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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2014

OR

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

For the transition period from _____ to _____

Commission file number: 333-190728

PIERIS PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Nevada	**EIN 30-0784346**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
Lise-Meitner-Strasse 30, Freising-Weihenstephan, Germany	**85354**
(Address of principal executive offices)	**(Zip Code)**

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

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

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

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

None
(Title of class)

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

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

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

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

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

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

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

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

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

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

DOCUMENTS INCORPORATED BY REFERENCE

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

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Forward Looking Statements

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

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

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

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

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

Currency Presentation and Currency Translation

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

The functional currency for our operations is the euro. With respect to our financial statements, the translation from the euro to U.S. Dollars is performed for balance sheet accounts using exchange rates in effect at the

balance sheet date and for revenue and expense accounts using a weighted average exchange rate during the period. The resulting translation adjustments are recorded as a component of other comprehensive income.

Where in this Report we refer to amounts in euros, we have for your convenience also in certain cases provided a conversion of those amounts to U.S. Dollars in parentheses. Where the numbers refer to a specific balance sheet account date or financial statement account period, we have used the exchange rate that was used to perform the conversions in connection with the applicable financial statement. In all other instances, unless otherwise indicated, the conversions have been made using the noon buying rate of €1.00 to U.S. $1.2101 in The City of New York for cable transfers of euro as certified for customs purposes by the Federal Reserve Bank of New York as of December 31, 2014.

PART I

Item 1. BUSINESS

Corporate History

General

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

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

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

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

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

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

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

In connection with the Private Placement, we also entered into a registration rights agreement, or the Registration Rights Agreement, with the Investors, the former stockholders of Pieris Operating and the holders of Placement Warrants. Pursuant to the terms of the Registration Rights Agreement, the Company agreed to file with the SEC, within 90 days following December 17, 2014, a registration statement to register for resale all of the 6,779,510 shares of the Company's common stock issued in the Private Placement, as well as an additional 20,000,000 shares of our common stock which the Company issued to former stockholders of Pieris Operating in connection with the closing of the Acquisition, and an additional 542,360 shares of common stock issuable to holders of the Placement Warrants. The Company also agreed to use commercially reasonable efforts to have such registration statement declared effective within 180 days following the date of its filing with the SEC. If the registration statement is not declared effective on or before the applicable effectiveness deadline or ceases to be effective during the required effectiveness period, except as permitted under the Registration Rights Agreement, the Company will be obligated pay to each selling stockholder an amount in cash equal to 1.0% of the value of such selling stockholder's shares of outstanding common stock on every monthly anniversary of such failure and prorated for any portion of a month, until it is cured or all of such selling stockholder's securities to be registered hereunder have been or may be sold without restriction pursuant to Rule 144. Furthermore, if the Company fails to timely file reports required to be filed by us pursuant to Section 13(a) or 15(d) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Company will be obligated pay to each selling stockholder an amount in cash equal to 1.0% of the value of such selling stockholder's shares of outstanding common stock. Notwithstanding the foregoing, the Company will not be obligated to make any such payments with respect to any of the securities to be registered thereunder that we are unable to register due to limits imposed by the SEC's interpretation of Rule 415 promulgated under the Securities Act of 1933, as amended, or the Securities Act. Under the Registration Rights Agreement, subject to exception in certain circumstances or pursuant to the Acquisition, as applicable, we have agreed to keep such registration statement effective until the later of December 17, 2016 and such time as all of the securities to be registered thereunder have been sold under the registration statement or pursuant to Rule 144 or may be sold without restriction pursuant to Rule 144. If there is not an effective registration statement covering the resale of the securities to be registered by such registration statement at any time prior to December 17, 2015, then the selling stockholders will have "piggyback" registration rights with respect to any such securities that are not eligible for resale pursuant to Rule 144 without volume or manner of sale restrictions in connection with any other registration statement we determine to file that would permit the inclusion of those shares.

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

Emerging Growth Company and Smaller Reporting Company Status

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

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

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

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

Business Overview

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

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

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

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

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

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

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

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

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

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

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

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

Strategy

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

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

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

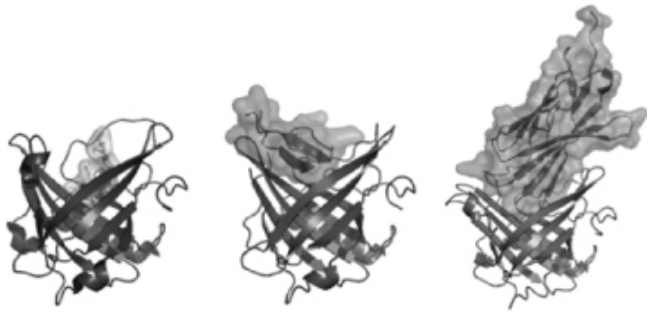
- ***Pursue and broaden opportunities for our Anticalin technology.*** We intend to continue to identify, vet and pursue opportunities to develop novel Anticalin therapeutics for oncology, pulmonary disease and a variety of additional diseases, as we continue to improve on the Anticalin platform technology.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

Anticalin platform technology

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

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

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



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

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

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

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

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

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

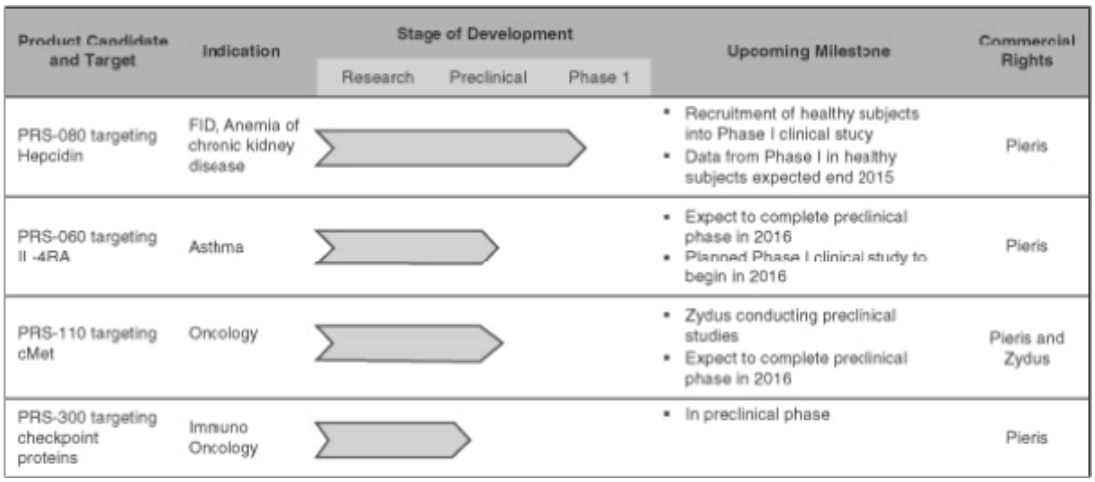
- *Optimization of half-life*. Anticalin proteins can be engineered to have a half-life that is optimal for the indication area and a desired dosing schedule. Antibodies typically have half-lives of two weeks or longer, whereas Anticalin proteins can be engineered to have half-lives from hours to weeks,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

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

Implementation of our Anticalin Platform Technology: Our Drug Candidates

Pipeline

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



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

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

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

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

Chronic kidney disease

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

Anemia and functional iron deficiency in the CKD population

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

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

Challenges in using conventional therapy

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

Our potential solution: binding hepcidin with PRS-080

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

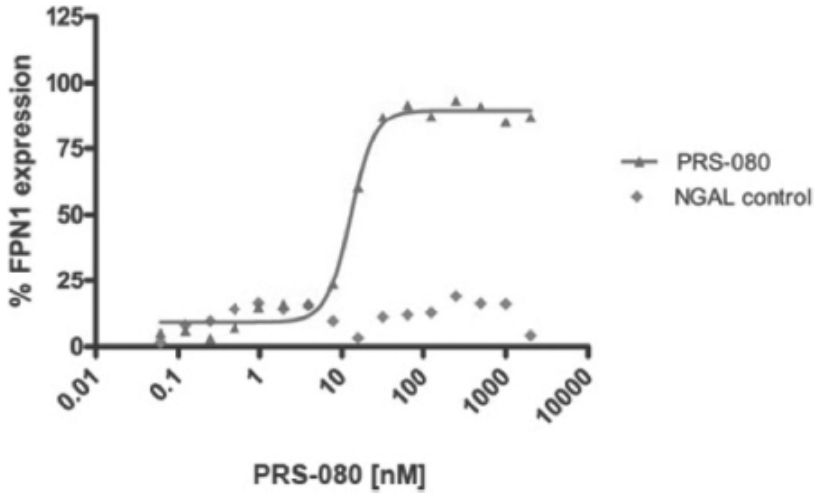
In patients suffering from anemia of CKD, and specifically in patients with FID, hepcidin is frequently produced by the body in abnormally large amounts. Therefore, we believe that the best way to inhibit its function is to administer an inhibitor frequently, such as once a week. Our approach will use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

Preclinical data

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

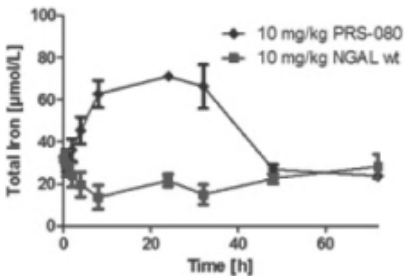
Hepcidin binds to ferroportin and induces its internalization and subsequent degradation, thus disabling iron mobilization from cells. PRS-080 binds strongly to hepcidin and inhibits its activity as shown in potency assays. These in vitro potency studies showed that the hepcidin-induced internalization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

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

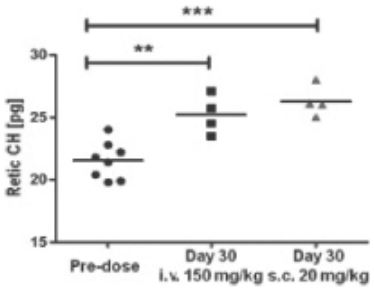


We then studied the functional consequences of hepcidin inhibition on iron mobilization in cynomolgus monkeys. A dose of 1 mg/kg PRS-080 produced a robust, transient and reversible increase in total iron levels from approximately 36 µM at baseline to 52 µM after 8 hours. Doses higher than 1 mg/kg elevated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

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



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



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

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

Phase I trial design

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

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

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

PRS-060 targeting IL-4RA in asthma

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

Asthma market

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

Challenges in using conventional therapy

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

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

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

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

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

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

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

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

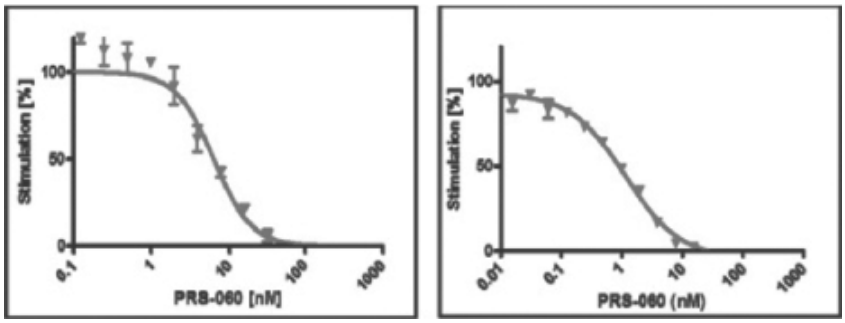
Advantages to inhalation as a route of administration for PRS-060

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

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

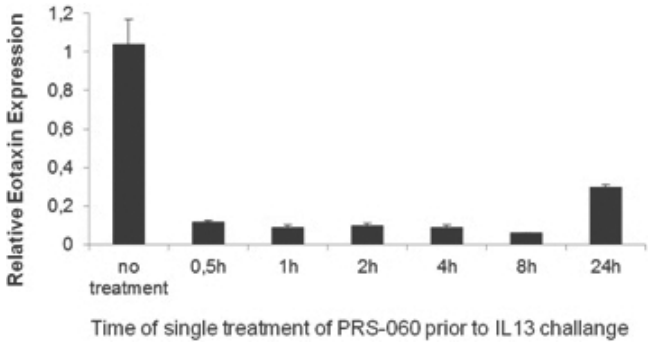
Preclinical data

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



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

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



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

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

Pipeline products: PRS-110 in cMet-related cancer

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

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

Pipeline products: 300 Series

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

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

Competition

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

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

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

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

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

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

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

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

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

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

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

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

PRS-080

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

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

PRS-060

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

PRS-110

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

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

PRS-300 series

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

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

Manufacturing

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

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

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

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

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

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

Intellectual Property and Exclusivity

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

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

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

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

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

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

In applicable jurisdictions, we will seek patent term extensions for certain of our patents including the patent term adjustment period in the U.S. If we obtain marketing approval for our drug candidates in the United States or in certain jurisdictions outside of the United States, we may be eligible for regulatory protection, such as twelve years of data exclusivity for new biological entities in the United States and as mentioned below, up to five years of patent term extension potentially available in the United States under the Hatch-Waxman Act, 8 to 11 years of data and marketing exclusivity potentially available for new drugs in the European Union, up to five years of patent extension in Europe (Supplemental Protection Certificate), and eight years of data exclusivity potentially available in Japan. There can be no assurance that we will qualify for any such regulatory exclusivity, or that any such exclusivity will prevent competitors from seeking approval solely on the basis of their own studies. See "—Government Regulation."

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

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

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

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

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

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

Strategic Partnerships

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

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

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

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

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

Our agreement with Allergan

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

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

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

Our collaboration with Sanofi

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

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

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

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

Our collaboration with Daiichi Sankyo

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

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

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

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

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

Our collaboration with Zydus

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

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

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

Our collaboration with Stelis

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

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

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

TUM License Agreement

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

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

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

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

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

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

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

Government Regulation

Government Regulation and Product Approval

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

U.S. Drug Development Process

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

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

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

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

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

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

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

The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Phase I, Phase II, and Phase III testing may not be completed successfully within any specified period, if at all.

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

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

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

U.S. Review and Approval Processes

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

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

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

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

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

Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of our drugs, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND, and the submission date of an NDA or BLA, plus the time between the submission date of an NDA or BLA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension, and the extension must be applied for prior to expiration of the patent. The United States Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

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

Biologics Price Competition and Innovation Act of 2009

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

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

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

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

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

Orphan Drug Designation

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

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

Fast Track Designation and Accelerated Approval

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

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

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

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

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

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

Post-Approval Requirements

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

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

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

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

Foreign Regulation

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

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

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

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

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

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

Reimbursement

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

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

Employees

As of March 27, 2015, we had 28 full-time employees and seven part-time employees, including 10 employees with Ph.D. degrees. Of these 35 employees, 29 are engaged in research and development activities and six work in general support and administration. None of our employees is represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good. To successfully develop our drug candidates, we must be able to attract and retain highly skilled personnel. We anticipate hiring additional employees for research and development, clinical and regulatory affairs and general and administrative activities over the next few years. We also utilize the services of consultants, clinical research organizations and other third parties on a regular basis.

Available Information

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

Item 1A. RISK FACTORS

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

Risks Related to Our Business, Financial Position and Capital Requirements

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to the Discovery and Development of Our Drug Candidates

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Dependence on Third Parties

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to the Commercialization of Our Drug Candidates

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Managing Any Growth We May Experience

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

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

In addition, our ability to manage our growth effectively will hinge upon our ability to expand, train, manage and motivate our employees. As of March 27, 2015, we had 28 full-time employees and seven part-time employees. As our development and commercialization plans and strategies develop, these demands may also require the hiring of additional research, development, managerial, operational, sales, marketing, financial, accounting, legal and other personnel.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

offset in any relevant later assessment period (calendar year) €1,000,000 ($1,210,100) plus 60% of the exceeding taxable income and trade profit of such period. Also, certain transactions, including transfers of shares or interest in the loss holding entity, may result in the partial or total forfeiture of tax losses existing at that date. Partial or total forfeiture of tax losses may further occur in corporate reorganizations of the loss holding entity.

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

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

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

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

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

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

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

While we currently have no specific plans to acquire any other businesses, we may, in the future, make acquisitions of, or investments in, companies that we believe have products or capabilities that are a strategic or commercial fit with our current business or otherwise offer opportunities for our company. In connection with these acquisitions or investments, we may:

- issue common stock or other forms of equity that would dilute our existing stockholders’ percentage of ownership;

- incur debt and assume liabilities; and
- incur amortization expenses related to intangible assets or incur large and immediate write-offs.

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

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

Risks Related to Our Intellectual Property

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to our Employees

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

Our ability to compete in the highly competitive biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified personnel. We are highly dependent on our management, scientific and medical personnel, especially Stephen S. Yoder, our Chief Executive Officer and President, whose services are critical to the successful implementation of our drug candidate development, our business development and partnerships, and our regulatory and commercialization strategies. Further, as our approach is built in part upon the drug discovery and development experience of our drug development team, which we believe is a significant contributor to our competitive advantage, we are dependent on the maintenance and growth of that team with qualified members containing high levels of expertise in specific scientific fields. As of March 27, 2015, we had 35 employees, and we may in the future hire additional employees for research and development or general and administrative activities.

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

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

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

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

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

In contrast, in Germany, there is no analogous doctrine of “employment at will”. By law, German employees must have written employment contracts that reflect the key aspects of the employment relationship. With respect to Pieris Operating, relations between German employers and employees are extensively regulated under German labor and employment laws and regulations. German employees enjoy, in particular, special protection against dismissals provided the employee has been employed by a company for more than six months and such company employs more than 10 employees.

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

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

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

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

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

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

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

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

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

Risks Related to the Ownership of our Common Stock

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that will need to be evaluated frequently. Our failure to maintain the effectiveness of our internal controls in accordance with the requirements of the Sarbanes-Oxley Act could have a material adverse effect on the tradability of our common stock, which in turn would negatively impact our business. We could lose investor confidence in the accuracy and completeness of our financial reports, which could have an adverse effect on the price of our common stock. In addition, if our efforts to comply with new or changed laws, regulations, and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

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

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

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

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

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

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

Prior to the closing of the Acquisition, we were deemed a "shell company" under applicable SEC rules and regulations because we had no or nominal operations and either no or nominal assets, assets consisting solely of cash and cash equivalents, or assets consisting of any amount of cash and cash equivalents and nominal other assets. Pursuant to Rule 144 promulgated under the Securities Act of 1933, as amended, or the Securities Act, sales of the securities of a former shell company, such as us, under that rule are not permitted (i) until at least 12 months have elapsed from December 18, 2014, the date on which our Current Report on Form 8-K reflecting our status as a non-shell company, was filed with the SEC and (ii) unless at the time of a proposed sale, we are subject to the reporting requirements of Section 13 or 15(d) of the Exchange Act and have filed all reports and other materials required to be filed by Section 13 or 15(d) of the Exchange Act, as applicable, during the preceding 12 months, other than Form 8-K reports. We are currently a "voluntary filer" and upon our becoming subject to the reporting rules under the Exchange Act, we will be subject to the reporting requirements under the Exchange Act. Therefore, unless we register our shares of common stock for sale under the Securities Act, most of our stockholders will be forced to hold their shares of our common stock for at least that 12-month period before they are eligible to sell those shares, and even after that 12-month period, sales may not be made under Rule 144 unless we and any such selling stockholders are in compliance with other requirements of Rule 144. Further, it will be more difficult for us to raise funding to support our operations through the sale of debt or equity securities unless we agree to register such securities under the Securities Act, which could cause us to expend significant time and cash resources. Additionally, our previous status as a shell company could also limit our use of our securities to pay for any acquisitions we may seek to pursue in the future (although none are currently planned). The lack of liquidity of our securities as a result of the inability to sell under Rule 144 for a longer period of time than a non-former shell company could cause the market price of our securities to decline.

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

Our Amended and Restated Articles of Incorporation authorizes the issuance of up to 300,000,000 shares of our common stock and up to 10,000,000 shares of preferred stock with the terms, limitations, voting rights, relative rights and preferences and variations of each series that our Board of Directors may determine from time to time. Upon the closings of the Private Placement on December 17, 18 and 23, 2014, we issued an aggregate of 6,779,510 shares of our common stock and in connection with the Private Placement, we issued 542,360 shares of common stock issuable upon exercise of common stock purchase warrants issued to the Placement Agents and their designees, which equals approximately 25% of our currently issued and outstanding capital stock. Possible business and financial uses for our authorized capital stock include, without limitation, equity financing, future stock splits, acquiring other companies, businesses or products in exchange for shares of our capital stock, issuing shares of our capital stock to partners or other collaborators in connection with strategic alliances, attracting and retaining employees by the issuance of additional securities under our equity compensation plan, or other transactions and corporate purposes that our Board of Directors deems are in the interests of our company. Additionally, issuances of shares of our capital stock could have the effect of delaying or preventing changes in control or our management. Any future issuances of shares of our capital stock may not be made on favorable terms or at all, they may have rights, preferences and privileges that are superior to those of our common stock, and may have an adverse effect on our business or the trading price of our common stock. The issuance of any additional shares of our common stock will reduce the book value per share and may contribute to a reduction in the market price of the outstanding shares of our common stock. Additionally, any such issuance will reduce the proportionate ownership and voting power of all of our current stockholders. Furthermore, the Securities Purchase Agreement contains certain anti-dilution provisions. Those anti-dilution provisions provide that, subject in certain exceptions, if we issue and sell equity securities or equity-linked or related securities at a purchase price per share of lower than $2.00 within the 180-day period following December 17, 2014, each Investor in the Private Placement shall be entitled to receive such number of additional shares of our common stock as they would have received had such lower purchase price per share been applicable in the Private Placement, which could result in additional dilution and cause the market price of our securities to decline.

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

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

In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our equity incentive plan will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, Rule 701 under the Securities Act, and any future registration of such shares under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

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

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

Pursuant to the 2014 Employee, Director and Consultant Equity Incentive Plan, or the Pieris Plan, we are authorized to grant equity awards to our employees, directors and consultants for up to an aggregate of 3,200,000 shares of our common stock and, as of March 27, 2015, we have granted options to purchase 2,519,500 shares of our common stock. The Pieris Plan also includes an “evergreen” provision which provides that the number of shares of our common stock reserved for issuance under the Pieris Plan shall be automatically increased on January 1 of each of year commencing in fiscal 2016 by the lesser of (i) 1,000,000 shares, (ii) 4% of the number shares of our common stock outstanding on such date, and (iii) such other amount determined by the Board of Directors. Any future grants of options, warrants or other securities exercisable or convertible into our common stock, or the exercise or conversion of such shares, and any sales of such shares in the market, could have an adverse effect on the market price of our common stock.

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

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

These provisions provide, among other things:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Item 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

Item 2. PROPERTIES

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

Item 3. LEGAL PROCEEDINGS

Arbitration Proceeding with Technische Universität München

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

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

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

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

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

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

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

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

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Market Information

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

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

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

Source:
OTCMarkets

Stockholders

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

Dividends

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

Unregistered Sales of Securities

None.

Issuer Purchases of Equity Securities

None.

Item 6. SELECTED FINANCIAL DATA

Not applicable.

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

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

Overview

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

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

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

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

indicative of a trend. We expect to continue incurring substantial losses for the next several years as we continue to develop our clinical and preclinical drug candidates and programs. Our operating expenses are comprised of research and development expenses and general and administrative expenses.

We have not generated any revenues from product sales to date, and we do not expect to generate revenues from product sales for at least the next several years. Our revenues for the fiscal years ended December 31, 2014 and 2013 were primarily from license and collaboration agreements with our partners, and, to a lesser extent, from grants from government agencies.

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

Private Placement

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

Acquisition

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

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

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

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

TUM Arbitration

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

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

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

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

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

Key Financial Terms and Metrics

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

Revenues

We have not generated any revenues from product sales to date, and we do not expect to generate revenues from product sales for at least the next several years. Our revenues for the last two years have been primarily from the license and collaboration agreements with Sanofi Group, or Sanofi, and Daiichi Sankyo Company Limited, or Daiichi Sankyo and, to a much lesser extent, grants from government agencies.

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

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

Expenses

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

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

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

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

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

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

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

Results of Operations

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

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

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

Revenues

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

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

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

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

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

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

Research and Development Expenses

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

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

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

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

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

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

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

General and Administrative Expenses

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

Other Income (Expense)

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

Liquidity and Capital Resources

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

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

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

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

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

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

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

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

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

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

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

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Critical Accounting Policies and Estimates

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

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

Multiple-element arrangements

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

Anticalin technology and (ii) research and development activities with respect to one or more therapeutics related to such licenses. Payments to us under these agreements may include upfront fees (which include license and option fees), payments for research and development services, payments based upon the achievement of certain milestones and royalties on product sales. There are no performance, cancellation, termination or refund provisions in any of the arrangements that contain material financial consequences to us. We follow the provisions of the Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Topic 605-25, *Revenue Recognition—Multiple-Element Arrangements* and ASC Topic 605-28, *Revenue Recognition—Milestone Method* in accounting for these agreements.

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

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

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

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

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

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

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

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

Milestone payments

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

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

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

Government grants

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

Loss contingencies

We record accruals for loss contingencies to the extent that we conclude that it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. We evaluate, on a quarterly basis, developments in legal proceedings and other matters that could cause an increase or decrease in the amount of the liability that has been accrued previously. We consider all claims on a quarterly basis in accordance with GAAP and based on known facts assess whether potential losses are considered reasonably possible, probable and estimable. Based upon this assessment, we then evaluate disclosure requirements and whether to accrue for such claims in our financial statements.

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

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

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

Income taxes

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

Where we determine that it is more likely than not that some portion or all of the deferred tax assets will not be realized in the future, the deferred tax assets are reduced by a valuation allowance. The valuation allowance is sufficient to reduce the deferred tax assets to the amount that we determine is more likely than not to be realized.

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

Recently Issued Accounting Pronouncements

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

Emerging Growth Company and Smaller Reporting Company Status

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

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

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

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

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

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

Voluntary Filer Status

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

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

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

Not applicable.

Item 9A. CONTROLS AND PROCEDURES

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

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

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

Management's Assessment of Internal Control over Financial Reporting

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

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

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

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

Item 9B. OTHER INFORMATION

Not applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

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

Item 11. EXECUTIVE COMPENSATION

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

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

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

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

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

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

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

PART IV

Item 15. **EXHIBITS, FINANCIAL STATEMENT SCHEDULES**

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

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

Item 15(a)(3) Exhibits

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

Exhibit Number	Description
2.1	Acquisition Agreement, dated as of December 17, 2014, by and among the Registrant, Pieris AG and the former stockholders of Pieris AG named therein (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 18, 2014).
3.1	Amended and Restated Articles of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 18, 2014).
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 18, 2014).
4.1	Form of Common Stock certificate (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 18, 2014).
10.1@	2014 Employee, Director and Consultant Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 18, 2014).
10.2@	Form of Stock Option Award Agreement under the Registrant's 2014 Employee, Director and Consultant Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 18, 2014).
10.3±	Collaboration Agreement by and between Pieris AG and Allergan Sales, LLC, dated as of August 21, 2009 (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 18, 2014).
10.4±*	Collaboration and License Agreement by and among Pieris AG, Sanofi-Aventis and Sanofi-Pasteur SA, dated as of September 24, 2010.
10.5±	First Letter Agreement to Collaboration and License Agreement by and among Pieris AG, Sanofi-Aventis and Sanofi-Pasteur SA, dated as of February 20, 2013 (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 18, 2014).
10.6±	Side Agreement to the Collaboration and License Agreement by and among Pieris AG, Sanofi-Aventis and Sanofi-Pasteur Inc., dated as of January 19, 2015 (incorporated by reference to Exhibit 10.6 to the Company's Registration Statement on Form S-1 (File No. 333-202123) filed with the SEC on February 2, 2015).

