of the securities of the selling stockholder, except to the extent of his or her pecuniary interest therein, if any.
- (64) Robert B. Prag, the trustee of the selling stockholder, has the power to vote or dispose of the securities held of record by the selling stockholder and disclaims beneficial ownership of such securities, except to the extent of his pecuniary interest therein.
- (65) Includes 10,603 shares the selling stockholder has the right to acquire through the exercise of a common stock warrant and includes 17,086 shares owned by the selling stockholder that are not being offered in this offering. The selling stockholder is an affiliate of a broker-dealer that acted as a sub-placement agent in the Private Placement.
- (66) Includes 14,159 shares the selling stockholder has the right to acquire through the exercise of a common stock warrant and includes 23,384 shares owned by the selling stockholder that are not being offered in this offering. The selling stockholder is an affiliate of a broker-dealer that acted as a sub-placement agent in the Private Placement.
- (67) The sole and fully authorized representative of the selling stockholder is Alexander von Mellenthin. Mr. von Mellenthin has the power to vote or dispose of the securities held of record by the selling stockholder. The sole stockholders of the selling stockholder and beneficial owners of the securities of record held by the selling stockholder are Dr. Stephan Goetz, Stefan Sanktjohanser, and Alexander von Mellenthin.
- (68) Includes 80,000 shares the selling stockholder has the right to acquire through the exercise of a common stock warrant. The selling stockholder is a broker-dealer who served as a sub-placement agent in the Private Placement. The selling stockholder is a limited liability company whose managing member and CEO is Jonathan Fassberg. Accordingly, Mr. Fassberg may be deemed to have voting and investment power over the shares held by the selling stockholder. Mr. Fassberg disclaims beneficial ownership with respect to such shares, except to the extent of their pecuniary interest therein, if any.

PLAN OF DISTRIBUTION

We are registering the shares of common stock issued to the selling stockholders to permit the resale of these shares of common stock by the holders of the shares of common stock from time to time after the date of this prospectus. We will not receive any of the proceeds from the sale by the selling stockholders of the shares of common stock. We will bear all fees and expenses incident to our obligation to register the shares of common stock.

The selling stockholders may sell all or a portion of the shares of common stock beneficially owned by them and offered hereby from time to time directly or through one or more underwriters, broker-dealers or agents. If the shares of common stock are sold through underwriters or broker-dealers, the selling stockholders will be responsible for underwriting discounts or commissions or agent's commissions. The shares of common stock may be sold in one or more transactions, which may involve crosses or block transactions, and may be sold on any national securities exchange or quotation service on which our common stock may be listed or quoted at the time of sale, in the over-the-counter market, or in transactions otherwise than on these exchanges or systems. Sales of the common stock to be registered hereunder could be made at prevailing market prices at the time of the sale, at fixed prices, at negotiated prices, or at varying prices determined at the time of sale. As a result, we cannot know the price at which any of our common stock to be registered hereunder may ultimately be sold by the holders thereof.

The selling stockholders may use any one or more of the following methods when selling shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales entered into after the effective date of the registration statement of which this prospectus is a part;
- broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
- through the writing or settlement of options or other hedging transactions, whether such options are listed on an options exchange or otherwise;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

The selling stockholders also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act, as permitted by that rule, or Section 4(a)(1) under the Securities Act, if available, rather than under this prospectus, provided that they meet the criteria and conform to the requirements of those provisions, including the requirements of Rule 144(i) applicable to former "shell companies."

Broker-dealers engaged by the selling stockholders may arrange for other broker-dealers to participate in sales. If the selling stockholders effect such transactions by selling shares of common stock to or through underwriters, broker-dealers or agents, such underwriters, broker-dealers or agents may receive commissions in the form of discounts, concessions or commissions from the selling stockholders or commissions from purchasers of the shares of common stock for whom they may act as agent or to whom they may sell as principal. Such commissions will be in amounts to be negotiated, but, except as set forth in a supplement to this prospectus, in the case of an agency transaction will not be in excess of a customary brokerage commission in compliance with FINRA Rule 5110.

In connection with sales of the shares of common stock or otherwise, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the shares of common stock in the course of hedging in positions they assume. The selling stockholders may also

Table of Contents

sell shares of common stock short and if such short sale shall take place after the date that this registration statement is declared effective by the SEC, the selling stockholders may deliver shares of common stock covered by this prospectus to close out short positions and to return borrowed shares in connection with such short sales. The selling stockholders may also loan or pledge shares of common stock to broker-dealers that in turn may sell such shares, to the extent permitted by applicable law. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction). Notwithstanding the foregoing, the selling stockholders have been advised that they may not use shares registered pursuant to this registration statement to cover short sales of our common stock made prior to the date the registration statement of which this prospectus forms a part is declared effective by the SEC.

The selling stockholders may, from time to time, pledge or grant a security interest in some or all of the shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock from time to time pursuant to this prospectus or any amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act, amending, if necessary, the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus. The selling stockholders also may transfer and donate the shares of common stock in other circumstances in which case the transferees, donees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

The selling stockholders and any broker-dealer or agents participating in the distribution of the shares of common stock offered hereby may be deemed to be “underwriters” within the meaning of Section 2(11) of the Securities Act in connection with such sales. In such event, any commissions paid, or any discounts or concessions allowed to, any such broker-dealer or agent and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Selling stockholders who are “underwriters” within the meaning of Section 2(11) of the Securities Act will be subject to the prospectus delivery requirements of the Securities Act and may be subject to certain statutory liabilities of, including but not limited to, Sections 11, 12 and 17 of the Securities Act and Rule 10b-5 under the Exchange Act.

Each selling stockholder has informed us that it is not a registered broker-dealer and does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the common stock. Upon us being notified in writing by a selling stockholder that any material arrangement has been entered into with a broker-dealer for the sale of common stock through a block trade, special offering, exchange distribution or secondary distribution or a purchase by a broker-dealer, a supplement to this prospectus will be filed, if required, pursuant to Rule 424(b) under the Securities Act, disclosing (i) the name of each such selling stockholder and of the participating broker-dealer(s), (ii) the number of shares involved, (iii) the price at which such the shares of common stock were sold, (iv) the commissions paid or discounts or concessions allowed to such broker-dealer(s), where applicable, (v) that such broker-dealer(s) did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus, and (vi) other facts material to the transaction. In no event shall any broker-dealer receive fees, commissions and markups, which, in the aggregate, would exceed eight percent (8%).

Under the securities laws of some states, the shares of common stock may be sold in such states only through registered or licensed brokers or dealers. In addition, in some states the shares of common stock may not be sold unless such shares have been registered or qualified for sale in such state or an exemption from registration or qualification is available and is complied with in all respects.

Any selling stockholder may sell some, all or none of the shares of common stock to be registered pursuant to the registration statement of which this prospectus forms a part.

Each selling stockholder and any other person participating in such distribution will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including, without limitation, Regulation M of the Exchange Act, which may limit the timing of purchases and sales of any of the shares of common stock by the selling stockholder and any other participating person. Regulation M may also restrict the ability of any person engaged in the distribution of the shares of common stock to engage in market-making activities with respect to the shares of common stock. All of the foregoing may affect the marketability of the shares of common stock and the ability of any person or entity to engage in market-making activities with respect to the shares of common stock.

[Table of Contents](#)

We will pay all expenses of the registration of the shares of common stock pursuant to the Registration Rights Agreement, including, without limitation, SEC filing fees and expenses of compliance with state securities or “blue sky” laws; *provided, however*, that each selling stockholder will pay all underwriting discounts and selling commissions, if any, and any legal expenses incurred by it. We will indemnify the selling stockholders against certain liabilities, including some liabilities under the Securities Act, in accordance with the Registration Rights Agreement, or the selling stockholders will be entitled to contribution. We may be indemnified by the selling stockholders against civil liabilities, including liabilities under the Securities Act, that may arise from any written information furnished to us by the selling stockholders specifically for use in this prospectus, in accordance with the Registration Rights Agreement, or we may be entitled to contribution.

DETERMINATION OF OFFERING PRICE

The selling stockholders will determine at what price they may sell the shares of common stock offered by this prospectus, and such sales may be made at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale, or at negotiated prices.

USE OF PROCEEDS

We will not receive any proceeds from the sale of our common stock offered by this prospectus. We have agreed to bear the expenses (other than any underwriting discounts or selling commissions or any legal expenses incurred by any selling stockholder) in connection with the registration of the shares of our common stock being offered for resale hereunder by the selling stockholders.

DESCRIPTION OF SECURITIES

The following describes the material terms of the capital stock of Pieris. The following description does not purport to be complete and is subject to, and qualified in its entirety by reference to, Pieris' Amended and Restated Articles of Incorporation and Amended and Restated Bylaws, which are attached as Exhibits 3.1 and 3.2, respectively, to this prospectus and incorporated herein by reference. All of our stockholders are urged to read our Amended and Restated Articles of Incorporation and Amended and Restated Bylaws carefully and in their entirety.

We currently have authorized capital stock of 310,000,000 shares, of which 300,000,000 are designated as common stock, par value \$0.001 per share, and 10,000,000 shares are designated as preferred stock, par value \$0.001 per share. The following is a summary of the rights of our common and preferred stock and some of the provisions of our Amended and Restated Articles of Incorporation and Amended and Restated Bylaws, and the Nevada Revised Statutes, or the NRS. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description you should refer to our Amended and Restated Articles of Incorporation and Amended and Restated Bylaws, copies of which have been filed as exhibits to this prospectus, as well as the relevant provisions of the NRS.

As of March 20, 2016, there were 39,833,023 shares of common stock outstanding and no shares of preferred stock issued and outstanding. In addition, there are warrants to purchase 542,360 shares of our common stock outstanding and, as of March 20, 2016, we have granted options to purchase 3,893,711 shares of our common stock under the Pieris Plan, and there were 433,789 shares of common stock reserved for future issuance under the Pieris Plan.

Common Stock

All of the securities being offered pursuant to the registration statement of which this prospectus is a part are shares of our common stock. The holders of our common stock are entitled to one vote per share on matters on which our stockholders vote. There are no cumulative voting rights. Subject to any preferential dividend rights of any outstanding shares of preferred stock, holders of our common stock are entitled to receive dividends, if declared by our Board of Directors, out of funds that we may legally use to pay dividends. If we liquidate or dissolve, holders of our common stock are entitled to share ratably in our assets once our debts and any liquidation preference owed to any then-outstanding preferred stockholders are paid. Our Amended and Restated Articles of Incorporation do not provide our common stock with any redemption, conversion or preemptive rights. All of the issued and outstanding shares of our common stock are duly authorized, validly issued, fully paid and non-assessable.

None of the 4,967,202 shares of our common stock issued in the Private Placement and to be registered under the registration statement of which this prospectus is a part will be subject to restrictions on alienability in addition to those imposed by applicable securities laws. However, certain of our other issued and outstanding shares of our common stock being registered hereunder are subject to certain lock-up agreements that impose restrictions on their alienability in addition to those imposed by applicable securities laws. See the description under “Market Price of and Dividends on Our Common Stock and Related Stockholder Matters—Shares Eligible for Future Sale” and “Market Price of and Dividends on Our Common Stock and Related Stockholder Matters—Lock-Up Agreements” for further information.

Preferred Stock

If we issue preferred stock in the future, such preferred stock may have priority over common stock with respect to dividends and other distributions, including the distribution of assets upon liquidation. Our Board of Directors has the authority, without further stockholder authorization, to issue from time to time up to 10,000,000 shares of preferred stock in one or more series and to fix the terms, limitations, voting rights, relative rights and preferences and variations of each series. Although we have no present plans to issue any shares of preferred stock, the issuance of shares of preferred stock, or the issuance of rights to purchase such shares, could decrease the amount of earnings and assets available for distribution to the holders of common stock, could adversely affect the rights and powers, including voting rights, of the common stock, and could have the effect of delaying, deterring or preventing a change of control of us or an unsolicited acquisition proposal. As of March 23, 2016, no shares of preferred stock were outstanding.

[Table of Contents](#)

Placement Warrants

Each Placement Warrant entitles the registered holder to purchase one share of our common stock at a price of \$2.00 per share, exercisable at any time at the option of the holder until the five-year anniversary of its date of issuance. The number of shares issuable upon exercise of each Placement Warrant is adjustable in the event of stock splits, stock dividends, combinations of shares and similar transactions. Furthermore, if we engage in a merger, sale of substantially all of our assets or similar transaction the holders of more than 50% of the outstanding shares of common stock accept a tender offer, each holder of a Placement Warrant that is outstanding shall have the right to receive the number of shares of the surviving corporation and any additional consideration receivable by a holder of the same number of shares of common stock for which such Placement Warrant is exercisable.

See “—Registration Rights Agreement” below for a description of the registration rights granted to the holders of the shares of common stock and common stock purchase warrants issued in connection with the Acquisition and the Private Placement.

No fractional shares of common stock will be issued upon exercise of the warrants. If, upon exercise of the warrants, a holder would be entitled to receive a fractional interest in a share, we will, upon exercise, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the exercise price or round up to the next whole share.

Registration Rights Agreement

On December 17, 2014, we entered into the Registration Rights Agreement with the investors that participated in the Private Placement.

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 GmbH 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 GmbH 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 registration statement to which this prospectus forms a part was declared effective on May 11, 2015. If the registration statement 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.

Table of Contents

The foregoing description of the Registration Rights Agreement does not purport to be complete, and is qualified in its entirety by the complete text of that agreement, which is attached as an exhibit to this prospectus and is incorporated herein by reference.

Dividends

Under NRS 78.288, the directors of a Nevada corporation may authorize, and the corporation may make, distributions (including cash dividends) to stockholders, but no such distribution may be made if, after giving it effect:

- the corporation would not be able to pay its debts as they become due in the usual course of business; or
- the corporation's total assets would be less than the sum of (x) its total liabilities plus (y) the amount that would be needed, if the corporation were to be dissolved at the time of distribution, to satisfy the preferential rights upon dissolution of stockholders whose preferential rights are superior to those receiving the distribution.

The NRS prescribes the timing of the determinations above depending on the nature and timing of payment of the distribution. For cash dividends paid within 120 days after the date of authorization, the determinations above must be made as of the date the dividend is authorized. When making their determination that a distribution is not prohibited by NRS 78.288, directors may consider:

- financial statements prepared on the basis of accounting practices that are reasonable in the circumstances;
- a fair valuation, including, but not limited to, unrealized appreciation and depreciation; and/or
- any other method that is reasonable in the circumstances.

Declaration and payment of any dividend will be subject to the discretion of our Board of Directors. The payment of any future dividends will be at the discretion of our Board of Directors; however, the time and amount of such dividends, if any, will be dependent upon our financial condition, operations, compliance with applicable law, cash requirements and availability, debt repayment obligations, capital expenditure needs and restrictions in our debt instruments, contractual restrictions, business prospects, industry trends, the provisions of Nevada law affecting the payment of distributions and any other factors our Board of Directors may consider relevant. Our ability to pay dividends on our common stock may depend in part on our receipt of cash dividends from our operating subsidiaries, which may be restricted from paying us dividends as a result of the laws of their jurisdiction of organization, agreements of our subsidiaries or covenants under any existing and future outstanding indebtedness we or our subsidiaries incur.

Anti-Takeover Effects of Our Amended and Restated Articles of Incorporation and Amended and Restated Bylaws and Certain Provisions of Nevada Law

Our Amended and Restated Articles of Incorporation, Amended and Restated Bylaws and the NRS contain provisions that may have the effect of maintaining continuity and stability in the composition of our Board of Directors. These provisions may help us avoid costly takeover battles, reduce our vulnerability to a hostile change of control and enhance the ability of our Board of Directors to effectively evaluate and negotiate in connection with any unsolicited offer to acquire us. However, these provisions may have an anti-takeover effect and may delay, deter or prevent a merger or acquisition of our company by means of a tender offer, a proxy contest or other takeover attempt that a stockholder might consider to be in its best interest, including attempts that might result in a premium over the prevailing market price for the shares of common stock held by stockholders.

Business Combinations and Acquisition of Control Shares

Pursuant to provisions in our Amended and Restated Articles of Incorporation, we have elected not to be governed by certain Nevada statutes that may have the effect of discouraging corporate takeovers.

[Table of Contents](#)

Nevada's "combinations with interested stockholders" statutes (NRS 78.411 through 78.444, inclusive) prohibit specified types of business "combinations" between certain Nevada corporations and any person deemed to be an "interested stockholder" for two years after such person first becomes an "interested stockholder" unless the corporation's board of directors approves the combination (or the transaction by which such person becomes an "interested stockholder") in advance, or unless the combination is approved by the board of directors and sixty percent of the corporation's voting power not beneficially owned by the interested stockholder, its affiliates and associates.

Furthermore, in the absence of prior approval certain restrictions may apply even after such two-year period. For purposes of these statutes, an "interested stockholder" is any person who is (1) the beneficial owner, directly or indirectly, of ten percent or more of the voting power of the outstanding voting shares of the corporation, or (2) an affiliate or associate of the corporation and at any time within the two previous years was the beneficial owner, directly or indirectly, of ten percent or more of the voting power of the then-outstanding shares of the corporation. The definition of the term "combination" is sufficiently broad to cover most significant transactions between a corporation and an "interested stockholder." These laws generally apply to Nevada corporations with 200 or more stockholders of record, but a Nevada corporation may elect in its articles of incorporation not to be governed by these particular laws. We have not made such an election in our Amended and Restated Articles of Incorporation.

Nevada's "acquisition of controlling interest" statutes (NRS 78.378 through 78.3793, inclusive) contain provisions governing the acquisition of a controlling interest in certain Nevada corporations. These "control share" laws provide generally that any person that acquires a "controlling interest" in certain Nevada corporations may be denied voting rights, unless a majority of the disinterested stockholders of the corporation elects to restore such voting rights. In our Amended and Restated Articles of Incorporation, we have elected to provide that these statutory provisions shall not apply to us or to any acquisition of our common stock. If at such later time when we no longer choose to so elect, and absent such provision in our articles of incorporation or a similar provision included in an amendment to our Amended and Restated Bylaws, these laws would then apply to us if we were to have 200 or more stockholders of record (at least 100 of whom have addresses in Nevada appearing on our stock ledger) and do business in the State of Nevada directly or through an affiliated corporation, unless our articles of incorporation or bylaws in effect on the tenth day after the acquisition of a controlling interest provide otherwise. These laws provide that a person acquires a "controlling interest" whenever a person acquires shares of a subject corporation that, but for the application of these provisions of the NRS, would enable that person to exercise (i) one-fifth or more, but less than one-third, (ii) one-third or more, but less than a majority or (iii) a majority or more, of all of the voting power of the corporation in the election of directors. Once an acquirer crosses one of these thresholds, shares which it acquired in the transaction taking it over the threshold and within the 90 days immediately preceding the date when the acquiring person acquired or offered to acquire a controlling interest become "control shares" to which the voting restrictions described above apply.

In addition, NRS 78.139 also provides that directors may resist a change or potential change in control if the directors, by majority vote of a quorum, determine that the change is opposed to, or not in, the best interest of the corporation.

Classified Board of Directors; Removal of Directors for Cause

Pursuant to our Amended and Restated Articles of Incorporation and Amended and Restated Bylaws, our Board of Directors is divided into three classes, with the term of office of the first class to expire at the first annual meeting of stockholders following the initial classification of directors and until their successors are duly elected and qualified, the term of office of the second class to expire at the second annual meeting of stockholders following the initial classification of directors and until their successors are duly elected and qualified, and the term of office of the third class to expire at the third annual meeting of stockholders following the initial classification of directors and until their successors are duly elected and qualified. At each annual meeting of stockholders, directors elected to succeed those directors whose terms expire, other than directors elected by the holders of any series of preferred stock under specified circumstances, will be elected for a three-year term of office. All directors elected to our classified Board of Directors will serve until the election and qualification of their respective successors or their earlier resignation or removal. Members of the Board of Directors may only be removed for cause and only by the affirmative vote of at least 80% of our outstanding voting stock. These provisions are likely to increase the time required for stockholders to change the composition of the Board of Directors. For example, at least two annual meetings will be necessary for stockholders to effect a change in a majority of the members of the Board of Directors.

[Table of Contents](#)

Advance Notice Provisions for Stockholder Proposals and Stockholder Nominations of Directors

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

Special Meetings of Stockholders

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

No Stockholder Action by Written Consent

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

Super Majority Stockholder Vote Required for Certain Actions

Our Amended and Restated Articles of Incorporation and Amended and Restated Bylaws provide that the Board of Directors is expressly authorized to make, alter, amend, change, add to, rescind or repeal, in whole or in part, our bylaws without a stockholder vote in any manner not inconsistent with Nevada law and our Amended and Restated Articles of Incorporation. Our Amended and Restated Articles of Incorporation require the affirmative vote of the holders of at least 80% of our outstanding voting stock to amend or repeal any of the provisions discussed in this section under the heading "Anti-Takeover Effects of Our Amended and Restated Articles of Incorporation and Amended and Restated Bylaws and Certain Provisions of Nevada Law," as well as certain other provisions of our Amended and Restated Articles of Incorporation. This 80% stockholder vote would be in addition to any separate class vote that might in the future be required pursuant to the terms of any preferred stock that might then be outstanding. An 80% vote is also required for any amendment to, or repeal of, our Amended and Restated Bylaws by the stockholders and for the removal of any member of or our entire Board of Directors. Our Amended and Restated Bylaws may be amended or repealed by a majority vote of the Board of Directors.

Deemed Notice and Consent

Our Amended and Restated Articles of Incorporation 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 all of the provisions of our Amended and Restated Articles of Incorporation, our Amended and Restated Bylaws and any amendment to our articles of incorporation or bylaws enacted in accordance therewith and applicable law.

Transfer Agent and Registrar

Our transfer agent and registrar is Computershare Trust Company, N.A. Its address is P.O. Box 30170, College Station, TX 77842-3170. Their telephone number is (877) 373-6374 from the United States, Canada and Puerto Rico and (781) 575-3100 from all other locations.

Liability and Indemnification of Directors and Officers

The Nevada Revised Statutes empower us to indemnify our directors and officers against expenses relating to certain actions, suits or proceedings as provided for therein. In order for such indemnification to be available, the

Table of Contents

applicable director or officer must not have acted in a manner that constituted a breach of his or her fiduciary duties and involved intentional misconduct, fraud or a knowing violation of law and was material to the action, or must have acted in good faith and reasonably believed that his or her conduct was in, or not opposed to, our best interests. In the event of a criminal action, the applicable director or officer must not have had reasonable cause to believe his or her conduct was unlawful.

Under applicable provisions of the Nevada Revised Statutes, our Amended and Restated Articles of Incorporation, Amended and Restated Bylaws or any separate agreement may provide for our payment of expenses incurred by any such director or officer in advance of the final disposition of the applicable action, suit or proceeding, upon delivery by such director or officer of an undertaking to repay all amounts so advanced if it is ultimately determined that the director or officer is not entitled to be indemnified by us.

Our Amended and Restated Articles of Incorporation provide for indemnification of our directors and officers substantially identical in scope to that permitted under applicable Nevada law. Our Amended and Restated Articles of Incorporation also provide that the expenses of our directors and officers incurred in defending any applicable action, suit or proceeding must be paid by us as they are incurred and in advance of the final disposition of the action, suit or proceeding, provided that the required undertaking by the director or officer is delivered to us.

We have also entered into separate indemnification agreements with each of our current directors and executive officers consistent with Nevada law and in the form approved by our Board of Directors and our stockholders, and we contemplate entering into such indemnification agreements with directors and certain executive officers that may be elected or appointed in the future. Those indemnification agreements require that under the circumstances and to the extent provided for therein, we indemnify such persons to the fullest extent permitted by applicable law against certain expenses incurred by any such person as a result of such person being made a party to certain actions, suits and proceedings by reason of the fact that such person is or was a director, officer, employee or agent of our company, any entity that was a predecessor corporation of our company or any of our affiliates. The rights of each person who is a party to such an indemnification agreement are in addition to any other rights such person may have under applicable Nevada law, our Amended and Restated Articles of Incorporation, our Amended and Restated Bylaws, any other agreement, a vote of our stockholders, a resolution adopted by our Board of Directors or otherwise. The foregoing is only a brief description of the form of indemnification agreement, does not purport to be a complete description of the rights and obligations of the parties thereunder and is qualified in its entirety by reference to the form of indemnification agreement filed as an exhibit to this prospectus and incorporated herein by reference.

We also maintain a customary insurance policy that indemnifies our directors and officers against various liabilities, including liabilities arising under the Securities Act that may be incurred by any director or officer in his or her capacity as such.

At present, there is no pending litigation or proceeding involving any of our directors or officers for which indemnification is sought, nor are we aware of any threatened litigation that is likely to result in claims for indemnification.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted for our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been informed that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event a claim for indemnification against such liabilities (other than payment by us for expenses incurred or paid by a director, officer or controlling person of ours in successful defense of any action, suit, or proceeding) is asserted by a director, officer or controlling person in connection with the securities being registered, we will, unless in the opinion of our counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction, the question of whether such indemnification by it is against public policy in the Securities Act and will be governed by the final adjudication of such issue.

MARKET PRICE OF AND DIVIDENDS ON THE REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Market Information

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

	Common Stock	
	High	Low
Year Ended December 31, 2015:		
First Quarter	\$3.25	\$2.75
Second Quarter	\$4.40	\$2.00
Third Quarter	\$3.70	\$1.74
Fourth Quarter	\$3.08	\$1.54
Year Ended December 31, 2014:		
First Quarter	(1)	(1)
Second Quarter	(1)	(1)
Third Quarter	(1)	(1)
Fourth Quarter	\$2.60	\$0.25

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

On April 8, 2016, the closing bid price for our common stock as reported on the NASDAQ Capital Markets was \$2.35 per share. As of March 20, 2016, there were: (i) outstanding options to purchase 3,893,711 shares of our common stock; (ii) outstanding warrants to purchase 542,360 shares of our common stock; and (iii) 39,833,023 outstanding shares of our common stock.

Holders

As of March 20, 2016, there were 148 holders 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.