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

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

Exhibit Number	Description
10.34	Split-Off Agreement, by and among the Registrant, Marika Enterprises Inc. and Aleksandrs Sviks, dated December 17, 2014 (incorporated by reference to Exhibit 10.33 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 18, 2014).
10.35	General Release Agreement, by and among the Registrant, Marika Enterprises Inc. and Aleksandrs Sviks, dated December 17, 2014 (incorporated by reference to Exhibit 10.34 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 18, 2014).
10.36	Form of Securities Purchase Agreement, dated December 17, 2014, by and among Pieris Pharmaceuticals, Inc. and the Purchasers (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 23, 2014).
10.37	Form of Registration Rights Agreement, dated December 17, 2014, by and among Pieris Pharmaceuticals, Inc. and the investors party thereto (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 23, 2014).
10.38	Form of Warrant to Purchase Common Stock, dated December 17, 2014, issued by Pieris Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 23, 2014).
14.1*	Corporate Code of Ethics and Conduct and Whistleblower Policy.
21.1	List of Subsidiaries (incorporated by reference to Exhibit 21.1 to the Company's Current Report on Form 8-K (File No. 333-190728) filed with the SEC on December 18, 2014).
31.1*	Certification of Stephen S. Yoder, Chief Executive Officer and President, pursuant to Section 302 of the Sarbanes—Oxley Act of 2002.
31.2*	Certification of Darlene Deptula-Hicks, Acting Chief Financial Officer, pursuant to Section 302 of the Sarbanes—Oxley Act of 2002.
32.1**	Certification of Stephen S. Yoder, Chief Executive Officer and President, pursuant to Section 906 of the Sarbanes—Oxley Act of 2002, 18 U.S.C. Section 1350.
32.2**	Certification of Darlene Deptula-Hicks, Acting Chief Financial Officer, pursuant to Section 906 of the Sarbanes—Oxley Act of 2002, 18 U.S.C. Section 1350.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

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

SIGNATURES

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

PIERIS PHARMACEUTICALS, INC.

Date: March 27, 2015

By: /s/ Stephen S. Yoder
Stephen S. Yoder
Chief Executive Officer and President

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated below and on the dates indicated.

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

PIERIS PHARMACEUTICALS, INC.

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Report of Independent Registered Public Accounting Firm

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

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

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

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

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

/s/ Richter
Wirtschaftsprüfer
[German Public Auditor]

Ernst & Young GmbH
Wirtschaftsprüfungsgesellschaft

Munich, Germany
March 27, 2015

PIERIS PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

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

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

PIERIS PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

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

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

PIERIS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

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

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

PIERIS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

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

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

PIERIS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

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

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

PIERIS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

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

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

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

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

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

2. Summary of Significant Accounting Policies

Basis of Consolidation

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

Use of Estimates

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

Foreign Currency Translation

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

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

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

Cash, Cash Equivalents and Restricted Cash

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

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

Fair Value of Financial Instruments

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

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

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

Concentration of Credit Risk and Other Risks and Uncertainties

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

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

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

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

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

Trade Accounts Receivable

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

Property and Equipment

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

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

Impairment of Long-lived Assets

The Company reviews its long-lived assets to be held and used for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. In performing an impairment review, the Company estimates undiscounted cash flows from products that are covered by these assets. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition is less than the carrying amount of the asset. If the evaluation indicates that the carrying value of an asset is not recoverable from its undiscounted cash flows, an impairment loss is measured by comparing the carrying value of the asset to its fair value. No such impairments were recorded during the years ended December 31, 2014 or 2013.

Revenue Recognition

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

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

Multiple-Element Arrangements

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

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

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

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

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

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

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

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

Milestone Payments and Royalties

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

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

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

Government Grants

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

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

Research and Development

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

Income Taxes

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

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

Share-based Payments

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

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

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

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

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

Warrants to Purchase Common Stock

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

Contingencies

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

Segment Reporting

Operating segments are identified as components of an enterprise where separate discrete financial information is available for evaluation by the chief operating decision maker in making decisions on how to allocate resources and asses performance. The Company operates as a single segment dedicated to the discovery and development of biotechnological applications and accordingly, views its operations and manages its business in one operating segment.

Basic and Diluted Earnings per Share

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

Adoption of New Accounting Standards

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

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

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

New Accounting Standards Not Yet Adopted

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3. Acquisition

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

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

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

4. Revenue

General

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

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

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

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

Collaborations and Other Agreements

Allergan Inc.

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

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

Daiichi Sankyo Co., Ltd.

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

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

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

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

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

Sanofi-Aventis and Sanofi-Pasteur

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

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

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

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

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

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

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

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

Stelis BioPharma

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

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

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

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

Cadila Healthcare Limited

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

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

Other Arrangement

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

Government Grants

BioCluster m4

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

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

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

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

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

The Company has received the following amounts:

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

The following balance sheet items relate to the FP7 agreement:

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

5. Property and Equipment, net

Property and equipment are summarized as follows:

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

Accumulated depreciation for each asset group is summarized as follows:

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

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

6. Income Taxes

The income tax benefits are as follows:

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

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

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

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

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

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

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

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

Tax field audit

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

7. Debt

Convertible Stockholder Loans

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

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

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

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

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

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

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

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

Unsecured Bank Loan

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

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

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

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

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

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

8. Stockholders´ Equity

Common Stock

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

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

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

Preferred Stock

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

2014 Series C Financing

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

Acquisition

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

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

Private Placement

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

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

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

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

9. Stock-Based Compensation

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

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

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

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

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

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

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

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

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

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

10. Warrants

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

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

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

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

11. Accrued Expenses

Accrued expenses consist of the following:

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

12. Related-Party Transactions

Research and License Agreement with Technische Universität München

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

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

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

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

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

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

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

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

EUROCALIN/FP7 Government Grant

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

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

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

Convertible Stockholder Loan

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

Receivables from Issuance of Shares

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

13. Commitments and Contingencies

Licensing Commitments

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

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

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

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

Leases

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

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

	Total
2015	$ 176,190

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

TUM Arbitration

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

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

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

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

14. Subsequent Events

TUM Arbitration

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

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

CONFIDENTIAL TREATMENT REQUESTED

COLLABORATION AND LICENSE AGREEMENT

This COLLABORATION AND LICENSE AGREEMENT (this "Agreement") is entered into effective as of September 24th, 2010 (the "Effective Date") by and between

Sanofi-Aventis ("Sanofi-Aventis") having its principal place of business at 174 avenue de France, 75013 Paris, France

and

Sanofi-Pasteur SA ("Sanofi-Pasteur"), having its principal place of business at 2 avenue Pont Pasteur, 69007 Lyon, France

on one side,

Sanofi-Aventis and Sanofi-Pasteur being also hereinafter collectively designated as "Sanofi"

and

Pieris AG ("Pieris"), having a place of business at Lise-Meitner-Str. 30, 85354 Freising, Germany,

on the other side.

Sanofi and Pieris shall also each individually be referred to herein as a "Party", and shall be referred to jointly as the "Parties".

RECITALS

WHEREAS, the Parties desire to collaborate upon a research and development project for the purpose of using Pieris' proprietary Anticalin® technology to discover and optimize certain Program Compound(s) (as defined below).

WHEREAS, the Parties intend that Sanofi shall have exclusive right to Program Compounds generated within a Program for further development and commercialization of Licensed Compound(s) and Licensed Product(s) within the Field (as defined below) against the payment of milestones and royalties to Pieris.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants set forth below, the Parties hereby agree as follows:

SECTION 1
DEFINITIONS

For purposes of this Agreement, the terms defined in this Section 1 and used in the Agreement with a capital initial letter shall have the respective meanings set forth below. Unless the context clearly and unambiguously requires otherwise, references to the singular include the plural and vice versa.

1.1 "Affiliate" shall mean, with respect to any person or entity, any other person or entity, which directly or indirectly controls, is controlled by, or is under common control with, such person or entity. A person or entity shall be regarded as in control of another person or entity if it owns, or directly or indirectly controls, more than fifty percent (50%) of the voting stock or other ownership interest of the other person or entity, or if it directly or indirectly possesses the power to direct or cause the direction of the management and policies of the other person or entity by any means whatsoever.

1.2 "Anticalin" shall mean any protein derived from any lipocalin by Pieris' proprietary technology of selecting a [***] lipocalin mutein [***] as defined by the Pieris Background IP.

1.3 "Anticalin Technology" shall mean the Anticalin technology Pieris will apply to each Program, as defined in Exhibit 1.3 (as such Exhibit may be updated for some or all Programs to include Anticalin Technology Improvement IP that has been agreed by the Parties to be applied under Phase A of any Program, as described in Section 6.3.1(b)).

1.4 "Anticalin Technology Improvement IP" shall mean any Intellectual Property [***] of any Program, while working on such Program, that (i) [***] and (ii) [***].

1.5 "BLA/NDA" shall mean a Biologics License Application, New Drug Application, Product License Application or any similar application for Marketing Authorization submitted to the FDA or any comparable application for Marketing Authorization in any other country.

1.6 "[***]" shall mean [***].

1.7 "Commercially Reasonable and Diligent Efforts" shall mean the level of effort, budget and resources normally used by a company of [***] for a product or compound owned or controlled by it, which is of similar market potential and at a similar stage in its development or product life, taking into account with respect to a product issues of safety and efficacy, product profile, the proprietary position of the product, the then-current competitive environment for the product and the likely timing of the product(s) entry into the market, the regulatory environment of the product and other relevant scientific technical and commercial factors. For the avoidance of doubt, the fact that [***] shall not constitute a factor to be taken into account in the determination of "Commercially Reasonable and Diligent Efforts".

1.8 "Confidential Information" shall have the meaning set forth in Section 8.1.

1.9 "Control" (whether used as a noun or as a verb) shall mean, with respect to a Party, the ownership of, or possession of the ability to license or sublicense, Intellectual Property, in any case without violating the terms of any agreement binding on such Party.

1.10 "Development Plan" shall mean a written development work plan relating to a Program which describes the work to be performed [***]. Any Development Plan shall cover the aspects and activities described in Exhibit 1.10, to the extent appropriate with respect to the concerned Licensed Compound(s) and subject to Sections 4.2 and 4.4.

1.11 "[***]" shall mean [***].

1.12 "EMA" shall mean the European Medicines Agency or any successor agency thereto.

1.13 "Effective Date" shall have the meaning set forth in the introductory paragraph of the Agreement.

1.14 "FDA" shall mean the United States Food and Drug Administration or any successor agency thereto.

1.15 "Field" shall mean any use of any Licensed Compound and/or Licensed Product for [***].

1.16 "[***]" shall mean, with respect to a Licensed Product, [***]. For the avoidance of doubt, [***].

1.17 "Foreground IP" shall mean any Intellectual Property conceived, developed or reduced to practice in connection with the activities performed under this Agreement.

1.18 "FTE" shall mean the equivalent of [***] full-time researcher of Pieris involved in [***] of a Program, taking into consideration statutory holidays and paid annual leave.

1.19 "[***]" shall mean [***].

1.20 "[***]" shall mean [***] which shall be defined in more detail in the Program Plan of each Program initiated by Sanofi pursuant to Section 2.6(b).

1.21 "[***]" shall mean [***].

1.22 "Indication" shall mean [***].

1.23 "[***] Program" shall mean any Program comprising one or more Anticalins or [***] directed against a Target [***].

1.24 "Intellectual Property" shall mean, with respect to any product or technology, (a) all Patent Rights which claim or cover such product technology, (b) all other intellectual property rights relating to such product or technology, including without limitation legally protected trade secrets, copyrights, trademarks and other intellectual property rights of any kind, and (c) all Know-How relating to such product or technology.

1.25 "Know-How" shall mean any information and materials, whether proprietary or not and whether patentable or not, including without limitation ideas, concepts, formulas, methods, protocols, procedures, knowledge, know-how, trade secrets, processes, assays, skills, experience, techniques, designs, compositions, plans, documents, results of experimentation and testing, including without limitation, pharmacological, toxicological, and pre-clinical and clinical test data and analytical and quality control data, improvements, discoveries, works of authorship, compounds and biological materials, which are non-obvious in view of the literature, confidential, substantial and identified in any appropriate form, and communicated by one Party to the other hereunder.

1.26 "Licensed Compound" shall mean any [***] in connection with the corresponding Program, for as long as (i) [***] pursuant to Section 4.3 and (ii) [***] pursuant to Section 4.

1.27 "Licensed Product" shall mean any product which comprises at least [***] Licensed Compound [***] under this Agreement. For the avoidance of doubt, [***].

1.28 "Marketing Authorization" shall mean collectively any Contingent Marketing Authorization or any Non-Contingent Marketing Authorization.

1.28.1 "Contingent Marketing Authorization" shall mean any approval (including all applicable pricing and governmental reimbursement approvals) required from the relevant Regulatory Authority to market and sell a Licensed Product in a particular country or jurisdiction, which approval (i) under FDA jurisdiction is pursuant to 21 CFR 314.510 (Subpart H) for new drug applications (NDAs) or 21 CFR 601.41 (Subpart E) for biologics license applications (BLAs) or (ii) under EMA jurisdiction is a "conditional approval" where the EMA Committee for Medicinal Products for Human Use (CHMP) adopts a positive opinion on data which, while not yet comprehensive, indicate that the medicine's benefits outweigh its risks. For the avoidance of doubt, the requirement by the FDA (or any foreign equivalent) to conduct a "Risk Evaluation & Mitigation Strategy" under the Food and Drug Administration Amendments Act (FDAAA) of 2007 (as amended from time to time) as part of such approval shall, without more, not render the approval as a Contingent Marketing Authorization.

1.28.2 "Non-Contingent Marketing Authorization" shall mean any approval (including all applicable pricing and governmental reimbursement approvals) required from the relevant Regulatory Authority to market and sell a Licensed Product in a particular country or jurisdiction, which approval is not a Contingent Marketing Authorization.

1.29 "Net Sales" shall mean, with respect to any Licensed Product sold by a Sanofi Party to any party who is not a Sanofi Party, the price, converted in Euros pursuant to Section 5.10.1, invoiced by such Sanofi Party to the Third Party (or in the case of a sale or other disposal otherwise than at arm's length, the price which would have been invoiced in a bona fide arm's length contract or sale) but deducting

(i) [***].

(a) In the event that the Licensed Product is sold in the form of a [***], Net Sales will be determined by multiplying actual Net Sales [***] If, on a [***] basis, the [***], Net Sales shall be determined by multiplying actual [***] in accordance with the Third Party expert proceedings set forth in Section 13.3.4).

(b) In the event that the Licensed Product [***], Net Sales shall be determined by a multiplying actual Net Sales of such [***], by a neutral Third Party in the absence of such mutual agreement, by a neutral Third Party in accordance with the Third Party expert proceedings set forth in Section 13.3.4), provided, however, that (i) [***] and (ii) Pieris shall at all times be entitled to receive at least a royalty of [***] calculated in accordance with the first paragraph of this Section 1.29.

For the avoidance of doubt, (a) and (b) shall apply cumulatively.

1.30 "Patent Rights" shall mean, with respect to any technology or product, (a) all patent applications heretofore or hereafter filed or having legal force in any country to the extent and only to the extent they claim or cover such technology or product or the use thereof, (b) all patents that have issued or in the future issue from such applications, including without limitation utility, model and design patents and certificates of invention, and (c) all divisionals, continuations, continuations-in-part, supplemental protection certificates, reissues, reexaminations, renewals, extensions or additions to any such patent applications and patents.

1.31 "Phase I Clinical Trial" shall mean one or more human clinical studies in any country designed to evaluate the safety, tolerability and pharmacokinetics effect of a drug in volunteer subjects or patients that would satisfy the requirements of 21 CFR 312.21(a), or other comparable regulation imposed by the FDA, the EMA or their foreign counterparts.

1.32 "Phase II Clinical Trial" shall mean one or more controlled human clinical studies conducted to evaluate the effectiveness of the drug for a particular indication in patients with the disease or condition under study and/or to determine the common short-term side effects and risks associated with a drug that would satisfy the requirements of 21 CFR 312.21(b) or other comparable regulation imposed by the FDA, the EMA or their foreign counterparts.

1.33 "Phase III Clinical Trial" shall mean one or more expanded human clinical studies intended to gather additional information about effectiveness and safety needed to evaluate the overall benefit-risk relationship of a drug for a particular indication that would satisfy the requirements of 21 CFR 312.21(c) or other comparable regulation imposed by the FDA, the EMEA or their foreign counterparts. For the avoidance of doubt, a "Phase III Clinical Trial" may encompass multiple studies to be performed at different clinical sites.

1.34 "Phase A" shall mean, under each Program, the phase that [***].

1.35 "Phase B" shall mean, under each Program, [***] of this Agreement.

1.36 "PhD" shall mean any employee or other individual acting on behalf of or for the account of Pieris that has a university degree (such as a PhD or a diploma).

1.37 "Pieris Background IP" shall mean Pieris Background Know-How and Pieris Background Patent Rights.

1.38 "Pieris Background Know-How" shall mean all Know-How Controlled by Pieris as of the Effective Date related to the Anticalin Technology.

1.39 "Pieris Background Patent Rights" shall mean, individually and collectively, all Patent Rights listed in Exhibit 1.39 (as such Exhibit may be updated for some or all Programs to include Anticalin Technology Improvement IP that have been agreed by the Parties to be applied under Phase A of any Program, as described in Section 6.3.1(b)).

1.40 "Pieris Foreground IP" shall mean all Foreground IP [***].

1.41 "Pieris Licensed IP" shall mean the Pieris Background IP and the Pieris Foreground IP.

1.42 "Pieris Valid Patent Claim" shall mean, with respect to the Patent Rights to which Sanofi has been granted license rights under Section 6.3, a claim of an issued and unexpired patent, which claim has not been held invalid or unenforceable in a final decision of a court or administrative authority of competent jurisdiction from which decision no appeal may be taken, and, for those jurisdictions where re-issue, re-examination, disclaimer or similar proceedings are available, which claim has not been disclaimed or admitted or determined to be invalid or unenforceable through reissue, re-examination, disclaimer or otherwise.

1.43 "Program" shall mean a therapeutic Anticalin research, development and/or commercialization program comprising either (i) one or more Anticalins directed against a Target or (ii) a [***].

1.44 "Program Compound" shall mean, for each Program, (i) [***] which is conceived, reduced to practice and/or developed [***] and which [***]) in accordance with the specifications agreed under the relevant Program Plan (as well as any fragments or derivates thereof); and (ii) [***].

1.45 "Program Plan" shall mean the written research work plan agreed between the Parties pursuant to Section 2.3 which defines (i) the work to be performed in Phase A of the relevant Program, (ii) [***], (iii) [***], and (iv) [***] [***]. The Program Plan for the first two Targets is attached hereto as Exhibit 1.45.

1.46 "Program Request" shall have the meaning set forth in Section 2.1.

1.47 "Program Response" shall have the meaning set forth in Section 2.2.

1.48 "Program Term" shall have the meaning set forth in Section 12.2.

1.49 "Regulatory Authority" shall mean the FDA, the EMA or any supranational, national or local agency, authority, department, inspectorate, minister, ministry official, parliament or public or statutory person (whether autonomous or not) of any government of any country having jurisdiction over any of the activities contemplated by this Agreement or the Parties, or any successor bodies thereto.

1.50 "Royalty Term" shall have the meaning set forth in Section 5.8.

1.51 "Sanofi Background IP" shall mean all Intellectual Property Controlled by Sanofi or any of its Affiliates which has been introduced by Sanofi into a Program.

1.52 "Sanofi Foreground IP" shall mean all Foreground IP [***].

1.53 "Sanofi Party" shall mean Sanofi, its Sublicensee(s) and any of Sanofi's or Sublicensee's Affiliates.

1.54 "Sanofi Valid Patent Claim" shall mean, with respect to the Patent Rights to which Sanofi has been granted license rights under Section 12.5.6, a claim of an issued and unexpired patent, which claim has not been held invalid in a final decision of a court

or administrative authority of competent jurisdiction from which no appeal may be taken, and which claim has not been disclaimed or admitted to be invalid or unenforceable through reissue or otherwise.

1.55 "Steering Committee" shall mean the committee established pursuant to Section 11.1 for the purpose of (a) directing, coordinating and supervising the research and development program under a Program until the commencement of the first Phase I Clinical Trial under such Program, and (b) exchanging information and strategies regarding Sanofi's further research, development and commercialization of Licensed Products under a Program after the commencement of the first Phase I Clinical Trial under such Program.

1.56 "Sublicensee" shall have the meaning set forth in Section 6.3.2(b).

1.57 "Success Criteria" shall mean the success criteria [***] a Program Plan [***], which shall be agreed in the relevant Program Plan.

1.58 "[***]" shall mean, [***] concerning a Program, the [***]. For the purpose of the preceding sentence, "[***]" shall mean [***]; whether [***] shall be agreed between the Parties prior to the initiation of the relevant clinical trial. For the avoidance of doubt, [***] in accordance with the above definition, then "[***]" shall have occurred [***].

1.59 "Target" shall mean, for each Program, [***]. Accordingly, a Target may be [***], such as [***], but a Target may not [***]. By way of example, a Target may comprise [***].

1.60 "Terminated Program" shall have the meaning set forth in Section 12.5.

1.61 "Territory" shall mean [***].

1.62 "Third Party" shall mean any entity or person other than Sanofi or Pieris or their respective Affiliates.

SECTION 2
TARGET SELECTION AND PROGRAM INITIATION

2.1 Program Request by Sanofi. For each Program that Sanofi wishes to initiate as permitted under Section 2.6 of the Agreement, Sanofi shall submit to Pieris a Program and license request on a signed copy of the Program Request Form set forth in Exhibit 2.1, specifying the proposed Target (or [***]) in as much detail as is reasonably possible ("Program Request").

2.2 Program Response by Pieris. Pieris shall promptly review each Program Request and shall provide a written notice to Sanofi within [***] days after its receipt of such Program Request, specifying whether or not the requested Program and license is available ("Program Response"). Provided that the Target proposed by Sanofi is not the subject matter of, [***] or (ii) [***], Pieris shall confirm, counter-sign and return to Sanofi the Program Request, and such Target shall, retroactively upon the day of the Program Request, be automatically licensed to Sanofi as specified in Section 6.3.

2.3 Establishment of Program Plan. If Pieris issues a positive Program Response pursuant to Section 2.2 above, the Steering Committee shall agree in good faith on a Program Plan in relation to the relevant Program in accordance with Section 11.1.2(a). The Program Plan shall be signed by authorized representatives of both Parties. Following the execution of the Program Plan, the Program Plan may [***] be amended by (i) [***] or (ii) [***].

2.4 Replacement Option of Sanofi. If (i) Pieris issues a negative Program Response pursuant to Section 2.2 or (ii) the Steering Committee cannot agree on a Program Plan pursuant to Section 2.3 within [***] days from a positive Program Response, Sanofi shall have the right to replace the affected Program proposal by submitting a Program Request for a different Target ([***]). In the event of any such replacement, Sections 2.1 to 2.4 shall apply accordingly to the replacement Program proposed by Sanofi.

2.5 Replacement Option for [***] Programs. If a Program is an [***] Program and if, [***], the Licensed Compound(s) selected by Sanofi [***], Sanofi will be allowed to replace the original Program by a Program relating to another Target ([***]. The above replacement option must be exercised by Sanofi within [***] months following [***]. Sections 2.1 to 2.4 shall apply accordingly to Sanofi's proposal for the replacing Program. [***].

2.6 Allocation of Committed and Optional Programs.

(a) Prior to the Effective Date, Sanofi has submitted to Pieris two (2) Program Requests and Pieris has issued two (2) positive Program Responses. Those two (2) Programs are listed in Exhibit 2.6.

(b) Sanofi shall have the right (but not the obligation) to propose (i) one (1) or two (2) Program Requests between the [***] anniversary and the [***] anniversary of the Effective Date and (ii) one (1) or two (2) further Program Requests between the [***] and the [***] anniversary of the Effective Date (and if Pieris issues a negative Program Response pursuant to Section 2.2 for any of these Program Requests, then Sanofi shall have the right to promptly submit a replacement request in accordance with Section 2.4 until Pieris issues a respective positive Program Response).

SECTION 3
PHASE A - GENERATION OF PROGRAM COMPOUND(S) BY PIERIS

3.1 Goal of Phase A. Under each Program, the goal of Phase A is to discover, research and develop one or more Program Compounds from which Sanofi may further develop and commercialize the Licensed Product(s). Unless otherwise agreed in the relevant Program Plan, Phase A of each Program shall commence upon a positive Program Response by Pieris.

3.2 Conduct of Phase A Research. In Phase A of each Program, Pieris shall use its [***] to discover, research, develop and deliver to Sanofi one or more Program Compounds that meet the Success Criteria agreed under such Program.

3.3 Support Obligations of Sanofi. Sanofi shall (i) provide all reasonable assistance to Pieris in connection with Pieris' performance of its obligations under the Program Plan ([***]) and (ii) provide to Pieris such materials and information required to be provided by Sanofi under the Program Plan. Pieris shall use such materials and information only to perform its obligations and permitted activities under the Program Plan or this Agreement.

3.4 Results and Reporting Under Phase A. Pieris shall keep Sanofi fully informed as to its progress, results, status and plans for performing and implementing the Program Plan. Such information shall be given during the quarterly Steering Committee meetings or more often, as necessary. Upon the completion of Phase A, Pieris will deliver to Sanofi [***] Program Compound(s) generated during Phase A, as further specified in the Program Plan, and provide to Sanofi a written summary report of its Phase A activities.

3.5 Maintenance of Records. Pieris shall maintain records, in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, which shall reflect the work done and the results achieved in the performance of the Program [***]. Pieris shall also keep appropriate records of the FTEs utilized for a Program and the costs associated therewith, and evidence that the work was conducted at a professional standard accepted in the scientific community in accordance with the requirements of the Program Plan. Pieris shall make such records available for inspection upon reasonable written request of Sanofi (but not more than twice per calendar year and not more than once in relation to the same time period) for the purpose of ensuring Pieris' compliance with its research obligations hereunder. Upon request by Sanofi, Pieris shall deliver to Sanofi copies of all records described in this Section, provided that Sanofi shall reimburse Pieris for reasonable costs incurred in providing such copies to Sanofi. This obligation shall survive any termination of a Program for a period of [***] years following such termination.

3.6 Termination by Pieris. Pieris shall be entitled to terminate its research and development activities under Phase A under any Program if [***]. Unless otherwise agreed in the relevant Program Plan, [***].

3.7 End of Phase A. For each Program, Pieris' obligation to use [***] to discover, research, develop and deliver Program Compounds to Sanofi shall end upon the date that (i) Pieris has completed delivery of one or more Program Compound(s) [***] or (ii) [***] or (iii) [***].

SECTION 4
PHASE B – DEVELOPMENT AND COMMERCIALIZATION BY SANOFI

4.1 Decision Point for Sanofi. Following the end of Phase A of each Program, Sanofi shall inform Pieris by written notice within [***] days whether it wishes to enter into Phase B of the relevant Program. In the event that [***]. In such event, [***].

4.2 Development by Sanofi. If Sanofi informs Pieris in writing that it wishes to enter into Phase B in accordance with Section 4.1 above, (i) the Steering Committee shall review and comment on the Development Plan established by Sanofi for the development of one or more Licensed Products under Phase B of such Program and (ii) Sanofi shall use

Commercially Reasonable and Diligent Efforts to develop [***] Licensed Product in [***] in accordance with the Development Plan.

4.3 Selection [***] of Licensed Compound(s). If Pieris has delivered more than one Program Compound during Phase A, then Sanofi shall select one or more Program Compound(s) to become the "Licensed Compound(s)" within [***] days of its decision to enter Phase B by delivery of written notice to Pieris identifying the applicable Program Compound(s). Notwithstanding the foregoing, [***].

4.4 Results and Reporting by Sanofi. During Phase B of each Program, Sanofi shall keep Pieris reasonably informed as to its progress, results, status and plans for performing the development under Phase B by delivering to Pieris a written report no later than [***] days following the end of [***]. Each such written report shall be sufficiently detailed to demonstrate that Sanofi continues to apply Commercially Reasonable and Diligent Efforts in relation to the relevant Program in accordance with the Development Plan, which may be updated from time to time as appropriate. In addition, Sanofi shall provide Pieris with (i) [***] and (ii) upon request of Pieris [***], [***].