Shares Eligible for Future Sale

As of March 20, 2016, there were 39,833,023 shares of our common stock outstanding, of which (i) 14,887,893 have been registered under the Securities Act and are freely tradeable without restriction, (ii) 245,765 may be tradeable in reliance on certain exemptions from registration under the Securities Act, (iii) 4,967,202 were issued and sold in the Private Placement and are being registered for resale pursuant to the registration statement of which this prospectus is a part, (iv) 12,472,543 were issued to former stockholders of Pieris GmbH in connection with the Acquisition and are being registered for re sale pursuant to the registration statement of which this prospectus is a part, and (v) 7,259,620 are beneficially owned by our directors and executive officers. All of the 12,472,543 shares of our common stock issued to former stockholders of Pieris GmbH in connection with the Acquisition and the 4,967,202 shares of our common stock issued to investors in the Private

Table of Contents

Placement have been issued as restricted securities, and as such none of those shares can be publicly sold unless and until they become eligible for sale under Rule 144 promulgated under the Securities Act or they are registered for resale under an effective registration statement under the Securities Act. We are filing the registration statement of which this prospectus is a part to register for resale the 4,967,202 shares issued and sold in the Private Placement, the 12,472,543 shares of our common stock issued to former stockholders of Pieris GmbH in connection with the Acquisition, and 542,360 shares of the registrant's common stock issuable upon exercise of Placement Warrants.

As of March 20, 2016, there were (i) outstanding options to purchase up to 3,893,711 shares of our common stock, and (ii) outstanding warrants to purchase up to 542,360 shares of our common stock.

Rule 144

Rule 144 promulgated under the Securities Act will generally permit the public sale of outstanding shares of our common stock that have been issued as restricted securities by the following persons and under the following circumstances commencing one year following the filing of our "Form 10 information" on our Current Report on Form 8-K, filed on December 18, 2014:

- any person that is not, and has not been for a period of at least 90 days, an affiliate of ours will be entitled to sell its restricted shares of our common stock freely and without restriction, provided that (i) such person has held its restricted shares of our common stock for at least 6 months, (ii) we are subject to the reporting obligations of the Exchange Act for at least 90 days prior to any such sale, and (iii) we remain compliant and current with our reporting obligations under the Exchange Act.
- any of our affiliates, which includes our directors, executive officers and any other person in control of us, will be entitled to sell its restricted shares of our common stock provided that each of clause (i), (ii) and (iii) set forth above with respect to sales by non-affiliates is satisfied, and the following additional conditions are met: (a) any such sale is made in compliance with certain manner of sale provisions, (b) a Form 144 is filed with the SEC, and (c) any such sale complies with certain volume limitations, which generally limit the sale of shares within any three-month period to a number of shares that does not exceed the greater of 1% of the total number of outstanding shares of our common stock and the average weekly trading volume of our common stock during the four calendar weeks preceding the filing of the Form 144 with respect to such sale.

Regulation S

Regulation S under the Securities Act provides that shares owned by any person may be sold without registration in the U.S., provided that the sale is effected in an offshore transaction and no directed selling efforts are made in the U.S. (as these terms are defined in Regulation S), subject to certain other conditions. In general, this means that our shares of common stock may be sold in some other manner outside the U.S. without requiring registration in the U.S.

Securities Authorized for Issuance under Equity Compensation Plans

Equity Compensation Plan Information

On December 17, 2014, Pieris' Board of Directors and the holders of at least a majority of its then-outstanding capital stock adopted the Pieris Plan, which initially authorized the issuance of 3,200,000 shares of our common stock. For a description of the terms of the Pieris Plan, please see "Executive Compensation—Description of Pieris Plan." As of March 20, 2016, options to purchase 3,893,711 shares of our common stock have been issued under the Pieris Plan to our executive officers, directors, employees and consultants. As a result of such grants, 433,789 shares of our common stock are available for future issuances under the Pieris Plan. For additional information, see "Executive Compensation—Director Compensation" and "Executive Compensation—Description of Pieris Plan."

We have filed a registration statement on Form S-8 under the Securities Act covering all of the shares of common stock subject to equity grants outstanding or reserved under the Pieris Plan. Accordingly, shares of our common stock issued under the Pieris Plan are eligible for sale in the public market, subject to vesting restrictions. However, resales of certain shares held by our affiliates registered on the Form S-8 will be subject to volume limitations, manner of sale, notice and public information requirements of Rule 144.

[Table of Contents](#)

Pursuant to a Stock Option Agreement with an executive officer, we granted an option to purchase 450,000 shares of our common stock outside of the Pieris Plan, subject to certain restrictions on exercise and subject to the approval of the Company's shareholders of an increase in the number of shares authorized under the Pieris Plan to provide sufficient shares for such issuance upon the exercise of such award. If such shareholder approval is not obtained by September 30, 2016, the option will be cancelled and of no further force and effect. This option, therefore, does not have an impact on the remaining shares available for future grants currently authorized under the Pieris Plan.

Pursuant to a Stock Option Agreement with another executive officer, we granted an option to purchase 500,000 shares outside of the Pieris Plan that was an inducement option, material to him entering into employment with the Company. This option, therefore, does not have an impact on the remaining shares available for future grants currently authorized under the Pieris Plan.

Issuer Purchases of Equity Securities

In connection with the Acquisition and pursuant to the Split-Off Agreement, we transferred our pre-Acquisition assets and liabilities to our former majority stockholder, Aleksandrs Sviks, in exchange for the surrender by him and cancellation of 11,363,635 shares of Pieris common stock.

Registration Rights Agreement

On December 17, 2014, we entered into a Registration Rights Agreement with the investors in the Private Placement. Pursuant to the terms of the Registration Rights Agreement, we are filing the registration statement of which this prospectus is a part with the SEC to register for resale 4,967,202 of the 6,779,510 shares of our common stock issued in the Private Placement, as well the shares of the Company's common stock issued to the former stockholders of Pieris GmbH, which such shareholders received in connection Acquisition, and the shares of the Company's common stock issuable upon exercise of the Placement Warrants. See the description of the Registration Rights Agreement under the heading "Description of Securities—Registration Rights Agreement" elsewhere in this prospectus.

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 prospectus. 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 prospectus. You should review the disclosure under the heading "Risk Factors" in this prospectus for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage biotechnology company that discovers and develops Anticalin[®] based drugs to target validated disease pathways in a unique and transformative way. Our pipeline includes immune-oncology multi-specifics tailored for the tumor micro-environment, an inhaled Anticalin to treat uncontrolled asthma and a half-life optimized Anticalin to treat anemia. Proprietary to Pieris, Anticalins are a novel class of protein therapeutics validated in the clinic and by partnerships with leading pharmaceutical companies, which are a naturally occurring low-molecular weight human proteins typically found in blood plasma and other bodily fluids.

Each of our development programs focus on the following:

- *300-Series oncology drug candidates* are multispecific Anticalin[®]-based proteins designed to engage immunomodulatory targets and consist of a variety of multifunctional biotherapeutics that genetically link an antibody with one or more Anticalin proteins, thereby constituting a multispecific protein;
- *PRS-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; and
- *PRS-080* is an Anticalin protein that binds to hepcidin, a natural regulator of iron in the blood. It has been designed to target hepcidin for the treatment of functional iron deficiency in anemic patients with chronic kidney disease particularly in end-stage renal disease patients requiring dialysis.

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, Sanofi Group (formerly Sanofi-Aventis and Sanofi-Pasteur S.A.), or Sanofi, and F.Hoffman-La Roche Inc., or Roche, 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. We have also begun 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, 2015 and 2014, we reported net loss of \$14.1 million and net income of \$9.8 million, respectively. As of December 31, 2015, we had an accumulated deficit of \$79.9 million. We expect to continue incurring substantial losses for the next several years as we continue to develop our clinical and preclinical drug candidates and programs. Our operating expenses are comprised of research and development expenses and general and administrative expenses.

We have not generated any revenues from product sales to date, and we do not expect to generate revenues from product sales for the foreseeable future. Our revenues for the fiscal years ended December 31, 2015 and 2014 were primarily from license and collaboration agreements with our partners, and, to a lesser extent, from grants from government agencies.

Table of Contents

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

Acquisition

On December 17, 2014, Pieris, Pieris GmbH and the former stockholders of Pieris GmbH entered into an Acquisition Agreement, or the Acquisition Agreement, and completed the Acquisition, pursuant to which the stockholders of Pieris GmbH contributed all of their equity interests in Pieris GmbH to Pieris in exchange for shares of Pieris common stock, which resulted in Pieris GmbH becoming a wholly owned subsidiary of Pieris, which we refer to as the Acquisition. The Acquisition was consummated on December 17, 2014. 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 prospectus 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 GmbH in exchange for all of the outstanding shares (common and preferred) of Pieris GmbH’s capital stock.

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

TUM Arbitration

Since March 20, 2014, the Company was in 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 the Company to TUM under the TUM Pieris Agreement. Under the agreement, TUM has exclusively licensed, or in some cases assigned, to Pieris GmbH certain intellectual property and know-how that has become part of the Anticalin® proprietary technologies. In return, Pieris GmbH 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 GmbH 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 instituted arbitration to request confirmation that our 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.

On November 19, 2015, the Company received notification from the arbitration of its award. In its award, as corrected on January 25, 2016, the tribunal dismissed the Company’s request for declaratory judgment and granted

[Table of Contents](#)

TUM's counterclaim in an amount of €0.9 million (\$0.9 million), plus interest expense \$0.2 million. The tribunal also ruled that TUM must reimburse us in the amount of €0.1 million (\$0.1 million) for legal fees incurred and dismissed TUM's claim for reimbursement of its cost.

For more information about the TUM arbitration, see "Business—Legal Proceedings—Arbitration Proceeding with Technische Universität München" and "Business—TUM License Agreement."

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 foreseeable future. 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 probability of the achievement of the milestone is near certain, (3) substantive effort on our part is involved in achieving the milestone, (4) the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with achievement of the milestone, and (5) a reasonable amount of time passes between the up-front license payment and the first milestone payment.

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

Research and Development Expenses

The process of researching and developing drugs for human use is lengthy, unpredictable and subject to many risks. We expect to continue incurring substantial expenses for the next several years as we continue to develop our clinical and preclinical drug candidates and programs. We are unable with any certainty to estimate either the costs or the timelines in which those costs will be incurred. Our current development plans focus on three lead drug candidates: PRS-080, PRS-060 and 300-Series. These programs consume a large proportion of our current, as well as projected, resources.

Our research and development costs include costs that are directly attributable to the creation of certain of our Anticalin[®] drug candidates and are comprised of:

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

In 2016 we expect our research and development expenses to increase significantly as a result of continuing to further our drug candidates and programs.

[Table of Contents](#)

General and Administrative Expenses

General and administrative expenses consist primarily of payroll, employee benefits, equity compensation, and other personnel-related costs associated with executive, administrative and other support staff. Other significant general and administrative expenses include the costs associated with obtaining and maintaining our intellectual property portfolio, professional fees for accounting, auditing, insurance costs, consulting and legal services.

Results of Operations

Comparison of Years Ended December 31, 2015 and December 31, 2014

The following table sets forth our revenues and operating expenses for the fiscal years ended December 31, 2015 and 2014 (in thousands):

	Year Ended December 31, 2015	Year Ended December 31, 2014
Revenues	\$ 2,932	\$ 5,365
Research and development expenses	(8,245)	(5,600)
General and administrative expenses	(8,368)	(6,963)
Other income (expense)	(174)	(2,652)
Income tax benefit	(204)	—
Net profit (loss)	<u>\$ (14,059)</u>	<u>\$ (9,850)</u>

[Table of Contents](#)

Revenues

The following table provides a comparison of revenues for the years ended December 31, 2015 and 2014 (in thousands):

	Year Ended December 31, 2015	Year Ended December 31, 2014
Upfront payments	\$ —	\$ 473
Research and development services	5	877
Milestone payments	2,539	3,185
Grants	388	830
Total	\$ 2,932	\$ 5,365

We did not record any revenues from upfront payments during the year ended December 31, 2015. The revenues from upfront payments recorded during the year ended December 31, 2014 were associated with payments from our collaboration partners. Revenues from research and development services decreased \$0.9 million, from 2014 to 2015 due to the successful hand over of all collaboration projects in 2014. During the year ended December 31, 2014 we received research funding from collaboration partners for two collaboration projects.

Pieris recorded collaboration milestone payments of \$2.5 million for the year ended December 31, 2015 compared to \$3.2 million for the year ended December 31, 2014. The decrease relates to two development milestones achieved during the year ended December 31, 2015 compared to four development milestones achieved during the year ended December 31, 2014.

Pieris recorded \$0.4 million in grant and other revenues for the year ended December 31, 2015 compared to \$0.8 million in grant and other revenues during the year ended December 31, 2014. This decrease results from a higher reimbursement from the European Commission for PRS-080's development during the last quarter of 2014.

Research and Development Expenses

The following table provides a comparison of the research and development expenses for our drug candidates and projects that are described in detail under "Business—Pipeline" for the years ended December 31, 2015 and 2014 (in thousands):

	Year Ended December 31, 2015	Year Ended December 31, 2014
PRS-060	\$ 532	\$ 86
PRS-080	1,631	1,384
PRS-300 Series	2,917	596
Other R&D activities	3,165	3,534
Total	\$ 8,245	\$ 5,600

Total research and development expenses were \$8.2 million for the fiscal year ended December 31, 2015 as compared to \$5.6 million for the fiscal year ended December 31, 2014.

The \$2.6 million increase in total research and development expenses in the fiscal year ended December 31, 2015 compared to the fiscal year ended December 31, 2014 is primarily due to a \$2.3 million increase for consulting expenses, labs supplies and personnel costs associated with our 300-Series programs in the fiscal year ended December 31, 2015. Our PRS-060 program increased \$0.4 million due to increased preclinical efforts involving research studies. Our PRS-080 program increased by \$0.2 million due to the Phase Ia clinical trial activity that

[Table of Contents](#)

began in late 2014, and was completed during 2015, as well as clinical manufacturing costs. Other R&D activities decreased by \$0.3 million. Included in other R&D activities in the 2015 period is \$0.9 million of license fees associated with the TUM license agreement offset by an estimated tax credit of \$0.3 million attributable to 2015 R&D expenses incurred in Australia and an additional reduction of costs related to other projects, as we focused work on our major projects during 2015.

General and Administrative Expenses

General and administrative expenses were \$8.4 million for the fiscal year ended December 31, 2015 as compared to \$7.0 million for the fiscal year ended December 31, 2014. The increase of \$1.4 million resulted primarily from a \$1.1 million increase in investor relations expense, directors and officer insurance premiums, and board fees associated with being a public company. Personnel and travel related costs increased by \$0.6 million, offset by a decrease of \$0.6 million in lower consulting costs. Stock compensation expenses increased by \$0.2 million for the year ended December 31, 2015 compared to the year ended December 31, 2014. For the 2015 period an additional amount of \$0.1 million is included for the estimated Massachusetts Net Worth Tax.

Interest Expense & Other Income (Expense), net

Other expense decreased to \$0.2 million in the fiscal year ended December 31, 2015 from \$2.7 million for the fiscal year ended December 31, 2014. This \$2.5 million decrease results primarily from the conversion of the convertible bridge loan in late 2014 that 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 and \$0.3 million in lower interest and other costs. 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.

Other expenses, net in the 2015 period relate to the interest charge associated with the TUM arbitration settlement reached in the fourth quarter of 2015.

Liquidity and Capital Resources

Through December 31, 2015, we have funded our operations with \$169.7 million of cash that has been obtained from the following main sources: \$102.7 million from sales of equity; \$6.5 million from loans; \$14.2 million from grants from government agencies; and \$46.4 million in total payments received under license and collaboration agreements, including \$7.9 million for research and development services costs 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, 2015, we had a total of \$29.3 million in cash and cash equivalents. Our cash and cash equivalents are highly liquid investments with original maturities of 90 days or less at date of purchase, and consist of cash in operating accounts.

We have experienced operating losses since its inception and had a total accumulated deficit of \$79.9 million as of December 31, 2015. We expect to incur additional costs and require additional capital. We have incurred losses in nearly every year since inception including the year ended December 31, 2015. These losses have resulted in significant cash used in operations. During the fiscal years ended December 31, 2015 and 2014, our cash used in operations was \$12.7 million and \$5.1 million, respectively. We have several research and development programs underway in varying stages of development and we expect they will continue to consume increasing amounts of cash for development, conducting clinical trials and the testing and manufacturing of product material. As we continue to conduct these activities necessary to pursue FDA approval of our 300-Series, including PRS-343, PRS-080 and PRS-060 and our other product candidates, we expect the cash needed to fund operations to increase significantly over the next several years. We also expect to incur increased costs in connection with operating and growth as a public company.

In April 2014, we entered into a repayment agreement with tbG Technologie-Beteiligungs-Gesellschaft mbH ("TBG"), the subsidiary of KfW Bank, Frankfurt ("KfW"), regarding our repayment of our liabilities to TBG outstanding at December 31, 2013 in a total amount €1.2 million (\$1.3 million). These liabilities were repaid during 2015 and as of December 31, 2015 there were no liabilities to TBG owed.

Table of Contents

On December 17, 2014 we entered into a 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 \$13.6 million. After deducting for placement agent and other fees and expenses, the aggregate net proceeds from the Private Placement were \$12.0 million.

On July 6, 2015 the Company closed a public offering of an aggregate of 9,090,909 shares of the Company's common stock at a purchase price of \$2.75 per share. On July 28, 2015 the underwriters exercised their option to purchase an additional 1,211,827 shares of common stock at the public offering price of \$2.75 per share. Gross proceeds from the offering, including the over-allotment option, were \$28.3 million and net proceeds were approximately \$25.8 million.

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 adequate enough at all. Due to often volatile nature of the financial markets, equity and debt financing may be difficult to obtain. In addition, any unfavorable development or delay in the progress for our 300-series programs, including PRS-343 and PRS-080 and PRS-060 could have a material adverse impact on our ability to raise additional capital.

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

[Table of Contents](#)

Leases

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

Our policy is to record rent expense on a straight-line basis over the lease term period. As of December 31, 2015, we recognized rent expense in an amount of \$18,399 under the Sublease Agreement. Rent expense under our operating lease for our Freising, Germany based facility was \$0.4 million and \$0.3 million for the years ended December 31, 2015 and 2014, respectively.

Our contractual commitments of the non-cancellable portion under these operating leases as of December 31, 2015 are as follows:

	Total
2016	\$ 318,186
2017	188,009
2018	191,959
2019	195,909
2020	199,859
Thereafter	238,371
Total minimum lease payments	\$1,332,293

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Critical Accounting Policies and Estimates

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

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

Multiple-element arrangements

When evaluating multiple-element arrangements, we identify the deliverables included within the agreement and evaluates which deliverables represent separate units of accounting based 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.

[Table of Contents](#)

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

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

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

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

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

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

Table of Contents

Milestone payments

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

We aggregate milestones into four categories (i) research milestones, (ii) development milestones 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. Sales milestones are typically achieved when an approved pharmaceutical product exceeds net sales as defined in each agreement.

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

Government grants

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

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

Contingencies

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

Income taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, and

[Table of Contents](#)

operating losses and tax credit carry forwards. Deferred tax assets and liabilities are measured using enacted statutory tax rates expected to apply to taxable income in the jurisdictions and years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

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

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

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

Recently Issued Accounting Pronouncements

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

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 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.

Table of Contents

- 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 filed 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. We 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.

BUSINESS

Overview

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

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

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

Our core Anticalin® technology and platform were developed in Germany, and we have collaboration arrangements with major multinational 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. Furthermore, we established a collaboration with F.Hoffmann—La Roche Ltd. and Hoffmann—La Roche Inc., or Roche in December 2015. 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., our wholly owned subsidiary.

We believe that the drug-like properties of the Anticalin® drug class were demonstrated in a Phase Ia/Ib clinical trials with our two Anticalin-branded drug candidates PRS-080 and PRS-050. Our anti-VEGF-A drug candidate, PRS-050, designed to inhibit blood vessel growth in solid tumors, was investigated in solid tumor patients. 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 phase Ib 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 PKs,

[Table of Contents](#)

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 current development plans focus mainly on three Anticalin® drug candidates, PRS-080, PRS-060 and our PRS 300-Series. 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 mAb, could lead to the accumulation of both the drug and the target beyond the typical residence time of hepcidin, resulting in large quantities of hepcidin bound to mAbs. PRS-080 was investigated in a single-ascending dose Phase Ia trial in healthy subjects under governance by the BfArM. This study demonstrated excellent safety and tolerability of PRS-080 as well as dose-proportional pharmacological activity and pharmacokinetics. The inhibition of hepcidin and the subsequent change in parameters of iron metabolism such as the increase in serum iron and transferrin saturation confirmed the mode of action of patients requiring hemodialysis, which commenced in the first quarter of 2016 and is expected to be completed in 2016 in order to study safety and pharmacological activity in CKD patients.

The second Anticalin® drug candidate, PRS-060, binds to the IL-4 receptor alpha-chain (IL-4RA), thereby inhibiting the actions of IL-4 and IL-13, two cytokines (small proteins mediating signaling between cells within the human body) known to be key mediators in the inflammatory cascade that causes asthma and other inflammatory diseases. The small size and biophysical stability of PRS-060 enables direct delivery to the lungs, such as through the use of an inhaler, which we believe will enable high pulmonary concentrations of the drug candidate to be achieved at substantially lower doses than would be reached with antibodies that are systemically delivered. Further, PRS-060 has a short systemic residence time which we believe may avoid undesired target engagement outside of the desired area in the lungs. PRS-060 is currently undergoing IND-enabling activities, and we intend to begin a Phase I clinical trial with PRS-060 in 2017.

The third Anticalin®-based drug candidate, PRS-343, is a bispecific protein targeting the immune receptor CD137 and the tumor target HER2. PRS-343 is the result of a genetic fusion of a variant of the HER2-targeting antibody trastuzumab with the Anticalin specific for CD137. The mode of action of this CD137/HER2 bispecific is to promote CD137 clustering by binding CD137-positive T cells with HER2-positive tumor cells, ad to thereby provide a potent costimulatory signal to tumor antigen-specific T cells. PRS-343 is intended to localize CD137 activation in the tumor, and to thereby both increase efficacy and reduce systematic toxicity compared to CD137-targeting antibodies being developed by third parties in clinical trials.

PRS-343 is a member of our second set of oncology drug candidates known as the 300-Series “platform within a product” opportunity in immuno-oncology. The 300-Series Anticalin® proteins target checkpoint or, like PRS-343, immune-stimulatory proteins and define a variety of multifunctional biotherapeutics that genetically link two distinct Anticalin proteins together or 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 while co-stimulatory proteins (e.g. CD-137) unregulate the immune response.

Strategy

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

- ***Continue to build our platform by entering into new partnerships and license and collaborative arrangements and advancing our currently-partnered programs.*** We have 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.

Anticalin platform technology

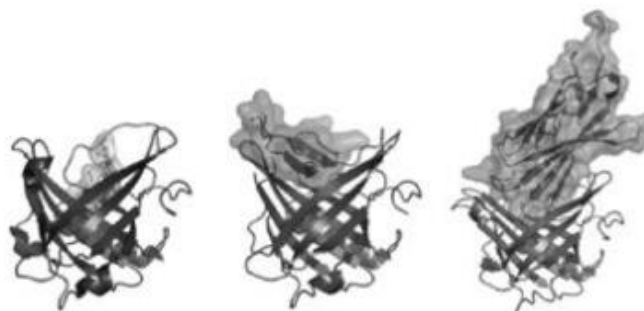
Our platform technology focuses on low molecular-weight Anticalin® proteins that bind tightly and specifically to a diverse range of targets. Anticalin proteins are derived from human proteins called lipocalins, which are naturally occurring low-molecular weight human proteins of approximately 18 to 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.

[Table of Contents](#)



Anticalin® proteins are created from either tear lipocalin, found in human tear fluid, or NGAL lipocalin, a protein involved in the innate immune system, by making discreet mutations in the genetic code for the binding regions. These mutations have the potential to lead to highly specific, high-affinity binding for both small and large molecular targets. Random mutations are introduced at pre-defined positions involved in endogenous ligand engagement, creating exponentially diverse pools of Anticalin proteins, the most potent and well behaved of which are selected and optimized in a customized manner through *in vitro* selection. Using techniques such as phage display, a successful technique in antibody-based drug discovery, to build and refine antibody libraries, the ability to introduce diversity and then select for the best binders among a large pool of Anticalin proteins gives us the opportunity to select Anticalin proteins for a wide variety of targets. The flexibility inherent in the Anticalin proteins' cup-like structure allows us to choose both small-molecule targets that fit inside the 'cup' as well as larger protein targets that can be bound by the Anticalin proteins' outward-facing arms. Our Phase Ia/Ib trial for PRS-080 and 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.

Table of Contents

- *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 for PRS-050, our anti-VEGF-A Anticalin-branded drug candidate designed to inhibit blood vessel growth in solid tumors, in a Phase Ib clinical trial in solid tumor patients. 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.





[Table of Contents](#)

PRS-080 showed excellent safety and tolerability with no infusion reactions, no signs of hypersensitivity and no Severe Adverse Events in a Phase Ia trial in healthy subjects. Besides dose-proportional pharmacokinetics, pharmacologic activity confirming the mode of action of PRS-080 was demonstrated. A dose-dependent increase of the area under the serum iron concentrations was observed to a statistically significant amount compared to healthy subjects receiving placebo ($P=0.0023$) subsequent to reduction of hepcidin blood levels, further demonstrating the drug-like properties of the Anticalin® drug class and supporting further development of PRS-080 in FID-anemic patients.

Implementation of our Anticalin Platform Technology: Our Drug Candidates

Pipeline

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

Product Candidate and Target	Indication	Stage of Development			Upcoming Milestone	Commercial Rights
		Research	Precinical	Phase 1		
PRS-080 targeting Hepcidin	FID, Anemia of chronic kidney disease				<ul style="list-style-type: none">Recruitment of healthy subjects into Phase I clinical studyData from Phase I in healthy subjects expected end 2015	Pieris
PRS-060 targeting IL-4RA	Asthma				<ul style="list-style-type: none">Expect to complete preclinical phase in 2016Planned Phase I clinical study to begin in 2016	Pieris
PRS-110 targeting cMet	Oncology				<ul style="list-style-type: none">Zyodus conducting preclinical studiesExpect to complete preclinical phase in 2016	Pieris and Zyodus
PRS-300 targeting checkpoint proteins	Immuno Oncology				<ul style="list-style-type: none">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 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

[Table of Contents](#)

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 to 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.

[Table of Contents](#)

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.