4.5 Remedy for Failing to Meet Obligations; Procedure. In the event that Pieris believes that Sanofi has failed to comply with its diligence obligations under Section 4.2, Pieris shall notify Sanofi in writing. [***] upon the expiration of the [***] day period provided within Section 12.3.2, unless Sanofi (i) has remedied the alleged failure in complying with its diligence obligations within such [***] day period (for the avoidance of doubt, "[***]) or (ii) by written notice reasonably disputes that it has failed to comply with its diligence obligations and provides Pieris with specific documents evidencing how Sanofi complied with its diligence obligations under Section 4.2. If Pieris receives notice within the above [***] day time period that Sanofi reasonably disputes that it has failed to comply with its diligence obligations under Section 4.2, and the Parties cannot reach agreement with respect to such Dispute (as defined in Section 13.3) as set forth in Section 13.3.1, Pieris shall [***] this Agreement shall be terminated pursuant to Section 12.3.2 if and when [***] there is a final determination that Sanofi has failed to comply with its diligence obligations under Section 4.2 and has not remedied its failure in complying with its diligence obligations within the above [***] day period.

4.6 Maintenance of Records. Sanofi shall maintain records, in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, which shall reflect the work done and the results achieved in the performance the development under Phase B [***]. This obligation shall survive any termination of a Program for a period of [***].

4.7 Support Services by Pieris. Upon Sanofi's request, Pieris will [***] support Sanofi in its development activities under Phase B. Any such development support shall be agreed between Sanofi and Pieris in writing and shall be charged by Pieris to Sanofi at Pieris' then-current FTE rates.

SECTION 5
FINANCIAL PROVISIONS

5.1 Upfront Payments.

5.1.1 Signing Fee. In consideration of the rights granted hereunder, the designation of two (2) Programs in accordance with Section 2.1 and the option to designate additional Program proposals in accordance with Section 2.6, Sanofi shall pay to Pieris an irrevocable upfront payment in the amount of three million five hundred thousand Euro (EUR 3,500,000) within [***] days following the Effective Date.

5.1.2 Upfront Payment for Additional Programs. If and to the extent Sanofi exercises any of its options to designate additional Programs under Section 2.6(b) above, Sanofi shall pay to Pieris [***] payments of [***]. Each such [***] payment shall become due and payable within [***] days after a positive Program Response of Pieris for such Program and agreement on the Program Plan has been reached between Pieris and Sanofi.

5.1.3 Upfront Payment for Replacements of [***] Programs. If Sanofi replaces any [***] Program in accordance with Section 2.5 above, Sanofi shall pay to Pieris an additional irrevocable upfront payment in the amount of [***]. Such additional upfront payment shall become due and payable within [***] days after a positive Program Response of Pieris for the replacing Program and agreement on the Program Plan has been reached between Pieris and Sanofi.

5.2 Research Funding.

5.2.1 FTE Rates. Sanofi shall pay to Pieris research funding for the FTEs agreed for Phase A of a Program under the relevant Program Plan in the following amounts: (i) PhDs: [***] Euro (EUR [***])[***], and (ii) technicians: [***] Euro (EUR [***])[***]. The research funding shall become due and payable pro rata in advance on a calendar half-year basis (or *pro rata temporis*, where applicable) for all activities to be performed by Pieris according to the Program Plan during such calendar half-year, as set forth in the corresponding Program Plan.

5.2.2 Reference Resources Required. By way of reference, the Parties estimate that [***] FTEs [***] for a period of about [***] months represents the resource required for a standard Program targeting [***].

5.2.3 Committed Resources. Beginning on the Effective Date, Sanofi shall fund and Pieris shall devote [***] for [***] months of the Agreement. FTE payments for Programs other than the [***] Programs shall become due upon the date of initiation of the relevant Phase A as defined in Section 3.1 and payable [***] days thereafter. All subsequent payments shall become due and payable upon the respective anniversary of such initiation date.

5.3 R&D Milestone Payments.

5.3.1 Phase A Research Milestones. With respect to any Program initiated by Sanofi pursuant to Section 2.6(b) only (including replacement Programs for such additional Programs under Section 2.5), Sanofi shall pay to Pieris a [***] milestone payment of [***] Euro (EUR [***]) per Program upon Pieris' achievement of [***]. Such milestone payment shall become due and payable within [***] days following Pieris' written report to Sanofi evidencing the achievement of [***]. For the avoidance of doubt, [***].

5.3.2 Phase B Research Milestones. Within [***] days of [***] of any of the following milestone events with respect to a Licensed Compound within a Program, Sanofi shall make the following payments to Pieris on a [***] basis (for the avoidance of doubt, [***][***]. For further clarity, [***]; [***]):

Milestone Payment		Milestone Event
EUR	[***]	[***]
EUR	[***]	[***]
EUR	[***]	[***]

5.4 Development Milestone Payments.

5.4.1 Development Milestone Payments for [***]. Within [***] days [***] of any of the following milestone events with respect to a Licensed Product for [***], Sanofi shall make the following payments to Pieris on a [***] basis (for the avoidance of doubt, [***], i.e. [***].)

Milestone Payment		Milestone Event
EUR	[***]	[***]
EUR	[***]	[***]
EUR	[***]	[***]
EUR	[***]	[***]
EUR	[***]	[***]
EUR	[***]	[***]
EUR	[***]	[***]

5.4.2 Milestone Payments for Contingent Marketing Authorization. Upon approval for Marketing Authorization from [***], which would trigger a payment under Section 5.4.1 or 5.4.3, the amount due shall be reduced by [***], to the extent the Marketing Authorization is a Contingent Marketing Authorization; and the remaining [***] of such payment shall become due at the date at which a Non-Contingent Marketing Authorization has been granted for the relevant Licensed Product by the relevant Regulatory Authority.

5.4.3 Development Milestone Payments for [***]. Upon [***] of any of the milestone events defined in Section 5.4.1 with respect to a Licensed Product under the same Program as a result of development in [***], Sanofi shall make to Pieris a milestone payment in the amount of [***] of the amount indicated for the relevant milestone in Section 5.4.1. Upon [***] of any of the milestone events defined in Section 5.4.1 with respect to a

Licensed Product under the same Program as a result of development in [***], Sanofi shall make to Pieris a milestone payment in the amount of [***] of the amount indicated for the relevant milestone in Section 5.4.1. [***] of any of the milestone events defined in Section 5.4.1 with respect to the same Licensed Product. For the avoidance of doubt, if, for example, [***] set forth in Section 5.4.1[***] set forth in this Section 5.4.3 [***].

5.5 Sales Milestones. Within [***] days of [***] of any of the following milestone events with respect to a Licensed Product, Sanofi shall make the following payments to Pieris on a [***] basis, it being expressly understood and agreed that each of the following sales milestones shall [***]:

Amount	Milestone Event
EUR[***]	[***]
EUR[***]	[***]
EUR[***]	[***]

5.6 Reporting on Milestone Achievement. Sanofi shall provide written notice to Pieris (i) of any occurrence of any of the milestones set forth in Sections 5.3.2 and 5.4.1 above no later than [***] days following the occurrence of the relevant milestone and (ii) of any occurrence of any of the milestones set forth in Section 5.5 above no later than [***] days following the year during which the corresponding milestone has been achieved. In addition, Sanofi shall inform Pieris promptly in writing if [***] within [***] days from [***]. For the avoidance of doubt, the [***] shall be [***]. Upon receipt of any of the aforesaid notices, Pieris shall send Sanofi-Aventis or Sanofi-Pasteur, as applicable, a corresponding invoice, which shall payable within [***] days.

5.7 Royalties. Sanofi shall pay to Pieris the following royalties on Net Sales on a [***] basis:

Worldwide Annual Net Sales of Respective Licensed Product	Royalty Rate
[***]	[***]%
[***]	[***]%
[***]	[***]%
[***]	[***]%

(Example: If, [***], [***], the royalty payable to Pieris will be: EUR [***] x [***] % + EUR [***] x [***] % + EUR [***] x [***] % + EUR [***] x [***] %.)

The above royalty rates shall be reduced by [***] ([***] %) on a [***] basis in each country in [***].

5.8 Duration of Royalty Payments. The royalties payable by Sanofi to Pieris pursuant to Section 5.7 shall be payable on a [***] basis for a period [***] (the "Royalty Term"): (i) [***] years [***], and (ii) the [***]. At the expiration of the [***], Sanofi shall [***]. Notwithstanding the foregoing, on a [***] basis, in the event that, [***], one or more Third Parties other than a Sanofi Party sell a Generic Product (as defined below) in any country in which a Licensed Product is then being sold by a Sanofi Party or its agents or distributors, then the royalty rate otherwise applicable to the Net Sales of the Licensed Product in such country shall be adjusted [***] in such country as follows: (i) if during [***] in which the Generic Product was introduced and any of the [***] in which the Generic Product was introduced the aggregate Net Sales of the Licensed Product by all Sanofi Parties in such country decrease by less than [***] of the [***] Net Sales on the [***] in which the Generic Product was introduced, there shall be no adjustment to the royalty rate, (ii) if during [***] in which the Generic Product was introduced and any of [***] in which the Generic Product was introduced the aggregate Net Sales of the Licensed Product by all Sanofi Parties in such country decrease by [***] or more but less than [***] of the average Net Sales on [***] in which the Generic Product was introduced, the royalty rate shall be reduced by [***] of the otherwise applicable royalty rate, (iii) if during the quarter in which the Generic Product was introduced and any of [***] in which the Generic Product was introduced the aggregate Net Sales of the Licensed Product by all Sanofi Parties in such country decrease by [***] or more but less than [***] of the average Net Sales on [***] in which the Generic Product was introduced, the royalty rate shall be reduced by [***] of the otherwise applicable royalty rate, and (iv) if during [***] in which the Generic Product was introduced and any of [***] in which the Generic Product was introduced the aggregate Net Sales the Licensed Product by all Sanofi Parties in such country decrease by more than [***] of the average Net Sales on [***] in which the Generic Product was introduced the royalty rate shall be reduced by [***] of the otherwise applicable royalty rate. For the sake of illustration, if during [***] in which the Generic Product was introduced, the average Net Sales of the Licensed Product amounted [***], and Net Sales amount [***] in which the Generic Product is introduced, [***] in which the Generic Product is introduced, [***] in which the Generic Product is introduced and [***] in which the Generic Product is introduced, the royalty rates will be reduced by [***] in which the Generic Product is introduced, by [***] in which the Generic Product is introduced, and by [***]. For purposes of this Section 5.8, a "Generic Product" means, with respect to a Licensed Product, a pharmaceutical product developed and manufactured by an entity or person other than a Sanofi Party that has received Marketing Authorization in the concerned country through an abbreviated regulatory approval process by which the sponsor or the applicant or the Regulatory Authority relies, in whole or in part, upon the data supporting the Licensed Product Marketing Authorization (such as the Abbreviated New Drug Application by FDA in the USA) or is considered a generic version of the Licensed Product in EU pursuant to Directive 2001/83/EC as amended.

5.9 [***]. [***] under this Agreement [***] in connection with [***] However, to the extent [***] To the extent [***] in connection with [***]. For the avoidance of doubt, [***].

5.10 Reports, Payments, Records, Audits and Taxes.

5.10.1 Currency, Payment Costs. Sanofi shall make the payments due to Pieris under this Section 5 in Euro. Where the payments due to Pieris are being converted from a currency other than Euro, conversion of Net Sales recorded in local currencies to Euros shall be performed in a manner consistent with Sanofi normal practices used to prepare its audited financial statements for internal and external reporting purposes, which uses a widely accepted source of published exchange rates. All payments will be made without deduction of exchange, collection or other charges. If by law, regulation or policy of a particular country, a remittance of royalties in the currency stipulated in Section 5.10.1 above is restricted or forbidden, notice thereof will be promptly given to Pieris, and payment of the royalty shall be made by the deposit thereof in local currency to the credit of Pieris in a recognized banking institution designated by Pieris or its Affiliates. When in any country a law or regulation that prohibits both the transmittal and deposit of such payments ceases to be in effect, all royalties or other sums that Sanofi would have been under obligation to transmit or deposit but for the prohibition, shall forthwith be deposited or transmitted promptly to the extent allowable.

5.10.2 [***] Royalty Reporting. All royalty payments will be made at [***] intervals. Within [***] days of the end of [***] after [***], Sanofi shall prepare a statement which shall show on a [***] basis for the previous [***] Net Sales of each Licensed Product by any Sanofi Party and all moneys due to Pieris based on such Net Sales. This statement shall include details of Net Sales broken down to show [***] the sales and the total Net Sales by all Sanofi Parties [***] and shall be submitted to Pieris within such [***]-day period and the amount due shall be paid by Sanofi within [***] days from receipt of the corresponding invoice from Pieris. [***], Sanofi shall document to Pieris the basis on which it has calculated the relevant Net Sales in accordance with Section 1.29 above.

5.10.3 Taxes. All payments shall be made free and clear of and without deduction or deferment in respect of any disputes or claims whatsoever and/or as far as is legally possible in respect of any taxes imposed by or under the authority of any government or public authority. Any tax (other than VAT) which Sanofi is required to pay or withhold with respect to the payments to be made to Pieris hereunder shall be deducted from the amount otherwise due provided that, in regard to any such deduction, Sanofi shall cooperate with respect to all documentation that may be required by any revenue authority and other revenue services, as may reasonably be necessary to enable Pieris to claim exemption therefrom or obtain a repayment thereof or a reduction thereof and shall upon request provide such additional documentation from time to time as is needed to confirm the payment of tax. In particular, at the request of Pieris, Sanofi shall forward to Pieris relevant application forms, which Pieris shall return to Sanofi duly filled and signed before the date when a payment is due. Failing such return, Sanofi shall declare and pay the due withholding tax at the local common rate applicable to the concerned payment and shall deduct such tax from the payment made to Pieris.

5.10.4 Records. Sanofi shall keep, and shall procure that all Sanofi Parties keep, true and accurate records and books of account containing all data necessary for the calculation of the amounts payable by it to Pieris pursuant to this Agreement. Those records and books of account shall be kept for [***] years following the end of the calendar year to which they relate. Upon Pieris' written request, a firm of accountants appointed by agreement between the Parties or, failing such agreement within [***] days of the initiation of discussions between them on this point, Pieris shall have the right to cause an international firm of independent certified public accountants that has not performed auditing or other

services for either Party or their Affiliates and is acceptable to Sanofi, such acceptance not to be unreasonably withheld, shall have the right to inspect such records and books of account. In particular such firm:

(a) shall be given access to and shall be permitted to examine and copy such books and records of any Sanofi Party upon [***] days' notice having been given by Pieris and at all reasonable times on business days for the purpose of certifying that the Net Sales or other relevant sums calculated by any Sanofi Party during the current and the [***] years were reasonably calculated, true and accurate or, if this is not their opinion, certify the Net Sales figure or other relevant sums for such period which in their judgment is true and correct;

(b) prior to any such examination taking place, such firm of accountants shall undertake to Sanofi that they shall keep all information and data contained in such books and records, strictly confidential and shall not disclose such information or copies of such books and records to any third person including Pieris, but shall only use the same for the purpose of calculations which they need to perform in order to issue the certificate to which this Section envisages;

(c) any such access examination and certification shall occur no more than [***];

(d) the relevant Sanofi Party shall make available personnel to answer queries on all books and records required for the purpose of that certification;

(e) any amount shown by the accountant to be owed but overpaid or underpaid and in need of reimbursement shall be paid or refunded (as the case may be) within [***] days from receipt of the corresponding invoice from the Party to which money is due pursuant to the accountant report, and

(f) the cost of the accountant (including reasonable attorneys' fees of Pieris, if applicable) shall be the responsibility of Sanofi if the certification shows it to have underpaid monies to Pieris by more than [***] and the responsibility of Pieris otherwise.

5.10.5 VAT. All payments due to Pieris under the terms of this Agreement are expressed to be exclusive of value added tax (VAT) howsoever arising. If Pieris is required to charge VAT on any such payment, due to German or EU VAT regulations, Pieris will notify Sanofi beforehand. If having used all commercially reasonable endeavors Sanofi is not able to reclaim the VAT (in whole or in part) the Parties agree that the amount of any VAT payable will be shared between them equally.

5.10.6 Payments Made by Wire Transfer. All payments made to Pieris under this Agreement shall be made by wire transfer to the following bank account of Pieris, or such other bank account as notified by Pieris to Sanofi from time to time:

Pieris AG
[***]
Account No.: [***]
BLZ (Routing Number): [***]

IBAN: [***]
BIC (SWIFT Code): [***]

5.10.7 Late Payments. If Sanofi fails to make any payment to Pieris hereunder on the due date for payment, without prejudice to any other right or remedy available to Pieris, Pieris shall be entitled to charge Sanofi interest [***] of the amount unpaid [***], calculated on a [***] basis until payment in full is made without prejudice to Pieris' right to receive payment on the due date.

SECTION 6
INTELLECTUAL PROPERTY

6.1 Pieris' Ownership Rights.

6.1.1 Pieris' Ownership. Pieris shall solely own all right, title and interest in and to (a) all Pieris Background IP, (b) all Pieris Foreground IP and (c) all Anticalin Technology Improvement IP.

6.1.2 [***] Except as expressly provided hereunder, [***] pursuant to this Agreement [***].

6.2 Sanofi's Ownership Rights.

6.2.1 Sanofi's Ownership. Sanofi shall solely own all right, title and interest in and to (a) all Sanofi Background IP, and (b) all Sanofi Foreground IP and (c) all Targets for which a Program has been agreed pursuant to Section 3.

6.2.2 [***]. Except as expressly provided hereunder, [***] pursuant to this Agreement [***].

6.3 License Grant by Pieris.

6.3.1 License Grants. Subject to the provisions in Section 12.3 regarding termination of any Programs or this Agreement, for each Target that is the subject of a positive Program Response, Pieris hereby grants to Sanofi in the Field in the Territory, under the Pieris Licensed IP:

(a) an exclusive license ([***] under this Agreement) to make, have made and use, during Phase A, Program Compounds directed against such Target; and

(b) an exclusive license ([***] under this Agreement) to make, have made and use, [***], Program Compounds directed against such Target under any Anticalin Technology Improvement IP which Sanofi has agreed [***]. If Sanofi has so agreed such Anticalin Technology Improvement IP shall become part of Pieris Licensed IP at no additional costs for Sanofi other than the financial terms set forth herein.

(c) an exclusive license ([***]) to develop, have developed, make, have made, use, sell, have sold, offer for sale, have offered for sale, import and have imported one or more Licensed Compound(s) and/or one or more Licensed Products directed against such Target.

The above license shall become non-exclusive on [***] basis at the end of the relevant Royalty Term, as set forth in Section 5.8.

6.3.2 Right to Sublicense.

(a) To Affiliates and Service Providers. Sanofi shall have the right to sublicense the rights granted to Sanofi under Section 6.3.1(c) above to (i) any subcontractor or other service provider of Sanofi, but only for the purpose of performing services on behalf or for the benefit of Sanofi, or (ii) any Sanofi Affiliate.

(b) To Other Parties. In addition, Sanofi shall be permitted to sublicense the rights granted to Sanofi under Section 6.3.1(c) above to any other Third Party (the "Sublicensee"), provided that the Sublicensee has committed in writing to Sanofi to assume (i) [***] in relation to its development of Licensed Compound(s) and/or Licensed Product(s) to which the sublicense relates (ii) [***] in relation to the Pieris Licensed IP to which the sublicense relates.

(c) [***]. For the avoidance of doubt, [***] hereunder [***] under this Agreement [***] set forth in [***].

(d) Notice to Pieris. Upon entering into any sublicense permitted under sub-section (b) above, Sanofi shall deliver written notice thereof to Pieris along with a redacted copy of the sublicense agreement, for the sole purpose of revealing the terms required to show Sanofi's compliance with the conditions set forth in sub-section (b) above.

6.3.3 No Implied Licenses. No rights or licenses with respect to any Intellectual Property owned or Controlled by either Party are granted or shall be deemed granted hereunder or in connection herewith, other than those rights expressly granted in this Agreement. Sanofi expressly agrees not to use any of the Pieris Licensed IP outside of the license granted under Section 6.3.1 above and Pieris agrees not to use any of the Sanofi Intellectual Property for any other purpose than conducting Phase A hereunder.

6.4 Patent Matters.

6.4.1 Technology owned by Pieris. Subject to Section 6.4.3, Pieris shall have the right (but not the obligation), at its sole expense and sole discretion, to control the preparation, filing, prosecution, maintenance and enforcement of all Patent Rights applicable to all technology owned by Pieris under Section 6.1.1.

6.4.2 Technology Owned by Sanofi. Subject to Section 6.4.3, Sanofi shall have the right (but not the obligation), at its sole expense and sole discretion, to control the preparation, filing, prosecution, maintenance and enforcement of all Patent Rights applicable to all technology owned by Sanofi under Section 6.2.1.

6.4.3 Prosecution and Enforcement of Pieris Foreground IP and Sanofi Foreground IP.

(a) Prosecution.

(i) The Parties will discuss in good faith and mutually agree on the best strategy for the prosecution of Patent Rights for Pieris Foreground IP and its use.

(ii) Unless otherwise agreed between the Parties, Pieris shall have the first right (but not the obligation) to control the preparation, filing, prosecution and maintenance of all Patent Rights relating to Pieris Foreground IP. Pieris shall (a) provide Sanofi with written notice in advance of undertaking to prepare, file, prosecute and maintain any patent application or patents for any of such Patent Rights, (b) provide Sanofi with any draft of patent application to be filed by Pieris in advance of filing and incorporate reasonable comments by Sanofi thereon; (c) provide Sanofi with any patent application filed by Pieris after such filing; (d) provide Sanofi with copies of all substantive communications received from or filed in patent office(s) with respect to such filings and incorporate reasonable comments by Sanofi thereon; and (e) notify Sanofi of any interference, opposition, reexamination request, nullity proceeding, appeal or other interparty action, review it with Sanofi as reasonably requested, and incorporate reasonable comments by Sanofi thereon. Sanofi shall reimburse Pieris for [***] all reasonable external costs and expenses incurred by Pieris in connection with the preparation, filing, prosecution and maintenance of all Patent Rights relating to Pieris Foreground IP (as documented by invoices) ***other than*** for the following activities, for which Sanofi shall have no reimbursement obligation: activities relating to the preparation, filing, prosecution and maintenance of (i) priority documents, (ii) applications filed under the Patent Cooperation Treaty, (iii) PCT regional and national stage filings [***] and (iv) [***]. Each Party shall cause its employees, agents or consultants, at its expense, to execute such documents and to take such other actions as reasonably necessary or appropriate to enable the Parties to prepare, file, prosecute and maintain such Patent Rights.

(iii) Pieris shall provide Sanofi with written notice (i) prior to abandoning any patent applications or patents covering any Patent Rights or (ii) after having decided not to file a patent application covering any Patent Rights, in both cases in a sufficient amount of time to allow Sanofi to take over the control of such patent applications or patents. In the event that Pieris provides Sanofi with such written notice prior to abandoning any such patent application or patent within such Patent Rights (or if Pieris decides not to file a patent application covering such Patent Rights), then Sanofi shall have the option, exercisable by delivery to Pieris of written notice thereof within [***] days thereafter, to assume the right (but not the obligation), at its sole expense and sole discretion, to control the preparation, filing, prosecution and maintenance of such patent application or patent. If Sanofi timely exercises such option, then with respect to such patent application or patent, (a) Sanofi shall thereafter assume the rights and obligations attributed to Pieris under the preceding paragraph and (b) such Patent Rights shall be thereafter owned by Sanofi. For the avoidance of doubt, such Patent Rights owned by Sanofi pursuant to this sub-section 6.4.3(a)(iii) shall thereafter be considered as Sanofi Patent Rights (and Sanofi Valid Patent Claims, as the case may be).

(iv) Unless otherwise agreed between the Parties, Sanofi shall have the first right (but not the obligation), at its sole expense, to control the

preparation, filing, prosecution and maintenance of all Patent Rights relating to Sanofi Foreground IP. With respect to such patent applications or patents, sub-sections (ii) and (iii) shall apply reciprocally *mutatis mutandis*.

(b) Enforcement Within Scope of Exclusive License.

(i) Sanofi shall have the first right (but not the obligation), at its sole expense and sole discretion, to control the enforcement or defense of Pieris Foreground IP and Sanofi Foreground IP, so long as Sanofi owns, or possesses a license under Section 6.3 under the respective Pieris Foreground IP and Sanofi Foreground IP. Prior to undertaking any such action to enforce such Patent Rights, Sanofi shall notify Pieris in writing. The Parties shall reasonably cooperate with each other in the planning and execution of any such action to enforce such Patent Rights (including the obligation to be named or joined as a party in a lawsuit, as applicable), provided that Sanofi shall reimburse to Pieris all costs incurred by Pieris in connection with such enforcement action. All monies recovered upon the final judgment or settlement of any such suit or action to enforce such Patent Rights shall be applied in the following order of priority: (x) first, the Parties shall be reimbursed for all costs incurred in connection with such suit or action paid by the Parties and not otherwise recovered; and (y) thereafter, any remainder shall be shared between the Parties as follows: [***] percent ([***]%) to Sanofi and [***] percent ([***]%) to Pieris. In the event that Sanofi does not wish to enforce such Patent Rights against such a potential infringer, then Sanofi shall deliver prompt written notice thereof to Pieris. For the avoidance of doubt, [***].

(ii) In the event that Sanofi delivers to Pieris written notice described in the previous paragraph that Sanofi does not wish to enforce such Patent Rights against such a potential infringer, then Pieris shall have the option to assume the right (but not the obligation), at its sole expense and sole discretion, to control such enforcement of such Patent Rights against such infringer. If Pieris timely exercises such option, then (x) Pieris shall thereafter assume the rights and obligations attributed to Sanofi under the preceding paragraph, and (y) Sanofi shall thereafter assume the rights and obligations attributed to Pieris under the preceding paragraph.

6.4.4 Notice to Pieris Regarding Licensed Products. Upon request by Pieris (which shall be permitted no more than once per calendar year), Sanofi shall inform Pieris about the status of its preparation, filing, prosecution and maintenance of Patent Rights of any Sanofi Party relating to the Licensed Product(s).

6.4.5 Cooperation. Each Party agrees to cooperate with, and perform such lawful acts and execute such documents in order to reasonably assist, the other Party with respect to the preparation, filing, prosecution, defense, enforcement and maintenance of Patent Rights pursuant to this Section 6.4. Furthermore, the Parties shall cooperate with each other in gaining patent term extensions wherever applicable to any of the Foreground IP.

SECTION 7
NON-COMPETITION AND RESTRICTIONS

7.1 Restrictions on Pieris.

7.1.1 Target Exclusivity. To the extent permitted by applicable law, during the Program Term of any Program, Pieris shall not apply its Anticalin Technology to perform any research or development activities for its own benefit or with or for the benefit of any Third Party on the Target to which the relevant Program relates.

7.1.2 [***] Program Exclusivity. In addition, and to the extent permitted by applicable law, with respect to [***] Programs [***], Pieris shall not pursue any research or development activities for its own benefit or with or for the benefit of any Third Party, nor grant any rights to any Third Party, in relation to any Anticalin [***] (i) [***] to which [***] Program relates or (ii) [***]. The obligation of this Section 7.1.2 shall apply from the initiation of Phase A of the relevant [***] Program until the earlier of (i) the termination of such I [***] Program, (ii) Sanofi's decision not to enter into Phase B of such [***] Program, and (iii) [***] months from the decision by Sanofi to enter into Phase B with respect to such [***] Program.

7.1.3 [***]. To the extent permitted by applicable law, during the Program Term of any Program, Pieris shall not pursue any research or development activities for its own benefit or with or for the benefit of any Third Party, nor grant any rights to any Third Party, [***].

7.1.4 [***]. To the extent [***], to the extent [***].

7.2 Injunctive Relief. Pieris acknowledges that money damages alone would not adequately compensate Sanofi in the event of any breach by Pieris of Section 7.1, and that, in addition to all other remedies available to Sanofi under this Agreement or at law, Sanofi shall be entitled to seek injunctive relief for the enforcement of its rights under Section 7.1.