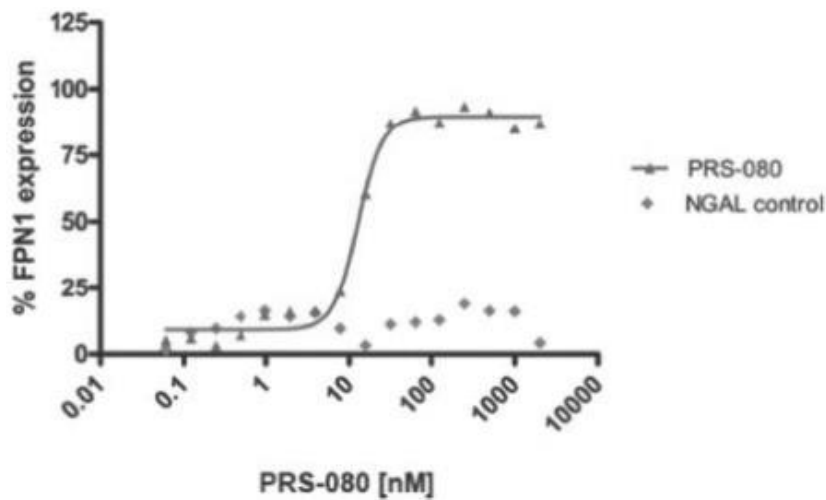
Preclinical data

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.

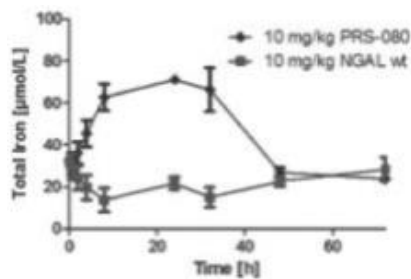
[Table of Contents](#)

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:



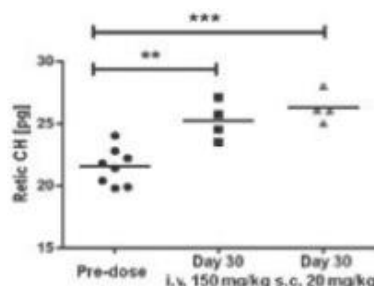
We then studied the functional consequences of hepcidin inhibition on iron mobilization in cynomolgus monkeys. A dose of 1 mg/kg PRS-080 produced a robust, transient and reversible increase in total iron levels from approximately 36 μ M at baseline to 52 μ M after 8 hours. Doses higher than 1 mg/kg elevated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

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



[Table of Contents](#)

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



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

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

Phase I trial design and results

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

PRS-080 was well tolerated. All treatment emergent Adverse Events, or AEs, were either mild or moderate and no Serious AEs were observed. No association of AEs to specific organs and no apparent dose dependency or difference between placebo and active treatment was observed. Notably, no hypersensitivity or infusion reactions were noted and vital signs, body temperature and electrocardiograms were unchanged. Pharmacokinetics of PRS were dose-proportional with a half-life of approximately 3 days. PRS-080 administration resulted in an immediate decrease in plasma hepcidin concentration which was followed by an increase in serum iron concentration and transferrin saturation. The duration of this response in iron and transferrin saturation increased dose dependently from about 18 hours at the lower dose to about 120 hours at the highest dose.

Based on the positive safety and pharmacological activity we are advancing PRS-080 in a Phase Ib study in CKD patients suffering from FID anemia. 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 hemoglobin levels in CKD patients.

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 for pulmonary delivery by inhalation, and we are actively preparing to carry out bioprocess optimization in preparation for cGMP, manufacturing and preclinical safety and tolerability studies. Pending the results of our preclinical studies, we intend to pursue a first-in-human clinical trial for PRS-060 in 2017. Some of the development of PRS-060 is conducted in Australia, where we intend to access leading pulmonologists for potential patient recruitment and to seek up to 40% or more in tax refunds from the Australian government in connection with research and development expenses related to PRS-060. We believe PRS-060 represents a first-in-class inhaled biologic for the treatment of asthma.

Asthma market

Asthma is a very common chronic airway disorder affecting approximately 300 million people worldwide according to the Global Initiative for Asthma and approximately 26 million Americans according to the U.S. Centers for Disease Control. Of these 26 million, about 7 million are children. In 2007 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 (Barnett and Nurmagambetov, 2011, the Journal of Allergy and Clinical Immunology, Volume 127, pp 145-152).

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 60%, or 19 million, of the group of moderate and severe uncontrolled asthma studied were considered to have moderate and severe uncontrolled asthma with an elevated Th2 signature. Inflammation brought about by Th2 immunity is addressed by standard asthma therapies. 5-10% of patients with asthma have moderate to severe disease that is not controlled with standard of care therapies.

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

The next generation of therapies beyond omalizumab targets a broader range than just IgE mediated mechanisms. These approaches target other immune mediators, including IL-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 and GlaxoSmithKline's, or GSK, mepolizumab which targets IL-5 was approved for severe eosinophilic asthma in adults and children older than 12 in 2015. However, eosinophils are only one of many cell types and immune system components that are involved with the body's exaggerated inflammation response in asthma. Mast

[Table of Contents](#)

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. Dupilumab is currently undergoing Phase 3 clinical trials for severe asthma.

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. Following the demonstration that inhaled PRS-060 is well tolerated in healthy volunteers, we plan to enter a proof-of-concept trial in these patients, where we will evaluate whether PRS-060 can improve patient symptoms. We intend to begin a Phase I clinical trial for PRS-060 in 2017.

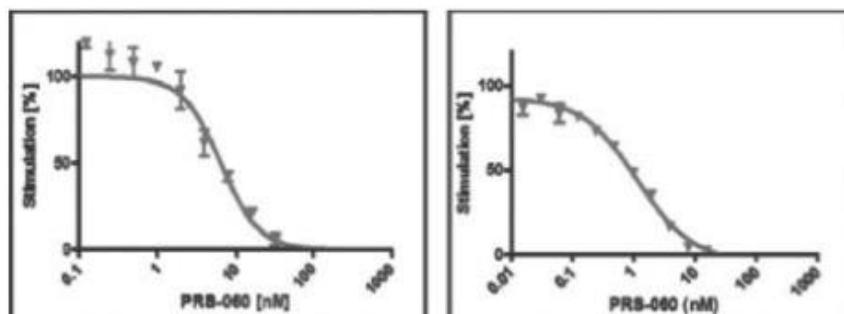
Advantages to inhalation as a route of administration for PRS-060

We have performed inhalation studies in mice and observed that systemic concentrations of PRS-060 are minimal when dosed by inhalation, 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 targeting. By our calculations, the total annual dose of PRS-060 can be significantly 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.

[Table of Contents](#)

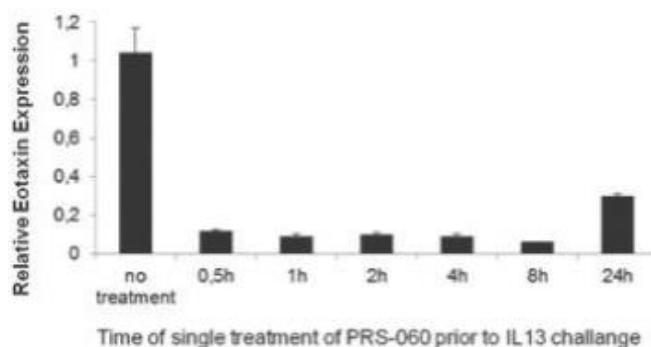
Preclinical data

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



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

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



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

PRS-343 targeting CD-137 in oncology

PRS-343 is a bispecific protein targeting the immune receptor CD137 and the tumor target HER2. It is generated by genetic fusion of an Anticalin specific for CD137 with a variant of the HER2-targeting antibody trastuzumab. The mode of action of this CD137/HER2 bispecific is to promote CD137 clustering by bridging CD137-positive T cells with HER2-positive tumor cells, and to thereby provide a potent costimulatory signal to tumor antigen-specific T cells. PRS-343 is intended to localize CD137 activation in the tumor, and to thereby both increase efficacy and reduce systemic toxicity compared to CD137-targeting antibodies being developed by third parties in clinical trials.

[Table of Contents](#)

Biology of the costimulatory immune receptor CD137

CD137, also known as 4-1BB, is a co-stimulatory immune receptor and a member of the tumor necrosis factor receptor, or TNFR, superfamily. It is mainly expressed on activated CD4+ and CD8+ T cells, activated B cells, and natural killer, or NK, cells. CD137 plays an important role in the regulation of immune responses and thus is a target for cancer immunotherapy. CD137 ligand (CD137L) is the only known natural ligand of CD137, and is constitutively expressed on several types of antigen-presenting cells, or APC. CD137-positive T cells are activated by engaging a CD137L-positive cell. The induced CD137 clustering leads to activation of the receptor and downstream signaling. Note that the trimeric CD137L as a soluble molecule is not an effective CD137 agonist, providing evidence that larger scale clustering is required for activation. In a T cell pre-stimulated by the T cell receptor binding to a cognate Major histocompatibility complex, or MHC, target, costimulation via CD137 leads to further enhanced activation, survival and proliferation, as well as the production of pro-inflammatory cytokines and an improved capacity to kill.

Validation of CD137 as a therapeutic target in cancer

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

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

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

Current approaches to clinical CD137 targeting

The preclinical demonstration of the potential therapeutic benefit of CD137 costimulation has spurred the development of therapeutic antibodies targeting CD137, PF-05082566 (22, 23) and BMS-663513 which are currently in early phase clinical trials. PF-05082566 is a fully humanized IgG2 monoclonal antibody that binds CD137 in a manner that blocks the binding of endogenous CD137L to CD137, and that according to publicly available data is well tolerated as a monotherapy and in combination with rituximab.

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

Rationale for bispecific targeting of CD137

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

[Table of Contents](#)

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

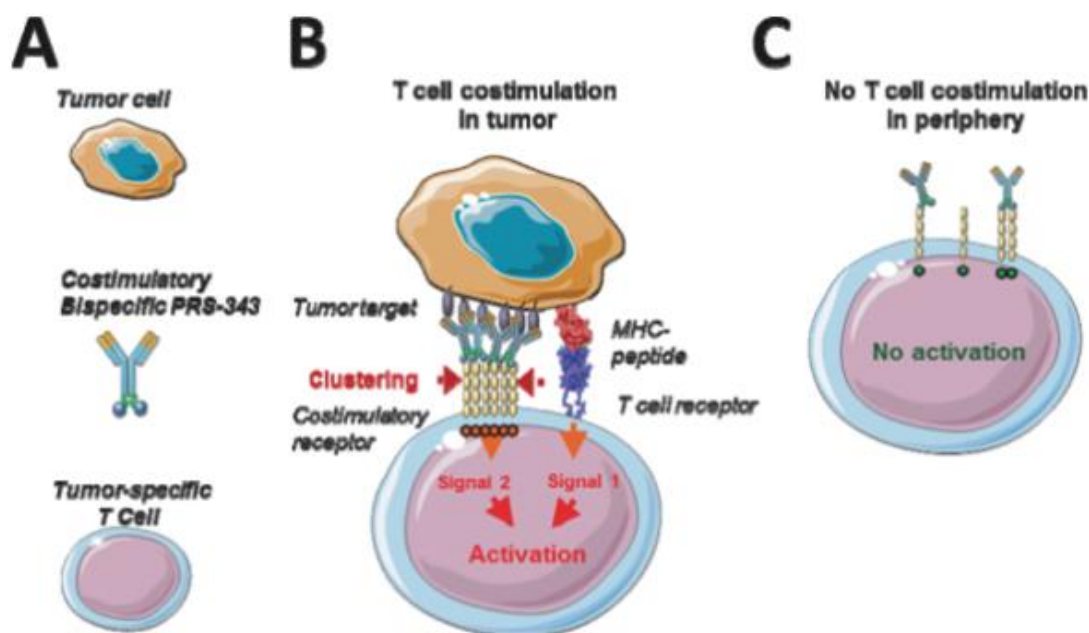


Figure 1 Concept of costimulatory T cell engagement. (A) The elements of the system are a target-positive tumor cell, a T cell with a TCR that is specific for an HLA/peptide combination on the tumor, and a costimulatory bispecific. (B) Within a patient's tumor, tumor-specific T cells are bridged with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

To obtain a molecule that would work by the mode of action of costimulatory T cell engagement, we generated the HER2/CD137 bispecific PRS-343. The molecule consists of two different building blocks binding to the two targets HER2 and CD137. To generate the CD137-specific building block of PRS-343, termed S0575.04J10, we utilized anticalin technology[®]. This technology works by engineering lipocalins to bind any desired target protein with high affinity and specificity, in a manner very similar to antibodies. The lipocalin family comprises a diverse group of mostly secreted soluble proteins that bind, store and transport a broad spectrum of molecules, ranging from small molecules to proteins. Lipocalins are structurally related by possessing an 8-stranded beta-barrel structure. Lipocalin-2, also known as neutrophil gelatinase-associated lipocalin, or NGAL, is a component of granules in neutrophils and is up-regulated during inflammation. The primary function of NGAL appears to be the sequestering of bacterial siderophores (iron chelators), leading to an inhibition of bacterial growth. A CD137-binding anticalin was generated based on a re-design of the natural binding pocket of NGAL using mutant anticalin libraries and a selection and screening process. The CD137-binding anticalin S0575.04J10 binds human CD137 with an affinity of 2 nM as determined by SPR, and is capable of costimulating human T cells when immobilized on a plastic dish together with an anti-CD3 antibody.

[Table of Contents](#)

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

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

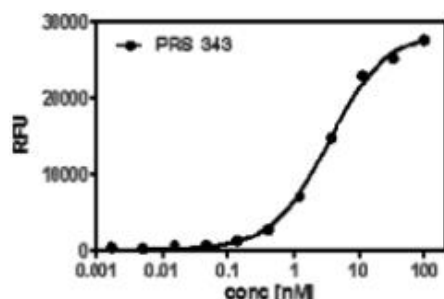


Figure 2 PRS-343 simultaneous binding to targets HER2 and CD137. Recombinant HER2 was coated on a microtiter plate, followed by titration of PRS-343. Subsequently, a constant concentration of biotinylated human CD137 was added, which was detected via a peroxidase-conjugated avidin variant, ExtrAvidin®.

Mode of action – costimulatory T cell activation

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

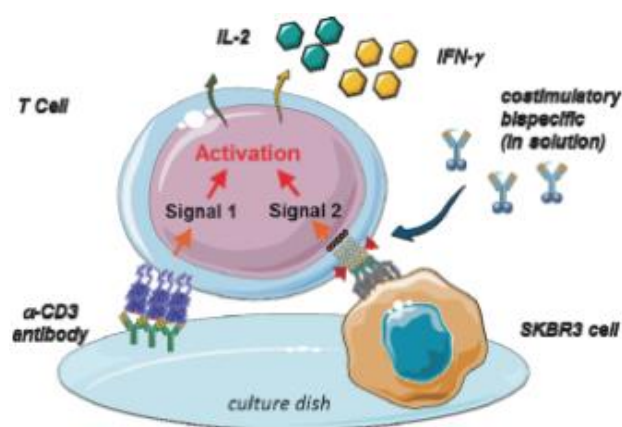


Figure 3 Visualization of costimulatory T cell activation assay. HER2-positive tumor cells are grown overnight on cell culture plates that have been precoated with low amounts of an anti-CD3 antibody to provide a limited primary activation of T cells via the T cell receptor. T cells are added to the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

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

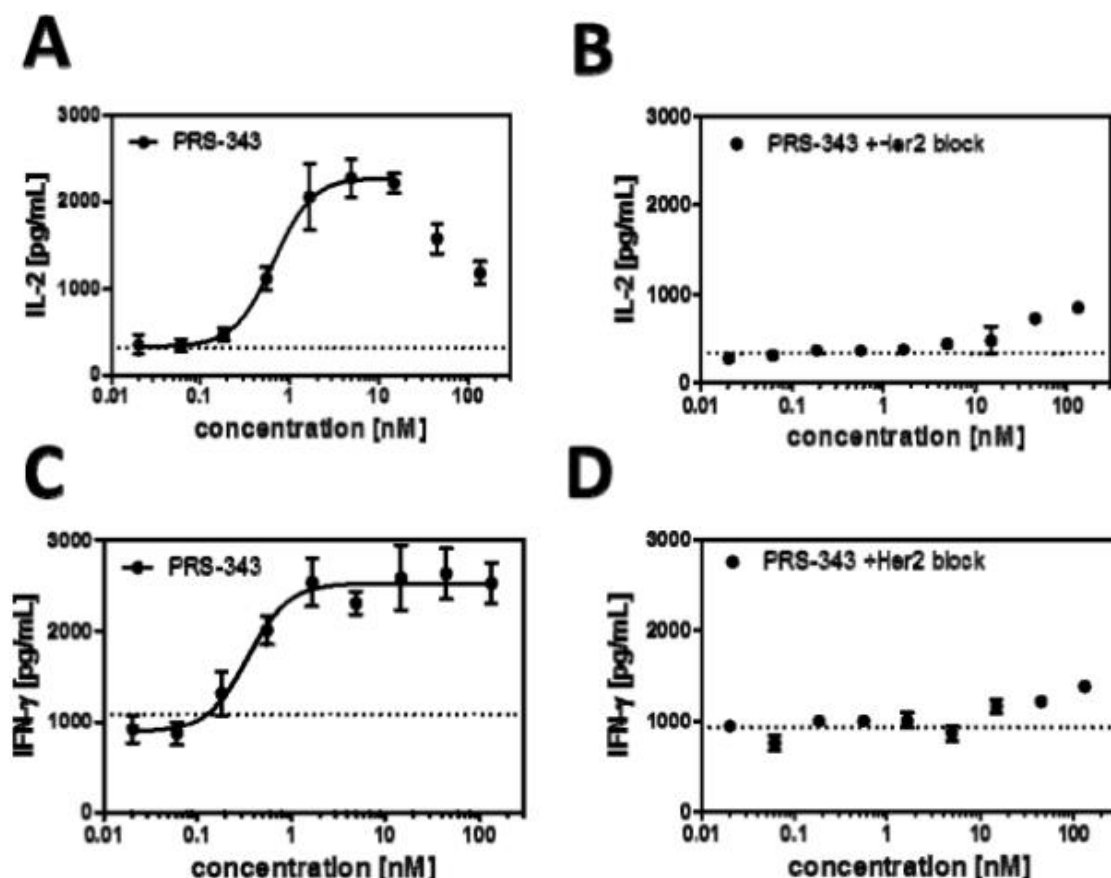


Figure 4 Experimental result of costimulatory T cell activation assay. HER2-positive SKBR3 tumor cells were grown overnight on 96-well plates that had been precoated with 0.25 μ g/mL anti-CD3 antibody for 1 h at 37°C. The next day, T cells purified from healthy donor PBMC were added to the wells together with the titrated CD137/HER2 bispecific PRS-343 (filled circle) or trastuzumab as a control (dotted line). After three days in culture, IL-2 (A) and IFN- γ levels in the culture supernatants were measured by an Electrochemoluminescence immunoassay. In parallel, the experiment was performed in the presence of an excess of trastuzumab (340 nM) to inhibit the binding of PRS-343 to the SKBR3 cells, and IL-2 (C) and IFN- γ (D) levels were measured.

Pipeline products: 300 Series

Current antibody-based therapies targeting tumor cell destruction or immune activation are hampered by, among other factors, low response rates and the induction of immune-related adverse events. The 300-Series Anticalin® proteins are designed to target checkpoint proteins or, like PRS-343, immune-stimulatory proteins and consist of a variety of multifunctional biotherapeutics that can combine, via a genetic fusion, antibodies with Anticalin proteins,

[Table of Contents](#)

or two or more Anticalin proteins to each other. These combined molecules have the potential to build upon current therapies through the capability of modifying or regulating one or more immune functions on a single fusion protein, thereby having the potential to elevate immune responses within a tumor microenvironment. We believe that a tethered Anticalin protein directed at checkpoint proteins can preferentially activate the immune system at the site of the tumor microenvironment thus providing efficacy with enhanced therapeutic index. We believe that the 300-Series Anticalin proteins represent a “platform within a product” opportunity in immuno-oncology since it may be possible to apply a single combined Anticalin-antibody molecule in a number of different cancers. This is based on the shared underlying biology such as checkpoint and costimulatory biology found within tumors arising in different organs.

Competition

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

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

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

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

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

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

Table of Contents

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. Auryxia by Keryx, which targets formulation of oral iron, completed a Phase III in a non-dialysis dependent CKD 3-5 patients recently (January 2016). There are also various companies conducting late-stage development of erythropoietin biosimilars.

PRS-060

Like PRS-060, new developments for the treatment of uncontrolled moderate to severe asthma patients mainly include drug candidates targeting the Th2 pathway by interfering with IL4/IL-13 or IL-5 actions. Such products include dupilumab (Sanofi/Regeneron, IL-4RA), 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 have been approved

[Table of Contents](#)

(mepolizumab) however in contrast to PRS-060, these mAbs are given to patients through injection and distribute systemically through the blood stream. There are a number of other companies presently marketing or developing other therapies for asthmatic patients. The mAb omalizumab, directed against IgE, is approved and marketed for the treatment of uncontrolled, moderate to severe asthma patients.

PRS-300 series

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

PRS-343

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

No known competitor is developing a CD137 and HER2 bispecific drug candidate but a number of companies such as Amgen, Affimed, MacroGenics, F-Star, Sutro Biopharma and Immunocore are pursuing multispecific approaches in immuno-oncology, which therapies are either approved, in clinical development or preclinical development.

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

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.

Table of Contents

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

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

We believe that PRS-080, PRS-060 and PRS-030 and our other Anticalin®-branded drug candidates can be manufactured in reliable and reproducible biologic processes from readily available starting materials. PRS-080 and PRS-060 are produced using bacterial expression systems similar to those that have been used in the past for the production of other proteins and which systems are widely used in the industry. PRS-343 is produced using a mammalian expression system similar to those systems which are widely used in the industry for the production of antibodies. We believe that the manufacturing process is amenable to scale-up and will not require unusual or expensive equipment. We expect to continue to develop, on our own or with our collaborators, drug candidates that can be produced cost-effectively at contract manufacturing facilities.

Intellectual Property and Exclusivity

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

We seek to protect our exclusive position of Anticalin® technologies by, among other means, prosecuting our own international, U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We established intellectual property protection in relation to our Anticalin technologies in key global markets, including Australia, Brazil, Canada, China, the European Union, Hong Kong, India, Japan, Korea, New Zealand, Russia, Singapore, South Africa and the United States. We believe we have patent exclusivity relating to drug candidates derived from lipocalin proteins that runs until at least 2020 in the United States. We also rely on trade secrets for confidential know-how, which we generally seek to protect through contractual (e.g. confidentiality) 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 23, 2016, 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.

[Table of Contents](#)

In applicable jurisdictions, we will seek patent term extensions for certain of our patents including the patent term adjustment period in the United States. If we obtain marketing approval for our drug candidates in the United States or in certain jurisdictions outside of the United States, we may be eligible for regulatory protection, such as twelve years of data exclusivity for new biological entities in the United States and as mentioned below, up to five years of patent term extension potentially available in the United States under the 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 23, 2016, 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 three 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.

[Table of Contents](#)

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

Strategic Partnerships

Since 2007, we have entered into several licensing, research and development collaborations to complement our drug discovery and early stage development capabilities. Specifically, we have entered into licensing, research and development agreements which are still active as of the date of this prospectus with Allergan, Inc., or Allergan, Sanofi Group (formerly Sanofi-Aventis and Sanofi-Pasteur SA) and collectively, Sanofi, Daiichi Sankyo and Roche. 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 €33.4 million (\$36.3 million) in revenue as of March 23, 2016, 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.

Our agreements with Allergan, Sanofi, Daiichi Sankyo and Roche 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. Under our collaboration with Roche we have received an upfront-payment in January 2016. We plan to continue to actively seek out additional collaboration partners.

In addition to our agreements with Allergan, Sanofi, Daiichi Sankyo and Roche, 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, we 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 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, Daiichi Sankyo and Roche are summarized below as well as certain terms and conditions of our co-development agreements with Zydus and Stelis.

Table of Contents

Our agreement with Allergan

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

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

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

Our collaboration with Sanofi

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

In consideration of our obligations, as a part of the collaboration we received a €3.5 million (\$3.8 million) upfront payment and specified research funding. We also are entitled to receive payments on the achievement of research, development and commercial milestones for each product, with up to €26.0 million (\$28.4 million) in development milestones and up to €18 million (\$19.6 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 (\$54.5 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.

Table of Contents

The remaining active collaboration project was handed over to Sanofi for further development in the fourth quarter of 2014. Additionally, in January 2015, Pieris GmbH 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, we entered into a definitive collaboration research and technology licensing agreement with Daiichi Sankyo, under which we agreed to use our proprietary Anticalin® scaffold technologies to discover novel drug candidates against two targets chosen by Daiichi Sankyo under two separate collaboration projects. Upon achievement of preclinical development milestones for lead drug candidates, Daiichi Sankyo assumes responsibility for, and to use commercially reasonable efforts in, the further development and marketing of products based on those candidates. We have handed over further development responsibility for the two collaboration projects to Daiichi Sankyo in March 2013 and June 2014, respectively.

We received €7.2 million (\$7.9 million) upon signing of the collaboration agreement and received research funding. We are entitled to payment on the achievement of research and development milestones of up to €35.9 million (\$39.2 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 (\$49.1 million) for a prophylactic or therapeutic product. On development and commercialization of a diagnostic product, we are entitled to development and commercialization milestones of up to approximately €0.7 million (\$0.8 million). We have the ability to receive up to approximately €200 million (\$218 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, we 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

Table of Contents

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 total 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 GmbH 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 GmbH 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.

Our collaboration with Roche

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

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

The parties will jointly pursue a preclinical research program with respect to the identification and generation of Anticalins that bind to a specific target for an expected period of 20 months, which may be extended under certain

[Table of Contents](#)

circumstances. During the research term of the agreement, Roche will fund the work to be performed by us pursuant to the research plan. Following the research program, Roche will be responsible for subsequent pre-clinical and clinical development of any product and will have worldwide commercialization rights.

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

TUM License Agreement

On July 4, 2003, we entered into a Research and Licensing agreement with TUM, which was subsequently renewed and amended, on July 26, 2007. The agreement 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 €0.2 million (\$0.2 million) in milestone payments to TUM under the agreement.

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

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

[Table of Contents](#)

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 are obligated to pay to TUM such milestone payment. We were also involved in a dispute with TUM, for which arbitration concluded in 2015, which is described in more detail under “—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.

Table of Contents

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 the FDA to reach agreement on the next phase of development. Sponsors typically use the End of Phase II meeting to discuss their Phase II clinical results and present their plans for the pivotal Phase III clinical trial that they believe will support approval of the new drug.

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

U.S. Review and Approval Processes

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling, and other relevant information are submitted to the FDA as part of an NDA or BLA requesting approval to market the product. The

[Table of Contents](#)

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. The FDA may refer the NDA or BLA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. The approval process is lengthy and often difficult, and the FDA may refuse to approve an NDA or BLA if the applicable regulatory criteria are not satisfied or may require additional clinical or other data and information. 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 the 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

Table of Contents

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

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

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

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 the 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.

[Table of Contents](#)

Orphan Drug Designation

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

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

Fast Track Designation and Accelerated Approval

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

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

In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions, or survives. 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 the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

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

[Table of Contents](#)

Under 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 the 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. The 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 the 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 the FDA promotion and advertising requirements. The FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label.

From time to time, 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

[Table of Contents](#)

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 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

[Table of Contents](#)

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 be significantly lower.

Employees

As of March 23, 2016, we have 38 full-time employees and one part-time employee. Of these 39 employees, 27 are engaged in research and development activities and 12 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.

Legal Proceedings

Arbitration Proceeding with Technische Universität München

On March 20, 2014, we 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 us to TUM under our 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 proceedings took place 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, we 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 us certain intellectual property and know-how that has become part of the Anticalin® proprietary technologies. In return, we 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 GmbH provided to TUM its calculation of the Out-License Fee owed by us 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 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 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, but we can provide no assurance regarding the timing, nature or consequences of such decision. Pieris GmbH instituted the TUM Arbitration to request the arbitration tribunal to hold that Pieris GmbH'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.

On November 19, 2015, we received notification from the DIS of the arbitration tribunal's award. In its award, as corrected on January 25, 2016, the tribunal dismissed the Company's request for declaratory judgment and granted TUM's counterclaim in an amount of only €0.9 million (\$0.9 million), of which, \$0.6 million is recorded as research and development expense in the consolidated statement of operations for the 2015 period due to a previous liability of \$0.3 million recorded for the arbitration settlement as of December 31, 2014. Interest expense of \$0.2 million was also included in the settlement and is recorded in the consolidated statement of operations as interest expense, net. The tribunal dismissed the remainder of TUM's counterclaim.

Table of Contents

The Tribunal also ruled that TUM must reimburse us in the amount of €0.1 million (\$0.1 million) for legal fees incurred and dismissed TUM's claim for reimbursement of its costs. We have decided not to challenge the award and paid the amount as calculated by the arbitration tribunal. The deadline for filing a motion to set aside the award expired on February 15, 2016.

As of the date of this prospectus, 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.

Properties

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

Available Information

Historically, we have filed periodic reports under the Securities Exchange Act of 1934, as amended, and file annual, quarterly and current reports and other information with the SEC. You may read and copy these reports and other information at the public reference facilities of the SEC at 100 F Street, NE., Washington, DC 20549, on official business days during the hours of 10 a.m. to 3 p.m. You may also obtain information on the operation of the Public Reference Room by calling the Commission at 1-800-SEC-0330. The Commission maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the Commission at <http://www.sec.gov>.

MANAGEMENT

Directors, Executive Officers and Other Non-Executive Officers

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

Name	Age	Position
Stephen S. Yoder	40	Chief Executive Officer, President and Director
Darlene Deptula-Hicks	58	Senior Vice President and Chief Financial Officer
Louis A. Matis	65	Senior Vice President and Chief Development Officer
Chau Khuong (1)(2)(3)	40	Chairman of the Board of Directors
Michael Richman (1)(3)	55	Director
Jean-Pierre Bizzari, Ph.D. (2)(3)	61	Director
Steven Prelack (2)	58	Director

- (1) Member of the compensation committee
- (2) Member of the audit committee
- (3) Member of the nominating and corporate governance committee

Business Experience

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

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

Darlene Deptula-Hicks. Darlene Deptula-Hicks was appointed Chief Financial Officer and Senior Vice President on September 1, 2015. Upon the effectiveness of the Acquisition and until September 2015, she served as our Acting Chief Financial Officer, Secretary and Treasurer of Pieris and provided her services pursuant to a consulting agreement with the financial advisory firm of Danforth Advisors, LLC. From November 2014 until the effectiveness of the Acquisition, Ms. Deptula-Hicks provided financial services relating to the Acquisition to Pieris GmbH. From June 2012 until November 2014, Ms. Deptula-Hicks served as the Executive Vice President and Chief Financial Officer of Microline Surgical, Inc., a surgical instruments and medical devices company. From 2006 to May 2011 Ms. Deptula-Hicks served as Executive Vice President and Chief Financial Officer of iCAD, Inc. (Nasdaq: ICAD), a publicly traded medical device company. From 2002 to 2006 Ms. Deptula-Hicks served as Executive Vice President and Chief Financial Officer of ONI Medical Systems, Inc., a venture capital-backed designer and manufacturer of high-field diagnostic imaging systems for orthopedic applications, and from 1998 to 2001 Ms. Deptula-Hicks was Executive Vice President and Chief Financial Officer of Implant Sciences Corporation (Amex:IMX), an early stage medical device company that had its initial public offering in June of 1999. Prior to 1998, Ms. Deptula-Hicks also held various senior financial and accounting positions at Abiomed, Inc., GCA Corporation, Edwards High Vacuum International and Puritan Bennett Corporation. Ms. Deptula-Hicks also serves on the Board of Directors and as Chair of the Audit Committee of Xenetic Biosciences, Inc. (OTCBB:XBIO) and between 2006 and October 2014 served on the Board of Directors of IMCOR Pharmaceutical Company, Technest Holdings, Inc., and USfalcon. Ms. Deptula-Hicks received her B.S. in accounting from Southern NH University and her MBA from Rivier College.

Table of Contents

Louis A. Matis, Ph.D. Louis A. Matis was appointed Senior Vice President and Chief Development Officer in August 17, 2015. Prior to joining Pieris, Dr. Matis served since June 2011 as Executive Director, Strategic Evaluation at Alexion Pharmaceuticals, where he also served from 1993 to 2000, during which time he advanced to the position of Chief Scientific Officer and had a leading role in discovering the first-in-class complement inhibitor monoclonal antibody Soliris® (eculizumab). Before re-joining Alexion in 2011, Dr. Matis served as Chief Executive Officer of CGI Pharmaceuticals, Inc. from 2000 to 2006, and of the Immune Tolerance Institute from 2007 to 2010. From 1977 until joining Alexion in 1993, Dr. Matis held senior research and clinical positions at the National Cancer Institute (the NCI), National Institutes of Health and the FDA Center for Biologics Evaluation and Research. Dr. Matis received a B.A. from Amherst College, an M.D. from the University of Pennsylvania, Perelman School of Medicine, and his clinical training in Internal Medicine at the University of Chicago Hospitals and Clinics, and in Medical Oncology at the NCI. Dr. Matis is the author of over 120 publications in major scientific and medical journals and is a co-inventor on multiple patents.

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

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

Jean-Pierre Bizzari, M.D. Dr. Bizzari joined the Board of Directors of Pieris on May 12, 2015. Dr. Bizzari served as Executive Vice-President, Group Head, Clinical Oncology Development at Celgene Corporation, a role he held from October 2008 until his retirement in December 2015. In this position, Dr. Bizzari was responsible for Celgene's clinical development and operations-statistics teams across the U.S., Europe and Asia/Japan, and has overseen the development and approval of a number of leading oncology products including REVLIMID® (lenalidomide), VIDAZA® (azacitidine), ISTODAX® (romidepsin) and ABRAXANE® (nab-paclitaxel). In addition, he was Chairman of Celgene's hematology oncology development committee and a member of the company's management committee. Prior to his role at Celgene and from 2004 to 2008, Dr. Bizzari was the Vice President, Clinical Oncology Development for Sanofi-Aventis where he oversaw the approval of Eloxatin® (oxaliplatin), Taxotere® (docetaxel) and Elitek® (rasburicase). From 2002 to 2004, he was Vice President, Clinical Development Oncology for Sanofi-Synthelabo and from 1993 to 2002 served in the same role for Rhône-Poulenc Rorer (Aventis). Dr. Bizzari is a member of the Scientific Advisory Board of France's National Cancer Institute and a board member of the EORTC. He is also currently a member of the board of directors of Halozyme Therapeutics, Inc., Celator Pharmaceuticals, Inc., Transgene SA, Items and Onxeo. Dr. Bizzari received his medical degree from the University of Nice (France) and is an oncologist, having trained at La Pitié-Salpêtrière hospital in Paris, followed by training at

[Table of Contents](#)

the Ontario Cancer Institute and McGill Cancer Center. We believe that Dr. Bizzari adds value to our Board of Directors based on his considerable experience in the pharmaceutical industry and his insight on clinical, regulatory and commercial aspects of drug development, particularly in oncology and global drug approval strategy.

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

Term of Office of Directors

We currently have authorized five directors. In accordance with our Amended and Restated Articles of Incorporation and Amended and Restated Bylaws, our board of directors is divided into three classes with staggered three-year terms. At each annual meeting of stockholders commencing with the meeting in 2015, the successors to the directors whose terms then expire will be elected to serve until the third annual meeting following the election. Our directors are divided among the three classes as follows:

- the Class I director is Jean-Pierre Bizzari and his term will expire at the annual meeting of stockholders to be held in 2018;
- the Class II directors are Chau Khuong and Steven Prelack, and their terms will expire at the annual meeting of stockholders to be held in 2016; and
- the Class III directors are Stephen S. Yoder and Michael Richman, and their terms will expire at the annual meeting of stockholders to be held in 2017.

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

Family Relationships

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

Involvement in Certain Legal Proceedings

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

Nominations to the Board of Directors

Director candidates are considered based upon various criteria, including without limitation their broad-based business and professional skills and experiences, expertise in or knowledge of the life sciences industry and ability to add perspectives relating to that industry, concern for the long-term interests of our stockholders, diversity, and

[Table of Contents](#)

personal integrity and judgment. Our Board of Directors has a critical role in guiding our strategic direction and overseeing the strategy of our business, and accordingly, we seek to attract and retain highly qualified directors who have sufficient time to engage in the activities of our Board of Directors and to understand and enhance their knowledge of our industry and business plans.

Committees of the Board of Directors

Our board has established three standing committees—audit, compensation, and nominating and corporate governance—each of which operates under a charter that has been approved by our board.

Our board has determined that all of the members of each of the board’s three standing committees are independent as defined under the rules of the NASDAQ Capital Market. In addition, all members of the audit committee meet the independence requirements contemplated by Rule 10A-3 under the Exchange Act.

Audit Committee

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

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

The members of our audit committee are Messrs. Steven Prelack and Chau Khuong and Dr. Jean-Pierre Bizzari. Mr. Prelack serves as the chairperson of the committee. All members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and the NASDAQ Capital Market. Our board of directors has determined that Steven Prelack is an “audit committee financial expert” as defined by applicable SEC rules and has the requisite financial sophistication as defined under the applicable NASDAQ rules and regulations.

Compensation Committee

Our compensation committee reviews and approves policies relating to compensation of our officers and directors and oversees our overall compensation structure, policies and programs. The compensation committee reviews and approves corporate goals and objectives relevant to the compensation of our Chief Executive Officer and other executive officers, evaluates the performance of these officers in light of those goals and objectives and approves the compensation of these officers based on such evaluations. The compensation committee also reviews and approves

[Table of Contents](#)

the issuance of stock options and other awards under our equity plan. The compensation committee will review and evaluate, at least annually, the performance of the compensation committee and its members, including compliance by the compensation committee with its charter.

The members of our compensation committee are Messrs. Michael Richman and Chau Khuong. Mr. Richman serves as the chairperson of the committee.

Nominating and Corporate Governance Committee

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

The members of our nominating and corporate governance committee are Dr. Jean-Pierre Bizzari and Messrs. Chau Khuong and Michael Richman. Dr. Bizzari serves as the chairperson of the committee.

EXECUTIVE COMPENSATION

The following table summarizes the compensation earned in each of our fiscal years ended December 31, 2015 and 2014 by our named executive officers, which consisted of our principal executive officer and our two next most highly compensated executive officers who earned more than \$100,000 during the fiscal year ended December 31, 2015 and were serving as executive officers as of such date. The following table includes compensation earned by Mr. Yoder for services performed for Pieris GmbH prior to that entity becoming our wholly owned subsidiary upon the completion of the Acquisition on December 17, 2014, as well as compensation earned following the closing of the Acquisition. The following table does not include compensation information for the individuals who served as Pieris' executive officers prior to the completion of the Acquisition, as all such individuals tendered their resignations from all such positions with us in connection with and effective as of the closing of the Acquisition and no compensation was earned by or paid to any such individuals for their services as officers of Pieris. We refer to the executive officers listed below as the Named Executive Officers.

Summary Compensation Table

Name and Principal Position	Year	Salary	Bonus (\$)	Option Awards (\$) (3)	All other compensation (\$)	Total
Stephen S. Yoder	2015(1)	\$375,000	\$150,000	\$ —	\$ 7,370(4)	\$ 532,370
Chief Executive Officer	2014(2)	\$266,222	\$ 54,455	\$1,643,005	\$ 15,973(4)	\$1,979,655
Darlene Deptula-Hicks	2015	\$100,000	\$ 40,000	\$ 812,623	\$ 3,013(5)	\$ 955,636
Chief Financial Officer						
Louis Matis	2015	\$131,250	\$140,000	\$1,066,220	\$ —	\$1,337,470
Chief Development Officer						

- (1) Mr. Yoder's 2015 salary was paid in euros from January 1, 2015 through June 30, 2015 as he was a resident of Germany at the time. Pieris converted each euro denominated amount into U.S. dollars by multiplying the euro amount by the noon buying rate of €1.00 to U.S. \$1.0906 in The City of New York for cable transfers of euro as certified for customs purposes by the Federal Reserve Bank of New York as of December 31, 2015. From the period of July 1, 2015 through December 31, 2015, Mr. Yoder's salary was paid in U.S. dollars.
- (2) All compensation received by Pieris GmbH's executive officers is paid in euros. For the purposes of completing this table with respect to compensation paid during the fiscal year ended December 31, 2014, Pieris converted each euro denominated amount into U.S. dollars by multiplying the euro amount by the noon buying rate of €1.00 to U.S. \$1.2101 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.
- (3) These amounts represent the aggregate grant date fair value for the option awards granted during the fiscal years presented, determined in accordance with FASB ASC Topic 718. All awards are recognized in expense over the service period.
- (4) Represents compensation paid for a monthly car allowance.
- (5) Represents compensation paid for a 401(k) employer contribution.

Narrative Disclosure to Summary Compensation Table

Employment Agreements with our Chief Executive Officer

Pieris GmbH

Stephen S. Yoder serves as the Chief Executive Officer of Pieris GmbH pursuant to a management agreement with Pieris GmbH dated August 30, 2009, as amended on March 12, 2012, or the Yoder AG Agreement. On December 17, 2014 in connection with the Acquisition, the Yoder AG Agreement was amended and restated to have Mr. Yoder continue as the Chief Executive Officer of Pieris GmbH and to provide him with the compensation and benefits set forth in his employment agreement with Pieris, as described below. The Yoder AG Agreement provided for a term of 18 months with the term automatically extending for additional one-year periods. Under the terms of the Yoder

Table of Contents

AG Agreement, beginning on January 1, 2013, Mr. Yoder received an annual base salary of \$266,222 (€220,000). In addition, Mr. Yoder was eligible to receive a bonus for each calendar year during the term in an amount up to \$54,455 (€50,000) based upon achievement of certain objectives, each as approved by the supervisory board of Pieris GmbH in consultation with Mr. Yoder. Pursuant to the terms of the Yoder AG Agreement Mr. Yoder was also provided with a car allowance of \$1,331 (€1,100) plus value added tax (VAT) per month.

Pieris Pharmaceuticals, Inc.

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

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

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

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

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

Termination for Any Reason

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

Termination by us Without Cause or by Executive for Good Reason

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

[Table of Contents](#)

immediately vest in full and become exercisable following termination and any forfeiture restrictions will immediately lapse. The Severance and acceleration of any unvested options is expressly conditioned on Mr. Yoder executing and delivering to Pieris a release of claims.

Chief Financial Officer

Consulting Agreement with Danforth Advisors, LLC

From November 19, 2014 to December 17, 2014, Darlene Deptula-Hicks was engaged pursuant to a consulting agreement with the financial advisory firm Danforth Advisors, LLC, or Danforth, as a financial consultant to Pieris, providing financial services relating to the Acquisition. As of the effectiveness of the Acquisition, she was appointed as the Acting Chief Financial Officer, Secretary and Treasurer of Pieris and continued to provide financial services through the Danforth consulting agreement until August 31, 2015. Pursuant to the Danforth consulting agreement, Pieris paid Danforth \$280 per hour for her services. The Danforth consulting agreement was terminated on August 31, 2015. The Danforth consulting agreement contains customary confidentiality obligations which apply to both Danforth and Ms. Deptula-Hicks and extend for a period of five years. We paid Danforth a fee equal to 3.33% of Ms. Deptula-Hicks's starting base salary upon her employment with Pieris pursuant to the terms of the Danforth consulting agreement. Further, we shall indemnify and hold harmless Danforth and Ms. Deptula-Hicks against any claims, losses, damages, or liabilities (or actions in respect thereof) that arise out of or are based on the services performed by Danforth or Ms. Deptula-Hicks for us, except for any such claims, losses, damages or liabilities arising out of the gross negligence or willful misconduct of Danforth or Ms. Deptula-Hicks.

Employment Agreement

Darlene Deptula-Hicks serves as our Senior Vice President and Chief Financial Officer pursuant to an employment agreement dated August 27, 2015, or the Deptula-Hicks Employment Agreement. The Deptula-Hicks Employment Agreement provides for a continuous term and may be terminated by either party at any time, provided that if Ms. Deptula-Hicks resigns, she shall provide us with at least 90 days' written notice. Pursuant to this agreement, Ms. Deptula-Hicks receives a base salary of \$300,000 and is eligible to receive an annual discretionary bonus award of up to 40% of her then-current base salary, based upon the achievement of specific individual and/or Company-wide performance goals as determined by the Board or a committee of the Board in its sole discretion.

Ms. Deptula-Hicks is entitled to participate in any employee benefit programs, plans and practices on the same terms as other salaried employees on a basis consistent with the participation of other senior executive officers. In connection with her employment, Ms. Deptula-Hicks was granted a stock option to purchase 450,000 shares of our common stock with the exercise price being the fair market value at the time of grant. The option is subject to and governed by the terms of the Pieris Plan and a stock option agreement, which stock option agreement provides for a ten year term, and that (i) 6.25% of the option vested immediately upon grant and (ii) 93.75% of the option shall vest ratably in equal installments each quarter thereafter, subject to Ms. Deptula-Hicks's continued employment. The option is subject to certain restrictions on exercise until the Company's shareholders have approved an increase in the number of shares of common stock authorized under Pieris Plan and if such shareholder approval is not obtained on or prior to September 30, 2016, the option will be cancelled and be of no further effect.

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

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

Table of Contents

Termination for Any Reason

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

Termination by us Without Cause or by Executive for Good Reason

If Ms. Deptula-Hicks's employment is terminated (i) by us without cause or (ii) by her for good reason, then we must pay Ms. Deptula-Hicks (a) an amount equal to twelve months of salary plus the target bonus amount, pro-rated based on the total number of days elapsed in the calendar year as of the termination date if, as of the date of termination, the Company and Ms. Deptula-Hicks were "on target" to achieve all applicable performance goals and (b) continuation of COBRA health insurance premiums at the Company's then-normal rate of contribution for twelve months. In addition, outstanding equity awards held by Ms. Deptula-Hicks shall automatically become vested and if, applicable, exercisable, except as otherwise provided in the Deptula-Hicks Employment Agreement, and any forfeiture restrictions shall immediately lapse with respect to 50% of the then-unvested equity awards.

Chief Development Officer

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

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

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

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

Termination for Any Reason

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

Termination by us Without Cause or by Executive for Good Reason

If Dr. Matis's employment is terminated (i) by us without cause or (ii) by him for good reason, then Dr. Matis will be entitled to receive (a) an amount equal to twelve months of salary plus the target bonus amount, pro-rated based on the total number of days elapsed in the calendar year as of the termination date if, as of the date of termination, the Company and Ms. Deptula-Hicks were "on target" to achieve all applicable performance goals and

Table of Contents

(b) continuation of COBRA health insurance premiums at the Company's then-normal rate of contribution for twelve months. In addition, outstanding equity awards held by Dr. Matis shall automatically become vested and if, applicable, exercisable, except as otherwise provided in the Matis Employment Agreement, and any forfeiture restrictions shall immediately lapse with respect to 75% of the then-unvested equity awards.

Potential Payments upon Termination or Change in Control

Chief Executive Officer

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

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

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

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

Chief Financial Officer

If, in connection with a change of control of Pieris, Pieris terminates Ms. Deptula-Hicks's employment without cause or Ms. Deptula-Hicks terminates her employment for good reason, she will be entitled to receive (a) an amount equal to twelve months of salary plus the target bonus amount for the year of termination and (b) continuation of COBRA health insurance premiums at the Company's then-normal rate of contribution for

[Table of Contents](#)

twelve months. In the case of such a termination in connection with a change in control, outstanding equity awards held by Ms. Deptula-Hicks shall automatically become vested and if, applicable, exercisable, except as otherwise provided in the Deptula-Hicks Employment Agreement, and all forfeiture restrictions shall immediately lapse.

Chief Development Officer

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

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

2015 Bonus Payments

On January 24, 2016, our Compensation Committee approved a discretionary cash bonus payments to (i) Mr. Yoder in the amount of \$150,000, which was equal to his target bonus amount, (ii) Dr. Matis in the amount of \$140,000, which was equal to his target bonus amount and (iii) Ms. Deptula-Hicks in the amount of \$40,000, which was equal to her target bonus amount and prorated from her start date in September 2015.

Outstanding Equity Awards at Fiscal Year-End

The table below summarizes the aggregate stock and option awards held by our named executive officers as of December 31, 2015.

Name	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Option exercise price (\$)	Option expiration date
Stephen S. Yoder Chief Executive Officer, President	640,000(1)	640,000(1)	\$ 2.00	12/17/2024
Darlene Deptula-Hicks Chief Financial Officer	0	450,000(2)	\$ 2.80	9/1/2025
Louis Matis Chief Development Officer	0	500,000(3)	\$ 3.36	8/17/2025

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

Table of Contents

- (2) The option award has a grant date of September 1, 2015 and vests pursuant to the following schedule: 6.25% of the option vested immediately upon grant on September 1, 2015 and 93.75% of the option shall vest in equal installments on a quarterly basis beginning on December 31, 2015 and ending on September 1, 2019. The option is subject to certain restrictions on exercise until the Company's shareholders have approved an increase in the number of shares of common stock authorized under the Company's 2014 Employee, Director and Consultant Equity Plan (or successor plan) and if such shareholder approval is not obtained on or prior to September 30, 2016, the option will be cancelled and be of no further effect.
- (3) The option award has a grant date of August 17, 2015 and vests pursuant to the following schedule: 25% of the option vests on the one-year anniversary of the grant date and 75% of the option shall vest ratably over three years in equal installments on a quarterly basis beginning on the last day of the next calendar quarter after the date of grant.

Description of Pieris Plan

In December 2014, our Board of Directors and stockholders adopted the 2014 Employee, Director and Consultant Equity Incentive Plan, or the Pieris Plan, which became effective upon closing of the Acquisition. The Pieris Plan is intended to encourage ownership of common stock by our employees and directors and certain of our consultants, in order to attract and retain such people, to induce them to work for the benefit of us and to provide additional incentive for them to promote our success. There are 4,200,000 shares of our common stock reserved for issuance under the Pieris Plan. In addition the Pieris Plan provides for an "evergreen" provision whereby 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 by the lesser of (i) 1,000,000 shares, (ii) 4% of the number of shares of our common stock outstanding on such date, and (iii) such other amount determined by the administrator. As of March 20, 2016, options to purchase 2,092,261 shares of our common stock have been issued under the Pieris Plan to our executive officers and directors, and options to purchase 1,801,450 shares have been issued under the Pieris Plan to other employees and consultants. For additional information, see "Executive Compensation—Director Compensation" and "Executive Compensation—Employment Agreements with our Chief Executive Officer." As a result of such grants, 433,789 shares of our common stock remain available for future issuances under the Pieris Plan.

Pursuant to a Stock Option Agreement with Ms. Deptula-Hicks, we granted her an option to purchase 450,000 shares of our common stock subject to certain restrictions on exercise and subject to the approval of the Company's shareholders of an increase in the number of shares authorized under the Pieris Plan to provide sufficient shares for such issuance upon the exercise of such award. If such shareholder approval is not obtained by September 30, 2016, the option will be cancelled and of no further force and affect. This option, therefore, does not have an impact on the remaining shares available for future grants currently authorized under the Pieris Plan.

Pursuant to a Stock Option Agreement with Dr. Louis Matis, we granted him an option to purchase 500,000 shares outside of the Pieris Plan that was an inducement option, material to him entering into employment with the Company. This option, therefore, does not have an impact on the remaining shares available for future grants currently authorized under the Pieris Plan.

Types of Awards. The Pieris Plan provides for the granting of incentive stock options, non-qualified stock options, stock grants and other stock-based awards, including restricted stock units.

- *Incentive and Non-Qualified Stock Options.* The plan administrator determines the exercise price of each stock option. The exercise price of a non-qualified stock option may not be less than the fair market value of our common stock on the date of grant. The exercise price of an incentive stock option may not be less than the fair market value of our common stock on the date of grant if the recipient holds 10% or less of the combined voting power of our securities, or 110% of the fair market value of a share of our common stock on the date of grant otherwise.
- *Stock Grants.* The plan administrator may grant stock, including restricted stock, to any participant, which purchase price, if any, may not be less than the par value of shares of our common stock. The stock grant will be subject to the conditions and restrictions determined by the administrator. The recipient of a stock grant shall have the rights of a stockholder with respect to the shares of stock as of the grant date.

Table of Contents

- *Stock-Based Awards.* The administrator of the Pieris Plan may grant other stock-based awards, including stock appreciation rights, phantom stock awards and restricted stock units, with terms approved by the administrator, including restrictions related to the awards. The holder of a stock-based award shall not have the rights of a stockholder until shares of our common stock are issued pursuant to such award.

Plan Administration. Our compensation committee is the administrator of the Pieris Plan, except to the extent it delegates its authority to a committee, in which case the committee shall be the administrator. The administrator has the authority to determine the recipients of the awards, the terms of awards, including exercise and purchase price, the number of shares subject to awards, the vesting schedule applicable to awards, the form of consideration, if any, payable upon exercise or settlement of an award and the terms of award agreements for use under the Pieris Plan. In addition, the administrator may amend any term or condition of any outstanding award including, without limitation, to reduce or increase the exercise price or purchase price, accelerate the vesting schedule or extend the expiration date, provided that no such amendment shall impair the rights of a participant without such participant's consent. *Eligibility.* The administrator will determine the participants in the Pieris Plan from among our employees, directors and consultants. A grant may be approved in advance with the effectiveness of the grant contingent and effective upon such person's commencement of service within a specified period. No participant may receive awards for more than 1,500,000 shares of our common stock in any fiscal year.