SECTION 8
CONFIDENTIALITY AND PUBLICITY

8.1 Confidential Information. During the term of this Agreement and for a period of [***] years after any termination or expiration thereof, each Party agrees to keep in confidence and not to disclose to any Third Party, or use for any purpose, except pursuant to, and in order to carry out, the terms and objectives of this Agreement, any Confidential Information of the other Party. As used herein, "Confidential Information" shall mean all trade secrets or confidential or proprietary information designated as such in writing by the disclosing Party, whether by letter or by the use of an appropriate stamp or legend, prior to or at the time any such trade secret or confidential or proprietary information is disclosed by the disclosing Party to the receiving Party. Notwithstanding the foregoing, information which is orally or visually disclosed to the receiving Party by the disclosing Party, or is disclosed in writing without an appropriate letter, stamp or legend, shall constitute Confidential Information if (i) it would be obvious to a reasonable person, familiar with the disclosing Party's activities and the industry in which it operates, that such information is of a confidential or proprietary nature, or if (ii) the disclosing Party, within [***] days after such disclosure, delivers to the receiving Party a written document or documents describing such information and referencing the place and date of such oral, visual or written disclosure and, if possible, the names of the employees or officers of the receiving Party to whom such disclosure was made. The restrictions on the disclosure and use of Confidential Information set forth in the first sentence of this Section 8.1 shall not apply to any Confidential Information that:

(a) was known by the receiving Party (or any of its Affiliates) prior to disclosure by the disclosing Party hereunder (as evidenced by the receiving Party's written records); or

(b) becomes part of the public domain through no fault of the receiving Party; or

(c) is disclosed to the receiving Party (or any of its Affiliates) by a Third Party having a legal right to make such a disclosure without violating any confidentiality or non-use obligation that such Third Party has to the disclosing Party; or

(d) is independently developed by the receiving Party (or any of its Affiliates) (as evidenced by the receiving Party's written records).

Notwithstanding the obligations of confidentiality and non-use set forth above, a receiving Party may provide Confidential Information disclosed to it to (i) governmental or other Regulatory Authorities in order to obtain, maintain or defend patents or to gain or maintain approval to conduct clinical studies or to otherwise develop, manufacture or commercialize a Licensed Product; provided, that such disclosure shall be subject to the prior written consent of the Party whose Confidential Information is intended to be disclosed (which consent shall not be unreasonably withheld or delayed), and such Confidential Information shall be disclosed only to the extent reasonably necessary to obtain, maintain or defend patents or authorizations, (ii) the extent required by applicable law, including without limitation by the rules or regulations of the United States Securities and Exchange Commission or similar regulatory agency in a country other than the United States or of any stock exchange or listing entity, (iii) any bona fide actual or prospective underwriters, investors, lenders or other financing sources or bona fide actual or prospective collaborators or strategic partners who are obligated to keep such information confidential, to the extent reasonably necessary to enable such actual or prospective underwriters, investors, lenders or other financing sources or collaborators to determine their interest in underwriting or making an investment in, or otherwise providing financing to, or collaborating with the receiving Party and (iv) consultants and advisors, subject to Section 8.2. In addition, if either Party is required to disclose Confidential Information of the other Party by regulation, law or legal process, including without limitation by the rules or regulations of the United States Securities and Exchange Commission or similar agency or other governmental or administrative body in a country or region other than the United States or of any stock exchange or listing entity, such Party shall provide prior notice of such intended disclosure to such other Party if practicable under the circumstances and shall disclose only such Confidential Information of such other Party as is required to be disclosed.

8.2 Employee, Consultant and Advisor Obligations. Each Party agrees that it and its Affiliates shall provide or permit access to Confidential Information received from the other Party only to the receiving Party's employees, consultants, advisors and permitted subcontractors who have a need to know such Confidential Information to assist the receiving Party with the development, manufacturing and/or commercialization of a Licensed Compound and/or Licensed Product and the activities contemplated by this Agreement and who are subject to obligations of confidentiality and non-use with respect to such Confidential Information similar to the obligations of confidentiality and non-use of the receiving Party pursuant to Section 8.1; provided, that Pieris and Sanofi shall each remain responsible for any failure by its Affiliates, and its Affiliates' respective employees, consultants, advisors and permitted

subcontractors, Sublicensees and distributors, to treat such Confidential Information as required under Section 8.1 (as if such Affiliates, employees, consultants, advisors and permitted subcontractors, Sublicensees and distributors were Parties directly bound to the requirements of Section 8.1).

8.3 Injunctive Relief. The Parties acknowledge that money damages alone would not adequately compensate the disclosing Party in the event of a breach by the receiving Party of this Section 8, and that, in addition to all other remedies available to the disclosing Party at law or in equity, it shall be entitled to seek injunctive relief for the enforcement of its rights under this Section 8.

8.4 Liability. A Party shall be liable for a breach of the obligations of this Section 8 by an Affiliate, Sublicensee, director, officer, employee, consultant or agent of such Party.

8.5 Return of Confidential Information. Upon termination or expiration of any Program or this Agreement, upon the request of the disclosing Party, the receiving Party shall promptly return to the disclosing Party or destroy the disclosing Party's Confidential Information, including all copies thereof, except to the extent that retention of such Confidential Information is reasonably necessary for the receiving Party to exploit any continuing rights it may have (in particular the rights under Section 12.4) and/or to fulfill its obligations contemplated herein, including its obligations of non-disclosure and non-use hereunder. Any such destruction requested by the disclosing Party shall be certified in writing to the disclosing Party by an authorized officer of the receiving Party. The return and/or destruction of such Confidential Information as provided above shall not relieve the receiving Party of its obligations under this Agreement.

8.6 Publicity. No public announcement or other disclosures concerning the terms of this Agreement shall be made to a Third Party, whether directly or indirectly, by either Party (except confidential disclosures to those parties described in Section 8.1 and 8.2) without first obtaining the written approval of the other Party and agreement upon the nature and text of such announcement or disclosure except that: (i) a Party may disclose those terms which it is required by regulation or law to disclose, provided that it takes advantage of all provisions to keep confidential as many terms as possible; and (ii) a Party desiring to make such public announcement or other public disclosure shall obtain the consent of the other Party to the proposed announcement or public disclosure prior to public release. Each Party agrees that it shall cooperate fully with the other with respect to all disclosures regarding this Agreement as required under the regulations of the U.S. Securities and Exchange Commission, applicable stock exchanges, NASDAQ and any other comparable foreign body including requests for confidential information or proprietary information of either Party included in any such disclosure. Sanofi agrees that Pieris may include Sanofi on a list of Pieris licensees. Pieris agrees that Sanofi and any Sanofi Party may state that they are licensed under the rights hereunder. The Parties agree to release a mutually agreeable press release within [***] days of executing this Agreement (for the avoidance of doubt, the Parties will not issue a joint press release but each Party will have the option but not the obligation to issue a press release it being understood that should either Party so decides, it will comply to such mutually agreeable content and such timeline).

8.7 Publication. In the event that either Party (the "Publishing Party") wishes to publish, in oral or written form, any Confidential Information of the other Party (the "Non-Publishing Party"), such Publishing Party will promptly notify the Non-Publishing Party and provide the Non-Publishing Party with a written copy of the proposed publication prior to its submission for publication. At the Non-Publishing Party's request, the Publishing Party will delay publication in order to permit the Non-Publishing Party to take the steps necessary to secure any Intellectual Property arising from the Publishing Party's use of Confidential Information, including the filing of one or more patent applications. In no event will such delay exceed [***] days from the date the Non-Publishing Party receives a written copy of the proposed publication. If the Non-Publishing Party makes such a request, the Publishing Party agrees to cooperate with the Non-Publishing Party in securing such Intellectual Property using the Non-Publishing Party's choice of counsel and the Non-Publishing Party will bear all costs of such patent filing. No patent application describing an invention resulting from the Publishing Party's use of Confidential Information will be filed or caused to be filed by the Publishing Party without first notifying the Non-Publishing Party as described above for proposed publications. Any publication or patent application will acknowledge the Non-Publishing Party's contribution. No publication or patent application will disclose any Confidential Information of a Party without the prior written permission of that Party.

SECTION 9
REPRESENTATIONS AND WARRANTIES

9.1 Mutual Representations. Each Party hereby represents and warrants to the other Party that as of the Effective Date, it has full corporate right, power and authority to enter into this Agreement, to grant the rights it grants to the other Party and to perform its respective obligations under this Agreement.

9.2 No Conflict. Each Party hereby represents and warrants to the other Party that, notwithstanding anything to the contrary in this Agreement, the execution and delivery of this Agreement by such Party, the performance of such Party's obligations hereunder and the licenses and sublicenses to be granted by such Party pursuant to this Agreement (a) to the best of its knowledge, do not conflict with or violate any requirement of any laws, rules or regulations existing as of the Effective Date and applicable to such Party and (b) do not conflict with, violate, breach or constitute a default under any contractual obligations of such Party or any of its Affiliates existing as of the Effective Date.

9.3 Disclaimer of Warranties. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH HEREIN, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, TO THE OTHER PARTY, AND EACH PARTY HEREBY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY AND ENFORCEABILITY OF ANY PATENT LICENSED HEREUNDER, AND NONINFRINGEMENT WITH RESPECT TO THE PROGRAM COMPOUNDS AND

LICENSED PRODUCTS. EACH PARTY HEREBY DISCLAIMS ANY REPRESENTATION OR WARRANTY THAT THE DEVELOPMENT, MANUFACTURE AND COMMERCIALIZATION OF THE PROGRAM COMPOUNDS OR LICENSED PRODUCTS PURSUANT TO THIS AGREEMENT WILL BE SUCCESSFUL.

9.4 Representations and Warranties of Pieris. Pieris represents and warrants to Sanofi, as of the Effective Date that:

9.4.1 It owns or Controls sufficient right, title and interest in the Pieris Background Patent Rights and the Pieris Background Know-How to enter into this Agreement and to grant the rights granted to Sanofi hereunder. For the avoidance of doubt, the existence of any Third Party intellectual property rights that may be infringed by the use or exploitation of the Pieris Background Patent Rights and/or the Pieris Background Know-How shall not constitute a violation of this warranty.

9.4.2 The Pieris Background Patent Rights have been filed in good faith, have been and are being reasonably prosecuted, no official deadlines with respect to the prosecution thereof have been missed and no fees due and owing remain unpaid with respect thereto.

9.4.3 The Pieris Background Patent Rights and Pieris Background Know-How are free and clear of all encumbrances or liens that would restrict Sanofi's rights as granted under this Agreement or use thereof as otherwise permitted under this Agreement. For the avoidance of doubt, the existence of any Third Party intellectual property rights that may be infringed by the use or exploitation of the Pieris Background Patent Rights and/or the Pieris Background Know-How shall not constitute a violation of this warranty.

9.4.4 To Pieris' best knowledge, Pieris has taken reasonable measures to protect the confidentiality or the Pieris Background Know-How and no event has occurred which has resulted in the unauthorized disclosure by Pieris or its personnel or consultants or subcontractors of any part of the Pieris Background Know-How of which otherwise resulted in any part of the Pieris Background Know-How falling in the public domain or becoming public knowledge.

9.4.5 Pieris has received no notice which claims that the use or exploitation of the Pieris Background IP infringes any Patent Rights or other intellectual property rights of any Third Party. To the knowledge of Pieris, the general operation or use of the Pieris Background IP does not infringe any Third Party Patent Rights and does not misappropriate any Third Party Know-How.

9.4.6 To the knowledge of Pieris, none of the Pieris Patent Rights is infringed by any Third Party.

SECTION 10
INDEMNIFICATION AND LIABILITY

10.1 Indemnification.

(a) By Sanofi. Sanofi will defend, indemnify and hold harmless Pieris, its Affiliates and their respective directors, officers, employees and agents (the "Pieris Indemnified Parties") from and against all claims, demands, liabilities, damages, penalties, fines, costs and expenses, including reasonable attorneys' and expert fees and costs, and costs or amounts paid to settle (subject to Section 10.1(c)(v) (collectively, "Losses"), arising from or occurring as a result of a Third Party's claim (including any Third Party product liability or infringement claim), action, suit, judgment or settlement to the extent such Losses are due to or based upon:

(i) the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions or violations of applicable law or regulation by or of Sanofi, its Affiliates, Sublicensees, wholesale distributors, contractors or their respective directors, officers, employees or agents in connection with the development, manufacture or commercialization of any Licensed Product by Sanofi, a Sanofi Party, wholesale distributors or contractors; or

(ii) the material breach by Sanofi of the terms of, or the material inaccuracy of any representation or warranty made by it in, this Agreement; or

(iii) any claim or allegation that any Licensed Compound and/or Licensed Product may infringe any Third Party intellectual property rights, except if such infringement is solely due to the use of Pieris Background IP; or

(iv) development, manufacture or commercialization of any Licensed Product by Sanofi or a Sanofi Party, wholesale distributors or contractors, except to the extent that such Losses arise out of, and are allocable to, the gross negligence, recklessness, bad faith, intentional wrongful acts, omissions or violations of law or breach of this Agreement committed by the Pieris Indemnified Parties.

(b) By Pieris. Pieris will defend, indemnify and hold harmless Sanofi, any Sanofi Party, wholesale distributors, contractors and their respective directors, officers, employees and agents (the "Sanofi Indemnified Parties") from and against all Losses arising from or occurring as a result of a Third Party's claim, action, suit, judgment or settlement (subject to Section 10.1(c)(v) below) that is due to or based upon the material breach by Pieris of the terms of, or the material inaccuracy of any representation or warranty made by it in, this Agreement.

(c) Claims for Indemnification.

(i) A person entitled to indemnification under this Section 10.1 (an "Indemnified Party") shall give prompt written notification to the person from whom indemnification is sought (the "Indemnifying Party") of the commencement of any action, suit or proceeding relating to a Third Party claim for which indemnification may be sought or, if earlier, upon the assertion of any such claim by a Third Party (it being understood and agreed, that the failure by an Indemnified Party to give notice of a Third Party claim as provided in this Section 10.1 shall relieve the Indemnifying Party of its indemnification obligation under this Agreement unless the Indemnified Party can demonstrate that such failure to give notice has not resulted in any prejudice to the Indemnifying Party).

(ii) Within thirty (30) days after receipt of such notification, the Indemnifying Party may, upon written notice thereof to the Indemnified Party, assume control of the defense of such action, suit, proceeding or claim with counsel of its choice. If the Indemnifying Party does not assume control of such defense, the Indemnified Party shall control such defense.

(iii) The Party not controlling such defense may participate therein at its own expense; provided, that if the Indemnifying Party assumes control of such defense and the Indemnified Party reasonably concludes, based on advice from counsel, that the Indemnifying Party and the Indemnified Party have conflicting interests with respect to such action, suit, proceeding or claim, the Indemnifying Party shall be responsible for the reasonable fees and expenses of counsel to the Indemnified Party solely in connection with the matter raising a conflict of interest between the Indemnifying Party and the Indemnified Party; provided further, however, that in no event shall the Indemnifying Party be responsible for the fees and expenses of more than one (1) counsel in any one (1) jurisdiction for all Indemnified Parties.

(iv) The Party controlling such defense shall keep the other Party advised of the status of such action, suit, proceeding or claim and the defense thereof and shall consider reasonable recommendations made by the other Party with respect thereto.

(v) The Indemnified Party shall not agree to any settlement of such action, suit, proceeding or claim without the prior written consent of the Indemnifying Party, which shall not be unreasonably withheld. The Indemnifying Party shall not agree to any settlement of such action, suit, proceeding or claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Indemnified Party from all liability with respect thereto or that imposes any liability or obligation on the Indemnified Party without the prior written consent of the Indemnified Party.

10.2 Limitation of Liability. IN NO EVENT SHALL EITHER PARTY BE LIABLE OR OBLIGATED TO THE OTHER PARTY IN ANY MANNER FOR ANY SPECIAL, NON-COMPENSATORY, CONSEQUENTIAL, INDIRECT, INCIDENTAL, STATUTORY OR PUNITIVE DAMAGES OF ANY KIND, INCLUDING, WITHOUT LIMITATION, LOST PROFITS AND LOST REVENUE, REGARDLESS OF THE FORM OF ACTION, WHETHER IN CONTRACT, TORT, NEGLIGENCE, STRICT PRODUCT LIABILITY, OR OTHERWISE, EVEN IF INFORMED OF OR AWARE OF THE POSSIBILITY OF ANY SUCH DAMAGES IN ADVANCE. THE LIMITATIONS SET FORTH ABOVE SHALL BE DEEMED TO APPLY TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW AND NOTWITHSTANDING THE FAILURE OF THE ESSENTIAL PURPOSE OF ANY LIMITED REMEDIES. THE PARTIES ACKNOWLEDGE AND AGREE THAT THEY HAVE FULLY CONSIDERED THE FOREGOING ALLOCATION OF RISK AND FIND IT REASONABLE, AND THAT THE FOREGOING LIMITATIONS ARE AN ESSENTIAL BASIS OF THE BARGAIN BETWEEN THE PARTIES. The above limitation of liability shall not apply to the

indemnifications set forth in Section 10.1 and any breach of Section 8 ("CONFIDENTIALITY").

10.3 Insurance. Each Party shall maintain, and shall require its Affiliates and Sublicensees hereunder to maintain, a commercial general liability and, as regards Sanofi only, a product liability insurance program on terms customary in the pharmaceutical and biopharmaceutical industry covering all activities and obligations of it, and, as the case may be, its Affiliates, hereunder, or other insurance programs with comparable coverage, up to and beyond the expiration or termination of this Agreement and a commercially reasonable period thereafter.

SECTION 11
PROJECT MANAGEMENT

11.1 Steering Committee.

11.1.1 Composition. Within [***] days following the Effective Date, the Parties shall establish a steering committee (the "Steering Committee"). The Steering Committee shall have a total of [***] members. [***] of the Steering Committee members shall be appointed by Sanofi, and [***] members of the Steering Committee shall be appointed by Pieris. [***]. Each Steering Committee member shall have sufficient authority to ensure acceptance and execution of Steering Committee decisions within its organization. Each Party may appoint substitutes or alternates for its Steering Committee members at any time by written notice the other Party.

11.1.2 Responsibility of Steering Committee. The responsibilities of the Steering Committee in relation to each Program shall depend on the status of the relevant Program:

(a) During the time period from the initiation of a Program until the end of Phase A for that Program, the Steering Committee shall be responsible for:

(i) Planning, approving and monitoring each Program Plan, and making necessary updates thereof.

(ii) Monitoring workflow, including experimental sample transfer, sample throughput, sample analysis and data quality control, data analysis and summarization, and overall research progress;

(iii) Monitoring budgets and timelines; and

(iv) Assigning tasks and responsibilities, taking into account each Party's respective specific capabilities and expertise in order to avoid duplication and to enhance efficiency and synergies.

(b) During the time between [***] and commencement [***], the Steering Committee shall be responsible for reviewing and approving the Development Plan for each Program and following its implementation and progress.

(c) Thereafter, the Steering Committee shall only have an informatory role in relation to such Program and only be responsible for exchanging information and strategies regarding the further research, development and commercialization of Licensed Products under the relevant Program.

11.1.3 Meetings.

(a) For as long as at least one Program is both active and has not reached a Phase I Clinical Trial, the Steering Committee shall meet at least quarterly. At least [***] of such meetings [***] shall be face-to-face, alternating between Pieris' facilities and Sanofi's facilities, or as otherwise determined by the Steering Committee. The remaining meetings may be conducted by telephone or video conference, unless one Party requests otherwise. Any additional meetings shall be held at places and on dates selected by the Steering Committee.

(b) Following the expiration of the time period described in the preceding paragraph, the Steering Committee meetings shall be scheduled from time to time by mutual agreement of the Parties, but in no event less than once per half-year. For all meetings, the Steering Committee may meet in person or by telephone or video conference.

(c) Within [***] days following each Steering Committee meeting, the Parties shall prepare in an alternating fashion and distribute reasonably detailed written minutes of such meeting for approval by the other Party, which minutes shall constitute Confidential Information of each Party.

11.1.4 Quorum and Decisions. At each Steering Committee meeting, at least [***] members appointed by each Party present in person or by telephone or video conference shall constitute a quorum. Decisions of the Steering Committee shall be made by consensus. In the event of a deadlock, [***] shall have the [***] shall have the [***] and provided further that [***] set forth in [***]. Unless explicitly set forth otherwise in this Agreement, [***] of this Agreement.

11.1.5 Reporting to Steering Committee. The Parties agree that the successful execution of the collaboration under this Agreement will require the collaborative use of each Party's area of expertise. The Parties shall report to the Steering Committee the status of the portions of the Program they respectively perform in a timely manner.

11.1.6 Duration of Steering Committee. The provisions relating to the Steering Committee under this Section 11.1 shall remain in effect only for so long as Sanofi's diligence obligations set forth in Section 4.2 remain in effect, and shall terminate upon the end of Sanofi's diligence obligation as set forth in Section 4.2.

11.2 Program Managers. Each Party shall appoint a person (a "Program Manager") for each Program to coordinate its part of the activities under such Program. The Program Managers shall be the primary contacts between the Parties with respect to all research and development activities performed under the relevant Program. Either Party may change its Program Manager upon written notice to the other Party. A Program manager may be a member of the Steering Committee.

SECTION 12
TERM AND TERMINATION

12.1 Agreement Term. Except as otherwise specified in this Agreement, the Parties' respective rights and obligations under this Agreement shall commence on the Effective Date and shall end upon the earlier of (i) expiration of all payment and related obligations of Sanofi under Section 5, and (ii) any termination of this Agreement in accordance with Section 12.3.5 below.

12.2 Program Term. Each Program shall commence upon the execution of the relevant Program Plan and shall end upon the earlier of (i) Sanofi's decision not to enter into Phase B of such Program as set forth in Section 4.1 and (ii) any termination of such Program in accordance with Section 12.3, and (iii) the expiration of the Royalty Term for the corresponding Licensed Product under such Program (the "Program Term").

12.3 Termination.

12.3.1 Termination for Convenience by Sanofi. Sanofi shall have the right to terminate any or all Programs at any time after the Effective Date on [***] days prior written notice to Pieris [***].

12.3.2 Termination for Breach. Subject to Section 4.5 in relation to Sanofi's failure to comply with its diligence obligations, either Party shall be entitled to terminate any Program(s) by written notice to the other with immediate effect if the other Party breaches any of its material obligations under this Agreement in relation to such Program(s) and fails to cure such breach within [***] days following its receipt of written notice thereof from the terminating Party if such breach is curable within the aforesaid period; ***provided, however,*** prior to giving any notice for breach, the Parties shall first attempt to resolve any disputes as to the existence of any breach as set forth in Section 13.3.

12.3.3 Termination for Insolvency. Either Party may terminate any or all Programs under this Agreement by written notice to the other with immediate effect if the other Party becomes insolvent, is compelled to file bankruptcy or is determined otherwise imminently subject to control by a bankruptcy trustee or its equivalent pursuant to the laws of the jurisdiction in which such Party is doing business.

12.3.4 Termination of Licenses for Challenges of Patent Rights. If a Sanofi Party (i) commences or participates in any action or proceeding (including, without limitation, any patent opposition or re-examination proceeding), or otherwise asserts in writing any claim, challenging or denying the validity of any of the Patent Rights licensed to Sanofi hereunder, or any claim thereof or (ii) actively assists any other Person in bringing or prosecuting any action or proceeding (including, without limitation, any patent opposition or re-examination proceeding) challenging or denying the validity of any of such Patent Rights or any claim thereof (each, a "Challenge"), then such Challenge shall constitute a material breach of the Agreement and Pieris will have the right to give warning notice to Sanofi (which notice must be given, if at all, within sixty (60) days after Pieris first learns of the foregoing) under Section 12.3.2, and, unless the Sanofi Party withdraws or causes to be withdrawn all such Challenge(s) within the sixty (60) day period set forth in 12.3.2, Pieris shall have the right to terminate this Agreement forthwith.

12.3.5 Termination of Agreement. Any termination of the last Program pursued under this Agreement shall constitute a termination of this Agreement.

12.4 Effect of Termination or Expiration of Programs or Agreement. In case of any termination or expiration of any Program(s), all rights and obligations of the Parties shall cease immediately with respect to the relevant Program(s) only, as applicable, unless otherwise indicated in this Section below or elsewhere in this Agreement. Upon expiration (but, for the avoidance of doubt, not termination) of the Agreement Sanofi shall be entitled to continue to exploit Licensed Products in its discretion without any payment to Pieris.

12.4.1 Obligations Accrued. Expiration or termination of this Agreement or termination of any Program shall not relieve the Parties of any obligation accruing prior to such expiration or termination.

12.4.2 Survival. The provisions of Sections 5.10.3, 5.10.4, 5.10.7, 6.1, 6.2, Section 8, Section 9, Section 10, 12.5 and Section 13 shall survive any termination of any Program or termination or expiration of this Agreement.

12.5 Transfer of Terminated Program Under Certain Circumstances. If any Program is terminated (i) by Pieris in accordance with Section 12.3.2 (termination for breach by Sanofi), or (ii) by Sanofi in accordance with Section 12.3.1 (termination for convenience) (such Program hereinafter referred to as the "Terminated Program"), the following terms and conditions shall apply in relation to the Terminated Program:

12.5.1 Sanofi shall as promptly as practicable transfer to Pieris or Pieris' designee (i) possession and ownership of all material governmental or regulatory correspondence, filings and approvals (including all Marketing Authorizations) relating to the development, manufacture or commercialization of all Licensed Products under the Terminated Program, (ii) copies of all data, reports, records and materials in Sanofi's possession or control relating to the development, manufacturing or commercialization of all Licensed Products under such Program, including all non-clinical and clinical data relating to any Licensed Products (provided that in relation to data, reports, records and materials which are required by Pieris to establish the manufacturing of the Licensed Product, this obligation shall only apply to the extent that Sanofi does not continue to manufacture and supply the relevant Licensed Product in accordance with Section 12.5.4 below), and (iii) all records and materials in Sanofi's possession or control containing Confidential Information of Pieris relating to the Terminated Program.

12.5.2 Sanofi shall appoint Pieris as Sanofi's agent for all Licensed Product-related matters under the Terminated Program involving Regulatory Authorities until all Marketing Authorizations and other regulatory filings and approvals have been transferred to Pieris or its designee, it being agreed that both Parties shall use [***] to have this transfer occur as rapidly as feasible.

12.5.3 If [***], then Sanofi shall appoint Pieris as its exclusive distributor of such Licensed Product and grant Pieris the right to appoint sub-distributors, until such time as all Marketing Authorizations have been transferred to Pieris or its designee it being agreed that both Parties shall [***] have this transfer occur as rapidly as feasible.

12.5.4 If a Sanofi Party is manufacturing a Licensed Product under a Terminated Program, then at Pieris's option Sanofi shall supply such Licensed Product to Pieris at [***] or, if termination occurs [***], [***], until such time [***], and Pieris has procured or developed its own source of Licensed Product supply, provided that [***] and provided further that [***]. [***] agrees that notwithstanding the foregoing, [***], provided that [***].

12.5.5 Subject to Section 12.5.4, if Pieris so requests, Sanofi shall transfer to Pieris any Third Party agreement relating to the development, manufacture or commercialization of a Licensed Product under a Terminated Program, to which Sanofi is a party, provided that such Third Party agreement permits such a transfer (and Sanofi hereby covenants to [***] obtain consent from the concerned Third Party to such a transfer) and provided further that, in relation to agreements relating to the manufacture of Licensed Products, this obligation shall only apply to the extent that Sanofi does not continue to manufacture and supply the relevant Licensed Product in accordance with Section 12.5.4 above.

12.5.6 Sanofi shall (i) assign ownership of Intellectual Property that relate solely to the Licensed Product under a Terminated Program to Pieris, as such Intellectual Property is in existence on the date of termination of the Program and (ii) grant Pieris a non-exclusive right and license, with the right to grant sublicenses upon Sanofi's prior written consent which may not be unreasonably withheld or delayed (for the avoidance of doubt and by way of example and not limitation, [***]), under all other Sanofi Background IP related to that Terminated Program and all other Sanofi Foreground IP related to that Terminated Program, for the sole purpose of developing, manufacturing and commercializing any Program Compound(s) which has/have been the subject of the Terminated Program or any pharmaceutical product containing any such Program Compound(s) in the Field in the Territory, and for no other purpose. If any of Sanofi Background IP or Sanofi Foreground IP has been licensed from Third Parties, Sanofi will sublicense or assign its rights under such Intellectual Property only to the extent it is able to do so.