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

Transferability. Awards under the Pieris Plan may not be transferred except by will or by the laws of descent and distribution, unless otherwise provided by our board in its discretion and set forth in the applicable agreement, provided that no award may be transferred for value.

Adjustment. In the event of a stock dividend, stock split, recapitalization or reorganization or other change in change in capital structure, the administrator will make appropriate adjustments to the number and kind of shares of stock or securities subject to awards.

Corporate Transaction. Upon a merger, consolidation or sale of all or substantially all of our assets, the administrator, or the board of directors of any corporation assuming our obligations, may, in its sole discretion, take any one or more of the following actions pursuant to our plan, as to some or all outstanding awards:

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

[Table of Contents](#)

Amendment and Termination. The Pieris Plan will terminate on December 17, 2024 or at an earlier date by vote of the stockholders or our Board of Directors; provided, however, that any such earlier termination shall not affect any awards granted under the Pieris Plan prior to the date of such termination. The Pieris Plan may be amended by our Board of Directors, except that our Board of Directors may not alter the terms of the Pieris Plan if it would adversely affect a participant's rights under an outstanding stock right without the participant's consent. Stockholder approval will be required for any amendment to the Pieris Plan to the extent such approval is required by law, include the Internal Revenue Code or applicable stock exchange requirements.

Director Compensation

The table below summarizes all compensation earned by each of our non-employee directors for services performed during our fiscal year ended December 31, 2015. Mr. Yoder is not in the table below because he receives no separate compensation for his services as a director of our company, and all of the compensation earned by Mr. Yoder during our 2015 fiscal year as an executive officer of our company is reflected in the Summary Compensation Table above.

	Fees earned or paid in cash (\$)	Stock awards (\$)	Option awards (\$)	Total (\$)
Chau Khuong (1)	\$ —	\$ —	\$41,250(6)	\$41,250
Dr. Christina Takke (2)	\$ 20,000	—	—	\$20,000
Michael Richman (3)	\$ —	—	\$38,750(6)	\$38,750
Steven Prelack (4)	\$ 40,000	—	—	\$40,000
Jean-Pierre Bizzari (5)	\$ 23,356	—	\$52,185(6)	\$75,541

- (1) As of December 31, 2015, Chau Khuong held option awards for 50,794 shares at exercise prices ranging from \$1.94 to \$3.00.
- (2) As of December 31, 2015, Dr. Christina Takke held no option awards for shares at an exercise price of \$2.00. Dr. Takke ceased serving as a member of the Board of Directors effective June 30, 2015.
- (3) As of December 31, 2015, Michael Richman held option awards for 79,535 shares at exercise prices ranging from \$1.94 to \$3.00.
- (4) As of December 31, 2015, Steven Prelack held option awards for 30,000 shares at an exercise price of \$2.00.
- (5) As of December 31, 2015, Dr. Jean-Pierre Bizzari held option awards for 30,000 shares at an exercise price of \$2.80.
- (6) These amounts represent the aggregate grant date fair value of option awards granted to each director in fiscal year 2015 computed in accordance with FASB ASC Topic 718.

On January 11, 2015, our Board of Directors approved a director compensation policy applicable to our non-employee directors which was amended in January 2016. This policy provides for annual cash compensation of \$25,000 for each non-employee member of our Board of Directors. In addition, the chair of our audit committee will receive an additional annual cash retainer of \$15,000, the chair of our compensation committee will receive additional annual cash compensation of \$10,000 and the chair of our nominating and corporate governance committee will receive additional annual cash compensation of \$7,500. The policy also provides for annual cash compensation of \$7,500 for each of the members of our audit committee, \$5,000 for each of the members of our compensation committee and \$3,750 for each of the members of our nominating and corporate governance committee.

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

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Related Party Transactions

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

Except as described below, in the fiscal years ended December 31, 2014 and 2015, there has not been, nor is there currently proposed, any transaction to which Pieris is or was a party in which the amount involved exceeds the lesser of \$120,000 and 1% of the average of its total assets at year-end for the last two completed fiscal years, and in which any of our current directors, executive officers, holders of more than 5% of any class of our voting securities or any of their respective affiliates or immediate family members, had, or will have, a direct or indirect material interest.

We have entered into indemnification agreements with each of our directors and executive officers. Each of those indemnification agreements is in the form approved by our Board of Directors. Those indemnification agreements require that, under the circumstances and to the extent provided for therein, we indemnify such persons to the fullest extent permitted by applicable law against certain expenses and other amounts incurred by any such person as a result of such person being made a party to certain actions, suits and proceedings by reason of the fact that such person is or was a director, officer, employee or agent of our company, any entity that was a predecessor corporation of our company or any of our affiliates. The rights of each person who is a party to such an indemnification agreement are in addition to any other rights such person may have under applicable Nevada law, our Amended and Restated Articles of Incorporation, our Amended and Restated Bylaws, any other agreement, a vote of our stockholders, a resolution adopted by our Board of Directors or otherwise. The foregoing is only a brief description of the form of indemnification agreement and does not purport to be a complete description of the rights and obligations of the parties thereunder, and is qualified in its entirety by reference to the form of indemnification agreement filed as an exhibit to this prospectus and incorporated herein by reference.

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 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. In connection with the Private Placement we received funding from the holders of more than 5% of our common stock as follows: (i) of \$495,282 from OrbiMed Private Investments III, LP, or OPI III, (ii) \$4,718 from OrbiMed Associates III, LP, an affiliate of OPI III, or Associates III, and (iii) approximately \$3.0 million from 1798 Fundamental Strategies Master Fund Ltd., or Fundamental Strategies. After giving effect to the Private Placement and as of April 29, 2015, each of OPI III and Fundamental Strategies is a holder of more than 5% of the outstanding capital stock of Pieris.

See “Description of Securities—Registration Rights Agreement” for a description of registration rights granted to the holders of the shares of common stock and common stock purchase warrants issued in connection with the Acquisition and the Private Placement, which description is incorporated herein by reference.

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

Pieris GmbH

Except as described below and except for employment compensation, since January 1, 2014, there has not been, nor is there currently proposed, any transaction to which it was or is a party in which the amount involved exceeds the lesser of \$120,000 and 1% of the average of Pieris GmbH's total assets at year-end for the last two completed fiscal years, and in which any of its directors, executive officers, holders of more than 5% of any class of its voting securities or any of their respective affiliates or immediate family members, had, or will have, a direct or indirect material interest.

Table of Contents

In 2001, Pieris GmbH entered into a consulting agreement with Dr. Arne Skerra, who was a member of its supervisory board, pursuant to which Dr. Skerra provides advice regarding the use of new proteins for the purpose of research and development. For each of the years ended December 31, 2014 and December 31, 2015, Pieris GmbH paid Dr. Skerra €20,000 (\$24,202) and under the consulting agreement.

In July 2007, Pieris GmbH entered into a Research and Licensing Agreement with Technische Universität München, or TUM and the TUM License Agreement. The TUM License Agreement granted certain licenses and protective rights to Pieris GmbH related to Anticalin®-brand drug and lipocalin research and Anticalin technology developed by a research team led by Dr. Arne Skerra, who is employed by TUM as Chair of Biological Chemistry. For these licenses and rights, we made no payments for such licenses and rights or any other payments in 2014 or 2015 and we paid €166,930 (\$182,054) in 2016.

Additionally, in connection with the outcome of an arbitration tribunal proceeding between us and TUM, in 2015 we paid to TUM €858,855 (\$936,667) for license and rights and €169,372 (\$184,717) and €2,681 (\$2,923) for interest due to TUM under the Research and License Agreement in 2015 and 2016, respectively. TUM paid to us €110,000 (\$134,613) as reimbursement for legal fees incurred by us in connection with the arbitration proceeding in 2016.

In November 2012, Pieris GmbH entered into the 2012 Bridge Loan. In connection with the financing, Pieris GmbH received (i) €492,113 (\$595,506) from OPI III, (ii) €4,687 (\$5,672) from Associates III, (iii) €421,015 (\$509,470) from Gilde Europe Food & Agribusiness Fund B.V., or Gilde, (iv) €219,225 (\$265,284) from Coöperatieve AAC LS U.A. (Forbion), or Forbion, (v) €252,173 (\$305,154) from The Global Life Science Ventures Funds II GmbH & Co. KG i.L., or Global Life KG, (vi) €196,145 (\$237,355) from The Global Life Science Ventures Fund II LP, an affiliate of Global Life KG, or Global Life LP, (vii) €199,606 (\$241,543) from Novo Nordisk A/S, or Novo, and (viii) €164,751 (\$199,365) from BioM AG, or BioM. The 2012 Bridge Loan accrued interest at a rate of 12% per year and had a maturity date of December 31, 2013, after which the loan amounts began to accrue interest at a rate of 18% per year. In 2012, Pieris GmbH accrued interest in the amounts of €3,445 (\$4,169), €33 (\$40), €3,368 (\$4,076), €1,461 (\$1,768), €1,008 (\$1,220), €0 (\$0), €1,397 (\$1,691) and €1,373 (\$1,661) under the loans to OPI III, Associates III, Gilde, Forbion, Global Life KG, Global Life LP, Novo and BioM, respectively. In 2013, Pieris GmbH accrued interest in the amounts of €59,054 (\$71,461), €562 (\$680), €50,522 (\$61,137), €26,307 (\$31,834), €30,261 (\$36,619), €23,537 (\$28,482), €23,953 (\$28,986) and €19,770 (\$23,924) to OPI III, Associates III, Gilde, Forbion, Global Life KG, Global Life LP, Novo and BioM, respectively. BioM Venture Capital GmbH & Co. KG, or BioM Venture, who, as of the date of execution of the 2012 Bridge Loan was a holder of more than 5% of the outstanding capital stock of Pieris GmbH, is an affiliate of BioM. As of the date of execution of the 2012 Bridge Loan, Forbion was a holder of more than 5% of the outstanding capital stock of Pieris GmbH.

In March 2014, the 2012 Bridge Loan was amended. Pursuant to the terms of the amendment, (i) the outstanding amount under the 2012 Bridge Loan was reduced by a \$400,000 payment to the holders under the 2012 Bridge Loan and (ii) the maturity date was extended to December 31, 2015. Due to the extension, interest under the amended facility accrued at a rate of 12% per year. In connection with the amended financing, Pieris GmbH had total repayment amounts due of (i) \$98,423 from OPI III, (ii) \$937 from Associates III, (iii) \$84,203 from Gilde, (iv) \$43,845 from Forbion, (v) \$50,435 from Global Life KG, (vi) \$39,229 from Global Life LP, (vii) \$39,921 from Novo, and (viii) \$32,950 from BioM. BioM Venture and Forbion, as of the date of execution of the amendment, were holders of more than 5% of the outstanding capital stock of Pieris GmbH. Immediately prior to the 2014 Series C Financing, as defined below, there was €2,000,000 (\$2,420,200) outstanding under the 2012 Bridge Loan, as amended. As of December 17, 2014 and pursuant to the terms of the 2014 Series C Financing under which the outstanding indebtedness was converted to equity, there were no amounts outstanding under the 2012 Bridge Loan, as amended.

In April 2014, Pieris GmbH entered into a second bridge loan agreement, or the 2014 Bridge Loan, with certain of its stockholders pursuant to which it received a commitment for financing in the aggregate amount of €2,000,000 (\$2,420,200), which loan amounts, if called by Pieris GmbH, would be convertible into shares of Pieris GmbH after the maturity date or upon the occurrence of certain events. 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). The Tranche A financing commitment consisted of commitments of (i) €598,400 (\$724,124) from OPI III, (ii) €3,751 (\$4,539) from

Table of Contents

Associates III, (iii) €149,705 (\$181,158) from Novo, (iv) €126,560 (\$153,150) from Global Life KG, (v) €98,440 (\$119,122) from Global Life LP, (vi) €225,000 (\$272,273) from Gilde, (vii) €97,500 (\$117,985) from Forbion, (viii) €150,000 (\$181,515) from Baytech Venture Capital GmbH & Co. KG, or Baytech, and (ix) €10,310 (\$12,476) from BioM. The Tranche B financing commitment consisted of (i) €199,497 (\$241,411) from OPI III, (ii) €1,250 (\$1,513) from Associates III, (iii) €49,902 (\$60,386) from Novo, (iv) €42,197 (\$51,063) from Global Life KG, (v) €32,813 (\$39,707) from Global Life LP, (vi) €75,000 (\$90,758) from Gilde, (vii) €32,500 (\$39,328) from Forbion, (viii) €50,000 (\$60,505) from Baytech and (ix) €10,310 (\$12,476) from BioM. Forbion, BioM Venture and Baytech, as of the date of execution of the 2014 Bridge Loan, were holders of more than 5% of the outstanding capital stock of Pieris GmbH. In June 2014, Pieris GmbH borrowed 67% of Tranche A, which equals €1,000,000 (\$1,210,100). The amount borrowed consisted of funds of (i) €398,993 (\$482,821) from OPI III, (ii) €2,501 (\$3,026) from Associates III, (iii) €99,803 (\$120,772) from Novo, (iv) €84,373 (\$102,100) from Global Life KG, (v) €65,627 (\$79,415) from Global Life LP, (vi) €150,000 (\$181,515) from Gilde, (vii) €65,000 (\$78,657) from Forbion, (viii) €100,000 (\$121,010) from Baytech, and (ix) €6,873 (\$8,317) from BioM. 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. Immediately prior to the 2014 Series C Financing, as defined below, there was €1,000,000 (\$1,210,100) outstanding under the 2014 Bridge Loan. In September 2014 and in connection with the 2014 Series C Financing, the stockholder parties to the 2014 Bridge Loan invested the remaining €1,000,000 (\$1,210,100) commitment under the bridge loan in cash directly in the 2014 Series C Financing, including funds of (i) €398,994 (\$482,823) from OPI III, (ii) €2,500 (\$3,025) from Associates III, (iii) €99,803 (\$120,772) from Novo, (iv) €84,373 (\$102,100) from Global Life KG, (v) €65,627 (\$79,415) from Global Life LP, (vi) €150,000 (\$181,515) from Gilde, (vii) €65,000 (\$78,657) from Forbion, (viii) €100,000 (\$121,010) from Baytech, and (ix) €6,874 (\$8,318) from BioM, which was treated as new investment under the 2014 Series C Financing, or the Convertible Cash Investment. As of December 17, 2014 and pursuant to the 2014 Series C Financing under which the outstanding indebtedness was converted to equity, there were no amounts outstanding under the 2014 Bridge Loan.

On October 10, 2014, Pieris GmbH entered into an investment agreement and consolidated shareholders' agreement, each dated October 10, 2014, pursuant to which (i) the aggregate outstanding amounts under the 2012 Bridge Loan, as amended, and 2014 Bridge Loan of €3,000,000 (\$3,630,300) were converted into shares of Series C Preferred Stock of Pieris GmbH and (ii) Pieris GmbH received a cash investment, including the Convertible Cash Investment, in the aggregate amount of €5,970,149 (\$7,224,477) in consideration for shares of Pieris GmbH's Series C Preferred Stock, or the 2014 Series C Financing.

The converted bridge loan portion of the 2014 Series C Financing included (a) €2,000,000 (\$2,420,200) outstanding under the 2012 Bridge Loan, as amended, including funds of (i) €492,113 (\$595,506) from OPI III, (ii) €4,687 (\$5,672) from Associates III, (iii) €421,015 (\$509,470) from Gilde, (iv) €219,225 (\$265,284) from Forbion, (v) €252,173 (\$305,155) from Global Life KG, (vi) €196,145 (\$237,355) from Global Life LP, (vii) €199,606 (\$241,543) from Novo and (viii) €164,751 (\$199,365) from BioM and (b) €1,000,000 (\$1,210,100) outstanding under the 2014 Bridge Loan including funds of (i) €398,994 (\$482,823) from OPI III, (ii) €2,500 (\$3,025) from Associates III, (iii) €99,803 (\$120,772) from Novo, (iv) €84,373 (\$102,100) from Global Life KG, (v) €65,627 (\$79,415) from Global Life LP, (vi) €150,000 (\$181,515) from Gilde, (vii) €65,000 (\$78,657) from Forbion, (viii) €100,000 (\$121,010) from Baytech, and (ix) €6,874 (\$8,318) from BioM.

The cash investment portion of the 2014 Series C Financing provided for two tranches of available financing. The first tranche consisted of a cash investment of €3,552,646 (\$4,299,057) and the second tranche consisted of a cash investment of €1,417,503 (\$1,715,320). In addition, the cash investment portion of the 2014 Series C Financing included €1,000,000 (\$1,210,100) from the Convertible Cash Investment as described above. In October to November 2014, the first tranche of the 2014 Series C Financing was consummated, consisting of an issuance of an aggregate of 1,629,469 shares of Series C Preferred Stock, including funds of (i) €2,218,972 (\$2,685,178) from OPI III, (ii) €19,843 (\$24,012) from Associates III, (iii) €150,000 (\$181,515) from Gilde, (iv) €65,000 (\$79,657) from Forbion, (v) €84,373 (\$102,100) from Global Life KG, (vi) €65,627 (\$79,415) from Global Life LP, (vii) €99,803 (\$120,772) from Novo, (viii) €6,874 (\$8,318) from BioM, (ix) €275,000 (\$332,778) from Baytech and (x) €1,492,537 (\$1,806,119) from Cadila Healthcare Limited, or Zydus. In November to December 2014, the second tranche of the 2014 Series C Financing was consummated, consisting of the issuance of an aggregate of 234,877 shares of Series C preferred stock including funds of €579,861 (\$701,690) from Mark N. Tompkins. Forbion, BioM Venture, Baytech and Zydus, as of the date of execution of the 2014 Series C Financing, were holders of more than 5% of the outstanding capital stock of Pieris GmbH.

Table of Contents

In the aggregate, as of April 29, 2015, Pieris GmbH received approximately €51.7 million (\$62.6 million) in equity investments from its stockholders as follows: (i) in 2001, seed round financing of €0.6 million (\$.7 million); (ii) in 2002, two tranches of Series A financing in an aggregate amount of approximately €12.2 million (\$14.8 million); (iii) in 2006, Series A-1 financing of approximately €4.9 million (\$5.9 million), (iv) in 2008, two tranches of Series B financing in an aggregate of approximately €25.0 million (\$30.3 million) and (v) the 2014 Series C Financing of approximately €9.0 million (\$10.9 million). Our stockholders have invested in these activities in the following aggregate amounts: (i) approximately €13.1 million (\$15.9 million) from OPI III and Associates III; (ii) approximately €8.0 million (\$9.7 million) from Global Life KG and Global Life LP; (iii) approximately €7.9 million (\$9.6 million) from Gilde; (iv) approximately €5.4 million (\$6.5 million) from Novo; (v) approximately €4.8 million (\$5.8 million) from Forbion; (vi) approximately €3.4 million (\$4.1 million) from Baytech; (vii) an aggregate of approximately €2.7 million (\$3.3 million) from Bio M and BioM Venture, an affiliate of BioM, (viii) approximately €1.5 million (\$1.8 million) from Zydus, and (ix) approximately €0.6 million (\$0.7 million) from Mark N. Tompkins. Other stockholders invested in aggregate approximately €4.4 million (\$5.3 million).

Each of OPI III, Gilde, Forbion, Global Life KG, Global Life LP, Novo, Baytech and Zydus was a holder of more than 5% of the outstanding capital stock of Pieris GmbH prior to the closing of the Acquisition, and each of OPI III, Gilde, Forbion, Global Life KG, Novo, Zydus and Mark N. Tompkins was a holder of more than 5% of the outstanding capital stock of Pieris as of December 17, 2014 giving effect to the Acquisition. After giving effect to the Private Placement and as of April 29, 2015, each of OPI III, Gilde, Global Life KG, Novo, Mark N. Tompkins and Fundamental Strategies is a holder of more than 5% of the outstanding capital stock of Pieris. Former members of the supervisory board of Pieris GmbH are associated with these 5% stockholders as follows: Dr. Michael Sheffery is a Partner Emeritus at OrbiMed Advisors LLC, which is the general partner of Associates III and the sole managing member of OPI III, Dr. Hans A. Küpper is a managing director of The Global Life Sciences Ventures GmbH, which is the general partner of Global Life KG and advisor to Global Life LP, and Edwin de Graaf is the managing director of Glide Healthcare Holding B.V., the parent company of Gilde Agribusiness Management B.V., the manager of Gilde. Further, Chau Khuong, a current member of our Board of Directors and a member of the supervisory board of Pieris GmbH, is also an employee of OrbiMed Advisors LLC. Last, in October 2013, Pieris GmbH entered into a development and license agreement with Zydus for the preclinical development of PRS-110, pursuant to which Pieris GmbH shares certain commercial rights to PRS-110 with Zydus. For more information about the Zydus agreement, see “Business—Strategic Partnerships”.

Review, Approval or Ratification of Transactions with Related Persons

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

Director Independence

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

[Table of Contents](#)

Subject to some exceptions, NASDAQ Listing Rule 5605(a)(2) provides that a director will only qualify as an “independent director” if, in the opinion of our Board of Directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director, and that a director cannot be an “independent director” if (a) the director is, or in the past three years has been, an employee of ours; (b) a member of the director’s immediate family is, or in the past three years has been, an executive officer of ours; (c) the director or a member of the director’s immediate family has received more than \$120,000 per year in direct compensation from us within the preceding three years, other than for service as a director or benefits under a tax-qualified retirement plan or non-discretionary compensation (or, for a family member, as a non-executive employee); (d) the director or a member of the director’s immediate family is a current partner of our independent public accounting firm, or has worked for such firm in any capacity on our audit at any time during the past three years; (e) the director or a member of the director’s immediate family is, or in the past three years has been, employed as an executive officer of a company where one of our executive officers serves on the compensation committee; or (f) the director or a member of the director’s immediate family is an executive officer, partner or controlling stockholder of a company that makes payments to, or receives payments from, us in an amount which, in any twelve-month period during our past three fiscal years, exceeds the greater of 5% of the recipient’s consolidated gross revenues for that year or \$200,000 (except for payments arising solely from investments in our securities or payments under non-discretionary charitable contribution matching programs). Additionally, in order to be considered an independent member of an audit committee under Rule 10A-3 of the Exchange Act, a member of an audit committee may not, other than in his or her capacity as a member of the audit committee, the Board of Directors, or any other committee of the Board of Directors, accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the applicable company or any of its subsidiaries or otherwise be an affiliated person of the applicable company or any of its subsidiaries.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth the number of shares of our common stock beneficially owned as of March 20, 2016, by (i) each of our current directors and named executive officers, (ii) all executive officers and directors as a group, and (iii) each person known by us to be the beneficial owner of more than 5% of the outstanding shares of our common stock. We have determined beneficial ownership in accordance with applicable rules of the SEC, which generally provide that beneficial ownership includes voting or investment power with respect to securities. Except as indicated by the footnotes to the table below, we believe, based on the information furnished to us, that the persons named in the table have sole voting and investment power with respect to all shares of common stock that they beneficially own, subject to applicable community property laws.

The information set forth in the table below is based on 39,833,023 shares of our common stock issued and outstanding on of March 20, 2016. In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of that person, we deemed to be outstanding all shares of common stock subject to options, warrants or other convertible securities held by that person that are currently exercisable or will be exercisable within 60 days after March 20, 2016. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person. Except as otherwise noted in the footnotes below, the address for each person listed in the table below, solely for purposes of filings with the SEC, is c/o Pieris Pharmaceuticals, Inc., 225 State Street, 9th Floor, Boston, Massachusetts 02109.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned	Percentage Beneficially Owned
<i>5%+ Stockholders:</i>		
OrbiMed Private Investments III, LP (1)	7,259,620	18.23%
Tekla Capital Management LLC (2)	3,848,191	9.66%
Lombard Odier Asset Management Corp (3)	2,848,804	7.15%
Global Life Bioventure IV, S.a.r.l (4)	2,483,949	6.24%
Novo Nordisk A/S (5)	2,051,802	5.15%
<i>Directors and Named Executive Officers:</i>		
Stephen S. Yoder (6)	720,000	1.78%
Michael Richman (7)	59,189	*
Chau Khuong (8)	48,571	*
Steven Prelack (9)	17,500	*
Jean-Pierre Bizzari (10)	35,000	*
Darlene Deptula-Hicks (11)	—	—
Louis Matis	—	—
All Current Directors and Executive Officers as a Group (7 persons)	880,260	2.16%

* Less than 1%.

- (1) Includes 7,194,222 shares held of record by OrbiMed Private Investments III, LP, or OPI III, and 65,398 shares held of record by OrbiMed Associates III, LP, or Associates III. The address for OPI III and Associates III is 601 Lexington Avenue, 54th Floor, New York, New York. Shares of Pieris are directly owned by OPI III and Associates III. OrbiMed Capital GP III LLC, or GP III, is the sole general partner of OPI III and, as such, may be deemed to indirectly beneficially own the shares held by OPI III. OrbiMed Advisors LLC, or OrbiMed, is the general partner of Associates III and the sole managing member of GP III and, as such, OrbiMed may be deemed to indirectly beneficially own the shares held by OPI III and Associates III. Samuel D. Isaly is the managing member of, and owner of a controlling interest in, OrbiMed. Accordingly, OrbiMed and Mr. Isaly may be deemed to have voting and investment power over the shares held by OPI III and Associates III. GP III, OrbiMed and Mr. Isaly disclaim beneficial ownership with respect to such shares, except to the extent of their pecuniary interest therein, if any.