12.5.7 To the extent [***], the license granted pursuant to Section 12.5.6(ii) above shall be royalty-free, fully-paid and perpetual except for Intellectual Property licensed from Third Parties for which, to the extent Sanofi is able to sublicense or assign its rights, any obligation of Sanofi to the Third Party will be assumed by Pieris. In particular, Pieris will be responsible for any milestones and royalties obligations related to such Third Party Intellectual Property. To the extent [***], the license granted pursuant to Section 12.5.6(ii) above shall be subject to the following royalty payments to be made by Pieris to Sanofi on the Net Sales of pharmaceutical products containing one or more Program Compounds of the Terminated Product made by Pieris, its Affiliates, sublicensees or sublicensees' Affiliates (and the definition of "Net Sales" shall apply *mutatis mutandis* to such sales):

Time of Termination	**Royalty Rate**
[***]	[***]%
[***]	[***]%

[***]	[***]%
[***]	[***]%

The above royalty rates shall be [***] on a [***] basis in [***].

The above royalty shall be payable by Pieris to Sanofi on [***] and on a [***] basis for a period [***] under this Section 12.5.7:

Time of Termination	Maximum Aggregate Royalty Amount	
[***]	EUR	[***]
[***]	EUR	[***]
[***]	EUR	[***]

Sections 5.9 and 5.10 shall apply reciprocally to royalty payments by Pieris under this Section 12.5.7.

For the sake of clarity, any milestone and royalty payments [***] in accordance to the terms of such sublicense or assignment.

12.5.8 If Sanofi decides to no longer maintain any patent that is subject to such license, Sanofi shall notify Pieris thereof and Pieris shall have [***] days to notify Sanofi whether it is interested to have the concerned patent(s) assigned to Pieris or not and if Pieris fails to notify its interest Sanofi shall not be obligated to maintain the concerned patent and the license to Pieris shall be terminated as regards such patent(s).

12.5.9 Sanofi shall execute all documents and take all such further actions as may be reasonably requested by Pieris in order to give effect to the terms of this Section 12.5.

SECTION 13
GENERAL PROVISIONS

13.1 Notices. Any consent, notice or report required or permitted to be given or made under this Agreement by one of the Parties to the other shall be in writing and delivered through registered mail with acknowledgement of receipt, and addressed to such other Party at its address indicated below, or to such other address as the addressee shall have last furnished in writing to the addressor, and shall be effective upon receipt by the addressee.

If to Sanofi:

Sanofi Pasteur SA
2 avenue Pont Pasteur
69007 Lyon, France
Attention: General Counsel

Sanofi-Aventis
174 avenue de France
75013 Paris, France
Attention : Legal Operations
With a copy to: Licenses Administration

If to Pieris: Pieris AG
Lise-Meitner-Str. 30
85354 Freising, Germany
Attention: Chief Executive Officer

13.2 Applicable Law. This Agreement shall be governed by and construed in accordance with the laws of Germany, without regard to the conflicts of law principles thereof.

13.3 Dispute Resolution. The Parties recognize that disputes as to certain matters may from time to time arise which relate to either Party's rights and/or obligations hereunder. It is the intent and objective of the Parties to establish procedures to facilitate the resolution of such disputes in an expedient manner by mutual cooperation and without resort to litigation. Accordingly, any controversy or claim arising out of or relating to this Agreement, including any such controversy or claim involving Affiliates of any Party (each, a "Dispute"), shall be resolved as set forth in this Sections 13.3.

13.3.1 Escalation. Any Dispute shall be brought to the attention of a senior management representative of each Party, who shall attempt to resolve the Dispute in good faith. If, however, the senior management representatives of the Parties are unable to resolve a Dispute within [***] days of being requested by a Party to do so, the CEOs or presidents (or their respective designee, provided the designee has authority to resolve the Dispute) of the Parties shall attempt in good faith to promptly resolve such Dispute within thirty [***] days. If, following this subsequent thirty [***] day period, the Dispute remains unresolved, then, Sections 13.3.2-13.3.4 shall apply.

13.3.2 [***]. Following the process set forth in Section 13.3.1, any Dispute, other than Disputes which are specifically required to be decided by a neutral third party expert [***]. [***]

13.3.3 Attorneys Fees and Costs. Except as specifically provided in this Agreement, in the event of any dispute between the Parties arising out of or relating to this Agreement, the prevailing Party shall be entitled to recover from the unsuccessful Party all costs, expenses and actual attorneys' fees relating to or arising from (i) any litigation, arbitration or mediation relating to or arising from, this Agreement; and/or (ii) the enforcement of any judgment or award resulting from any such litigation, arbitration or mediation. Any such judgment or award shall contain a specific provision for the recovery of all costs, expenses and actual attorneys' fees incurred in enforcing any such judgment or award.

13.3.4 Third Party Expert Proceedings. In the event of a dispute on the fair market value [***] as set forth in Section 1.29, either Party may initiate the resolution procedure contained in this Section 13 by delivery of written notice to the other Party thereof. If a Party delivers such notice, then within [***] days after the other Party's receipt of such notice, the Parties shall either (i) discuss in good faith and agree upon a mutually acceptable independent expert to decide on the question in dispute, or (ii) if the Parties cannot reach such agreement within such [***] day period, then each Party shall designate one (1) independent expert within an additional period of [***] days, and a third (3rd) independent expert shall be appointed by the two (2) experts designated by the Parties. After the designation of the one (1) or three (3) (as applicable) experts, the Parties shall reasonably comply with the requests of such expert(s) with the objective of reaching a decision on the question in dispute within [***] days after such expert(s) have been designated. The conclusion of the one (1) expert designated, or the majority of the three (3) experts designated (as applicable), shall be binding upon the Parties. All costs and expenses of the third party experts shall be shared between the Parties. Each Party shall bear its own costs in connection with any such third party expert proceeding.

13.4 Assignment. Except as otherwise expressly provided under this Agreement, neither Party may assign or otherwise transfer this Agreement or any right or obligation hereunder (whether voluntarily, by operation of law or otherwise), without the prior express written consent of the other Party; ***provided however***, that (i) in the event a Party is acquired or is to be acquired by a third party by merger, acquisition, or the sale of substantially all of the assets of the division of such Party to which the subject matter of this Agreement relates, then such Party may effect such an assignment or transfer to such acquiring Third Party without the consent of the other Party, (ii) Sanofi shall be permitted to effect such an assignment or transfer to any of its Affiliates, without the consent of Pieris, and (iii) following the conclusion of Phase A for the last Program, Pieris shall be permitted to effect such an assignment or transfer to any of its Affiliates, with the consent of Sanofi which shall not be unreasonably withheld. Any purported assignment or transfer in violation of this Section 13.4 shall be null and void.

13.5 Severability. Each Party hereby agrees that it does not intend to violate any public policy, statutory or common laws, rules, regulations, treaty or decision of any government agency or executive body thereof of any country or community or association of countries. Should one or more provisions of this Agreement be or become invalid, the Parties hereto covenant and agree to renegotiate any such term, covenant or application thereof in good faith in order to provide a reasonably acceptable alternative to the term, covenant or condition of this Agreement or the application thereof that is invalid, illegal or unenforceable, said renegotiated term, covenant or condition being deemed to be effective as of the Effective Date, it being the intent of the Parties that the basic purposes of this Agreement and the economical balance between the Parties as contemplated upon the execution of the Agreement are to be effectuated as nearly as possible.

13.6 Headings. The captions to the sections hereof are not a part of this Agreement, but are merely guides or labels to assist in locating and reading the sections hereof.

13.7 Terminology. Unless otherwise expressly specified, all references to days, months, quarters, semesters, years and the like shall mean calendar days, months,

quarters, semesters, half-years or years and the words monthly, quarterly, annual or annually shall be considered as being references to calendar periods of time.

13.8 Independent Contractors. Nothing in this Agreement or in the course of business between Pieris and Sanofi shall make or constitute either Party a partner, employee, joint venturer or agent of the other. Neither Party shall have any right or authority to commit or legally obligate or bind the other in any way whatsoever including, without limitation, the making of any agreement, representation or warranty.

13.9 Waiver. The terms or conditions of this Agreement may be waived only by a written instrument executed by the Party waiving the benefit of a right hereunder. The waiver by a Party of any right hereunder shall not be deemed a continuing waiver of such right or of another right hereunder, whether of a similar nature or otherwise.

13.10 Modification. This Agreement (including the attached Exhibit(s) and this Section 13.10) shall not be amended or otherwise modified without a written document signed by a duly authorized representative of each Party. In the event that the terms of any Exhibit are inconsistent with the terms of this Agreement, this Agreement shall control, unless otherwise explicitly agreed to in writing by the Parties.

13.11 Entire Agreement. This Agreement (including the attached Exhibit(s)) contains the entire understanding of the Parties with respect to the subject matter hereof. All other express or implied representations, agreements and understandings with respect to the subject matter hereof, either oral or written, heretofore made are expressly superseded by this Agreement.

13.12 Counterparts; Facsimile. This Agreement may be executed in counterparts, each and every one of which shall be deemed an original and all of which together shall constitute one and the same instrument. Signing and delivery of this Agreement may be evidenced by an electronic transmission of the signed signature page to the other Party, provided however that such electronic signing and delivery is confirmed in written paper copy signed by and delivered to each Party promptly following electronic signing and delivery.

[Signatures continued on the following page]

IN WITNESS WHEREOF, the Parties have executed this Agreement in triplicate as of the Effective Date.

PIERIS AG

By: /s/ Stephen Yoder

Name: Stephen Yoder

Title: Chief Executive Officer

SANOFI-AVENTIS

By: /s/ Philippe Goupit

Name: Philippe Goupit

Title: Vice President, Corporate Licenses

SANOFI-PASTEUR SA

By: /s/ Wayne Pisano

Name: Wayne Pisano

Title: Chairman & Chief Executive Officer

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

CONFIDENTIAL TREATMENT REQUESTED

CONFIDENTIAL

EXHIBIT 1.3

ANTICALIN TECHNOLOGY

Technology appendix

Anticalin Technology shall mean Anticalin Libraries, Anticalin Selection, Anticalin Expression and Anticalin Half-life Extension methods
Anticalin Libraries shall mean [***]
Anticalin Selection shall mean [***].
Anticalin Expression shall mean [***]
Anticalin Half-life Extension shall mean [***]

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

CONFIDENTIAL TREATMENT REQUESTED

CONFIDENTIAL

EXHIBIT 1.10

DEVELOPMENT PLAN
GENERIC CHECKLIST FOR IND ENABLING STUDIES

[***]

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

EXHIBIT 1.39

PIERIS BACKGROUND PATENT RIGHTS as of the Effective Date

PCT/DE/98/02898	Anticalins, filed: 25.09.1998
PCT/EP02/10490	Muteins of Human Neutrophil Gelatinase-Associated Lipocalin and Related Proteins, filed: 18.09.2002
PCT/EP04/009447	Muteins of Tear Lipocalin, filed: 24.08.2004
PCT/EP07/057971	Muteins of Tear Lipocalin and Methods for Obtaining the Same, filed: 01.08.2007
PCT/EP09/057925*	Muteins of hNGAL and Related Proteins with affinity for a given Target, filed: 24.06.2009
US prov. 61/267,098	Muteins of Human Lipocalin 2 (Lcn2, hNGAL) with affinity for a given target, filed: 07.12.2009

*: owned by TUM, exclusive license to Pieris with right to grant sublicenses

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

CONFIDENTIAL TREATMENT REQUESTED

CONFIDENTIAL

EXHIBIT 1.45
PROGRAM PLANS FOR INITIAL PROGRAMS

[***]

[***]	**[***]**	**[***]**
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

[***]

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Success Criteria: Key defined Deliverables, Milestones and Decision points [***]

[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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Gantt chart for Phase A of [***]

[***]

[***]

[***]	**[***]**	**[***]**	**[***]**
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

[***]				**[***]**				**[***]**			
[***]	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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[***]

[***]	**[***]**	**[***]**
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

[***] **[***] Success Criteria:** key defined Deliverables, Milestones and Decision points [***] Key defined deliverables, milestones and decision points for SA1.1/1.3:

[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

[***] Key defined deliverables, milestones and decision points for SA1.2:

[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

[***] Gantt chart for Phase A of [***]

[***]

[***]

[***]	**[***]**	**[***]**	**[***]**
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

[***]				**[***]**				**[***]**			
[***]	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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EXHIBIT 2.1

Program and Section 6.3 License Request Form

(To be completed for each Program)

Target(s) requested pursuant to Section 2.1 of the COLLABORATION AND LICENSE AGREEMENT (define: by common name(s), accession number, and amino acid sequence, if possible):

SANOFI

By: _____

Name:

Title:

this day of ,

PIERIS

By: _____

Name:

Title:

this day of ,

Portions of the exhibit, indicated by the mark "[***],"* were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

CONFIDENTIAL TREATMENT REQUESTED

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EXHIBIT 2.6

Program Requests / Responses

[***]

Such programs being described in detail in Exhibit 1.45

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

CONFIDENTIAL TREATMENT REQUESTED

Collaboration Research and Technology Licensing Agreement

This Definitive Collaboration Research and Technology Licensing Agreement (this "Agreement") is effective as of May 31, 2011 (the "Effective Date"), and is entered into by and between

Pieris AG, having its office at Lise-Meitner Str. 30, 85354 Freising-Weihenstephan, Germany ("Pieris"), and

Daiichi Sankyo Company Limited, having its principal place of business at 3-5-1 Nihonbashi-honcho, Chuo-ku, Tokyo, 103-8426 Japan ("DS").

Pieris and DS are referred to herein individually as a "Party", and collectively "Parties".

RECITALS

WHEREAS, Pieris and DS desire to carry out certain research collaboration arrangements using Pieris' Anticalin Technology, and have agreed upon the basic terms for the collaboration in that certain Collaboration Research and Technology Licensing Agreement (the "Initial Agreement") executed by the Parties on the Initial Agreement Effective Date (as defined below).

WHEREAS, according to Section 12 of the Initial Agreement, the Parties agreed to execute a definitive agreement relating to their collaboration within sixty (60) days of the Initial Agreement Effective Date.

WHEREAS, this Agreement constitutes the definitive agreement contemplated by Section 12 of the Initial Agreement.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, Pieris and DS agree as follows:

1. DEFINITIONS

"Affiliate" shall mean, with respect to any person or entity, any other person or entity, which directly or indirectly controls, is controlled by, or is under common control with, such person or entity. A person or entity shall be regarded as in control of another person or entity if it owns, or directly or indirectly controls, more than fifty percent (50%) of the voting stock or other ownership interest of the other person or entity, or if it directly or indirectly possesses the power to direct or cause the direction of the management and policies of the other person or entity by any means whatsoever.

***Portions of the exhibit, indicated by the mark "[***],"* were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.**

"Anticalin" means, whether in nucleic acid or protein form, (i) any lipocalin mutein isolated from an Anticalin Library [***] that [***], or (ii) any lipocalin mutein that, in each case, has been derived (either physically, intellectually or by reverse engineering, in one (1) or more steps) from any lipocalin mutein referred to in Section (i) of this definition.

"Anticalin Library" shall have the meaning set forth in Exhibit B.

"Anticalin Technology" shall have the meaning set forth in Exhibit B.

"Background Technology" means (i) any intellectual property and know-how within Pieris' or DS' pre-existing technology existing as of the Initial Agreement Effective Date and which such Party has the right to license to the other Party as provided for herein; and (ii) any improvements to Pieris' Anticalin Library that has been generated or conceived by Pieris following the Initial Agreement Effective Date and which Pieris has the right to license to DS as provided for herein. For the avoidance of doubt, as of the Effective Date it is the Parties' understanding that the Patent Rights listed in Exhibit C will be the Patent Rights included in the Background Technology relevant for the collaboration under this Agreement.

"BLA/NDA" shall mean a Biologics License Application, New Drug Application, Product License Application or any similar application for marketing authorizations submitted to the FDA or any comparable application for marketing authorizations in any other country.

"Collaboration Research" means research and development activities carried out by or on behalf of Pieris and/or DS to identify or generate Project Compounds and/or Licensed Products in accordance with a Project Plan.

"Commercially Reasonable Efforts" means those efforts consistent with prudent business judgment devoting at least the same degree of attention and diligence to such efforts that DS devotes to such activities for its own products [***], provided that Commercially Reasonable Efforts shall be deemed not to have been met [***]. For the avoidance of doubt, [***] shall not constitute a factor to be taken into account in the determination of Commercially Reasonable Efforts.

"Confidential Information" is defined in Section 8.1.

"Development Milestone" means the success criteria defined for the Development Milestone payments set forth in Section 5.6.

"DS Foreground Technology" means any Foreground Technology [***].

"DS Target" means each of two (2) targets selected by DS and confirmed by Pieris as available for licensing to DS under this Agreement in accordance with Section 2.1. The first DS Target is listed on Exhibit D.

"Effective Date" is defined on the cover page of this Agreement.

"Foreground Technology" means any intellectual property, know-how and data generated or conceived by or on behalf of [***] from the activities under this Agreement and [***].

"Indication" means ([***]) those indications defined by [***] (e.g. [***]); and all indications [***] [***] (e.g [***]") shall be understood to belong to the same one Indication. The current online version of [***].

"Initial Agreement" is defined in the Preamble of this Agreement.

"Initial Agreement Effective Date" shall mean March 31, 2011.

"Joint Research Committee" or "JRC" means the committee established in accordance with Article 6.

"Licensed Product" means a product containing a Project Compound, which [***].

"Net Sales" shall mean the gross amount billed or invoiced by DS or any of its Affiliates or Sublicensees to third parties throughout the Territory for sales or other dispositions or transfers for value of Licensed Products less (a) allowances for normal and customary trade, quantity and cash discounts (including discounts imposed by way of wholesaler fees) actually allowed and taken, (b) transportation, insurance and postage charges, if prepaid by DS or any Affiliate or Sublicensee of DS and included on any such party's bill or invoice as a separate item, (c) credits, rebates, or returns pursuant to agreements (including, without limitation, managed care agreements) or government regulations, to the extent any of the foregoing is actually allowed, and (d) sales, use and other consumption taxes incurred, to the extent included on the bill or invoice as a separate item.

"Patent Right" means, with respect to any technology or product, (a) all patent applications heretofore or hereafter filed or having legal force in any country to the extent and only to the extent they claim or cover such technology or product or the use thereof (b) all patents that have issued or in the future issue from such applications, including without limitation utility model and design patents and certificates of invention and (c) all divisionals, continuations, continuations-in-part, supplemental protection certificates, re-issues, re-examinations, renewals, extensions or additions to any such patent applications or patents.

"Phase I Clinical Trial" shall mean any human clinical study in any country designed to evaluate the safety, tolerability and pharmacokinetics effect of a drug in volunteer subjects or patients that would satisfy the requirements of 21 US CFR 312.21(a), or other comparable regulation imposed by the FDA, the EMA, the MHLW or their foreign counterparts.

"Phase II Clinical Trial" shall mean any controlled human clinical study conducted to

evaluate the effectiveness of the drug for a particular indication in patients with the disease or condition under study and/or to determine the common short-term side effects and risks associated with a drug that would satisfy the requirements of 21 US CFR 312.21(b) or other comparable regulation imposed by the FDA, the EMA, the MHLW or their foreign counterparts.

"Phase III Clinical Trial" shall mean any expanded human clinical study intended to gather additional information about effectiveness and safety needed to evaluate the overall benefit-risk relationship of a drug for a particular indication that would satisfy the requirements of 21 US CFR 312.21(c) or other comparable regulation imposed by the FDA, the EMA, the MHLW or their foreign counterparts.

"Phase A" means, for each Program relating to a DS Target, the period [***].

"Phase B" means, for each Program relating to a DS Target, the period [***].

"Pieris Foreground Technology" means any Foreground Technology [***].

"Program" shall mean, for each DS Target, the research, development and commercialization activities to be performed by either Party in relation to such DS Target pursuant to the terms of this Agreement.

"Project Compound" means [***] which is conceived, reduced to practice and/or developed by or on behalf of [***], as well as any fragments or derivatives thereof.

"Project Plan" means the research plan including roles and responsibilities between the Parties for [***] of a Program, which shall contain [***].

"Research License" is defined in Section 3.1.

"Research Milestone" means [***].

"Sublicensee" is defined in Section 3.4.

"Territory" means worldwide.

"Valid Patent Claim" means any claim of an issued, unexpired patent right included in the Pieris Background Technology or the Pieris Foreground Technology that has not been held invalid or unenforceable in a final decision of a court or administrative authority of competent jurisdiction from which decision no appeal may be taken, and, for those jurisdictions where re-issue, re-examination, disclaimer or similar proceedings are available, which claim has not been disclaimed or admitted or determined to the invalid or unenforceable through re-issue, re-examination, disclaimer or otherwise.

2. INITIATION AND PERFORMANCE OF COLLABORATION RESEARCH

2.1 Nomination of DS Targets. The Parties agree to collaborate in relation to two (2) DS Targets pursuant to the terms and conditions of this Agreement. The first DS Target is listed on Exhibit D. The second DS Target shall be nominated [***], but in any event [***]. Provided that such second DS Target proposed by DS is not the subject matter of (i) [***] or (ii) [***], Pieris shall confirm that such nominated second DS Target is available for licensing to DS under this Agreement within [***] days of Pieris' receipt of DS' nomination notice. Notwithstanding the foregoing, in case that any second DS Target nominated by DS is not available for licensing to DS because of the abovementioned reason, DS may nominate the second DS Target [***], ***provided that*** DS makes a substitute nomination within [***] days of DS after any written response by Pieris that the nominated DS Target is not available for licensing, until such time as [***].

2.2 Project Plans. The Collaboration Research for each DS Target shall be performed in accordance with the Project Plan agreed in relation to such DS Target. The Project Plan applicable to the first DS Target is set forth in Exhibit A. The Project Plan for the second DS Target shall be discussed between the Parties and agreed upon by the JRC [***] no later than [***] days following Pieris' confirmation that such second DS Target is available for licensing pursuant to Section 2.1 above. Following the execution of any Project Plan, such Project Plan may only be amended by a decision of the JRC in accordance with Section 6.3.

2.3 Commencement of Programs. Pieris will commence the Collaboration Research activities for the first DS Target in accordance with the Project Plan as promptly as reasonably possible following the Initial Agreement Effective Date, but no later than [***] months thereafter, provided that [***]. Pieris will commence the Collaboration Research activities for the second DS Target [***], but in any event [***] than (i) [***] months [***] and (ii) [***] months [***] [***] as specified in the Project Plan.

2.4 Conduct of Phase A. In Phase A of each Program, Pieris shall use its good faith reasonable efforts to [***] (as specified in the Project Plan) [***]. DS shall provide [***] under the Project Plan [***] in connection with [***] under the Project Plan (such as, e.g., [***]). Pieris shall [***] under the Project Plan or this Agreement. Pieris shall keep DS fully informed as to its progress, results, status and plans for performing and implementing the Project Plan. Such information shall be given during the JRC meetings or more often, as necessary.

2.5 End of Phase A; Decision Point for DS to enter Phase B. Phase A shall end at the earlier of [***]. Following the end of Phase A of each Program, DS shall inform Pieris by written notice within [***] days whether it wishes to enter into Phase B of the relevant Program. In the event that [***], [***]. In such event, the relevant Program shall [***]-day period.

2.6 Conduct of Phase B. If DS informs Pieris in writing that it wishes to enter into Phase B in accordance with Section 2.5, [***], to (i) [***] and (ii) [***]. During Phase B of each Program, DS shall keep Pieris reasonably informed as to [***] days

following the end of every half calendar year. Each such written report shall be sufficiently detailed to demonstrate that DS continues to apply Commercially Reasonable Efforts in relation to the relevant Program in accordance with its obligations under this Agreement, and shall include [***].

2.7 Remedy for Failure to Meet Diligence Obligations. In the event that Pieris believes that DS has failed to comply with its diligence obligations under Section 2.6 in relation to a Program, Pieris shall notify DS in writing. Following [***] days of such notice, Pieris shall be entitled to terminate the relevant Program in writing, unless DS (i) has remedied the alleged failure in complying with its diligence obligations within such [***]-day period or (ii) by written notice reasonably disputes that it has failed to comply with its diligence obligations and provides Pieris with specific documents evidencing how DS complied with its diligence obligations under Section 2.6. If Pieris receives such notice within the above [***]-day period, and the Parties cannot reach agreement with respect to such dispute within [***] days following receipt of such notice, [***] in accordance with [***] pursuant to [***].

3. LICENSES

3.1 Research License. Subject to the terms and conditions herein, Pieris grants to DS, on a [***], an exclusive[***], [***], [***] license in the Territory, under the Pieris Background Technology and the Pieris Foreground Technology, to use, have used, make, have made, and import Project Compounds [***], solely for research purposes (the "Research License"). For clarity, DS may [***].

3.2 Term of Research License. The Research License shall, for each DS Target, commence upon [***] and shall expire [***] as defined in Section [***].

3.3 Commercial License. Following the decision of DS [***] pursuant to Section [***], Pieris hereby grants to DS:

(i) an exclusive license in the Territory, under the Pieris Background Technology and the Pieris Foreground Technology, to develop, have developed, make, have made, use, have used, sell, offer for sale, have sold, import and export Licensed Product in the field of [***]; and

(ii) subject to Section 5.8, a non-exclusive license in the Territory, under the Pieris Background Technology and the Pieris Foreground Technology, to develop, have developed, make, have made, use, have used, sell, offer for sale, have sold, import and export Licensed Product in the field of [***].

The license under Section 3.3(i) shall become fully-paid up, royalty free, non-exclusive on a [***] basis at the end of the relevant Royalty Term as set forth in Section 5.10.

3.4 Sublicenses. DS may sublicense the commercial licenses granted under Section 3.3

above to Affiliates or any third parties (each, a "Sublicensee"), provided that the [***]. DS shall inform Pieris of any sublicense granted pursuant to this Section 3.4 in writing.

4. NON-COMPETE

Pieris shall not, (i) [***] and (ii) [***], [***] conduct research or commercial activities (in either case) in the field of [***] [***] as a DS Target using Pieris' Anticalin patents and Pieris' Anticalin know-how on its own or with any third parties.

5. PAYMENTS

5.1 Upfront Payments. Pieris hereby confirms that DS has paid to Pieris the non-refundable, non-creditable upfront payments set forth in Section 7.1 of the Initial Agreement.

5.2 Research Funding. DS shall pay to Pieris, [***], within [***] days after receiving a corresponding invoice from Pieris, research funding in the amount of [***] Euros (EUR [***]) per [***] per [***] put into (i) [***] in accordance with the Project Plan, and (ii) any extra research activities, if requested by DS and agreed upon by Pieris.

5.3 Research Milestones. DS shall pay to Pieris Research Milestone payments [***] within [***] days after the occurrence of the relevant Research Milestone event. With respect to the first DS Target, the following Research Milestone payments shall apply:

No.	Milestone Payment		Research Milestone Event
[***]	EUR	[***]	[***]
[***]	EUR	[***]	[***]
[***]	EUR	[***]	[***]
[***]	EUR	[***]	[***]

With respect to the second DS Target, the Parties will agree on [***] within the framework of the relevant Project Plan.

5.4 Reporting on Research Milestone Achievement. Pieris shall provide written notice to DS of any occurrence of Research Milestones [***] under any Program, and

DS shall provide written notice to Pieris of any occurrence of Research Milestones [***] under any Program. If DS agrees that Research Milestones [***] have been met, it shall notify Pieris accordingly within [***] days. Once the occurrence of a Research Milestone has been agreed between the Parties, Pieris shall send DS an invoice for the relevant Research Milestone payment which shall be payable within [***] days. In the event of any disagreement between DS and Pieris whether a Research Milestone has been met, such dispute may be escalated by either Party in accordance with Section 12.3.

In any event, [***].

5.5 Timelines for Research Milestones. Notwithstanding the foregoing, if, in relation to the first Program:

(i) [***] within [***] months from commencement by Pieris of the research activities under Phase A, or

(ii) [***] within [***] months from [***], or

(iii) [***] within [***] months from [***], or

(iv) [***] within [***] months from [***],

then (in any of the foregoing cases) DS and Pieris shall discuss in good faith whether [***]. The Parties will agree on similar timelines for the second Program within the framework of the relevant Project Plan.

If DS [***] after the expiration of the relevant timeline, then (i) to the extent the Parties agree in good faith[***], the Parties will discuss in good faith how to [***] and the Parties will [***] with Section [***] governing [***], or (ii) to the extent the Parties agree in good faith that [***] the corresponding [***] shall be regarded [***].

If DS does not wish to [***], it shall [***] pursuant to Section [***] and the licenses and rights [***] under this Agreement [***] including all [***].

5.6 Development Milestones for [***]. DS shall pay to Pieris the following Development Milestone payments for Licensed Products in the field of [***], as set forth below, in each case within [***] after the occurrence of the following events:

No.	Milestone Payment		Development Milestone Event
[***]	EUR	[***]	[***]
[***]	EUR	[***]	[***]
[***]	EUR	[***]	[***]

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

[***]	EUR	[***]	[***]
[***]	EUR	[***]	[***]
[***]	EUR	[***]	[***]
[***]	EUR	[***]	[***]
[***]	EUR	[***]	[***]
[***]	EUR	[***]	[***]

The Development Milestone payments for [***] shall be [***] of the [***] for such Licensed Product set forth above; and the Development Milestones for [***] shall be [***] of the [***] set forth above. [***].

[***].

5.7 Sales Milestones for [***]. DS shall pay to Pieris the following sales milestone payments [***], [***] as set forth below, in each case within [***] days after the occurrence of the following events:

No.	**Milestone Payment**		**Sales Milestone Event**
[***]	EUR	[***]	[***] EUR [***]
[***]	EUR	[***]	[***] EUR [***]
[***]	EUR	[***]	[***] EUR [***]

5.8 [***] Milestones. DS shall pay to Pieris the following [***] milestone payments [***] [***], [***] as set forth below, in each case within [***] days after the occurrence of the following events:

No.	**Milestone Payment**		**Diagnostic Milestone Event**
[***]	EUR	[***]	[***]
[***]	EUR	[***]	[***]
[***]	EUR	[***]	[***]

5.9 Reporting on Development Milestone and Sales Milestone Achievement. DS shall provide written notice to Pieris (i) of any occurrence of any of the Development

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Milestones set forth in Sections 5.6 and 5.7 no later than [***] days following the occurrence of the relevant milestone event and (ii) of any occurrence of any of the sales milestones set forth in Section 5.8 no later than [***] days following [***]. Upon receipt of any of the aforesaid notices, Pieris shall send DS a corresponding invoice, which shall be payable within [***] days.

5.10 Royalties. DS shall pay to Pieris, [***], tiered royalties on [***] Net Sales generated by DS, its Affiliates and Sublicensees from the commercialization of Licensed Products for [***] at the following rates:

Royalty	Worldwide Annual Net Sales
[***]	[***] Net Sales [***] EUR [***]
[***]	[***] Net Sales [***] EUR [***]
[***]	[***] Net Sales [***] EUR [***]

(Example: If, [***], [***] reach EUR [***], the royalty payable to Pieris will be: EUR [***] x [***] + EUR [***] x [***] + EUR [***] x [***].)

DS shall pay to Pieris, during the Royalty Term, royalties on [***] Net Sales generated by DS, its Affiliates and Sublicensees from the commercialization of Licensed Products [***] at the rate of: [***] for [***] Net Sales [***] EUR [***]; [***] for [***] Net Sales [***] EUR [***], but [***]; and [***] for [***] Net Sales [***] EUR [***].

The "Royalty Term" shall be, on a [***] basis, the time period [***] and ending on the later of (i) the [***] and (ii) [***]. In case that there is [***], then [***]. For the purposes of this Agreement, "[***]" means [***] in the relevant country with, [***] [***] [***] in that country (and "[***]" means, with respect to a Licensed Product, (i) [***], or (ii) [***]. If, at the time of expiration of the Royalty Term, there exists any other Pieris patents than Pieris Royalty Bearing Patent Claims that are reasonably required for freedom to operate to commercialize such Licensed Product as contemplated herein, [***].

5.11 Taxes.

5.11.1 Withholding Tax. If applicable laws or regulations require withholding taxes on the payments provided in this Section 5, such taxes will be deducted by DS from such payments in an amount and will be paid by DS to the proper taxing authority, and proof of tax payment shall be sent to Pieris. The Parties agree to reasonably cooperate with each other to proceed exemptions from any double taxation. Notwithstanding the foregoing, DS shall not be permitted to reduce any fees related to FTE payments.

5.11.2 VAT. The consideration set forth in this Agreement excludes value added tax (VAT) and any VAT that becomes payable shall be paid by DS in addition to the consideration.

5.12 Other Payment Terms.

5.12.1 Currency, Payment Costs. DS shall make the payments [***] Euro. Where the payments due to Pieris are being converted from a currency [***] Euro, conversion of Net Sales recorded in local currencies to Euros shall be performed in a manner consistent with DS' normal practices used to prepare its audited financial statements for internal and external reporting purposes, which uses a widely accepted source of published exchange rates. All payments will be made [***].

5.12.2 [***] Royalty Reporting. All royalty payments will be made at [***] intervals. Within [***] days of the end of each [***] after the first commercial sale of the relevant Licensed Product in [***], DS shall prepare a statement which shall show on a [***] basis for the previous [***] all Net Sales of each Licensed Product by DS, its Affiliates and Sublicensees and all moneys due to Pieris based on such Net Sales. This statement shall include details of Net Sales broken down to show [***] of the sales and the total Net Sales in [***] and shall be submitted to Pieris within such [***] day period and the amount due shall be paid by DS within [***] days from receipt of the corresponding invoice from Pieris.

5.12.3 Records. DS shall keep, and shall procure that all Affiliates and Sublicensees, keep, true and accurate records and books of account containing all data necessary for the calculation of the amounts payable by it to Pieris pursuant to this Agreement. Those records and books of account shall be kept for [***] years following the end of the calendar year to which they relate. Upon Pieris' written request, a firm of accountants appointed by agreement between the Parties (or, failing such agreement within [***] days of the initiation of discussions between them on this point, Pieris shall have the right to cause an international firm of independent certified public accountants that has not performed auditing or other services for either Party or their Affiliates and is acceptable to DS, such acceptance not to be unreasonably withheld) shall have the right to inspect such records and books of account. In particular such firm:

(i) shall be given access to and shall be permitted to examine and copy such books and records DS, its Affiliates and Sublicensees upon [***] days' notice having been given by Pieris and at all reasonable times on business days for the purpose of certifying that the Net Sales or other relevant sums calculated by DS, its Affiliates and Sublicensees during the current and the [***] years were reasonably calculated, true and accurate or, if this is not their opinion, certify the Net Sales figure or other relevant sums for such period which in their judgment is true and correct;

(ii) prior to any such examination taking place, such firm of accountants shall undertake to DS that they shall keep all information and data contained in such books and records, strictly confidential and shall not disclose such information or copies of such books and records to any third person including Pieris, but shall only use the same for the purpose of calculations which they need to perform in order to issue the certificate to which this Section envisages;

(iii) any such access examination and certification shall occur during DS's normal business hours and no more than [***] per [***];

(iv) DS, its Affiliates and Sublicensees shall make available personnel to answer queries on all books and records required for the purpose of that certification;

(v) any amount shown by the accountant to be owed but overpaid or underpaid and in need of reimbursement shall be paid or refunded (as the case may be) within [***] days from receipt of the corresponding invoice from the Party to which money is due pursuant to the accountant report, and

(vi) the cost of the accountant (including reasonable attorneys' fees of Pieris, if applicable) shall be the responsibility of DS if the certification shows it to have underpaid monies to Pieris by more than [***] and the responsibility of Pieris otherwise.

5.12.4 Payments Made by Wire Transfer. All payments made to Pieris under this Agreement shall be made by wire transfer to the following bank account of Pieris, or such other bank account as notified by Pieris to DS from time to time:

Pieris AG
[***]
Account No.: [***]
BLZ (Routing Number): [***]
IBAN: [***]
BIC (SWIFT Code): [***]

5.12.5 Late Payments. If DS fails to make any payment to Pieris hereunder on the due date for payment, without prejudice to any other right or remedy available to Pieris, Pieris shall be entitled to charge DS interest of the amount unpaid [***], calculated on a [***] basis until payment in full is made without prejudice to Pieris' right to receive payment on the due date.

6. JOINT RESEARCH COMMITTEE

6.1. Establishment of JRC. Within [***] days following Effective Date of the Agreement, Pieris and DS shall establish a Joint Research Committee (comprising equal representation by each Party and at least [***] but not more than [***] members from each Party) to [***]. JRC member shall have sufficient authority to ensure acceptance and execution of JRC decisions within its organization. Each Party may appoint substitutes or alternates for its JRC members at any time by written notice to the other Party.

6.2. Meetings; Quorum. JRC meetings will be held quarterly (with in-person meetings twice a year), or any other frequency agreed between the Parties, during Phase A.

Portions of the exhibit, indicated by the mark "[***],"

Each Party may invite non-voting participants to the JRC meetings. The JRC shall be furnished in advance by the Program managers with a reasonably detailed report on the progress of the Program and decisions that are requested under Phase A. At each JRC meeting, at least [***] JRC members from each Party shall constitute a quorum and, therefore, need to be present in person or by telephone or video conference in order to take decisions.

6.3. Decisions. Any decisions on the activities of Phase A shall be made by consensus between DS and Pieris, provided however, that, if the JRC is unable to decide any matter by consensus, then such matter shall be decided by DS. Notwithstanding the foregoing, (i) [***] and (ii) [***]. Within [***] days following each JRC meeting, the Parties shall prepare in an alternating fashion and distribute reasonably detailed written minutes of such meeting for approval by the other Party, which minutes shall constitute Confidential Information of each Party.

6.4 Role of JRC after Phase A. During the period of Phase B, DS will keep Pieris reasonably informed by delivering to Pieris a written report in relation to the relevant Program pursuant to Section 2.6; and upon mutual agreement of the Parties, the JRC will be convened to discuss matters related to the development of the Project Compound.

6.5 Science Meetings. Both Parties shall hold joint science meetings to discuss and consult on the activities of the Phase A, once per month or such agreed frequency between the Parties, by video conference, teleconference or face to face, as mutually agreed between the Parties.

7. INTELLECTUAL PROPERTY

7.1 Background Technology. Each Party shall solely own, and will continue to solely own, all intellectual property rights and know-how in its pre-existing technology existing as of the Initial Agreement Effective Date or developed outside of the Collaboration Research.

7.2 Inventorship in Foreground Technology. The inventorship for any invention, improvements and discoveries, whether patentable or unpatentable, arising or derived from the course of the Collaboration Research shall be decided in accordance with the [***].

7.3 Ownership and Prosecution of Foreground Technology.

7.3.1 [***] Ownership in Foreground Technology. [***] shall [***] Foreground Technology as well as all improvements to [***]. It is the intent of the Parties to pursue intellectual property rights on [***] Foreground Technology relating to Project Compounds in a collaborative manner, with the intent to maximize the scope of intellectual property protection for Project Compounds. Therefore, despite its ownership

interest in [***] Foreground Technology, [***] may not file, prosecute, withdraw, maintain or abandon any patent applications relating to any Project Compound [***], handle any dispute relating to any such patent applications, or decide not to do any of them, without the prior written agreement from [***] (including agreement per e-mail), which shall not be unreasonably withheld. [***] shall be responsible for any cost of such filing, prosecution, withdrawal, maintenance and abandonment of patent applications or patents based thereon prior to any assignment by [***] interest in such [***] Foreground Technology in accordance with Section 7.3.2.

7.3.2 Transfer of Pieris Foreground Technology. Upon DS's decision to enter into Phase B pursuant to Section 2.5 above in relation to any Project Compound, Pieris shall assign, without any additional fees or costs, all interests and ownership in any Pieris Foreground Technology relating to such Project Compound to DS, provided that all financial terms under this Agreement shall remain unaffected by such assignment. [***] DS shall provide reasonable advanced written notice to Pieris before abandoning any Pieris Foreground Technology assigned to DS, in which case Pieris shall have the right to assume, without any additional fees or costs, ownership of such Pieris Foreground Technology as well as the right to continue prosecution and/or maintenance thereof. Pieris shall not assign any such Pieris Foreground Technology reverted back to Pieris to any third party unless Pieris first offers in writing to assign such technology on substantially the same terms to DS and DS does not accept such offer in writing within [***] days thereof. In case that Pieris assigns any such Pieris Foreground Technology reverted back to Pieris to a third party, then such technology shall be excluded from Pieris Foreground Technology thereafter.

7.3.3 [***] Ownership in Foreground Technology. [***] shall [***] Foreground Technology, and [***] shall have the right (but not the obligation), at its sole expense and sole discretion, to control the preparation, filing, prosecution, maintenance and enforcement of all Patent Rights applicable to any [***] Foreground Technology.

7.4 Enforcement.

7.4.1 Enforcement of Pieris Foreground Technology within Scope of Exclusive License. To the extent and for as long as the Pieris Foreground Technology has been (i) exclusively licensed to DS pursuant to Section 3.3(i) or (ii) assigned to DS pursuant to Section 7.3.2, DS shall have the first right (but not the obligation), [***] Prior to undertaking any such action to enforce such Pieris Foreground Technology, DS shall notify Pieris in writing. The Parties shall reasonably cooperate with each other in the planning and execution of any such action to enforce such Pieris Foreground Technology (including the obligation to be named or joined as a party in a lawsuit, as applicable), [***]. All monies recovered upon the final judgment or settlement of any such suit or action to enforce such Pieris Foreground Technology shall be treated as [***]. In the event that DS does not wish to enforce such Pieris Foreground Technology against such a potential infringer, then DS shall deliver prompt written notice thereof to Pieris. For the avoidance of doubt, [***].

In the event that DS delivers to Pieris written notice described in the previous paragraph that DS does not wish to enforce such Pieris Foreground Technology against such a potential infringer, then Pieris shall have the option to assume the right (but not the obligation), [***]. If Pieris timely exercises such option, then (i) Pieris shall thereafter assume the rights and obligations attributed to DS under the preceding paragraph, and (ii) DS shall thereafter assume the rights and obligations attributed to Pieris under the preceding paragraph; provided that monies recovered upon the final judgment or settlement of any such suit or action to enforce such Pieris Foreground Technology shall be applied in the following order of priority: (x) first, [***]; and (y) thereafter, any remainder shall be [***].

7.4.2 Other Enforcements. In all other cases the Party owning the relevant Patent Rights shall have the exclusive right to enforce such Patent Rights in its own name and at its own cost and risk.

7.5 Cooperation. Each Party agrees to cooperate with, and perform such lawful acts and execute such documents in order to reasonably assist, the other Party with respect to the preparation, filing, prosecution, defense, enforcement and maintenance of Patent Rights pursuant to this Article 7. Furthermore, the Parties shall cooperate with each other in gaining patent term extensions wherever applicable to any of the Foreground Technology.

8. CONFIDENTIALITY

8.1 Confidential Information. "Confidential Information" shall mean all trade secrets or confidential or proprietary information designated as such in writing by the disclosing Party, whether by letter or by the use of an appropriate stamp or legend, prior to or at the time any such trade secret or confidential or proprietary information is disclosed by the disclosing Party to the receiving Party. Notwithstanding the foregoing, information which is orally or visually disclosed to the receiving Party by the disclosing Party, or is disclosed in writing without an appropriate letter, stamp or legend, shall constitute Confidential Information if (i) it would be obvious to a reasonable person, familiar with the disclosing Party's activities and the industry in which it operates, that such information is of a confidential or proprietary nature, or if (ii) the disclosing Party, within [***] days after such disclosure, delivers to the receiving Party a written document or documents describing such information and notifying it as proprietary or confidential.

8.2 Confidentiality. During the Term, and for a period of [***] years thereafter, each Party shall:

(i) except to the extent permitted by this Agreement or otherwise agreed to in writing, keep confidential and not disclose to any third party any Confidential Information of the other Party;

(ii) except in connection with the activities contemplated by or the exercise of rights permitted by this Agreement or as otherwise agreed to in writing, not use for any purpose any Confidential Information of the other Party; and

(iii) take all reasonable precautions to protect the Confidential Information of the other Party (including all precautions a Party employs with respect to its own confidential information of a similar nature and taking reasonable precautions to assure that no unauthorized use or disclosure is made by others to whom access to the Confidential Information of the Party is granted).

8.3 Exceptions. Notwithstanding anything set forth in this Article 8 to the contrary, the obligations of Section 8.2 above shall not apply to the extent that the Party seeking the benefit of the exclusion can demonstrate that the Confidential Information of the other Party:

(i) was already known to the receiving Party, other than under an obligation of confidentiality, at the time of receipt by the receiving Party;

(ii) was generally available to the public or otherwise part of the public domain at the time of its receipt by the receiving Party;

(iii) became generally available to the public or otherwise part of the public domain after its receipt by the receiving Party other than through any act or omission of the receiving Party in breach of this Agreement;

(iv) was received by the receiving Party without an obligation of confidentiality from a third party having the right to disclose such information without restriction;

(v) was independently developed by or for the receiving Party without use of or reference to the Confidential Information of the other Party;

(vi) was released from the restrictions set forth in this Agreement by express prior written consent of the other Party; or

(vii) is required to be disclosed by court order or any competent government authority or under applicable stock exchange or similar rules or regulations, in which case the receiving Party will provide reasonable advanced written notice to the disclosing Party and will use reasonable efforts to limit public disclosure of the Confidential Information by seeking a protective order or similar protection permitted under applicable law.

If any of the Confidential Information becomes subject to the exceptions above, then the receiving Party shall all the same not disclose to any third party the fact that such information was received from or used by the disclosing Party, unless such fact becomes subject to the exceptions listed in subsections (i)-(vii) above.

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

The Confidential Information shall not be deemed to be in the public domain merely because any part of the Confidential Information is embodied in any general disclosure or because individual features, components or combinations thereof are known to the public.

8.4 Disclosure to Employees, Consultants and Investors. Each Party agrees that it and its Affiliates shall provide or permit access to Confidential Information received from the other Party only to the receiving Party's employees, scientific consultants, scientific or professional advisors and permitted subcontractors who have a need to know such Confidential Information to assist the receiving Party with the development, manufacturing and/or commercialization of a Project Compound and/or Licensed Product and the activities contemplated by this Agreement and who are subject to obligations of confidentiality and non-use with respect to such Confidential Information similar to the obligations of confidentiality and non-use of the receiving Party pursuant to Section 8.2; provided, that Pieris and DS shall each remain responsible for any failure by its Affiliates, and its and its Affiliates' respective employees, consultants, advisors and permitted subcontractors, Sublicensees and distributors, to treat such Confidential Information as required under Section 8.2 (as if such Affiliates, employees, consultants, advisors and permitted subcontractors, Sublicensees and distributors were Parties directly bound to the requirements of Section 8.2). In addition, a receiving Party may provide Confidential Information disclosed to it to any bona fide actual or prospective collaborators or strategic partners who are obligated to keep such information confidential, to the extent reasonably necessary to enable such actual or prospective collaborators to determine their interest in or collaborating with the receiving Party.

8.5 Return of Confidential Information. Upon termination or expiration of any Program or this Agreement, upon the request of the disclosing Party, the receiving Party shall promptly return to the disclosing Party or destroy the disclosing Party's Confidential Information, including all copies thereof, except to the extent that retention of such Confidential Information is reasonably necessary for the receiving Party to exploit any continuing rights it may have (in particular the rights under Section 11.10) and/or to fulfill its obligations contemplated herein, including its obligations of non-disclosure and non-use hereunder. Any such destruction requested by the disclosing Party shall be certified in writing to the disclosing Party by an authorized officer of the receiving Party. The return and/or destruction of such Confidential Information as provided above shall not relieve the receiving Party of its obligations under this Agreement.

9. REPRESENTATIONS AND WARRANTIES

9.1 Mutual Representations. Each Party hereby represents and warrants to the other Party that as of the Effective Date, it has full corporate right, power and authority to enter into this Agreement, to grant the rights it grants to the other Party and to perform its respective obligations under this Agreement.

9.2 No Conflict. Each Party hereby represents and warrants to the other Party

that, notwithstanding anything to the contrary in this Agreement, the execution and delivery of this Agreement by such Party, the performance of such Party's obligations hereunder and the licenses and sublicenses to be granted by such Party pursuant to this Agreement (a) to the best of its knowledge, do not conflict with or violate any requirement of any laws, rules or regulations existing as of the Effective Date and applicable to such Party and (b) do not conflict with, violate, breach or constitute a default under any contractual obligations of such Party or any of its Affiliates existing as of the Effective Date.

9.3 Disclaimer of Warranties. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH HEREIN, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, TO THE OTHER PARTY, AND EACH PARTY HEREBY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY AND ENFORCEABILITY OF ANY PATENT LICENSED HEREUNDER, AND NON-INFRINGEMENT WITH RESPECT TO THE PROGRAM COMPOUNDS AND LICENSED PRODUCTS. EACH PARTY HEREBY DISCLAIMS ANY REPRESENTATION OR WARRANTY THAT THE DEVELOPMENT, MANUFACTURE AND COMMERCIALIZATION OF THE PROGRAM COMPOUNDS OR LICENSED PRODUCTS PURSUANT TO THIS AGREEMENT WILL BE SUCCESSFUL.

10. INDEMNIFICATION AND LIABILITY

10.1 Indemnification.

10.1.1 Indemnification [***]. [***] will defend, indemnify and hold harmless [***], its Affiliates and their respective directors, officers, employees and agents (the "[***]") from and against all claims, demands, liabilities, damages, penalties, fines, costs and expenses, including reasonable attorneys' and expert fees and costs, and costs or amounts paid to settle (collectively, "Losses"), arising from or occurring as a result of a third party's claim (including any third party product liability or infringement claim), action, suit, judgment or settlement to the extent such Losses are due to or based upon:

(i) [***]; or

(ii) [***]; or

(iii) [***].

10.1.2 Indemnification [***]. [***] will defend, indemnify and hold harmless [***], its Affiliates, and their respective directors, officers, employees and agents (the "[***]") from and against all Losses arising from or occurring as a result of a third party's claim, action, suit, judgment or settlement that is due to or based upon the material breach by [***] of the terms of, or the material inaccuracy of any representation or warranty made by it in, this Agreement.

10.2 Claims for Indemnification.

10.2.1 A person entitled to indemnification under this Section 10.1 (an "Indemnified Party") shall give prompt written notification to the person from whom indemnification is sought (the "Indemnifying Party") of the commencement of any action, suit or proceeding relating to a third party claim for which indemnification may be sought or, if earlier, upon the assertion of any such claim by a third party (it being understood and agreed, that the failure by an Indemnified Party to give notice of a third party claim as provided in this Section 10.2.1 shall relieve the Indemnifying Party of its indemnification obligation under this Agreement unless the Indemnified Party can demonstrate that such failure to give notice has not resulted in any prejudice to the Indemnifying Party).

10.2.2 Within [***] days after receipt of such notification, the Indemnifying Party may, upon written notice thereof to the Indemnified Party, assume control of the defense of such action, suit, proceeding or claim with counsel of its choice. If the Indemnifying Party does not assume control of such defense, the Indemnified Party shall control such defense.

10.2.3 The Party not controlling such defense may participate therein at its own expense; provided, that if the Indemnifying Party assumes control of such defense and the Indemnified Party reasonably concludes, based on advice from counsel, that the Indemnifying Party and the Indemnified Party have conflicting interests with respect to such action, suit, proceeding or claim, the Indemnifying Party shall be [***].

10.2.4 The Party controlling such defense shall keep the other Party advised of the status of such action, suit, proceeding or claim and the defense thereof and shall consider reasonable recommendations made by the other Party with respect thereto.

10.2.5 The Indemnified Party shall not agree to any settlement of such action, suit, proceeding or claim without the prior written consent of the Indemnifying Party, which shall not be unreasonably withheld. The Indemnifying Party shall not agree to any settlement of such action, suit, proceeding or claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Indemnified Party from all liability with respect thereto or that imposes any liability or obligation on the Indemnified Party without the prior written consent of the Indemnified Party.

10.3 Limitation of Liability. IN NO EVENT SHALL EITHER PARTY BE LIABLE OR OBLIGATED TO THE OTHER PARTY IN ANY MANNER FOR ANY SPECIAL, NON-COMPENSATORY, CONSEQUENTIAL, INDIRECT, INCIDENTAL, STATUTORY OR PUNITIVE DAMAGES OF ANY KIND, INCLUDING, WITHOUT LIMITATION, LOST PROFITS AND LOST REVENUE, REGARDLESS OF THE FORM OF ACTION, WHETHER IN CONTRACT, TORT, NEGLIGENCE, STRICT PRODUCT LIABILITY, OR OTHERWISE, EVEN IF INFORMED OF OR AWARE OF THE POSSIBILITY OF ANY SUCH DAMAGES IN ADVANCE. THE LIMITATIONS SET FORTH ABOVE SHALL BE DEEMED TO APPLY TO THE

MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW AND NOTWITHSTANDING THE FAILURE OF THE ESSENTIAL PURPOSE OF ANY LIMITED REMEDIES. THE PARTIES ACKNOWLEDGE AND AGREE THAT THEY HAVE FULLY CONSIDERED THE FOREGOING ALLOCATION OF RISK AND FIND IT REASONABLE, AND THAT THE FOREGOING LIMITATIONS ARE AN ESSENTIAL BASIS OF THE BARGAIN BETWEEN THE PARTIES. The above limitation of liability shall not apply to the indemnifications set forth in Section 10.1 and any breach of Article 8 ("CONFIDENTIALITY").

10.4 Insurance. Each Party shall maintain, and shall require its Affiliates and Sublicensees hereunder to maintain, a commercial general liability and, as regards DS only, a product liability insurance program on terms customary in the pharmaceutical and biopharmaceutical industry covering all activities and obligations of it, and, as the case may be, its Affiliates, hereunder, or other insurance programs with comparable coverage, up to and beyond the expiration or termination of this Agreement and a commercially reasonable period thereafter.

11. TERM

11.1 Agreement Term. This Agreement shall become effective as of the Effective Date and shall continue in full force and effect until (i) expiration of all payment and related obligations of DS under Article 5, (ii) the decision of DS not to enter into any Phase B under any Program, or (iii) any termination of this Agreement in accordance with Section 2.7 or Sections 11.2 to 11.6 below.

11.2 Termination for Convenience by DS. Following [***] of any Program, DS shall have the right to terminate such Program at any time on thirty (30) days prior written notice to Pieris without any liability to Pieris in that respect (other than to perform obligations which survive such termination in accordance with this Agreement)

11.3 Termination for Breach. Subject to Section 2.7 in relation to DS's failure to comply with its diligence obligations, either Party shall be entitled to terminate any Program(s) by written notice to the other with immediate effect if the other Party breaches any of its material obligations under this Agreement in relation to such Program(s) and fails to cure such breach within [***] days following its receipt of written notice thereof from the terminating Party if such breach is curable within the aforesaid period; ***provided, however***, prior to giving any notice for breach, the Parties shall first attempt to resolve any disputes as to the existence of any breach as set forth in Section 12.3.

11.4 Termination for Insolvency. Either Party may terminate any or all Programs under this Agreement by written notice to the other with immediate effect if the other Party becomes insolvent, is compelled to file bankruptcy or is determined otherwise imminently subject to control by a bankruptcy trustee or its equivalent pursuant to the laws of the jurisdiction in which such Party is doing business.

11.5 Termination for Challenges of Patent Rights. If DS or any of its Affiliates or Sublicensees (i) commences or participates in any action or proceeding (including, without limitation, any patent opposition or re-examination proceeding), or otherwise asserts in writing any claim, challenging or denying the validity of any of the Patent Rights licensed to DS hereunder, or any claim thereof, or (ii) actively assists any other Person in bringing or prosecuting any action or proceeding (including, without limitation, any patent opposition or re-examination proceeding) challenging or denying the validity of any of such Patent Rights or any claim thereof (each, a "Challenge"), then such Challenge shall constitute a material breach of the Agreement and Pieris will have the right to give warning notice to DS under Section 11.3, and, unless DS or the relevant Affiliate or Sublicensee withdraws or causes to be withdrawn all such Challenge(s) within the sixty (60) day period set forth in Section 11.3, Pieris shall have the right to terminate this Agreement forthwith.