Table of Contents

- (2) The address for Tekla Capital Management LLC is 100 Federal St., 19th Floor, Boston, MA 02110.
- (3) The address for Lombard Odier Asset Management Corp is 452 Fifth Avenue, 25th Floor, New York, NY 10018.
- (4) The address for FundsGlobal Life Bioventure IV, S.a.r.l. (“Global Life”) is Amicorp Luxembourg S.A., 11-13, Boulevard de la Foire, L-1528 Luxembourg. Omega Fund IV G.P. Manager, Ltd. (“Omega Ltd”) serves as the general partner of Omega Fund IV GP, L.P. (“Omega GP”), which serves as the general partner of Omega Fund IV, L.P. (“Omega Fund”), which holds all of the outstanding equity interests in Global Life. Each of Omega Fund, Omega GP and Omega Ltd may be deemed to have sole voting power and sole dispositive with respect to the shares, and Richard Lim (“Lim”), Otello Stampacchia (“Stampacchia”) and Anne-Mari Paster (“Paster”), the directors of Omega Ltd, may be deemed to have shared voting power and shared dispositive power with respect to these shares. Each of Lim, Stampacchia and Paster may each be deemed to beneficially own the shares held by Global Life and each expressly disclaims beneficial ownership of the Shares except to the extent of his or her pecuniary interest in the Shares.
- (5) The address for Novo Nordisk A/S is Novo Allé, 2880 Bagsvaerd, Denmark. Novo Nordisk A/S is a corporation governed by a board of directors comprised of 11 directors. The members of the board of directors disclaim beneficial ownership with respect to such shares, except to the extent of their pecuniary interest therein, if any.
- (6) Includes options to purchase 720,000 shares of our common stock that are exercisable within 60 days of March 18, 2016, and does not include options to purchase 1,052,000 shares of our common stock which have not vested and will not be exercisable within 60 days after March 18, 2016.
- (7) Includes options to purchase 59,189 shares of our common stock that are exercisable within 60 days of March 18, 2016, and does not include options to purchase 50,000 shares of our common stock which have not vested and will not be exercisable within 60 days after March 18, 2016.
- (8) Includes options to purchase 48,571 shares of our common stock that are exercisable within 60 days of March 18, 2016, and does not include options to purchase 32,500 shares of our common stock which have not vested and will not be exercisable within 60 days after March 18, 2016.
- (9) Includes options to purchase 17,500 shares of our common stock that are exercisable within 60 days of March 18, 2016, and does not include options to purchase 32,500 shares of our common stock which have not vested and will not be exercisable within 60 days after March 18, 2016.
- (10) Includes options to purchase 35,000 shares of our common stock that are exercisable within 60 days of March 18, 2016, and does not include options to purchase 15,000 shares of our common stock which have not vested and will not be exercisable within 60 days after March 18, 2016.
- (11) Does not include options to purchase 450,000 shares of our common stock which have vested but will not be exercisable within 60 days after March 18, 2016.
- (12) Does not include options to purchase 500,000 shares of our common stock which have not vested and will not be exercisable within 60 days after March 18, 2016

LEGAL MATTERS

The validity of the common stock being offered by this prospectus is being passed upon by Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.

EXPERTS

The consolidated financial statements of Pieris Pharmaceuticals, Inc. at December 31, 2015 and 2014, and for each of the two years in the period ended December 31, 2015, appearing in this prospectus and elsewhere in the registration statement have been audited by Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft, independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

Upon the effectiveness of registration statement of which this prospectus forms a part or our earlier registration of a class of our securities under Section 12 of the Exchange Act, we will be required to file annual, quarterly and current reports and proxy statements and other information with the SEC. Prior to that time, we are not required to file such reports, but expect to do so as a “voluntary filer” under the Exchange Act. You may read and copy any document that we file at the SEC’s Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549, on official business days during the hours of 10:00 am and 3:00 pm. Please call the SEC at 1-800-SEC-0330 for further information on the Public Reference Room. All filings we make with the SEC are also available on the SEC’s web site at <http://www.sec.gov>. Our website address is <http://www.pieris.com>. We have not incorporated by reference into this prospectus the information on our website, and you should not consider it to be a part of this document.

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock being offered by this prospectus. This prospectus is part of that registration statement. This prospectus does not contain all of the information set forth in the registration statement or the exhibits to the registration statement. For further information with respect to us and the shares we are offering pursuant to this prospectus, you should refer to the complete registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract, agreement or other document referred to are not necessarily complete, and you should refer to the copy of that contract or other documents filed as an exhibit to the registration statement. You may read or obtain a copy of the registration statement at the SEC’s public reference room and website referred to above.

[Table of Contents](#)

PIERIS PHARMACEUTICALS, INC.

Table of Contents

<u>Report of Independent Registered Public Accounting Firm</u>	F-2
<u>Consolidated Balance Sheets as of December 31, 2015 and 2014</u>	F-3
<u>Consolidated Statements of Operations for the years ended December 31, 2015 and 2014</u>	F-4
<u>Consolidated Statements of Comprehensive Loss for the years ended December 31, 2015 and 2014</u>	F-5
<u>Consolidated Statements of Changes in Stockholders' Equity for the years ended December 31, 2015 and 2014</u>	F-6
<u>Consolidated Statements of Cash Flows for the years ended December 31, 2015 and 2014</u>	F-7
<u>Notes to Consolidated Financial Statements</u>	F-8

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. as of December 31, 2015 and 2014, and the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity and cash flows for each of the two years in the period ended December 31, 2015. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. 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, 2015 and 2014, and the consolidated results of its operations and its cash flows for each of the two years in the period ended December 31, 2015, in conformity with U.S. generally accepted accounting principles.

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

/s/ Christ
Wirtschaftsprüfer
[German Public Auditor]

Ernst & Young GmbH
Wirtschaftsprüfungsgesellschaft

Munich, Germany
March 23, 2016

[Table of Contents](#)

PIERIS PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS

	December 31,	
	2015	2014
Assets		
Current assets:		
Cash and cash equivalents	\$ 29,349,124	\$ 18,474,211
Prepaid expenses and other current assets	2,311,385	1,331,214
Total current assets	31,660,509	19,805,425
Property and equipment, net	2,162,771	2,052,221
Other non-current assets	126,781	—
Total assets	\$ 33,950,061	\$ 21,857,646
Liabilities and Stockholders' Equity		
Current liabilities:		
Trade accounts payable	\$ 1,058,536	\$ 1,260,015
Accrued expenses and other current liabilities	1,739,380	986,620
Bank loan, including accrued interest, current portion	—	1,270,605
Total current liabilities	2,797,916	3,517,240
Accrued expenses and other non-current liabilities	23,852	333,988
Total liabilities	2,821,768	3,851,228
Stockholders' equity:		
Common stock, \$0.001 par value per share, 300,000,000 shares authorized and 39,833,023 and 29,279,522 shares issued and outstanding at December 31, 2015 and 2014	39,833	29,280
Additional paid-in capital	112,226,723	84,627,283
Accumulated other comprehensive loss	(1,272,574)	(843,097)
Accumulated deficit	(79,865,689)	(65,807,048)
Total stockholders' equity	31,128,293	18,006,418
Total liabilities and stockholders' equity	\$ 33,950,061	\$ 21,857,646

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

PIERIS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	Years ended December 31,	
	2015	2014
Revenue	\$ 2,931,931	\$ 5,365,054
Operating expenses		
Research and development	8,244,751	5,600,421
General and administrative	8,368,215	6,962,891
Total operating expenses	16,612,966	12,563,312
Loss from operations	(13,681,035)	(7,198,258)
Interest expense, net	(184,645)	(2,654,727)
Other income/(expense), net	10,905	3,003
Loss before income taxes	(13,854,775)	(9,849,982)
Provision/(benefit) for income tax	203,866	(18)
Net Loss	<u>\$(14,058,641)</u>	<u>\$ (9,849,964)</u>
Net loss per share		
Basic and diluted	<u>\$ (0.41)</u>	<u>\$ (0.71)</u>
Weighted average number of common shares outstanding		
Basic and diluted	<u>34,392,636</u>	<u>13,872,390</u>

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

PIERIS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Years ended December 31,	
	2015	2014
Net loss	\$14,058,641	\$9,849,964
Other comprehensive (loss)/income components:		
Foreign currency translation	(429,477)	113,176
Total other comprehensive (loss)/income	(429,477)	113,176
Comprehensive loss	\$14,488,118	\$9,736,788

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

PIERIS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

	Common shares			Receivable	Accumulated		
	No. of	Share	Additional	from issuance	other	Accumulated	Total equity
	shares	capital	paid-in capital	of shares	comprehensive	deficit	
					loss		
Balance as of January 1, 2014	11,828,975	\$11,829	\$ 57,608,336	\$ (121,801)	\$ (956,273)	\$(55,957,084)	\$ 585,007
Net loss	—	—	—	—	—	(9,849,964)	(9,849,964)
Foreign currency translation adjustment	—	—	—	—	113,176	—	113,176
Beneficial conversion feature	—	—	2,236,583	—	—	—	2,236,583
Series C share conversion	5,008,870	5,009	4,254,096	121,801	—	—	4,380,906
Issuance of series C cash shares net \$100,820 in offering costs	5,662,167	5,662	7,336,414	—	—	—	7,342,076
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)	18,006,418
Net loss	—	—	—	—	—	(14,058,641)	(14,058,641)
Foreign currency translation adjustment	—	—	—	—	(429,477)	—	(429,477)
Stock based compensation expense	—	—	1,164,633	—	—	—	1,164,633
Issuance of restricted shares	150,000	150	446,250	—	—	—	446,400
Issuance of consulting shares	95,765	95	224,905	—	—	—	225,000
Issuance of Common Stock net \$2,568,565 in offering costs	10,302,736	10,303	25,753,657	—	—	—	25,763,960
Options exercised	5,000	5	9,995	—	—	—	10,000
Balance as of December 31, 2015	39,833,023	\$39,833	\$112,226,723	\$ —	\$ (1,272,574)	\$(79,865,689)	\$ 31,128,293

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

PIERIS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years ended December 31,	
	2015	2014
Operating activities:		
Net loss	\$(14,058,641)	\$ (9,849,964)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	307,906	366,979
Non-cash interest expense	—	2,589,025
Stock-based compensation	1,164,633	571,382
Non-cash restricted shares	446,400	—
Non-cash consulting shares	225,000	—
Warrants issued in Private Placement	—	664,064
Changes in operating assets and liabilities:		
Restricted cash	—	70,026
Trade accounts receivable	—	465,385
Prepaid expenses and other assets	(1,256,151)	(921,587)
Trade accounts payable	(90,924)	1,115,987
Accrued expenses and other liabilities	556,297	(136,997)
Net cash used in operating activities	(12,705,480)	(5,065,700)
Investing activities:		
Purchase of property and equipment	(620,747)	(267,406)
Net cash used in investing activities	(620,747)	(267,406)
Financing activities:		
Proceeds from exercise of options	10,000	—
Issuance of Common Stock, net of issuance costs	25,763,960	11,963,188
Issuance of Preferred Stock—series C, net of issuance costs	—	7,342,076
Proceeds from convertible stockholder loan	—	1,210,100
Repayment of debt	(1,157,940)	(181,515)
Net cash provided by financing activities	24,616,020	20,333,849
Effect of exchange rate change on cash and cash equivalents	(414,880)	(215,914)
Net increase in cash and cash equivalents	10,874,913	14,784,829
Cash and cash equivalents at beginning of year	18,474,211	3,689,382
Cash and cash equivalents at end of year	\$ 29,349,124	\$18,474,211
Supplemental cash flow disclosures:		
Cash paid for interest	\$ 206,269	\$ 71,757
Cash paid for income taxes	\$ 203,866	\$ —
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.

PIERIS PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Corporate Information

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

Effective as of August 26, 2015 and with notification from the Amtsgericht München as of September 29, 2015 Pieris AG was transformed to Pieris GmbH as a result of a change in the legal entity, Pieris Pharmaceuticals, Inc. and its consolidated subsidiaries (collectively “Pieris” or the “Company”) is a clinical-stage biopharmaceutical company that discovers and develops Anticalin® based drugs to target validated disease pathways in a unique and transformative way.

The Company’s pipeline includes, among other programs, an immuno-oncology multi-specific tailored for the tumor micro-environment, an inhaled Anticalin to treat uncontrolled asthma and a half-life-optimized Anticalin to treat anemia.

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

2. Summary of Significant Accounting Policies

Basis of Consolidation

The accompanying consolidated financial statements of Pieris Pharmaceuticals, Inc. and its wholly owned subsidiaries were prepared in accordance with accounting principles generally accepted in the United States (“U.S. GAAP”). The consolidated financial statements include the accounts of all subsidiaries. All intercompany balances and transactions have been eliminated.

Reclassifications

For comparability purposes, certain prior period amounts in the consolidated financial statements have been reclassified to conform to the current period’s presentation within the consolidated balance sheets and consolidated statements of cash flows.

Use of Estimates

The preparation of the financial statements in accordance with U.S. GAAP requires management to make estimates, judgments and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses and the related disclosures at the date of the financial statements and during the reporting period. Significant estimates are used for, but are not limited to, revenue recognition, deferred tax assets, liabilities and valuation allowances, fair value of stock options and various accruals. Management evaluates its estimates on an ongoing basis. Actual results and outcomes could differ materially from management’s estimates, judgments and assumptions.

[Table of Contents](#)

Foreign Currency Translation

The financial statements of Pieris' foreign subsidiaries are translated from local currency into reporting currency, which is U.S. dollars, using the current exchange rate at the balance sheet date for assets and liabilities, and the average exchange rate prevailing during the period for revenues and expenses. The functional currency for Pieris' foreign subsidiaries is considered to be the local currency for each entity and, accordingly, translation adjustments for these subsidiaries are included in accumulated other comprehensive loss within stockholders' equity.

Realized and unrealized gains and losses resulting from foreign currency transactions denominated in currencies other than the functional currency are reflected as other income (expense), net in the consolidated statements of operations.

Cash, Cash Equivalents and Restricted Cash

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

The Company held \$17,302 in restricted cash as of December 31, 2015. There was no restricted cash as of December 31, 2014. Such bank balances in 2015 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 Measurement

ASC Topic 820 *Fair Value Measurement* defines fair value as the price that would be received to sell an asset or be paid to transfer a liability in an orderly transaction between market participants at the measurement date. Pieris applies the following fair value hierarchy, which prioritizes the inputs used to measure fair value into three levels and bases the categorization within the hierarchy upon the lowest level of input that is available and significant to the fair value measurement.

Level 1 inputs are quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date.

Level 2 utilizes quoted market prices in markets that are not active, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency.

Level 3 inputs are unobservable inputs for the asset or liability in which there is little, if any, market activity for the asset or liability at the measurement date.

Cash equivalents recorded by Pieris consist of highly liquid money market funds and are measured at fair value on a recurring basis. These funds are classified as Level 1 because they are valued using quoted prices for the periods ended December 31, 2015 and December 31, 2014. The carrying amounts of zero and \$4.8 million as of December 31, 2015 and December 31, 2014, respectively, equal the fair value of the cash equivalents.

The Company's debt instruments are classified as Level 2. 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. There are no remaining debt instruments as of December 31, 2015. The fair values for these debt instruments approximated carrying values as of December 31, 2014.

All of other current assets and current liabilities on our consolidated balance sheets approximate their respective carrying amounts.

[Table of Contents](#)

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that subject Pieris to concentrations of credit risk include cash and cash equivalents and trade accounts receivable. Pieris maintains cash and cash equivalents with various major financial institutions. Pieris maintains deposits and owns money market funds only in highly rated financial institutions to minimize the credit risk from the financial institutions. There were no money market funds held at December 31, 2015. Management periodically reviews the credit standing of these financial institutions and believes that Pieris is not exposed to significant credit risk from the institutions in which those deposits are held and through which money-market funds are owned at December 31, 2014.

As of December 31, 2015 and December 31, 2014, respectively, Pieris has no trade accounts receivable. See Note 4 *Revenue*, for additional information regarding Pieris's collaboration agreements.

Pieris relies on third parties to conduct preclinical and clinical studies. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, Pieris may not be able to obtain regulatory approval for Pieris's drug candidates and Pieris's business could be substantially impacted. Furthermore, Pieris is exposed to the risks associated with third parties formulating and manufacturing its preclinical and clinical drug supplies and any approved product candidates. The development and commercialization of any of its drug candidates could be stopped, delayed or made less profitable if those third parties fail to provide Pieris with sufficient quantities of such drug candidate or fail to do so at acceptable quality levels, including in accordance with applicable regulatory requirements and prices.

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

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, 2015 and 2014 as there were no accounts receivables on the consolidated balance sheets. Historically, Pieris has not had collectability issues with third parties and collaboration partners.

Property and Equipment

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

Asset Classification	Estimated useful life (in years)
Leasehold improvements	shorter of useful life or remaining life of the lease
Laboratory equipment	1 - 14
Office and computer equipment	1 - 15

[Table of Contents](#)

Impairment of Long-lived Assets

Pieris reviews its long-lived assets to be held and used for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Pieris evaluates the realizability of its long-lived assets based on profitability and cash flow expectations for the related asset. Any write-downs are treated as permanent reductions in the carrying amount of the assets. Pieris believes that, as of each of the balance sheets presented, none of Pieris' long-lived assets were impaired.

Revenue Recognition

Pieris has entered into several licensing and development agreements with collaboration partners for the development of Anticalin[®] therapeutics against a variety of targets in diseases and conditions. The terms of these agreements contain multiple elements and deliverables, which may include (i) licenses, or options to obtain licenses, to Pieris's Anticalin technology and (ii) research activities to be performed on behalf of the collaborative partner. Payments to Pieris under these agreements may include upfront fees (which include license and option fees), payments for research activities, payments based upon the achievement of certain milestones and royalties on product sales. There are no performance, cancellation, termination or refund provisions in any of the arrangements that could result in material financial consequences to Pieris. Pieris follows the provisions of the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 605-25, *Revenue Recognition—Multiple-Element Arrangements* and ASC Topic 605-28, *Revenue Recognition—Milestone Method* in accounting for these agreements.

Multiple-Element Arrangements

When evaluating multiple-element arrangements, Pieris identifies the deliverables included within the agreement and evaluates which deliverables represent separate units of accounting based on whether the delivered element has stand-alone value to the 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. Pieris has used best estimate of selling price methodology to estimate the selling price for licenses and options to acquire additional licenses to its proprietary technology because Pieris does not have Vendor Specific Objective Evidence or Third Party Evidence of selling price for these deliverables. To determine the estimated selling price of a license to its proprietary technology, Pieris considers market conditions as well as entity-specific factors, including those factors contemplated in negotiating the agreements, terms of previous collaborative agreements, similar agreements entered into by third parties, market opportunity, estimated development costs, probability of success and the time needed to commercialize a product candidate pursuant to the license. In validating Pieris's best estimate of selling price, Pieris evaluates whether changes in the key assumptions used to determine the best estimate of selling price will have a significant effect on the allocation of arrangement consideration among multiple deliverables.

Pieris 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, Pieris generally recognizes revenue attributable to the license on a straight-line basis over Pieris's contractual or estimated performance period, which is typically the term of

Table of Contents

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

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

Milestone Payments and Royalties

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

Pieris aggregates milestones into four categories (i) research milestones, (ii) development milestones, (iii) commercial milestones and (iv) sales milestones. Research milestones are typically achieved upon reaching certain success criteria as defined in each agreement related to developing an Anticalin[®] protein against the specified target. Development milestones are typically reached when a compound reaches a defined phase of clinical research or passes such phase, or upon gaining regulatory approvals. Commercial milestones are

Table of Contents

typically achieved when an approved pharmaceutical product reaches the status for commercial sale or certain defined levels of net sales by the licensee, such as when a product first achieves global sales or annual sales of a specified amount. Sales milestones are typically achieved when an approved pharmaceutical product exceed net sales as defined in each agreement.

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

Government Grants

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

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

Research and Development

Research and development 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 Pieris'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.

From time to time the Company may receive tax credits in the form of cash in our Australian jurisdiction, irrespective of a tax liability. When a tax credit is due to us it is our policy to have that flow through operating expenses in the consolidated statements of operations, as this was where the original expense was recorded.

[Table of Contents](#)

Stock-based Compensation

Pieris measures share-based payments in accordance with ASC Topic 718, *Stock Compensation*. Pieris records its stock-based compensation expense over the requisite service period. Determining the appropriate fair value model and related assumptions requires judgment, including estimating share price volatility and expected terms of the awards. For employee options, the fair value measurement date is generally on the date of grant and the related compensation expense is recognized on a straight-line basis over the requisite period of the awards, less expense for estimated forfeitures.

The Company uses the Black-Scholes option pricing model to determine the estimated fair value for stock-based awards. Option-pricing models require the input of various subjective assumptions, including the option's expected life, expected dividend yield, price volatility, risk free interest rate and forfeitures of the underlying stock. Accordingly, the weighted-average fair value of the options granted during the years ended December 31, 2015 and 2014 was \$1.87 and \$1.30, respectively based on the following assumptions:

	Years Ended December 31,	
	2015	2014
Risk free interest rate	1.47%-1.89%	1.77%
Expected term	5.0 – 6.1 years	5.6 – 5.8 years
Dividend yield	—	—
Expected volatility	72.65%-75.07%	74.66%

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.

Pieris recorded stock-based compensation expense of \$1.2 million and \$0.6 million for the years ended December 31, 2015 and 2014, respectively.

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

	Years Ended December 31,	
	2015	2014
Research and development	\$ 379,066	\$ 7,623
General and administrative	785,567	563,759
Total stock-based compensation	<u>\$1,164,633</u>	<u>\$571,382</u>

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. Pieris 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 11 *Warrants* for further information.

[Table of Contents](#)

Contingencies

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

Segment Reporting

Operating segments are identified as components of an enterprise where separate discrete financial information is available for evaluation by the chief operating decision maker in making decisions on how to allocate resources and assess performance. Pieris operates as a single segment dedicated to the discovery and development of biotechnological applications and the Company's chief operating decision maker ("CODM") makes decisions based on the Company as a whole. The Company has determined that its CODM is its CEO.

Net Loss per Common Share

Basic net loss per share was determined by dividing net loss by the weighted average common shares outstanding during the period. Diluted net loss per share was determined by dividing net loss by diluted weighted average shares outstanding. Diluted weighted average shares reflect the dilutive effect, if any, of common stock options based on the treasury stock method.

For all financial statement periods presented the number of basic and diluted weighted average shares outstanding was the same because any increase in the number of shares of common stock equivalents for any period presented would be antidilutive based on the net loss for the period.

Shares to be issued upon the exercise of the outstanding options and warrants excluded from the loss per share calculation amounted to 2.6 million for the year ended December 31, 2015 because the awards were anti-dilutive. There were no shares to be issued upon the exercise of the outstanding options and warrants excluded from the loss per share calculation for the year ended December 31, 2014.

Accumulated Other Comprehensive Loss

Changes to accumulated other comprehensive income as of December 31, 2015 were as follows:

	Foreign Currency Translation Adjustment	Accumulated Other Comprehensive Income
Balance—December 31, 2013	\$ (956,273)	\$ (956,273)
Current period other comprehensive loss	113,176	113,176
Balance—December 31, 2014	(843,097)	(843,097)
Current period other comprehensive loss	(429,477)	(429,477)
Balance—December 31, 2015	<u><u>\$ (1,272,574)</u></u>	<u><u>\$ (1,272,574)</u></u>

Recent Accounting Pronouncements

Adopted Standards for current period

In November 2015, the FASB issued ASU No. 2015-17, *"Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes"* (ASU 2015-17). The amendments in ASU 2015-17 eliminates the current

Table of Contents

requirement for organizations to present deferred tax liabilities and assets as current and noncurrent in a classified balance sheet. Instead, organizations will be required to classify all deferred tax assets and liabilities as noncurrent. This guidance is effective for fiscal years beginning after December 15, 2017, and interim periods within fiscal years beginning after December 15, 2018. Early adoption is permitted. The Company does not believe this ASU will have a material impact on its financial statements. The Company has decided to early adopt ASU 2015-17 as of December 31, 2015 and is reflected in our income tax footnote (refer to Note 6—*Income taxes*). As a result of the early adoption of ASU 2015-17 the deferred tax assets reported in 2014 were netted. The overall impact to this adoption was not material to the overall financial statements.

Standards not yet adopted

In May 2014, the FASB issued ASU No. 2014-09, “Revenue from Contracts with Customers,” (ASU 2014-09) which provides guidance for revenue recognition. The standard’s core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. ASU 2014-09 is effective for the Company beginning January 1, 2018, and at that time the Company may adopt the new standard under the full retrospective approach or the modified retrospective approach. Early adoption is not permitted. The Company is currently evaluating the potential impact the adoption of this standard will have on its financial statements and related disclosures.

In June 2015, the FASB issued ASU No. 2015-10, “Technical Corrections and Improvements” (ASU 2015-10). The amendments in ASU 2015-10 represent changes to clarify the FASB Accounting Standards Codification (the “Codification”), correct unintended application of guidance, or make minor improvements to the Codification that are not expected to have a significant effect on current accounting practice or create a significant administrative cost to most entities. In addition, some of the amendments are intended to make the Codification easier to understand and easier to apply by eliminating inconsistencies, providing needed clarifications, and improving the presentation of guidance in the Codification. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015. The Company does not believe this ASU will have an impact on its financial statements.

In February 2016, the FASB issued ASU No. 2016-02, “*Leases (Topic 842)*”. Under the amendments in ASU 2016-02 lessees will be required to recognize (i) a lease liability, which is a lessee’s obligation to make lease payments arising from a lease, measured on a discounted basis; and (ii) a right-of-use asset, which is an asset that represents the lessee’s right to use, or control the use of, a specified asset for the lease term for all leases (with the exception of short-term leases) at the commencement date. This guidance is effective for fiscal years beginning after December 15, 2019 including interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the potential impact the adoption of this standard will have on its financial statements and related disclosures.

Pieris has considered other recent accounting pronouncements and concluded that they are either not applicable to the business, or that the effect is not expected to be material to the unaudited condensed consolidated financial statements as a result of future adoption.

3. Acquisition

On December 17, 2014, Pieris, Pieris GmbH and the former shareholders of Pieris GmbH entered into an Acquisition Agreement (the “Acquisition Agreement”). Pursuant to the Acquisition Agreement, the former shareholders of Pieris GmbH contributed all of their equity interests in Pieris GmbH in exchange for 20,000,000 shares of the Company’s common stock, which resulted in Pieris GmbH becoming a wholly owned subsidiary of the Company (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

[Table of Contents](#)

split became 13,863,647 shares of common stock outstanding immediately thereafter. Effective as of December 16, 2014, Pieris amended and restated its Articles of Incorporation to, among other things, change its name from Marika Inc. to “Pieris Pharmaceuticals, Inc.” and increase its authorized capital stock from 75,000,000 shares of common stock, par value \$0.001 per share, to 300,000,000 shares of common stock, par value \$0.001 per share, and 10,000,000 shares of “blank check” preferred stock, par value \$0.001 per share. On December 17, 2014, Pieris 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.

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 GmbH is the acquirer for financial reporting purposes and Pieris 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 GmbH and are recorded at the historical cost basis of Pieris GmbH, 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.

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.

	Years ended December 31,	
	2015	2014
License fees	\$ —	\$ 473,039
Research and development services	5,593	876,619
Milestone payments	2,538,698	3,184,988
Government grants	369,200	830,408
Other Revenues	18,440	—
Total Revenue	\$2,931,931	\$5,365,054

Revenue from two collaboration partners and from one government grant exceeded 10% of total revenue, amounting to \$2.0 million, \$0.5 million and \$0.4 million, respectively, in the year ended December 31, 2015. Revenue from two collaboration partners and from one government grant exceeded 10% of total revenue, amounting to \$3.0 million, \$1.4 million and \$0.7 million, respectively, in the year ended December 31, 2014.