11.6 Termination of Agreement. Any termination of the last Program pursued under this Agreement shall constitute a termination of this Agreement.

11.7 Effect of Termination of Programs or Agreement. In case of any termination of any Program(s), all rights and obligations of the Parties (including the licenses granted under Sections 3.1 and 3.3) shall cease immediately with respect to the relevant Program(s), unless otherwise indicated in this Section below or elsewhere in this Agreement, and DS shall re-assign to Pieris all Pieris Foreground Technology assigned to DS pursuant to Section 7.3.2 in relation to Project Compounds developed under the relevant Program(s).

11.8 Obligations Accrued. Expiration or termination of this Agreement or termination of any Program shall not relieve the Parties of any obligation accruing prior to such expiration or termination.

11.9 Survival. The provisions of Sections 5.12.2 to 5.12.5, 7.1, 7.2, 7.3.1 (first sentence only), 7.3.3, 7.5, 8, 9, 10, 11.7 to 11.10 and 12 shall survive any termination of any Program or termination or expiration of this Agreement.

11.10 Transfer of Terminated Program Under Certain Circumstances. If any Program is terminated (i) by Pieris in accordance with Section 11.3 (termination for breach by DS) or Section 2.7 (failure to comply with diligence obligations), or (ii) by DS in accordance with Section 11.2 (termination for convenience) (such Program hereinafter referred to as the "Terminated Program"), the following terms and conditions shall apply in relation to the Terminated Program:

11.10.1 DS shall as promptly as practicable transfer to Pieris or Pieris' designee (i) possession and ownership of [***], (ii) copies of [***], and (iii) all records [***].

11.10.2 DS shall appoint Pieris as DS' agent for all Licensed Product-related matters under the Terminated Program involving regulatory authorities until all marketing authorizations and other regulatory filings and approvals have been

transferred to Pieris or its designee, it being agreed that both Parties shall use reasonable and diligent efforts to have this transfer occur as rapidly as feasible.

11.10.3 If the effective date of termination of the Terminated Program is [***], then DS shall [***] and grant [***], until such time as [***] it being agreed that both Parties shall use reasonable and diligent efforts to have [***] as rapidly as feasible.

11.10.4 If DS or any of its Affiliates or Sublicensees is manufacturing a Licensed Product under a Terminated Program, then, at Pieris' option, DS shall [***] until such time as [***], provided that Pieris can demonstrate it has been [***] and [***] shall not continue for more than [***] months from the date of [***].

11.10.5 If Pieris so requests, DS shall transfer to Pieris any third party agreement relating to the development, manufacture or commercialization of a Licensed Product under a Terminated Program, to which DS is a party, provided that such [***] and provided further that, in relation to agreements relating to [***], this obligation shall only apply to the extent that DS does not continue to manufacture and supply the relevant Licensed Product in accordance with Section 11.10.4 above.

11.10.6 [***] shall[***] that [***] as such [***] only to the extent [***] set forth in [***] whether it is [***]

11.10.7 To the extent a Program has been terminated by Pieris in accordance with Section 11.3 (termination for breach by DS), (i) the assignment pursuant to Section 11.10.6(i) above shall be without any compensation and (ii) [***]. Notwithstanding foregoing sentence in this Section, intellectual property licensed from third parties for which, to the extent DS is able to sub-license or assign its rights, any payment obligation of DS to the third party will be assumed by Pieris to the extent such payment obligation relates to the Terminated Program.

To the extent a Program has been terminated by Pieris in accordance with Section 2.7 (failure to comply with diligence obligations) or by DS in accordance with Section 11.2 (termination for convenience), the assignment pursuant to Section 11.10.6(i) above and the license granted pursuant to Section 11.10.6(ii) above shall be subject to the following royalty payments to be made by Pieris to DS on the Net Sales of pharmaceutical products containing one or more Project Compounds of the Terminated Program made by Pieris, its Affiliates, sublicensees or sublicensees' Affiliates (and the definition of "Net Sales" shall apply *mutatis mutandis* to such sales):

Time of termination	**Royalty rate**
[***]	[***]
[***]	[***]

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

[***]	[***]

The above royalty shall be payable by Pieris to DS on a [***] basis for a period [***][***]:

Time of termination	Maximum aggregate royalty amount
[***]	EUR [***]
[***]	EUR [***]
[***]	EUR [***]

Sections 5.11 and 5.12 shall apply reciprocally to royalty payments by Pieris to DS under this Section 11.10.7.11.10.8 DS shall execute all documents and take all such further actions as may be reasonably requested by Pieris in order to give effect to the terms of this Section 11.10.

12. MISCELLANEOUS

12.1 Notices. Unless provided otherwise, any consent or notice required or permitted to be given or made under this Agreement by one of the Parties to the other shall be in writing and delivered through registered mail with acknowledgement of receipt, and addressed to such other Party at its address indicated below, or to such other address as the addressee shall have last furnished in writing to the addressor, and shall be effective upon receipt by the addressee.

If to DS: Daiichi Sankyo Company Limited
[***]

If to Pieris: Pieris AG
Lise-Meitner-Str. 30
85354 Freising, Germany

Attention: Chief Executive Officer

For the avoidance of doubt, reports or other exchanges of information on an operational level may also be sent by facsimile or electronic transmission.

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

12.2 Governing Law. This Agreement (including Exhibits attached hereto) shall be governed by and construed in accordance with the laws of [***] without regard to the application of principles of conflict of laws.

12.3 Dispute Resolution. Each Party shall exercise reasonable effort to resolve any dispute regarding this Agreement. If the Parties hereto are unable to resolve such dispute amicably, then such dispute shall [***] in accordance with the process set forth in Exhibit E [***].

12.4 Attorneys Fees and Costs. Except as specifically provided in this Agreement, in the event of any dispute between the Parties arising out of or relating to this Agreement, the prevailing Party shall be entitled to recover from the unsuccessful Party all costs, expenses and actual attorneys' fees relating to or arising from (i) any litigation, arbitration or mediation relating to or arising from, this Agreement; and/or (ii) the enforcement of any judgment or award resulting from any such litigation, arbitration or mediation. Any such judgment or award shall contain a specific provision for the recovery of all costs, expenses and actual attorneys' fees incurred in enforcing any such judgment or award.

12.5 Severability. Each Party hereby agrees that it does not intend to violate any public policy, statutory or common laws, rules, regulations, treaty or decision of any government agency or executive body thereof of any country or community or association of countries. Should one or more provisions of this Agreement be or become invalid, the Parties hereto covenant and agree to renegotiate any such term, covenant or application thereof in good faith in order to provide a reasonably acceptable alternative to the term, covenant or condition of this Agreement or the application thereof that is invalid, illegal or unenforceable, said renegotiated term, covenant or condition being deemed to be effective as of the Effective Date, it being the intent of the Parties that the basic purposes of this Agreement and the economical balance between the Parties as contemplated upon the execution of the Agreement are to be effectuated as nearly as possible.

12.6 Assignment. This Agreement may not be assigned or transferred by either Party without the prior written consent of the other Party. Notwithstanding the foregoing, either Party shall have the right to assign this Agreement to its Affiliates or to a third party in connection with any transaction ("Transaction"), including but not limited to: (i) acquisition (of or by), consolidation with, or merger into, any other corporation or other entity or person; (ii) any corporate reorganization; or (iii) the sale of its business to which this Agreement is related, ***provided that*** in any such Transaction the assignee expressly obligates itself in a written instrument delivered to the non-assigning Party to this Agreement, on or before the date of closing of such Transaction, to fully perform all of the obligations of the assigning Party under this Agreement. This right of assignment shall likewise be available to the assignee in the same manner as it is to the assigning Party, and subsequent assignees in like manner, provided that in each instance of assignment, the assignee provides the writing specified above to the non-assigning Party to this Agreement prior to the date of closing of such Transaction.

12.7 Entire Agreement. This Agreement constitutes the entire agreement between the Parties, and supersedes all written or oral agreements or understandings with respect thereto, including the Initial Agreement. Neither Party shall claim any amendment, modification, or release from any provision hereof unless such an amendment is in writing signed by an authorized representative of each Party.

12.8 Counterparts; Facsimile. This Agreement may be executed in counterparts, each and every one of which shall be deemed an original and all of which together shall constitute one and the same instrument. Signing and delivery of this Agreement may be evidenced by an electronic transmission of the signed signature page to the other Party, provided however that such electronic signing and delivery is confirmed in written paper copy signed by and delivered to each Party promptly following electronic signing and delivery.

[signatures continued on the following page]

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Pieris AG:

By: /s/ Stephen S. Yoder

Name: Stephen S. Yoder

Title: CEO

Date: 31 May 2011

Daiichi Sankyo Company, Ltd.:

By: /s/ Masahiko Ohtsuki

Name: Masahiko Ohtsuki

Title: Vice President
R&D Planning Department, R&D Division
Global Head of R&D Planning

Date: 20 May 2011

***Portions of the exhibit, indicated by the mark "[***],"* were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.**

CONFIDENTIAL TREATMENT REQUESTED

Exhibit A

Project Plan for first Program

[***]

[***]

[***]	**[***]**	**[***]**	**[***]**
[***]			
[***]		**[***]**	**[***]**
[***]	[***]	[***]	
[***]	[***]		
[***]	[***]		
[***]	[***]		
• **[***]**			
[***]		**[***]**	**[***]**
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[***]		**[***]**	**[***]**
[***]	[***]		
[***]	[***]		
[***]	[***]		
[***]	[***]		
[***]		[***]	
[***]			
[***]		**[***]**	**[***]**

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

[***] [***]

[***]

[***]
[***] [***] **[***]**

[***]
[***]
[***] [***] **[***]**
[***] [***] **[***]**

[***]
[***] [***] **[***]**
[***] [***] **[***]**
[***]

[***]

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

CONFIDENTIAL TREATMENT REQUESTED

Exhibit B

[***]

[***] shall mean [***].

[***] shall mean any [***]).

[***] shall mean [***].

[***] shall mean [***].

[***] shall mean [***].

[***] shall mean [***].

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

CONFIDENTIAL TREATMENT REQUESTED

Exhibit C

[***]

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

CONFIDENTIAL TREATMENT REQUESTED

Exhibit D

[***]

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

CONFIDENTIAL TREATMENT REQUESTED

Exhibit E

Dispute Resolution

(a) Any dispute unresolved for more than [***] after its written documentation shall be brought to the attention of a senior management representative of each Party, who shall attempt to resolve such dispute in good faith. If the senior management representatives of the Parties are unable to resolve a dispute within [***] days, the CEOs or presidents of the Parties shall attempt in good faith to resolve such dispute within [***] days.

(b) If the CEOs or presidents are unable to resolve such dispute within such period, [***] Except as may be required by law, [***] to that effect [***]

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

CONFIDENTIAL TREATMENT REQUESTED

EXECUTION COPY

DEVELOPMENT AND LICENSE AGREEMENT

THIS LICENSE AGREEMENT (the "**Agreement**") is made and is effective as of this 7th day of October, 2013 (the "**Effective Date**") by and between

Cadila Healthcare Limited, a corporation organized and existing under the laws of India, whose principal place of business is at Zydus Tower, Satellite Cross Roads, Ahmedabad - 380 015, India ("**Zydus**"),

and

Pieris AG, a corporation organized and existing under the laws of Germany, whose principal place of business is at Lise-Meitner-Straße 30, 85354 Freising, Germany ("**Pieris**").

Pieris and Zydus are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**".

RECITALS

A. Pieris is engaged in the research and development of biopharmaceutical products and has developed a novel technology to develop Anticalin® proteins and proprietary know-how and data relating thereto;

B. Zydus is engaged in the research, development, manufacture and marketing of pharmaceutical and biopharmaceutical products, including but not limited to therapeutic proteins, monoclonal antibodies and vaccines.

C. Pieris and Zydus desire to grant each other certain exclusive license rights in the further research and development, clinical development and marketing & commercialization of the Products (hereinafter defined), subject to and in accordance with the terms in this Agreement.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, the Parties hereby agree as follows:

ARTICLE 1

DEFINITIONS

As used throughout this Agreement, the singular includes the plural and vice versa, and words denoting any gender include all genders. Where the context so admits or requires, references to Zydus or Pieris shall include their respective employees, officers, directors or agents.

"AFFILIATE" means any Person that directly (or indirectly through one or more intermediaries) controls, is controlled by, or is under common control with a Party. For the purposes of this definition only, the terms "controls," "controlled," and "control" mean: (i) the direct or indirect ability or power to direct or cause the direction of the management and policies of an entity or otherwise direct the affairs of such entity, whether through ownership of equity, voting securities or beneficial interest, by contract, or otherwise: or (ii) the ownership, directly or indirectly, of more than fifty percent (50%) of the voting securities (or other comparable ownership interest for an entity other than a corporation) of a Party.

"API" or "ACTIVE PHARMACEUTICAL INGREDIENT" means the active pharmaceutical ingredient of a Drug Product in bulk form such as a Drug Substance, which, if appropriately formulated and finished, would constitute the Drug Product. For avoidance of doubt, API for Product 1 is the c-Met Anticalin,

(herein referred to as PRS-110) and API for Product 2 shall be determined by the CC pursuant to Section 3(3).

"APPLICABLE LAWS" means all applicable statutes, ordinances, regulations, judicial decisions, rules or orders of any kind whatsoever of any Governmental Authority, including, without limitation, the Regulatory Laws, all as amended from time to time.

"AUTHORIZED PERSONS" means Recipient's directors, officers, employees and professional advisors and consultants who are legally bound to keep confidential any of the Confidential Information disclosed by the Discloser on terms at least as onerous as those set out herein.

"[***]" means [***] (for the sake of clarity, [***] among other information).

"CALENDAR MONTH" means each successive period of 30/31 (or 28/29) days (as applicable) commencing on 1st day of every month and ending on the last day of that month.

"CALENDAR YEAR" means each successive period of twelve (12) months commencing on January 1 and ending on December 31.

"CMC" means chemistry, manufacturing and control.

"COMMERCIALIZATION" means all activities before and after a Marketing Approval for a Product or otherwise relating specifically to the marketing, sale and/or distribution of Product including, without limitation: (i) sales force detailing, advertising, education, planning, marketing, sales force training and distribution; (ii) scientific and medical affairs; (iii) the manufacture of Product intended for commercial sale, including, without limitation, formulation, bulk API and/or Drug Product production, fill/finish, distribution, manufacturing process improvement and quality assurance technical support.

"COMMERCIALLY REASONABLE EFFORTS" means that level of effort and application of expertise and resource, typical in the pharmaceutical industry in the research, development and commercialization of a product or compound owned by a Third Party or resulting from a Party's own research efforts, that is of similar market potential and at a similar stage in its development or product life, taking into account issues of safety and efficacy, product profile, difficulty in developing a Product, competitiveness of the marketplace for resulting products, the patent position of the compound or product, the regulatory structure involved, the potential total profitability of the applicable products marketed or to be marketed, and other relevant factors affecting the cost, risk and timing of development and the total potential reward (profit) to be obtained if a product is commercialized.

"CONFIDENTIAL INFORMATION" means the Pieris Confidential Information or the Zydus Confidential Information, as applicable.

"CONTROL" or "CONTROLLED" means with respect to any intellectual property right, that the applicable Party owns or has a license to such intellectual property right and has the ability to grant access, a license, or a sublicense to such intellectual property right to the other Party as provided for in this Agreement without violating an agreement with a Third Party as of the time such Party would be first required under this Agreement to grant the other Party such access, license or sublicense; provided, however, that for rights acquired from Third Parties after the Effective Date, such intellectual property right shall be deemed to be "CONTROLLED" only if such access can be granted without additional cost.

"CO-ORDINATION COMMITTEE" or "CC" means the committee of representatives from each Party established to co-ordinate the Pieris Activities and Zydus Activities, as further detailed in Section 3(3).

"DISCLOSER" means the Party disclosing its Confidential Information to the other Party or to the other Party's Authorized Persons pursuant to this Agreement.

"DISPUTE" means any dispute arising from or relating to this Agreement, including, without limitation, the interpretation of any term of this Agreement and/or the assessment of a Party's compliance with any of its obligations under this Agreement.

"DEVELOPMENT" means all activities undertaken under any Plan with respect to the clinical development of a Product that are reasonably required to obtain one or more Marketing Approvals of Product, including, without limitation: (i) pre-clinical studies (including, without limitation, pharmacology, toxicology and pharmacokinetics); (ii) regulatory affairs, project management, clinical operations, medical writing, bio-statistics, data management and drug safety, and clinical trials (including without limitation Bridging Studies) in accordance with the current Good Laboratory Practices (cGLPs), current Good Clinical Practices (cGCPs) and current Good Manufacturing Practices (cGMPs) or other designated quality standards and Applicable Laws; (iii) all activities relating to developing the ability to manufacture such Product, including, without limitation, formulation, stability/analytical, packaging, delivery technologies and devices, bulk API and/or Drug Product production, manufacturing fill/finish, manufacturing process development, and quality assurance technical support, clinical supplies distribution and QC (quality-control) testing and release, until such time as manufacturing of such Product intended for commercial sale commences; and (iv) any required post-Marketing Approval commitments.

"DRUG PRODUCT" or "DP" means the final dosage form which contains a Product in association with other active or inactive ingredients.

"DRUG SUBSTANCE" or "DS" means any substance or mixture of substances, comprising a Product, intended to be used in the manufacture of a Drug Product and that, when used in the production of the Drug Product, becomes the Active Pharmaceutical Ingredient of the Drug Product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body.

"DCGI" means the Drug Controller General of India, or any successor federal agency having responsibility over India Marketing Approvals.

"EMA" means the European Medicines Agency, or any successor federal agency having responsibility over Europe Union (EU) Marketing Approvals.

"FDA" means the United States (U.S.) Food and Drug Administration, or any successor federal agency having responsibility over U.S. Marketing Approvals.

"FIELD" means (i) with respect to Product 1 (PRS-110), [***] provided, however, [***] and (ii) with respect to Product 2, t[***] to be agreed upon in good faith upon the nomination of Product 2 pursuant to Section 3(3).

"GOVERNMENTAL AUTHORITY" means any court tribunal, arbitrator, agency, commission, official or other instrumentality of any federal, state, or other political subdivision, or supranational body, domestic or foreign.

"ICH" means the International Conference on Harmonization.

"ICH-GCP" means ICH / World Health Organization (WHO) Good Clinical Practice standards.

"IMPROVEMENT" means any findings, developments, discoveries, inventions, additions, modifications, enhancements, formulations, or changes to the composition of matter, or method of use of Product, or its manufacture made by, or coming under Control of either Party or Sublicensees during the Term which are

necessary for the Research and Development of a Product and/or the manufacture and Commercialization of the Product, including without limitation, new or improved methods of synthesis, manufacture, ingredients, preparation, presentation, means of delivery, dosage, formulation, or analysis, whether or not patentable.

"IND Application" means an Investigational New Drug Application (together with all additions, deletions, and supplements thereto) or the equivalent application in a regulatory jurisdiction, filed with the Regulatory Authority in that jurisdiction, the filing of which is necessary to commence and conduct human clinical trials of a pharmaceutical product in that jurisdiction such as a Clinical Trial Authorization Application in European Union (EU).

"INFORMATION" means any information controlled (including Controlled) by either Party during the Term that is necessary for the Research and Development and/or the manufacture and Commercialization. Information may include, but is not limited to: (a) any and all inventions, know-how, developments, Improvements, materials, data, analyses, and the like, regardless of whether the information is stored or transmitted in oral, documentary, or electronic form; and (b) information relating to research and development plans, experiments, results, compounds, therapeutic leads, candidates and products, clinical and preclinical data, trade secrets and manufacturing, marketing, financial, regulatory, personnel and other business information and plans, and all scientific, clinical, regulatory, marketing, financial and commercial information or data; in each case, to the extent necessary for the Research and Development and/or the manufacture and Commercialization.

"INVESTIGATIONAL MEDICAL PRODUCT" or "IMP" means a pharmaceutical form of a DP or DS being tested in one or more clinical trials.

"JOINT ARISING IP" means all intellectual property, including Improvements and any and all inventions, patents, copyrights and trademarks and other rights relating thereto, that arises from the joint research and development conducted by Zydus and Pieris, during the Term, under the Plans, as well as during the term of the Prior MTA, and including without limitation, Joint Know-How and Joint Patents, but explicitly excluding (i) Pieris Arising IP & Zydus Arising IP and (ii) Pieris Confidential Information & Zydus Confidential Information and (iii) Pieris Acquired IP & Zydus Acquired IP.

"JOINT KNOW-HOW" means all Information that is created by Zydus and Pieris jointly, during the Term, under the Plans, but specifically excluding (i) Joint Patents and (ii) the Information contained in Joint Patents.

"JOINT PATENTS" mean all Patents disclosing and/or claiming Joint Arising IP, together with the Information contained therein, to be registered by the Parties jointly in the Territory in such manner as stated in Article 10.

"LICENSE" shall have the meaning provided under Article 2.

"MARKETING APPROVAL" means the act of a Regulatory Authority necessary for the Commercialization of a Product for one or more indications in a regulatory jurisdiction in the Territories, including, without limitation, the approval of an NDA by a Regulatory Authority and satisfaction of all applicable regulatory and notification requirements.

"NDA" or "NEW DRUG APPLICATION" means an application or set of applications (and any other required registrations, notifications, forms, amendments or supplements) for a Marketing Approval for a Product and/or pre-market approval to make and commercialize the Product, filed with a Regulatory Authority including, without limitation, all documents, data and other information concerning a pharmaceutical product which are necessary for gaining the Marketing Approval.

"NET SALES" means, with respect to a Product, the gross amount (excluding VAT or excise duty or similar taxes) invoiced by Zydus or Pieris or any of their Affiliates or Sub-licensees to a Third Party that is not a Related Third Party, in the Zydus Territory / Pieris Territory as the case may be, less:

a) [***];

b) [***];

c) [***];

d) [***];

e) [***]; and

f) [***].

Such amount shall be determined from the books and records of Zydus or Pieris or their respective Sublicensees and Affiliates, as the case may be, maintained in accordance with any then-current Internationally-recognized accounting standard [***], in the case of Sublicensees or Affiliates, such similar accounting principles, consistently applied.

"OUTLICENSE" and "OUTLICENSING" shall mean [***] pursuant to a Sub-license in accordance with Article 2.

"PATENT" or "PATENTS" means in respect of a Product: (a) all patent applications (including provisional applications and applications for certificates of invention); (b) all patents issuing from such patent applications (including certificates of invention); (c) all patents and patent applications based on, corresponding to, or claiming priority from any of the foregoing; (d) all reissues, substitutions, confirmations, registrations, validations, re-examinations, additions, continuations, continued prosecution applications, continuations-in-part, or divisions of or to any of the foregoing; and (e) all term extensions, supplementary protection certificates and other governmental action beyond the original patent expiration date.

"PERSON" means a natural person, a corporation, a partnership, a trust, a joint venture, a limited liability company, any governmental authority or any other entity or organization.

"PHASE I TRIAL" means a human clinical trial conducted in healthy volunteers or patients anywhere in the world with a Product in accordance with ICH cGCP guidelines intended to establish an initial safety profile and the pharmacokinetics and/or pharmacodynamics of the Product. Phase I Trials shall include any Phase Ia Trial and any Phase Ib (multiple ascending dose) Trial. In case of Oncology drug development expansion trials of Phase I that can lead to a Phase III approval or Marketing Approval will be considered.

"PHASE II TRIAL" means a human clinical trial conducted in patients anywhere in the world with a Product in accordance with ICH cGCP guidelines and intended to demonstrate efficacy and a level of safety of the Product in the particular indication tested, as well as to determine the unit and/or daily dosage regimen required for testing the Product in the following Phase III Trial. Phase II Trials shall include any Phase IIa Trial and any Phase IIb Trial.

"PHASE III TRIAL" means a human clinical trial conducted in patients anywhere in the world with a Product in accordance with ICH cGCP guidelines and intended to demonstrate efficacy and a level of safety of the Product in the particular indication tested sufficient to obtain the Marketing Approval of the Product from a Regulatory Authority.

"PLAN" means a written plan for the Zydus Activities and Pieris Activities, prepared and approved by the CC and implemented by Zydus and Pieris, respectively, on an ongoing basis. A copy of the initial Plan for the Zydus Activities and Pieris Activities is attached hereto as Schedule 3. Subsequent Plan(s), e.g. for Additional Product(s), will be agreed between the Parties.

"PRODUCT(S)" means [***].

"PRODUCT 1" means an anti-c-Met Anticalin® protein, made using Pieris Technology [***] (herein referred to as PRS-110); provided, however, that Product 1 shall exclude (i) [***]0 (ii) any PRS-110 drug conjugate and (iii) Additional Product(s) unless explicitly agreed by the Parties.

"ADDITIONAL PRODUCT" means any [***] named by mutual agreement between the Parties after the Effective Date, including the Product 2 which will be named between the Parties pursuant to Section 2(5)(c).

"PRODUCT LAUNCH" means [***].

"PIERIS ACQUIRED IP" means all Information, know-how, intellectual property, including Improvements and any and all inventions, Patents, copyrights and trademarks and other rights, in each case necessary to the Development and/or Commercialization of a Product and over which Pieris acquires Control during the Term.

"PIERIS ACTIVITIES" means the activities undertaken by Pieris under the Plans in relation to (i) the Research, Development, manufacture and Commercialization of a Product in the Pieris Territory pursuant to the terms of this Agreement and (ii) its obligations in respect of the grant of the License and as stated in Article 3 and Schedule 3 herein.

"PIERIS ARISING IP" means all intellectual property, including Improvements and any Information, inventions and Patents relating thereto, [***], during the Term, under the Plans, as well as during the term of the Prior MTA.

"PIERIS CONFIDENTIAL INFORMATION" means all Pieris Rights and all Information disclosed or provided by, or on behalf of, Pieris to Zydus in connection with this Agreement, whether by letter or by the use of an appropriate proprietary stamp or legend. Notwithstanding the foregoing, Information which is orally or visually disclosed, or is disclosed in writing without an appropriate letter, proprietary stamp or legend, shall constitute Pieris Confidential Information if Pieris, within [***] days after such disclosure, delivers to Zydus a written document or documents describing such Confidential Information and referencing the place and date of such oral, visual or written disclosure.

"PIERIS KNOW-HOW" means (i) all Information that Pieris Controls as of the Effective Date relating to a Product and (ii) Pieris materials, in each case as is necessary to enable Zydus to conduct the Zydus Activities or exercise/use the License granted hereunder. Pieris Know-How does not include the Pieris Patents.

"PIERIS PATENTS" means all Patents Controlled by Pieris as of the Effective Date that are necessary to enable Zydus to conduct the Zydus Activities or exercise/use the License granted hereunder, together with the Information contained therein.

"REVENUES" means [***]. Notwithstanding the foregoing, "Revenues" shall not include any payments that constitute: (a) [***]; (b) [***]; (c) [***]; (d) [***]; and (e) [***].

"PIERIS RIGHTS" means Pieris Patents and Pieris Know-How.

"PIERIS TERRITORY" means [***].

"PRIOR CDA" means the Mutual Confidential Disclosure Agreement, made on [***], by and between the Parties.

"PRIOR MTA" means the Material Transfer Agreement, made on [***], by and between the Parties, wherein Pieris and Zydus have agreed that Zydus shall conduct Research Program as set forth in Exhibit B attached to the Original Agreement.

"RECIPIENT" means the Party receiving the Confidential Information from the other Party.

"REGULATORY AUTHORITY" means, in a particular country or geographical region (each, hereafter, is a regulatory jurisdiction), any applicable Governmental Authority involved in granting Marketing Approvals and/or to the extent required in such country or region, pricing approval of a Product in such country or region, including without limitation: (a) in India, the ICMR (Indian Council of Medical Research), DCGI, CDSCO (Central Drugs Standard Control Organization), and any other applicable Governmental Authority in India having jurisdiction over such Product, and any successor Governmental Authority having substantially the same function; (b) in the U.S., the FDA, and any other applicable Governmental Authority in the U.S. having jurisdiction over such Product; and (c) any foreign equivalent of (a) or (b), such as in EU, the EMA.