Collaborations and Other Agreements

Daiichi Sankyo Co., Ltd.

In May 2011, Pieris granted an exclusive, worldwide license for the research, development and commercialization of drug candidates identified by the Company for targets selected by Daiichi Sankyo Co., Ltd. (“Daiichi Sankyo”) pursuant to an agreement with Daiichi Sankyo. Under this agreement Pieris will use its proprietary Anticalin® scaffold technology to identify drug candidates against certain selected targets, with further development and commercialization performed by Daiichi Sankyo.

Daiichi Sankyo has agreed to pay various upfront payments for certain research programs, payments for services provided by Pieris in conjunction with the research programs and certain milestone payments as development

[Table of Contents](#)

milestones are achieved. During the years ended December 31, 2015 and 2014, Pieris recorded revenue of \$2.0 million and \$3.0 million, respectively. The revenues recorded during the year ended December 31, 2015 were associated with achieving certain milestones within a research program. The revenues recorded during the year ended December 31, 2014 were associated with recognizing the final component of the upfront payment. Pieris provided various services in connection with the ongoing research programs as well as achieved development milestones during the years ended December 31, 2014.

The milestone payments in 2015 and 2014 are based on successful in vitro and in vivo studies and for the initiation on a toxicity study in non-human primates. The milestones could not be achieved solely upon the passage of time. For revenue recognition purposes, management determined these milestones to be substantive in accordance with applicable accounting guidance related to milestone revenue. Substantive uncertainty existed at the inception of the arrangements as to whether the milestones would be achieved because of the numerous variables, such as the high rate of failure inherent in research and development activities and the uncertainty involved with obtaining regulatory approval. Therefore, each of the milestone payments were recognized in their entirety as revenues during the respective years ended December 31, 2015 and 2014 in which they were received.

Pieris is entitled to receive potential milestone payments of \$89.1 million, plus royalties on the commercial sales of any commercial products. The total milestones are categorized as follows: research milestones—\$2.6 million; development milestones—\$36.5 million; commercial milestones—\$49.1 million; additional diagnostic milestones of \$0.9 million.

Sanofi-Aventis and Sanofi-Pasteur

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

Sanofi has agreed to pay various upfront payments for certain research programs, payments for services provided by Pieris in conjunction with the research programs and certain milestone payments as development milestones are achieved. During the years ended December 31, 2015 and 2014, Pieris recorded revenue of \$0.5 million and \$1.4 million, respectively. The revenues recorded during the year ended December 31, 2015 were associated with achieving a development milestone within a research program during the period. The revenues recorded during the year ended December 31, 2014 were associated with recognizing the final component of the upfront payment as well as Pieris providing various services in connection with the ongoing research programs including achieving development milestones during the period.

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. The milestone payment in 2015 result from Sanofi’s decision to continue advancing the tetraspecific Anticalin-based program for infectious disease. 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, 2015 and 2014 in which they were received.

Table of Contents

The Company is entitled to receive milestone payments up to \$50.4 million, plus royalties on the sales of any commercial products. The total milestones are categorized as follows: research milestones—\$1.9 million; development milestones—\$28.9 million; commercial milestones—\$19.6 million.

F.Hoffmann-La Roche Ltd and Hoffmann- La Roche Inc.

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

The parties will jointly pursue a preclinical research program with respect to the identification and generation of Anticalins that bind to a specific target for an expected period of 20 months, which may be extended under certain circumstances. Roche has the ability to continue exclusivity rights for up to an additional 5 years. During the research term of the agreement, Roche will fund the work to be performed by us pursuant to the research plan. Following the research program, Roche will be responsible for subsequent pre-clinical and clinical development of any product and will have worldwide commercialization rights.

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

Under the terms of the agreement Roche has agreed to pay an upfront payment of \$6.5 million, which was received in January 2016, for the research program which will be recognized over the expected performance period, beginning on January 1, 2016. Roche also committed research funding, and the Company may receive development and regulatory-based milestone payments, sales-based milestone payments as well as mid-single-digit to low double-digit royalties on any future product sales. If all milestones and other conditions are met, the total consideration to us could surpass CHF 415 million (\$415.7 million), excluding royalties.

Other Collaborations

The Company has entered into several other research and collaboration agreements for which the Company could achieve future milestone payments up to \$14.0 million. For revenue recognition purposes, management determined these milestones to be substantive in accordance with applicable accounting guidance related to milestone revenue. Substantive uncertainty existed at the inception of the arrangements as to whether the milestones would be achieved because of the numerous variables, such as the high rate of failure inherent in research and development activities and the uncertainty involved with obtaining regulatory approval. No milestones or other revenues related to these agreements were recognized during the years ended December 31, 2015 and 2014, respectively.

Government Grants

BioCluster m4

In 2011 Pieris applied for a government grant from the German Federal Ministry for Education and Research for the project “Spitzencluster m4, Cooperation personalized medicine: ‘Preclinical development of PRS-110 an Anticalin® targeted against c-Met as a monovalent antagonist in the field of oncology (PM18).’” The funding

[Table of Contents](#)

rate amounts to 40% of the actual costs incurred, with an aggregate cap of \$1.4 million for the approval period from February 1, 2012 to September 30, 2014. The amounts received are non-refundable, and the grant funds may only be claimed for costs incurred within the approval period.

The payments are received quarterly in arrears based on expenses already incurred. The Company recorded \$8,654 and \$0.1 million for the years ended December 31, 2015 and 2014, respectively, which was recorded as grant revenue.

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

EUROCALIN is a program that started in August 2011 with the objective of developing and producing new high-affinity protein scaffolds for therapeutic use. The focus is on the development of non-immunoglobulin protein scaffolds as alternatives to antibodies and oligo-nucleotides. The grant involves a consortium of ten companies and universities in Europe and was initiated for a collaboration focused on attaining and completing initial clinical development of a novel Anticalin® therapeutic. The consortium is seeking to develop, manufacture and clinically test an Anticalin specific for hepcidin. The program is a small molecule enhancers (“SME”) targeted project, which is funded by the European Union (“EU”) in the amount of \$7.3 million and also includes a respective funding rate of approximately 64% of the eligible costs occurred in connection with the research project. All payments received from the EU in connection with the grant are non-refundable. Under this grant agreement, Pieris is the coordinator. The EU has scheduled three tranches of payments. The first tranche (pre-financing) was received as of December 7, 2011 and the second tranche as of August 4, 2013. The third tranche was completed in November 2015 and is currently included in prepaid and other current assets on the consolidated balance sheet as the Company is awaiting final payment. Pieris, 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. Pieris pays the other members of the consortium based on the eligible costs. The Company owes the other member of the consortium an amount of \$0.4 million and \$0.3 million as of December 31, 2015 and 2014, respectively. Under this program the Company recognized \$0.4 million and \$0.7 million as revenue from grant during the years ended December 31, 2015 and 2014, respectively.

The following balance sheet items relate to the FP7 agreement:

	Years Ended December 31,	
	2015	2014
Other current assets (receivables from FP7 grant)	\$ 980,936	\$ 857,489
Cash (restricted cash)	\$ 17,302	\$ —
Accounts payable trade	\$ 424,441	\$ 325,864

5. Property and Equipment, net

Property and equipment are summarized as follows:

	Years Ended December 31,	
	2015	2014
Laboratory equipment	\$ 3,701,517	\$ 3,840,368
Office and computer equipment	443,562	343,835
Leasehold improvements	304,363	50,791
Property and equipment at cost	4,449,442	4,234,994
Accumulated depreciation	(2,286,671)	(2,182,773)
Property and equipment, net	\$ 2,162,771	\$ 2,052,221

[Table of Contents](#)

Depreciation expense was \$0.3 million and \$0.4 million for the years ended December 31, 2015 and 2014, respectively. There were no other changes in accumulated depreciation other than foreign currency impact.

6. Income Taxes

(Loss) before income taxes consists of the following:

	Years Ended December 31,	
	2015	2014
Domestic	\$ (7,563,300)	\$(1,235,446)
Foreign	(6,291,475)	(8,614,536)
Loss before income taxes	<u>\$(13,854,775)</u>	<u>\$(9,849,982)</u>

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

	Years Ended December 31,	
	2015	2014
Current:		
Federal	\$ —	\$ —
State	—	—
Foreign	203,866	(18)
Total current	203,866	(18)
Deferred:		
Federal	—	—
State	—	—
Foreign	—	—
Total deferred	—	—
Provision (benefit) for income taxes	<u>\$ 203,866</u>	<u>\$ (18)</u>

The reconciliation of the federal statutory rate to Pieris's effective tax rate is as follows:

	2015	2014
Federal income tax rate	34.0%	34.0%
Foreign rate differential	(2.1)%	(4.3)%
State tax, net of federal benefit	3.1	—
Permanent Items: Non-deductible expenses	(1.7)	(4.5)
Deferred adjustments	2.9	—
Loss of German NOL's	(66.0)	(74.2)
Withholding tax	(1.5)	—
Other	—	0.1
Change in valuation allowance	<u>29.8</u>	<u>48.9</u>
Effective income tax rate	(1.5)%	0.0%

The Company follows the provisions of FASB ASC 740, "Accounting for Uncertainty in Income Taxes—An Interpretation of FASB No. 109." FASB ASC 740 provides detailed guidance for the financial statement recognition, measurement and disclosure of uncertain tax positions recognized in the financial statements in accordance with ASC 740-20. Tax positions must meet a "more-likely-than-not" recognition threshold at the effective date to be recognized upon the adoption of FASB ASC 740 and in subsequent periods. Pieris recognizes interest and penalties, if any, related to uncertain tax positions in income tax expense. No uncertain tax positions nor any interest and penalties related to uncertain tax positions were accrued at December 31, 2015 and December 31, 2014.

[Table of Contents](#)

The Company operates in multiple countries. Accordingly, separate tax filings are required based on jurisdiction. In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax-planning strategies in making this assessment. Management believes it is more likely than not that the results of future operations will not generate sufficient taxable income in the U.S. or in its foreign jurisdictions to realize the full benefits of its U.S. deferred tax assets. As of December 31, 2015, we continue to maintain a full valuation allowance against all net deferred tax assets.

As of December 31, 2015, the Company has U.S. federal and state tax net operating loss carryforwards of approximately \$6.0 million, which expire through 2035. Utilization of the tax net operating loss carryforwards may be limited in any year due to limitations in the Internal Revenue Code. As of December 31, 2015, the Company had Australia tax net operating loss carryforwards of approximately \$0.3 million, which will not expire.

As of December 31, 2015, the Company had German corporate income tax and trade tax net operating loss carryforwards of approximately \$5.9 million and \$5.7 million respectively. Based on German tax law, the losses can be carried forward indefinitely. The operating loss carryforwards generated are subject to restrictions under German tax law. These regulations may limit the future use of operating loss carryforwards if there is a change in ownership. As a result of the ownership change Pieris GmbH experienced from the Acquisition and Private Placement in December 2014, the Company believes that it is more likely than not that future use of the net operating loss carryforwards that existed prior to the Acquisition may be limited significantly or forfeited entirely and as such the Company has written them off accordingly during the 2014 and 2015 period. The Company files federal income tax returns as well as returns in multiple foreign jurisdictions. Tax years ended December 31, 2013 or later remain subject to examination by the German tax authorities. Tax years ended December 31, 2014 and later remain subject to examination by the U.S. tax authorities.

The components of deferred tax assets and liabilities related to net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income taxes purposes were as follows:

	Years Ended December 31,	
	2015	2014
Deferred tax assets:		
Share based awards compensation	\$ 692,906	\$ —
Accrued expenses	4,201	—
Book accumulated depreciation net of tax	12,276	—
Net operating loss carryforwards	4,147,012	9,951,666
Bank loan	—	12,653
Accrued compensation	129,624	—
Other	10,149	1,129
Total deferred tax assets	4,996,168	9,965,448
Less: valuation allowance:	(4,996,168)	(9,916,553)
Net deferred tax asset	\$ —	\$ 48,895
Deferred tax liabilities:		
Accrued expenses	\$ —	\$ (8,811)
Prepaid expenses	—	(9,438)
Depreciation	—	(30,646)
Total deferred tax liabilities	—	(48,895)
Net deferred taxes	\$ —	\$ —

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 led 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

In November 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, 2015 and 2014, respectively, due to the conversion to equity as discussed below. 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, 2015 and 2014, respectively 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, \$2.2 million were recognized for a beneficial conversion feature related to the Bridge Loans and was recorded as interest expense in the consolidated statement of operations.

In accordance with the Bridge Loans, the Company recognized interest expense of \$326,429 for the year ended December 31, 2014. As the investors in the Bridge Loan exercised their option to convert all of the outstanding principal and interest amounts under the Bridge Loan into shares during the fourth quarter of 2014, no interest expense was recognized for the year ended December 31, 2015. No principal or interest payments were made for the Bridge Loans in 2015.

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.

[Table of Contents](#)

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

	Years ended December 31,	
	2015	2014
Orbimed Private Investments III, LP	\$ —	\$ 63,955
The Global Life Science Ventures Funds	—	57,709
Gilde Europe Food & Agribusiness Fund B.V.	—	54,158
Coöperative AAC LS U.A. (Forbion B.V.)	—	28,288
Total of related-party interest expense relating to the Convertible Bridge Loan	\$ —	\$ 204,110

Unsecured Bank Loan

In May 2003, the Company signed an unsecured loan agreement (the “Bank Loan”) under a silent partnership agreement with Technologie-Beteiligungs-Gesellschaft (“TBG”), a minority interest stockholder. As of April 3, 2014, the Company and TBG, the subsidiary of KfW Bank, Frankfurt (“KfW”), signed a repayment agreement concerning the Company’s repayment of its liabilities to TBG outstanding at December 31, 2013 in a total amount of €1.2 million (\$1.34 million). The principal amount bore interest at a rate of 10.53%. On December 11, 2014, the Company and TBG entered into an accelerated repayment agreement in respect of the claims of TBG against the Company. Pursuant to terms of the accelerated repayment agreement and as stated on the 2014 consolidated balance sheet, conditioned upon closing of the Acquisition, the Company was obligated to pay €1,050,000 (\$1.27 million), the outstanding amount under the repayment agreement, in two tranches as follows: €600,000 (\$726,060) plus accrued interest on January 31, 2015 and €450,000 (\$544,545) on March 31, 2015. The outstanding principal amount for the first and the second tranches net of capital gain tax withheld, was repaid in full in March 2015 and such next payment was €931,312 (\$1,027,051). The capital gain tax withheld in the amount of €118,688 (\$130,889) was paid on April 9, 2015 and no further amounts are payable in respect of TBG loan.

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, 2015 and 2014 there were 39,833,023 and 29,279,522 shares of common stock issued and outstanding, respectively. As a result of the Acquisition, the equity structure of Pieris GmbH was retroactively adjusted using the exchange ratio established pursuant to the Acquisition Agreement to reflect the number of shares of the Company issued in the Acquisition.

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

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

Preferred Stock

The Company has authorized 10,000,000 shares of “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 2015 and 2014. 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.

[Table of Contents](#)

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 \$7.4 million. Additionally, outstanding principal and interest related to the Bridge Loans of \$4.4 million was converted into 5,008,870 shares of common stock.

Acquisition

Immediately following the closing of the Acquisition in December 2014, 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, 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 contained certain anti-dilution provisions. Those anti-dilution provisions provided that if the Company issued and sold 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 would 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. The 180-day period has passed as of December 31, 2015 and no anti-dilution provisions were triggered.

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 11 *Warrants*.

Public Offering

On July 6, 2015 the Company closed a public offering of an aggregate of 9,090,909 shares of the Company's common stock at a purchase price of \$2.75 per share. All shares of common stock were offered by the Company. On July 24, 2015 the underwriters exercised their over-allotment option to purchase 1,211,827 additional shares of the Company's common stock at the public offering price of \$2.75, the sale of which closed on July 28, 2015.

[Table of Contents](#)

Gross proceeds raised by the Company in the offering, including the exercise of the over-allotment option, were \$28.3 million and net of equity issuance costs are \$25.8 million. The Company intends to use the net proceeds from the offering to fund research and development, including preclinical and clinical research and development of its drug candidates, working capital and general corporate purposes.

As result of the Acquisition, the Private Placement, the Public Offering and the Consulting Shares (for more information on the Consulting Shares refer to Note 10 *Consulting Shares*) the Company has 39,833,023 shares of common stock issued and outstanding at December 31, 2015.

9. Stock-Based Compensation

In December 2014, the Company adopted the 2014 Employee, Director and Consultant Equity Incentive Plan, (the “Plan”) which provides for the grant of stock options to certain designated employees of the Company, non-employee directors of the Company and certain other persons performing significant services for the Company as designated by the Compensation Committee of the Board of Directors. At December 31, 2015, the number of common shares reserved for issuance under the 2014 plan was 3,200,000. In addition the Plan provides for an “evergreen” provision whereby the number of shares of the Company’s common stock reserved for issuance under the 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. Vesting periods are determined by our Board of Directors; options primarily vest over a three or four year period. As of December 31, 2015, there were 487,671 shares available for future grant under the Plan.

The Company’s stock options have a maximum term of ten years from the date of grant. Stock options granted under the Plan may be either incentive stock options (“ISOs”), or nonqualified stock options. The exercise price of stock options granted under the Plan must be at least equal to the fair market value of the common stock on the date of grant. The Company’s general policy is to issue common shares upon the exercise of stock options.

Cash received from option exercises was \$10,000 during the year ending December 31, 2015. There were no option exercises in the year ended December 31, 2014.

Pieris granted 755,329 and 2,519,500 stock options during the years ended December 31, 2015 and 2014, respectively. Of these stock options granted in the 2015 period, an option for 450,000 shares was granted to a newly-hired executive officer subject to certain restrictions on exercise that require the Company’s shareholders to approve an increase in the number of shares authorized under the Plan; if such shareholder approval is not obtained by September 30, 2016, the option will be cancelled and of no further force and affect. This option, therefore, does not have impact on the remaining shares available for future grants currently authorized under the Plan and no compensation expense was recorded in 2015.

The Company granted an option to purchase 500,000 shares outside of the Plan to a newly-hired executive officer that was an inducement option, material to the executive officer entering into employment with the Company during the 2015 period. The compensation expense with this inducement option was \$0.1 million and is included in research and development expense for the year ended December 31, 2015.

Table of Contents

A summary of the status of the Company's stock option plans as of December 31, 2015 and changes during the year then ended is as follows:

	Number of Options	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Life	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2014	2,519,500	\$ 2.00	9.96 years	\$ —
Granted	305,329	2.47		
Exercised	(5,000)	2.00		1
Forfeited	(112,500)	2.00		
Outstanding, December 31, 2015	<u>2,707,329</u>	<u>\$ 2.05</u>	9.17 years	<u>\$ 741</u>
Vested or expected to vest	<u>2,707,329</u>	<u>\$ 2.05</u>	9.17 years	<u>\$ 741</u>
Exercisable, December 31, 2015	<u>1,209,601</u>	<u>\$ 2.06</u>	9.17 years	<u>\$ 328</u>

Excluded from the table above is the option to purchase 500,000 shares outside of the Plan granted to a newly-hired executive officer. The weighted-average exercise price of these options amounts to \$3.36 with a remaining contractual life of 9.63 years.

10. Consulting Shares

Del Mar Consulting Group & Alex Partners

On March 6, 2015, the Company entered into an independent consulting agreement (the "Consulting Agreement") with the Del Mar Consulting Group, Inc. and Alex Partners, LLC (the "Consultants"), pursuant to which the Company issued 150,000 restricted shares of its common stock (par value \$0.01 per share) to the Consultants (the "Consulting Shares"). The Company agreed to retain the Consultants to provide investor relations consulting to the Company for a period commencing on March 6, 2015 (the "Commencement Date") and ending thirteen months after the Commencement Date (such period, the "Term"). The shares issued in connection with the Consulting Agreement were deemed to be exempt from registration in reliance upon Section 4(a)(2) of the Securities Act as a transaction by an issuer not involving any public offering.

The terms of the Consulting Agreement state that Pieris has the right to terminate this agreement at any time during the Term of the Consulting Agreement, upon providing Consultants ten days' written notice of the Company's intention to terminate or immediately upon notice in the event of a breach of this agreement by either consultant. If the Company had elected to terminate this agreement for any reason within one hundred eighty days (180) following the effective date each Consultant would have been required to promptly surrender to the Company forty percent (40%) of the number of Consulting Shares issued to it.

The Company uses the Black-Scholes model and estimated the fair value of the 90,000 non-cancellable Consulting Shares to be \$0.3 million based on the closing price per share of \$3.16 as quoted on the OTCQB tier of the OTC Markets Group Inc., or the OTCQB, on the grant date, March 6, 2015. The remaining 60,000 shares were then marked to market based on the Black-Scholes model at each reporting period with the expense being recorded in the consolidated statement of operations as general and administrative expenses.

On September 2, 2015, the remainder of the Consulting Shares vested and the remaining expense was recorded based on the fair value of the shares on that date. The Company recorded expense in an amount of \$0.4 million for the non-cancellable and cancellable Consulting Shares for the year ended December 31, 2015.

Aquilo Partners

On September 4, 2015 the Company entered into a Letter Agreement (the "Letter Agreement") with Aquilo Partners, L.P. ("Aquilo Partners"). Aquilo Partners has been engaged by the Company as an advisor.

[Table of Contents](#)

Upon execution of the Letter Agreement, the Company has recorded a retainer fee of \$0.1 million. In addition to the cash retainer fee, the Company issued 27,272 shares of the Company's common stock equal in value to \$0.1 million based on the closing price of \$2.75 per share of the Company's common stock on September 4, 2015, the date of the Letter Agreement. The compensation for Aquilo Partners has been recorded in the consolidated statements of operations as general and administrative expenses for the year ended December 31, 2015.

Trout Capital LLC

On November 20, 2015 the Company entered into an Agreement with Trout Capital LLC for advisory services. Upon execution of this agreement, Trout Capital was entitled to receive a one-time transaction fee. The Company issued 68,493 shares of the Company's common stock equal in value to \$0.2 million based on the closing price of \$2.19 per share of the Company's common stock on November 20, 2015, the date of the agreement. The compensation for Trout Capital LLC has been recorded in the consolidated statements of operations as general and administrative expenses for the year ended December 31, 2015.

11. 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 \$0.7 million and recognized the full amount in general and administrative expense for the year ended December 31, 2014. There was no expense associated with the Placement Warrants for the year ended December 31, 2015.

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

[Table of Contents](#)

12. Accrued Expenses and Other Liabilities

Accrued expenses consist of the following:

	Years Ended December 31,	
	2015	2014
Accrued expenses and other current liabilities		
Accrued payroll and benefits	\$ 704,597	\$ 416,896
Accrued audit and tax fees	179,223	—
Accrued professional fees	194,790	404,461
Accrued R&D fees	466,076	—
Accrued other	194,694	165,263
Total amount of accrued expenses and other current liabilities	1,739,380	986,620
Accrued expenses and other non-current liabilities		
Reserve for litigation TUM	—	327,937
Accrued other, non-current	23,852	6,051
Total amount of accrued expenses and other non-current liabilities	23,852	333,988
Total amount of accrued expenses and other liabilities	\$1,763,232	\$1,320,608

13. Related-Party Transactions

Research and License Agreement with Technische Universität München

On July 4, 2003, the Company entered into the TUM License Agreement, which was subsequently renewed and, on July 26, 2007, superseded and replaced. The agreement established a joint research effort led by Prof. Arne Skerra, Chair of Biological Chemistry of TUM, to optimize Anticalin® technologies for use in therapeutic, prophylactic and diagnostic applications and as research reagents, and to gain fundamental insights in lipocalin scaffolds. Prof. Dr. Skerra was a member of the Company's supervisory board when the parties entered into such agreement and during the period covered by the consolidated financial statements in this report. The Company provided certain funding for TUM research efforts performed under the agreement.

As a result of research efforts to date under the agreement, the Company holds a worldwide exclusive license under its license agreement with TUM to multiple patents and patent applications, 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 was 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 expenses related to TUM in connection with the transfer of licenses and protective rights of \$41,791 during the nine month period ended September 30, 2015. Effective as of the fourth quarter of 2015, Pieris no longer deems TUM a related party due to Prof. Dr. Skerra no longer having a supervisory board position in Pieris GmbH or other direct relationship with the Company after the Acquisition. The Company has incurred expenses related to TUM as a related party of \$0.1 million for the year ended December 31, 2014.

[Table of Contents](#)

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

EUROCALIN/FP7 Government Grant

TUM is a member of the EUROCALIN consortium and thus is entitled to receive payments under the grant agreement for research activities. Research activities are carried out by Prof. Dr. Skerra, who was a member of the Company's supervisory board when the parties entered into such agreement and during the period covered by the financial statements in this report. As Pieris AG was transformed to Pieris GmbH the change in legal entity removed the requirement of having a supervisory board; accordingly Prof. Dr. Skerra no longer holds a seat on the supervisory board. The government grant agreement with FP7 is further discussed in Note 4—Revenue.

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 GmbH, and since August 1, 2013, has served as a consultant to Pieris GmbH. During 2001 and through October 10, 2014, Prof. Dr. Skerra was the deputy chairman of Pieris GmbH supervisory board. In connection with the consummation of the Acquisition, the Company waived all deferred payment claims against the aforementioned stockholders.

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

In 2001, the Company entered into a Consulting Agreement with Prof. Dr. Skerra, pursuant to which Prof. Dr. Skerra provides advice regarding the use of new proteins, in particular Anticalin[®] proteins and antibodies, for the purpose of research and development. The Consulting Agreement has an unlimited term but can be terminated by the Company upon three months' notice with effect from the end of a month and by Prof. Dr. Skerra upon one year's notice with effect from the end of a year. Under the Consulting Agreement, the Company incurred and paid to Prof. Dr. Skerra consulting fees of \$16,717 during the nine months ended September 30, 2015. As of the fourth quarter of 2015 Pieris no longer deems Prof. Dr. Skerra a related party due to Prof. Dr. Skerra no longer having a supervisory board position in Pieris GmbH or other direct relationship with the Company after the Acquisition. The Company incurred and paid to Prof. Dr. Skerra consulting fees of \$26,593 for the year ended December 31, 2014.

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*.

14. 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 \$32,718 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 13 *Related-Party Transactions*). Under this agreement, the Company is obliged to pay a minimum annual license fee of \$0.1 million to TUM. The agreement expires in 2027.

[Table of Contents](#)

The table below shows the minimum annual license fee commitments under the two agreements as of December 31, 2015:

	License payments
2016	\$ 87,248
2017	87,248
2018	87,248
2019	87,248
2020	87,248
Thereafter	512,582
Total minimum license payments	\$948,822

Leases

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

The Company records rent expense on a straight-line basis over the lease term period. For the year ended December 31, 2015, the Company has recognized rent expense in an amount of \$18,399 under the Sublease Agreement. Rent expense under the Company's operating lease for its Freising, Germany based facility was \$0.4 million and \$0.3 million for the years ended December 31, 2015 and 2014, respectively.

The Company's contractual commitments of the non-cancellable portion under these operating leases as of December 31, 2015 are as follows:

	Total
2016	\$ 318,186
2017	188,009
2018	191,959
2019	195,909
2020	199,859
Thereafter	238,371
Total minimum lease payments	\$1,332,293

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.

Table of Contents

On March 20, 2014, the Company 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 the Company 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 (the “DIS”).

On July 4, 2003, or the Effective Date, the Company 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 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 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, the Company provided to TUM its calculation of the Out-License Fee owed by the Company to TUM for the period beginning on the Effective Date and ending on December 31, 2012, the Dispute Period, in the amount of \$0.3 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. The Company believes 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 the Company in its final decision regarding the proper amount of the Out-License Fee, but the Company can provide no assurance regarding the timing, nature or consequences of such decision. The Company commenced the TUM Arbitration to request that the arbitration tribunal hold that the Company’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. 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 €2.5 million (\$2.8 million) to suspend the statute of limitations on its claim. The Company has reserved a liability on its balance sheet in respect of such payment in the amount of €0.3 million (\$0.3 million). An adverse ruling in the TUM Arbitration could have a material adverse effect on the Company’s results of operations and financial condition.

On November 19, 2015, the Company received notification from the DIS of the arbitration tribunal’s award. In its award, as corrected on January 25, 2016, the tribunal dismissed the Company’s request for declaratory judgment and granted TUM’s counterclaim in an amount of €0.9 million (\$0.9 million) of which, \$0.6 million is recorded as research and development expense in the consolidated statement of operations for the 2015 period due to a previous liability of \$0.3 million recorded for the arbitration settlement as of December 31, 2014. Interest expense of \$0.2 million was also included in the settlement and is recorded in the consolidated statement of operations as interest expense, net. The tribunal dismissed the remainder of TUM’s counterclaim.

The Tribunal also ruled that TUM must reimburse the Company in the amount of €0.1 million (\$0.1 million) for legal fees incurred and dismissed TUM’s claim for reimbursement of its costs. The Company has decided not to challenge the award and paid the amount as calculated by the arbitration panel. The deadline for filing a motion to set aside the award expired on February 15, 2016.

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

As used in this Part II, unless the context indicates or otherwise requires, the terms “we”, “us”, “our”, the “Company” and “Pieris” refer to Pieris Pharmaceuticals, Inc., a Nevada corporation, and its consolidated subsidiary, and the term “Pieris GmbH” refers to Pieris Pharmaceuticals GmbH, a company organized under the laws of Germany that, through a reverse acquisition transaction completed on December 17, 2014, or the Acquisition, has become our wholly owned subsidiary. Pieris effected a forward stock split of its capital stock at a ratio of 2.272727-for-1 on December 5, 2014, and unless the context indicates or otherwise requires, all share numbers and share price data included in this Part II have been adjusted to give effect to that forward stock split.

Item 13. Other Expenses of Issuance and Distribution.

Set forth below is an estimate (except for registration fees, which are actual) of the approximate amount of the types of fees and expenses listed below that were paid or are payable by us in connection with the issuance and distribution of the shares of common stock to be registered by this registration statement. None of the expenses listed below are to be borne by any of the selling stockholders named in the prospectus that forms a part of this registration statement.

<u>Expense</u>	<u>Amount</u>
SEC Registration Fee	\$ 9,049
Accounting Fees and Expenses	37,000
Legal Fees and Expenses	85,000
Transfer Agent Fees and Expenses	100
Miscellaneous Fees and Expenses	1,851
Total	<u>\$133,000</u>

Item 14. Indemnification of Directors and Officers.

Our Amended and Restated Articles of Incorporation and our Amended and Restated Bylaws provide that each person who was or is made a party or is threatened to be made a party to or is otherwise involved (including, without limitation, as a witness) in any action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that he or she is or was one of our directors or officers or is or was serving at our request as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, whether the basis of such action, suit or proceeding is alleged action in an official capacity as a director, officer or trustee or in any other capacity while serving as a director, officer or trustee, shall be indemnified and held harmless by us to the fullest extent authorized by the Nevada Revised Statutes, or NRS, against all expense, liability and loss (including attorneys’ fees and amounts paid in settlement) reasonably incurred or suffered by such.

NRS 78.7502 permits a corporation to indemnify any director or officer of the corporation against expenses (including attorneys’ fees) and amounts paid in settlement actually and reasonably incurred in connection with any action, suit or proceeding brought by reason of the fact that such person is or was a director or officer of the corporation, if such person (i) is not liable pursuant to NRS 78.138 and (ii) acted in good faith and in a manner which he or she reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe the conduct was unlawful. In a derivative action (i.e., one brought by or on behalf of the corporation), indemnification may be provided only for expenses actually and reasonably incurred by any director or officer in connection with the defense or settlement of such an action or the suit if such person (i) is not liable pursuant to NRS 78.138 and (ii) acted in good faith and in a manner which he or she reasonably believed to be in or not opposed to the best interests of the corporation, except that no indemnification shall be provided if such person shall have been adjudged to be liable to the corporation, unless and only to the extent that the court in which the action or suit was brought or some other court of competent jurisdiction determines that such person is fairly and reasonably entitled to indemnity for such expenses as the court deems proper.

Our Amended and Restated Articles of Incorporation provide that the liability of our directors and officers shall be eliminated or limited to the fullest extent permitted by the NRS. NRS 78.138(7) provides that, subject to limited statutory exceptions and unless the articles of incorporation or an amendment thereto (in each case filed on or after October 1, 2003) provide for greater individual liability, a director or officer is not individually liable to a corporation or its stockholders or creditors for any damages as a result of any act or failure to act in his or her capacity as a director or officer unless it is proven that: (i) the act or failure to act constituted a breach of his or her fiduciary duties as a director or officer and (ii) the breach of those duties involved intentional misconduct, fraud or a knowing violation of law.

Table of Contents

We have entered into indemnification agreements with our directors and certain officers, in addition to the indemnification provided in the NRS, our Amended and Restated Articles of Incorporation and our Amended and Restated Bylaws, and intend to enter into indemnification agreements with any new directors and officers in the future. We have purchased and intend to maintain insurance on behalf of any person who is or was a director or officer against any loss arising from any claim asserted against him or her and incurred by him or her in any such capacity, subject to certain exclusions.

The foregoing discussion of our Amended and Restated Articles of Incorporation, Amended and Restated Bylaws, indemnification agreements, indemnity agreement, and Nevada law is not intended to be exhaustive and is qualified in its entirety by such Amended and Restated Articles of Incorporation, Amended and Restated Bylaws, indemnification agreements, indemnity agreement, or law.

Item 15. Recent Sales of Unregistered Securities.

The following summarizes all sales of unregistered securities by us within the past three years:

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 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 Catalyst Securities, LLC served as co-exclusive placement agents, or the Placement Agents, for 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. 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. The issuance and sale of all such shares has not been registered under the Securities Act, and such shares were issued and sold in reliance upon an exemption from registration afforded by Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated under the Securities Act as a transaction by an issuer not involving any public offering.

Upon the closing of the Acquisition, we issued 20,000,000 shares of our common stock to 21 former stockholders of Pieris GmbH in exchange for all of the outstanding shares of Pieris GmbH's capital stock and a waiver by certain stockholders of all subscription and conversion rights with respect to certain stockholder agreements with former stockholders of Pieris GmbH. The issuance and sale of such securities was not registered under the Securities Act, and such securities were issued in reliance upon exemptions from registration afforded by Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder as a transaction by an issuer not involving any public offering.

On June 26, 2013, Pieris issued 5,000,000 shares of its common stock, prior to adjustment for the forward stock split effected on December 5, 2014, to Aleksandrs Sviks, its former sole director and officer, for \$5,000. There were no underwriters, and there were no underwriting discounts or commissions, in respect of the sale or the transactions thereunder. The shares issued to Aleksandrs Sviks were deemed to be exempt from registration under the Securities Act in reliance upon Section 4(a)(2) of the Securities Act (or Regulation D promulgated thereunder) as a transaction by an issuer not involving any public offering.

As more fully described in "Management's Discussion and Analysis of Financial Condition and results of Operations—2014 Series C Financing", in October through December 2014, Pieris GmbH concluded a Series C financing round, or the 2014 Series C Financing, in which Pieris GmbH issued Series C preferred shares for €5,970,149.15 (\$7,224,477.49) in cash and the conversion of €3,000,000 (\$3,630,300) outstanding under an existing convertible loan agreement dated November 12, 2012, or the 2012 Bridge Loan, as amended, and a second convertible loan agreement dated April 14, 2014, or the 2014 Bridge Loan. The convertible loan agreements terminated upon the effectiveness of the 2014 Series C Financing. As part of the 2014 Series C Financing, parties to existing investment agreements and shareholders' agreement relating to prior rounds of financing agreed to become parties to the investment agreement and the consolidated shareholders' agreement for the 2014 Series C Financing and the prior agreements were terminated. The shares issued in connection with the 2014 Series C Financing were deemed to be exempt from registration under the Securities Act in reliance upon Section 4(a)(2) of the Securities Act (or Regulation D promulgated thereunder) as a transaction by an issuer not involving any public offering.

On March 6, 2015, we entered into an independent consulting agreement, pursuant to which we issued 150,000 shares of our common stock, 60,000 of which are subject to certain forfeiture provision within 180 days following the date of entry into the agreement. The shares issued in connection with consulting agreement were deemed to be exempt from registration under the Securities Act in reliance upon Section 4(a)(2) of the Securities Act as a transaction by an issuer not involving any public offering.

Table of Contents

On August 17, 2015, the Company issued an option grant to Louis A. Matis, M.D., its Chief Development Officer, as a new hire inducement grant pursuant to NASDAQ Listing Rule 5635(c)(4) and Section 4(a)(2) of the Securities Act. Dr. Matis's option grant is for the purchase of an aggregate of 500,000 shares of Common Stock at a price per share of \$3.36 subject to his continued employment with the Company.

On September 4, 2015, we entered into a letter agreement, pursuant to which we issued 27,272 shares of our common stock to a consulting company, in exchange for certain advisory services. The shares were valued based on the closing price per share of \$2.75 of the Company's common stock on the grant date, September 4, 2015. The shares issued in connection with the letter agreement were deemed to be exempt from registration in reliance upon Section 4(a)(2) of the Securities Act as a transaction by an issuer not involving any public offering.

On November 20, 2015, we entered into a letter agreement, pursuant to which we issued 68,493 shares of our common stock to an advisor, in exchange for certain consulting and other services. The shares issued in connection with consulting agreement were deemed to be exempt from registration in reliance upon Section 4(a)(2) of the Securities Act as a transaction by an issuer not involving any public offering.

Item 16. Exhibits and Financial Statements Schedules.

(a) Exhibits.

See the Exhibit Index immediately following the signature page hereto, which is incorporated into this Item 16 by reference.

(b) Financial Statements Schedules.

No financial statement schedules are provided because the information called for is not applicable or not required or is shown in the financial statements or the notes thereto.

Item 17. Undertakings.

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of the securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered that remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A (§ 230.430A of Title 17 of the Code of Federal Regulations), shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. *Provided, however*, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

Table of Contents

(5) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities:

The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424 (§230.424 of Title 17 of the Code of Federal Regulations);

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

SIGNATURES

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

PIERIS PHARMACEUTICALS, INC.

Date: April 14, 2016

By: /s/ Stephen S. Yoder
Stephen S. Yoder
Chief Executive Officer and President

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Stephen S. Yoder</u> Stephen S. Yoder	President, Chief Executive Officer and Director (Principal Executive Officer)	April 14, 2016
<u>/s/ Darlene Deptula-Hicks</u> Darlene Deptula-Hicks	Acting Chief Financial Officer, Secretary and Treasurer (Principal Financial and Accounting Officer)	April 14, 2016
<u>*</u> Chau Khuong	Chairman of the Board of Directors	April 14, 2016
<u>/s/ Jean-Pierre Bizzari</u> Jean-Pierre Bizzari	Director	April 14, 2016
<u>*</u> Michael Richman	Director	April 14, 2016
<u>*</u> Steven Prelack	Director	April 14, 2016

* Pursuant to power of attorney

By: /s/ Darlene Deptula-Hicks
Darlene Deptula-Hicks

[Table of Contents](#)

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Incorporated by Reference herein from Form or Schedule</u>	<u>Filing Date</u>	<u>SEC File / Registration Number</u>
2.1	Acquisition Agreement, dated as of December 17, 2014, by and among the Registrant, Pieris AG and the former stockholders of Pieris AG named therein	Form 8-K (Exhibit 2.1)	December 18, 2014	333-190728
3.1	Amended and Restated Articles of Incorporation of the Registrant	Form 8-K (Exhibit 3.1)	December 18, 2014	333-190728
3.2	Amended and Restated Bylaws of the Registrant	Form 8-K (Exhibit 3.2)	December 18, 2014	333-190728
4.1	Form of Common Stock certificate	Form 8-K (Exhibit 4.1)	December 18, 2014	333-190728
4.2	Form of Common Stock certificate	Form 10-K (Exhibit 4.2)	March 23, 2016	333-190728
5.1	Opinion of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.	*		
10.1	2014 Employee, Director and Consultant Equity Incentive Plan	# Form 8-K (Exhibit 10.1)	December 18, 2014	333-190728
10.2	Form of Stock Option Award Agreement under the Registrant's 2014 Employee, Director and Consultant Equity Incentive Plan	# Form 8-K (Exhibit 10.2)	December 18, 2014	333-190728
10.3	Collaboration Agreement by and between Pieris AG and Allergan Sales, LLC, dated as of August 21, 2009	± Form 8-K (Exhibit 10.3)	December 18, 2014	333-190728
10.4	Collaboration and License Agreement by and among Pieris AG, Sanofi-Aventis and Sanofi-Pasteur SA, dated as of September 24, 2010	± Form 10-K (Exhibit 10.4)	March 30, 2014	333-190728
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	± Form 8-K (Exhibit 10.5)	December 18, 2014	333-190728
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	± Form S-1 (Exhibit 10.6)	February 2, 2015	333-202123
10.7	Collaboration Research and Technology Licensing Agreement by and between Pieris AG and Daiichi Sankyo Company Limited, dated as of May 31, 2011	± Form 10-K (Exhibit 10.7)	March 30, 2014	333-190728
10.8	Development and License Agreement by and between Pieris AG and Cadila Healthcare Limited, dated as of October 7, 2013	± Form 10-K (Exhibit 10.8)	March 30, 2014	333-190728

Table of Contents

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Incorporated by Reference herein from Form or Schedule</u>	<u>Filing Date</u>	<u>SEC File / Registration Number</u>
10.9	Joint Development and License Agreement by and between Pieris AG and Stelis BioPharma Private Limited, dated as of November 21, 2013	± Form 10-K (Exhibit 10.9)	March 30, 2014	333-190728
10.10	Research and Licensing Agreement by and between Pieris AG and Technische Universität München, dated as of July 26, 2007	± Form 10-K (Exhibit 10.10)	March 30, 2014	333-190728
10.11	Research Collaboration and License Agreement by and among the Registrant, Pieris GmbH, Hoffmann-La Roche Inc. and F. Hoffmann-La Roche Ltd., dated as of December 8, 2015	± Form 10-K (Exhibit 10.11)	March 23, 2016	333-190728
10.12	Form of Indemnification Agreement by and between the Registrant and each of its current directors and executive officers	# Form 8-K (Exhibit 10.10)	December 18, 2014	333-190728
10.13	Management Agreement by and between Pieris AG and Stephen S. Yoder, dated as of August 30, 2009	# Form 8-K (Exhibit 10.11)	December 18, 2014	333-190728
10.14	Amendment to Management Agreement by and between Pieris AG and Stephen S. Yoder, dated as of March 12, 2012	# Form 8-K (Exhibit 10.12)	December 18, 2014	333-190728
10.15	Amended and Restated Management Agreement by and between Pieris AG and Stephen S. Yoder, dated as of December 17, 2014	# Form 8-K (Exhibit 10.13)	December 18, 2014	333-190728
10.16	Acknowledgement and Waiver Agreement by and between Pieris AG and Stephen S. Yoder, dated as of December 12, 2014	# Form 8-K (Exhibit 10.14)	December 18, 2014	333-190728
10.17	Employment Agreement by and between the Registrant and Stephen S. Yoder, dated as of December 17, 2014	# Form 8-K (Exhibit 10.15)	December 18, 2014	333-190728
10.18	Management Agreement by and between Pieris AG and Claus Schalper, dated as of February 6, 2008	# Form 8-K (Exhibit 10.16)	December 18, 2014	333-190728
10.19	Consulting Agreement by and between Pieris AG and Claus Schalper, dated as of July 9, 2013	# Form 8-K (Exhibit 10.17)	December 18, 2014	333-190728
10.20	Employment Agreement by and between Pieris AG and Dr. Ulrich Moebius, dated as of June 26, 2013	# Form 8-K (Exhibit 10.18)	December 18, 2014	333-190728
10.21	Amendment to Employment Agreement by and between Pieris AG and Dr. Ulrich Moebius, dated as of January 28, 2014	# Form 8-K (Exhibit 10.19)	December 18, 2014	333-190728
10.22	Amendment to Employment Agreement by and between Pieris AG and Dr. Ulrich Moebius, dated as of October 21, 2014	# Form 8-K (Exhibit 10.20)	December 18, 2014	333-190728
10.23	Management Agreement by and between Pieris AG and Dr. Laurent Audoly, dated as of May 18, 2010	# Form 8-K (Exhibit 10.20)	December 18, 2014	333-190728
10.24	Consulting Agreement by and between Pieris AG and Danforth Advisors, LLC, effective as of November 19, 2014	# Form 8-K (Exhibit 10.22)	December 18, 2014	333-190728

Table of Contents

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Incorporated by Reference herein from Form or Schedule</u>	<u>Filing Date</u>	<u>SEC File / Registration Number</u>
10.25	Employment Agreement by and between the Registrant and Darlene Deptula-Hicks, dated as of August 27, 2015	# Form 10-Q (Exhibit 10.2)	November 11, 2015	001-37471
10.26	Employment Agreement by and between the Registrant and Louis A. Matis, M.D., dated as of July 20, 2015	# Form 10-Q (Exhibit 10.1)	November 11, 2015	001-37471
10.27	Lease Agreement by and between Pieris AG and Födergesellschaft IZB mbH, dated as of May 4, 2011	Form 8-K (Exhibit 10.23)	December 18, 2014	333-190728
10.28	Agreement of Sublease by and between Berenberg Capital Markets LLC and the Registrant, dated as of August 27, 2015	Form 10-Q (Exhibit 10.3)	November 11, 2015	001-37471
10.29	Convertible Bridge Loan Agreement by and among Pieris AG and the Stockholder parties listed therein, dated as of November 12, 2012	Form 8-K (Exhibit 10.24)	December 18, 2014	333-190728
10.30	Amendment to Convertible Bridge Loan Agreement by and among Pieris AG and the Stockholders listed therein, dated as of March 4, 2014	Form 8-K (Exhibit 10.25)	December 18, 2014	333-190728
10.31	Participation Agreement (silent partnership agreement) between Pieris AG and tbG Technologie-Beteiligungs-Gesellschaft mbH, dated May 13, 2003	Form 8-K (Exhibit 10.26)	December 18, 2014	333-190728
10.32	Repayment Agreement by and between Pieris AG and tbG Technologie-Beteiligungs-Gesellschaft mbH, dated as of April 3, 2014	Form 8-K (Exhibit 10.27)	December 18, 2014	333-190728
10.33	Settlement Agreement (Accelerated Repayment Agreement) by and between Pieris AG and tbG Technologie-Beteiligungs-Gesellschaft mbH, dated as of December 11, 2014	Form 8-K (Exhibit 10.28)	December 18, 2014	333-190728
10.34	Convertible Bridge Loan Agreement by and among Pieris AG and the Stockholders listed on Exhibit A thereto, dated as of April 14, 2014	Form 8-K (Exhibit 10.29)	December 18, 2014	333-190728
10.35	Consolidated Shareholders' Agreement 2014, Pieris AG, Freising, Germany, by and among Pieris AG and the Stockholders party thereto, dated October 10, 2014	Form 8-K (Exhibit 10.30)	December 18, 2014	333-190728
10.36	Investment Agreement, Pieris AG, Freising, Germany, by and among Pieris AG, Stephen Yoder and the Existing Shareholders party thereto, dated October 10, 2014	Form 8-K (Exhibit 10.31)	December 18, 2014	333-190728
10.37	Agreement, by and among Pieris AG and the Stockholders party thereto, dated December 5, 2014	Form 8-K (Exhibit 10.32)	December 18, 2014	333-190728
10.38	Split-Off Agreement, by and among the Registrant, Marika Enterprises Inc. and Aleksandrs Sviks, dated December 17, 2014	Form 8-K (Exhibit 10.33)	December 18, 2014	333-190728
10.39	General Release Agreement, by and among the Registrant, Marika Enterprises Inc. and Aleksandrs Sviks, dated December 17, 2014	Form 8-K (Exhibit 10.34)	December 18, 2014	333-190728

Table of Contents

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Incorporated by Reference herein from Form or Schedule</u>	<u>Filing Date</u>	<u>SEC File / Registration Number</u>
10.40	Form of Securities Purchase Agreement, dated December 17, 2014, by and among Pieris Pharmaceuticals, Inc. and the Purchasers	Form 8-K (Exhibit 10.1)	December 23, 2014	333-190728
10.41	Form of Registration Rights Agreement, dated December 17, 2014, by and among Pieris Pharmaceuticals, Inc. and the investors party thereto	Form 8-K (Exhibit 10.2)	December 23, 2014	333-190728
10.42	Form of Warrant to Purchase Common Stock, dated December 17, 2014, issued by Pieris Pharmaceuticals, Inc.	Form 8-K (Exhibit 10.3)	December 23, 2014	333-190728
14.1	Corporate Code of Ethics and Conduct and Whistleblower Policy	Form 10-K (Exhibit 14.1)	March 30, 2014	333-190728
21.1	List of Subsidiaries	Form 10-K (Exhibit 21.1)	March 23, 2016	333-190728
23.1	Consent of Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft	*		
23.2	Consent of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. (contained in Exhibit 5.1)	*		
24.1	Power of Attorney (contained on signature page hereto).	*		
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.

** Previously filed with the Company's Registration Statement on Form S-1 (File No. 333-202123) filed with the SEC on February 17, 2015.

Management contract or compensatory plan or arrangement

± Confidential treatment requested



One Financial Center
Boston, MA 02111
617-542-6000
617-542-2241 fax
www.mintz.com

April 14, 2016

Pieris Pharmaceuticals, Inc.
255 State Street, 9th Floor
Boston, MA 02109

Ladies and Gentlemen:

We have acted as counsel to Pieris Pharmaceuticals, Inc. (the “Company”) in connection with the filing by the Company of a Registration Statement on Form S-1 (as amended, the “Registration Statement”) with the Securities and Exchange Commission (the “Commission”) relating to the registration under the Securities Act of 1933, as amended (the “Securities Act”), the offering from time to time by the selling stockholders, as described in the Registration Statement, of up to 17,982,105 shares of the Company’s common stock, par value \$0.001 per share (the “Common Shares”), consisting of (a) 4,967,202 Common Shares issued and sold to accredited investors (the “PP Shares”) in a private placement offering in a series of closings on December 17, 2014, December 18, 2014 and December 23, 2014 (the “Private Placement”), (b) 12,472,543 Common Shares issued to former stockholders of Pieris GmbH, a wholly-owned subsidiary of the Company, in connection with the closing of a share exchange transaction on December 17, 2014 (the “Acquisition Shares” and together with the PP Shares, the “Transaction Shares”) and (c) 542,360 Common Shares (the “Warrant Shares”) issuable upon exercise of warrants issued to the co-exclusive placement agents, and their designees in connection with the Private Placement (the “Warrants”).

As the counsel to the Company in connection with the Registration Statement, we have examined the actions taken by the Company in connection with the authorization of the issuance of the Common Shares, and such documents as we have deemed necessary to render this opinion. In our examination, we have assumed the genuineness of all signatures, the legal capacity of natural persons, the authenticity of all documents submitted to us as originals, the conformity to original documents of all documents submitted to us as certified or photostatic copies and the authenticity of the originals of such copies. As to questions of fact material to this opinion, we have relied upon certificates or comparable documents of public officials and of officers and representatives of the Company.

Our opinion is limited to the general corporate laws of the State of Nevada and we express no opinion with respect to the laws of any other jurisdiction. No opinion is expressed herein with respect to the qualification of the Common Shares under the securities or blue sky laws of any state or any foreign jurisdiction.

Based upon and subject to the foregoing, it is our opinion that the Transaction Shares are validly issued, fully paid and non-assessable and that the Warrant Shares have been duly authorized and, when issued and delivered by the Company upon exercise of the Warrants in accordance with the Warrants and the Registration Statement, including the payment of the exercise price therefor, the Warrant Shares will be validly issued, fully paid and non-assessable.

Please note that we are opining only as to the matters expressly set forth herein, and no opinion should be inferred as to any other matters. This opinion is based upon currently existing statutes, rules, regulations and judicial decisions, and we disclaim any obligation to advise you of any change in any of these sources of law or subsequent legal or factual developments which might affect any matters or opinions set forth herein.

April 14, 2016

Page 2

We understand that you wish to file this opinion with the Commission as an exhibit to the Registration Statement in accordance with the requirements of Item 601(b)(5) of Regulation S-K promulgated under the Securities Act and to reference the firm's name under the caption "Legal Matters" in the prospectus which forms part of the Registration Statement, and we hereby consent thereto. In giving this consent, we do not admit that we are within the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations of the Commission promulgated thereunder.

Very truly yours,

/s/ Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.
Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.

Consent of Independent Registered Public Accounting Firm

We consent to the reference to our firm under the caption “Experts” and to the use of our report dated March 23, 2016 in Post-Effective Amendment No. 1 to the Registration Statement (Form S-1 No. 3330202123) and related Prospectus of Pieris Pharmaceuticals, Inc. for the registration of 17,982,105 shares of its common stock.

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

/s/ Christ
Wirtschaftsprüfer
[German Public Auditor]

Ernst & Young GmbH
Wirtschaftsprüfungsgesellschaft

Munich, Germany
April 14, 2016