"REGULATORY LAW" means any applicable statutes, ordinances, regulations, rules or orders of any kind whatsoever of any Governmental Authority governing the Development, import, export, manufacture or distribution of a Product (including, without limitation, Marketing Approvals) together with any rules and regulations promulgated thereunder.

"REGULATORY MATERIALS" means any regulatory applications, submissions, notifications, registrations, approvals and/or other filings made to or with a Regulatory Authority that may be necessary or reasonably desirable to research, develop, make, have made, use, sell, have sold, offer for sale and import/export Product, and shall include without limitation, NDAs and IND Applications or their equivalents in other jurisdictions.

"REGULATORY SUBMISSION" means the submission by either Party or any of its Affiliates or Sublicensees of Regulatory Materials to a Regulatory Authority for the purpose of seeking relevant or required approvals for a Product Launch including the Marketing Approval.

"RESEARCH" means any and all activities undertaken under the Plans with respect to the research and pre-clinical evaluation of compounds for the Development of a Product.

"RELATED THIRD PARTY" means any Third Party [***].

"SUBLICENSEE" means any Third Party to which either Party grants any right to make, have made, use, sell, have sold, offer for sale and/or import/export Product in accordance with Article 2. For the avoidance of doubt, a [***].

"TERM" has the meaning provided in Section 11(1).

"TERRITORY" shall mean the Pieris Territory or the Zydus Territory, as applicable.

"TERRITORIES" shall mean both the Pieris Territory and the Zydus Territory.

"THIRD PARTY" means any Person other than Pieris or Zydus and their respective Affiliates.

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

"TIMELINES" means those timelines to be met by Zydus or Pieris in relation to Zydus Activities or Pieris Activities (as applicable) as set forth in Schedule 3 hereto, as may be agreed, updated and amended between the Parties. [***]

"ZYDUS ACQUIRED IP" means all Information, know-how, intellectual property, including Improvements and any and all inventions, Patents, copyrights and trademarks and other rights, in each case necessary to the Development and/or Commercialization of a Product and over which Zydus acquires Control during the Term.

"ZYDUS ACTIVITIES" means the activities undertaken by Zydus hereunder in relation to (i) the Research, Development, manufacture and Commercialization in the Zydus Territory pursuant to the terms of this Agreement and (ii) its obligations in respect of the grant of the License and as stated in Article 3 and Schedule 3 herein.

"ZYDUS ARISING IP" means all intellectual property, including Improvements and any Information, inventions and Patents [***], during the Term, under the Plans, as well as during the term of the Prior MTA.

"ZYDUS CONFIDENTIAL INFORMATION" means all Zydus Rights and all Information disclosed or provided by, or on behalf of, Zydus to Pieris in connection with this Agreement, whether by letter or by the use of an appropriate proprietary stamp or legend. Notwithstanding the foregoing, Information which is orally or visually disclosed, or is disclosed in writing without an appropriate letter, proprietary stamp or legend, shall constitute Zydus Confidential Information if Zydus, within [***] days after such disclosure, delivers to Pieris a written document or documents describing such Confidential Information and referencing the place and date of such oral, visual or written disclosure.

"ZYDUS KNOW-HOW" means all Information that Zydus Controls as of the Effective Date relating to a Product, necessary to enable Pieris to conduct the Pieris Activities or exercise/use the License granted hereunder. Zydus Know-How does not include the Zydus Patents.

"ZYDUS PATENTS" means all Patents Controlled by Zydus as of the Effective Date that are necessary to enable Pieris to conduct the Pieris Activities or exercise/use the License granted hereunder, together with the Information contained therein.

"ZYDUS RIGHTS" means Zydus Patents and Zydus Know-How.

"ZYDUS TERRITORY" means all regions/countries set forth in Schedule 4 attached hereto.

ARTICLE 2

THE LICENSE

1) LICENSE GRANTS

a) Subject to the terms and conditions of this Agreement such as Section 2(5) and Article 4, Pieris hereby grants to Zydus (a) an exclusive [***] royalty-bearing license under the Pieris Rights, the Pieris Arising IP, the Pieris Acquired IP and Pieris' interests in the Joint Arising IP and the Joint Patents, with the right to grant sublicenses to Sublicensees, to use, have used, sell, have sold, offer for sale and import/export Product in the Zydus Territory in the Field; (b) a [***] license under the Pieris Rights, the Pieris Arising IP, the Pieris Acquired IP and Pieris' interests in the Joint Arising IP and the Joint Patents, with the right to grant sublicenses to Sublicensees, (i) to research, develop, make or have made a Product (including, without limitation, the DP or DS thereof) in the Zydus Territory in the Field, by itself or

through an Affiliate or a Third Party; and (ii) to conduct Research and/or Development and manufacture of a Product (including, without limitation, the DP or DS thereof), by itself or through an Affiliate or a Third Party, in the Pieris Territory in the Field so long as such activities are solely in support of Development and/or Commercialization in the Zydus Territory in the Field; and (iii) a [***], [***] license under the Pieris Arising IP and Pieris' interests in the Joint Arising IP, with the right to grant sublicenses, to exploit Zydus' know-how and intellectual property available at Zydus before the Effective Date in a manner consistent with the terms and conditions of this Agreement such as Subsections (a) and (b) above as well as Section 2(4).

b) Subject to the terms and conditions of this Agreement such as Section 2(5) and Article 4, Zydus hereby grants to Pieris (a) [***] license under the Zydus Rights, the Zydus Arising IP, the Zydus Acquired IP and Zydus' interests in the Joint Arising IP and the Joint Patents, with the right to grant sublicenses to Sublicensees, to use, have used, sell, have sold, offer for sale and import/export Product in the Pieris Territory in the Field; (b) a [***] license under the Zydus Rights, the Zydus Arising IP, the Zydus Acquired IP and Zydus' interests in the Joint Arising IP and the Joint Patents, with the right to grant sublicenses to Sublicenses, but subject to Section 5(2), (i) to research, develop, make or have made a Product (including, without limitation, the DP or DS thereof) in the Pieris Territory in the Field, by itself or through an Affiliate or a Third Party; and (ii) to conduct Research and/or Development and manufacture of a Product (including, without limitation, the DP or DS thereof), by itself or through an Affiliate or a Third Party, in the Zydus Territory in the Field so long as such activities are solely in support of Development and/or Commercialization in the Pieris Territory in the Field; and (iii) a [***] license under the Zydus Arising IP and Zydus' interests in the Joint Arising IP, with the right to grant sublicenses, to exploit Pieris' know-how and intellectual property available at Pieris before the Effective Date in a manner consistent with terms and conditions of this Agreement such as Subsections (a) and (b) above Section 2(4), [***].

c) The rights described in the preceding paragraphs of this Section 2(1) are referred as the "**License**" in this Agreement.

2) Formal Licenses

- The Parties shall execute such formal licenses in accordance with terms and conditions set out in Section 2(1), whenever such formal licenses are necessary for registration with relevant patent offices and other relevant authorities in particular countries throughout the Territories.
- Prior to the execution of the formal licenses (if any) referred to in this Section 2(2), the Parties shall so far as possible have the same rights and obligations towards one another as if such licenses had been granted. In the event of any conflict in meaning between any such license and the provisions of this Agreement, the provisions of this Agreement shall prevail wherever possible.

3) NO IMPLIED LICENSES

Only the licenses granted pursuant to the express terms of this Agreement shall be of any legal force or effect. No other license rights shall be created by implication, estoppel or otherwise.

4) NON-COMPETE

The Parties agree that, during the Term [***], neither Party nor its Affiliate(s) shall, directly or indirectly, (a) sell a Product (including, without limitation, the DP or DS thereof) in the other Party's Territory in the Field or (b) enable a Third Party to sell the Product (including, without limitation, the DP or DS thereof) in the other Party's Territory in the Field.

5) COMMERCIALLY REASONABLE EFFORTS

a) Subject to Article 11 and Section 4(4), Zydus shall use Commercially Reasonable Efforts in and take the overall responsibilities for (i) [***] and (ii) [***]. Further, Zydus shall use Commercially Reasonable Efforts [***]. Following [***] and during the Development, Zydus may sublicense the License to a Third Party in accordance with this Article 2, to co-develop the Product with the Third Party within the Zydus Territory, provided, however, that [***].

b) Subject to Article 11 and Section 4(4) and following [***], Pieris shall use Commercially Reasonable Efforts in [***].

c) Subject to Article 11, both Parties shall use Commercially Reasonable Efforts to (i) name the Product 2 through the CC, and (ii) agree on its respective Field and the financial rights and obligations between the Parties with respect to the Product 2; within [***] months after the Effective Date.

ARTICLE 3

ZYDUS ACTIVITIES; PIERIS ACTIVITIES; COORDINATION COMMITTEE.

1) SCOPE OF ZYDUS RESPONSIBILITIES

a) SCOPE. Zydus shall control, be obligated to conduct, and be solely responsible for the Zydus Activities in accordance with the Plans. Zydus shall perform the Zydus Activities with reasonable care and skill. Zydus Activities shall include, without limitation:

i. Conducting and/or continuing to conduct the Research Program (as defined in the Prior MTA) in accordance with Exhibit B of the Prior MTA, including expressing Product 1 through Pieris Material set out in Schedule 5 attached hereto this Agreement;

ii. Conducting animal [***] efficacy and toxicology testing necessary for the preparation and filing of IND Applications with the respective local Regulatory Authorities within the Zydus Territory (e.g. the DCGI in India) for a Product, and which testing is acceptable per ICH-GCP guidelines;

iii. Conducting suitable clinical trials [***] in the Zydus Territory as per ICH-GCP guidelines and conforming to the aforementioned Regulatory Authorities' requirements for IND Applications. The sample size for conducting clinical trials shall meet said Regulatory Authorities' requirements, as detailed and agreed by the Parties through the CC.

For avoidance of doubt, [***].

iv. Conducting clinical trials as per ICH-GCP guidelines and necessary for Marketing Approvals of the Product throughout the Zydus Territory; all aspects of such clinical trials, including but not limited to the trial design and the number of patients enrolled, shall be as detailed and agreed by the Parties through the CC and set forth in the Plans;

v. Developing and optimizing processes and procedures used to manufacture and formulate the Drug Product to achieve a yield that is sufficient to deliver adequate amounts of Drug Product for Development and Commercialization;

vi. Production of the Drug Substance for pre-clinical studies throughout the Development in the Zydus Territory per applicable Regulatory Authorities' requirements;

vii. Performance of formulation, fill and finish of the Drug Substance and/or Drug Product and subsequent activities necessary for achieving the yield of Section 3(1)(a)(iv);

viii. Manufacturing of the Drug Product per ICH-GMP guidelines, and conforming to the Indian Regulatory Authorities' requirements, for Development and Commercialization and supplying sufficient amounts of Drug Product for the clinical trials in the Zydus Territory as referred in Section 3(1)(a)(iii); and

ix. Providing data (such as data of clinical trials and CMC data) to Regulatory Authorities within the Territories, when any one of said Authorities so requires from either Party or its Affiliates or Sublicensees.

b) COSTS. Zydus shall be solely responsible for all costs and expenses arising from and/or relating to the Zydus Activities from the Effective Date. Zydus shall also be solely responsible for all Third Party costs and expenses incurred by Zydus and not included in the Plans related to Research, Development and/or Commercialization.

c) INFORMATION DISSEMINATION BY ZYDUS. Zydus shall promptly share with Pieris, and provide Pieris with total access to, all data and reports generated by Zydus during the Term relating to Product, including all such data and reports generated pursuant to this Article 3 and Article 6, all Regulatory Materials, Zydus Arising IP, Joint Arising IP, Zydus Acquired IP, Zydus Know-How, safety data information and other Information generated by Zydus on an "AS IS" basis, for use by Pieris with regard to the Development in the Pieris Territory. For the avoidance of doubt, [***]. Zydus shall fulfill its obligations under this paragraph on at least a semi-annual basis throughout the Term.

2) SCOPE OF PIERIS RESPONSIBILITIES

a) SCOPE. Pieris shall control, be obligated to conduct, and be solely responsible for the Pieris Activities in accordance with the Plans. Pieris shall perform the Pieris Activities with reasonable care and skill. Pieris Activities shall include, without limitation:

i. Conducting [***] experiments of a Product pursuant to the respective Plan; [***];

ii. Sharing the data, generated in Subsection (i) above, with Zydus, such as, [***];

iii. Transferring to Zydus all clones, know-how / technologies for cloning, and upstream-and/or-downstream-process-development know-how, available at Pieris, with respect to the Product;

iv. Supporting Zydus in developing and optimizing processes and procedures used to manufacture and formulate the Drug Substance and/or the Drug Product; and

v. Developing (together with Zydus) the clinical and regulatory strategy for the Product in the Zydus territory.

vi. In case Pieris performs one or more clinical trials itself for a Product, the terms and conditions of this Agreement shall not change.

vii. Providing then-existing data (such as data of clinical trials and CMC data) to Regulatory Authorities within the Territories, when any one of said Authorities so requires.

b) COSTS. Pieris shall be solely responsible for all costs and expenses arising from and/or relating to the Pieris Activities [***] in the Pieris Territory from the Effective Date. Pieris shall also be solely

responsible for all Third Party costs and expenses incurred by Pieris and not included in the Plans related to Research, Development and/or Commercialization.

c) INFORMATION DISSEMINATION BY PIERIS. Pieris shall share with Zydus and provide (i) upon request of the CC, copies of clinical trial results and stability data for Product in existence as of the Effective Date, and any data, materials, Pieris Arising IP, Joint Arising IP, Pieris Acquired IP, safety data information and other Information generated by Pieris during the Term relating to Product, and (ii) Zydus with access to, and copies of, any technical information relating to Product and in its possession at the Effective Date and which is requested by a Regulatory Authority. The information described in (i) and (ii) of the preceding sentence is for use by Zydus with regard to the Development solely in the Zydus Territory. For the avoidance of doubt, [***].

3) COORDINATION COMMITTEE

(a) Scope and Responsibilities of the CC. For the purpose of open and effective communication between each Party on all ongoing matters with regard to the Zydus Activities and the Pieris Activities, the Parties shall, within [***] days of the Effective Date, establish the CC and hold the first meeting. The purpose of the CC shall be to set the overall strategy for Development of a Product and to monitor and govern the activities of the Parties in relation to Research and Development and the manufacturing and Commercialization, and the CC shall have the following specific responsibilities:

(i) Determination of Additional Product(s), including Product 2;

(ii) Preparation of, and agreement upon, Plans;

(iii) Modification and/or amendment of the Plans;

(iv) Information and data dissemination and provision of detailed progress updates between the Parties related to the Zydus Activities and the Pieris Activities;

(v) Oversight of [***] the Party's Development, manufacture and Commercialization activities conducted under this Agreement following [***]; and

(vi) Any other matters which the Parties agree, throughout the Term, should be discussed by or decided upon by the CC.

(b) Membership. The CC will be comprised of at least [***] members [***] and the initial membership shall be as set forth in Schedule 2.

(c) Chairmanship. The CC shall appoint a Chairman from among its members. The role of Chairman shall be to convene and preside at meetings of the CC. The Chairmanship shall alternate between a Zydus member of the CC and a Pieris member of the CC, on a semi-annual basis.

(d) Quorum and Decision-Making. The presence of at least [***] shall constitute a quorum for the purpose of consideration and action of the CC. All decisions of the CC shall be unanimous vote, with each Party having one vote. In the event that the CC fails, after good faith efforts, to arrive at a decision, the matter shall be referred to the President or CEO of each Party for resolution except for the situation referred in Section 3(3)(e) below. In the event that the President(s) or CEO(s) cannot resolve the matter within [***] days, the matter may be submitted for Dispute resolution pursuant to Article 12.

(e) In case the CC is unable to reach a consensus, via unanimous vote, on [***], then [***]; provided, however, that [***].

(f) Meetings. The CC shall meet [***] throughout the Term. Such meetings may be in-person, via videoconference or via teleconference. In-person meetings will be held alternately at Zydus' premises at Ahmedabad, India and Pieris' premises in Freising, Germany, unless the Parties otherwise agree. Each Party will bear the expenses of its participation in meetings. [***] days prior to each meeting, each Party shall provide written notice to the other Party of agenda items for the meeting, together with appropriate information related thereto. The first CC meeting shall be held within [***] days of the Effective Date. Non-member Authorized Persons of either Party can also attend such meetings.

(g) Minutes. Material information provided or discussed at a CC meeting will be documented and signed by both Parties within [***] days of the end of the meeting. Reasonably detailed written minutes will be kept of all meetings and will reflect, without limitation, material information provided at such meetings. Responsibility for drafting the minutes will be held by the Party that has Chairmanship of the CC at the applicable meeting. The draft minutes are subject to the other Party's review, comment and/or approval within [***] days of receipt from the drafting Party. Failure by the other Party to provide comments within such [***] day period shall be deemed to be an approval of the applicable draft minutes.

4) INFORMATION MANAGEMENT

The Parties agree to work together to identify methods appropriate for dissemination of information. Subject to the terms of this Agreement, each Party shall ensure that upon reasonable notice, it shall: (i) make its employees and non-employee consultants reasonably available to the other Party on issues in relation to the Development, including, without limitation, on regulatory, scientific, technical and clinical issues; and (ii) allow a reasonable number of appropriately qualified representatives of the other Party to have access to written records, accounts, notes, reports and data relating to the activities hereunder. The CC shall be responsible for arranging such information audit(s) referred in Section 3(5) or other procedures.

5) INFORMATION AUDITS AND SHARING

Pieris may carry out [***] of the facility of Zydus at which the Product(s) are manufactured, as well as the documentation generated in connection with the manufacture and testing of Product(s), including all relevant standard operating procedures. Such audit, which shall typically last no longer than [***] days, will take place during regular business hours and upon no less than four (4) weeks' prior written notice by Pieris. In addition, Pieris shall be entitled to perform additional for cause audits upon [***] days' prior written notice, including without limitation in the event of (i) any documented [***] regarding the Product(s) or the process of making the Product(s) (for example but not limited to [***] or (ii) any [***] during a Regulatory Authority's inspection or audit where such inspection or audit relates to the Product(s) or the process of making the Product(s); and Zydus shall immediately share with Pieris any and all findings during a Regulatory Authority's inspection or audit where such inspection or audit relates to the Product(s) or the process of making the Product(s). All audits mentioned above will be carried out by Pieris at Pieris' own costs but free of charge to Zydus. Notwithstanding the foregoing, [***].

6) DEBARMENT

In the course of the Development of Products, neither Party shall use, during the Term, any employee, agent or independent contractor who has been debarred by any Regulatory Authority, or, to the best of such Party's knowledge, is the subject of debarment proceedings by a Regulatory Authority;

ARTICLE 4

CONTINUED DEVELOPMENT AND COMMERCIALIZATION

1) [***]

The Zydus Activities and the Pieris Activities are intended to progress the clinical Development of each Product through the [***] conducted by Zydus in the Zydus Territory pursuant to the respective Plan, including, without limitation, [***].

2) CONTINUED ACTIVITIES IN A PARTY'S TERRITORY

(a) [***], (i) [***] and (ii) [***]. In addition, the Parties may elect to co-develop such Product [***] by mutual agreement. If both Parties elect to co-develop a Product, then the resulting ownership share shall be as the Parties mutually agree in a separate agreement. During the Term, each Development Party shall share all data generated in the continued Development of a Product in its Territory with the non-Development Party, so long as neither Party has opted out under Section 4(4).

(b) If, [***]y Pieris has not, [***], then Pieris shall [***]. If [***], or if [***], then [***].

3) CONTINUED DEVELOPMENT IN PORTIONS OF THE PIERIS TERRITORY [***]

[***], if Pieris [***], Pieris shall promptly notify Zydus [***] and shall [***], wherein [***] will agree that (i) [***]; (ii) [***] For the avoidance of doubt, [***]. For the avoidance of doubt, [***] under this Agreement [***].

4) OPT-OUT OF DEVELOPMENT BY A PARTY IN ITS TERRITORY

(a) [***], either Party shall be permitted to discontinue the Development and/or Commercialization of a Product and inform the other Party about such discontinuation pursuant to Section 13(3), in which case the other Party shall have the right to elect, by notifying the first Party pursuant to Section 13(3), to continue the Development and/or Commercialization of the Product and shall be designated as the sole-continuing Party for such Product. In case the other Party does so elect, it [***]. The Party ceasing to continue the Development and/or Commercialization of the Product (the "Opt-Out Party") shall [***] the Party continuing such Development and/or Commercialization (the "Continuing Party"). Further, the License granted by the Continuing Party to the Opt-Out Party hereunder shall terminate concurrently, and the License granted by the Opt-Out Party to the Continuing Party hereunder shall survive such termination and remain in effect, subject to the terms and conditions of this Agreement applicable thereto.

(b) Notwithstanding Article 7, the Opt-Out Party shall [***] in relation to [***] as follows:

(i) if the Continuing Party [***], the Continuing Party will [***] in accordance with Section [***]; provided, however, that [***] as mentioned in Section [***];

(ii) if the Continuing Party [***], the Continuing Party will [***] in accordance with Section [***];

(iii) if the Continuing [***], the Continuing Party will [***]; provided, however, that [***] as mentioned in Section [***]; and/or

(iv) if the Continuing Party [***], the Continuing Party [***] in accordance with Section [***].

(c) The Parties agree that the Opt-Out Party will be notified once [***]. For the avoidance of doubt, [***].

(d) [***] of same nature, related to [***] shall be agreed between the Parties in good faith [***].

5) OUTLICENSING

(a) Except where Pieris opts out under Section 4(4), Pieris [***]. Terms of the Outlicensing agreement shall [***]. Pieris will keep Zydus regularly informed of the progress of any Outlicensing in the Pieris Territory through regular reports to the CC. Zydus [***]. During the term, Pieris may Outlicense the Product in the Zydus Territory in case Zydus, during the Term, opts out under Section 4(4).

(b) Zydus will, at Pieris' request, cooperate in the preparation of such information and materials, participate in such presentations, due diligence procedures and other meetings and otherwise contribute toward such efforts as may be required to negotiate and complete any such Outlicensing in the Pieris Territory. Zydus shall grant such licenses and other rights to, and cooperate with, such Sublicensee as reasonably necessary to enable the Sublicensee to further develop and commercialize the Product in the Pieris territory and in the applicable Filed.

(c) Payments by Pieris to Zydus in connection with [***] shall be made [***].

(d) During the Term [***] Territory, Zydus may Outlicense a Product [***], except where Zydus opts out under Section 4(4). During the Term, Zydus may Outlicense the Product in the Pieris Territory in case Pieris opts out under Section 4(4).

(e) Nothing in this Agreement shall [***].

(f) Each Party will decide the procedures for Outlicensing the Product(s) in its respective Territory. Within [***] days of [***] related to a Product in [***], in each case within the one Party's Territory, that Party shall [***]. Any [***] shall be considered part of the providing Party's Confidential Information.

6) OUTLICENSING RESTRICTIONS

Neither Party shall contact Third Parties to discuss any potential Outlicenses other than such Outlicenses as are permitted pursuant to Section 4(5). During the Term, each Party shall notify the other Party of any unsolicited contacts from Third Parties that relate to any potential Outlicenses, except for such Outlicenses as are permitted pursuant to Section 4(5).

ARTICLE 5

MANUFACTURING

1) MANUFACTURING OF PRODUCT BY ZYDUS IN THE ZYDUS TERRITORY

For the avoidance of doubt, [***], [***].

2) MANUFACTURING AND SUPPLY AGREEMENT FOR THE PIERIS TERRITORY

Subject to Section [***], [***]. Notwithstanding the foregoing, [***], if [***],

Zydus shall use Commercially Reasonable Efforts and negotiate in good faith, with Pieris, its Affiliates, its Sublicensees and/or its successor-in-interest, the manufacturing and supply terms for the Product (including the API thereof), to be undertaken at Zydus' facilities, which shall be reflected in a definitive manufacturing and supply agreement (the "Manufacturing and Supply Agreement") containing customary terms and conditions of a contract manufacture and supply agreement, with the objective that Zydus is the world-wide supplier of the Product (including the API thereof). Notwithstanding the foregoing, [***].

[***] Notwithstanding the foregoing, [***]t, [***], provided, however, that the Third Party must be bound by obligations of confidentiality and non-use at least as equivalent in scope as and no less restrictive than those set forth in this Article 8. [***].

ARTICLE 6

REGULATORY

1) GENERAL

Pieris and Zydus, respectively, shall assume sole responsibility for the preparation, submission and maintenance of Regulatory Materials and for seeking Marketing Approvals in the Pieris Territory and the Zydus Territory, respectively. Such responsibilities shall include seeking necessary approvals from Regulatory Authorities for any label, labeling, package inserts and packaging, samples and promotional materials to be used in their respective Territory for Product and continuing relations with, and responding to inquiries and other communications of, applicable Regulatory Authorities.

2) REGULATORY MATERIALS.

All Regulatory and Marketing Approvals in the Zydus Territory and the Pieris Territory, respectively, shall be held in the respective name of, and shall be owned by, the respective Party. A Party shall consult with the other Party in its preparation of Regulatory Materials and in relation to any Regulatory Submission, and shall keep each other fully informed of any Regulatory Authority review, and approval of Regulatory Materials filings and Regulatory Submission in their respective Territory. Each Party shall be entitled to integrate data within the other Party's Control into its Regulatory Materials and, pursuant to the terms of this Agreement, shall have full access to the manufacturing data within the other Party's Control to assist with preparation of its Regulatory Materials. Neither Party shall file any Regulatory Materials with any Regulatory Authority without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed in light of the intent and purposes of this Agreement.

3) GENERAL REGULATORY ASSISTANCE AND ACCESS TO REGULATORY INFORMATION.

Each Party will cooperate and provide the other Party with all Information and assistance reasonably necessary for such other Party to carry out and comply with any regulatory obligations or requirements of Regulatory Authorities for each Product in connection with the Research and/or Development and/or the manufacture and/or Commercialization in such other Party's Territory to the extent contemplated under the terms and intent of this Agreement, including, without limitation, providing such Information and assistance to such other Party as is necessary for such other Party to: (i) submit, obtain, maintain and update Regulatory Material for each Product with Regulatory Authorities in such other Party's regulatory jurisdiction (including, without limitation, sharing clinical data, pre-clinical data, Development data, manufacturing data, and notes and documents related to discussions with Regulatory Authorities in connection with such Regulatory Material); (ii) submit or file promotional materials with Regulatory Authorities in connection with the Products in the other Party's regulatory jurisdiction; and (iii) comply with any other requirements of Regulatory Authorities in connection with the Products in the other Party's regulatory jurisdiction.

ARTICLE 7

PAYMENTS, TERM AND FINANCIAL REPORTING

1) PAYMENTS [***]

a) DEVELOPMENT MILESTONE PAYMENTS [***]

To the extent [***], Zydus shall pay to Pieris milestone payments in accordance with the following schedule and amounts:

Stage	**Amount** (USD)
[***]	$ 1,000,000

b) DEVELOPMENT MILESTONE PAYMENTS [***]

To the extent [***], Pieris shall pay to Zydus milestone payments in accordance with the following schedule and amounts:

Event	**Amount** (USD)
[***]	$ [***]
[***]	$ [***]

2) [***]

If [***], Pieris shall share the Revenue with Zydus in accordance with [***] as stipulated below:

Development Phase in the Zydus Territory by Zydus	**Pieris**	**Zydus**
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

Pieris agrees that if [***], then Pieris shall share [***] of such [***] Revenue with Zydus. If [***], then Pieris and Zydus shall [***].

Pieris agrees to promptly notify Zydus [***], to provide a reasonable amount of time for an audit set forth in this [***]. For the avoidance of doubt, [***].

(B) [***]

Upon and following [***], Revenue [***] in [***] shall be shared between the Parties in the following proportion:

Pieris	**Zydus**
[***]	[***]

Zydus agrees to promptly notify Pieris [***].

3) ROYALTY OBLIGATIONS.

a) ROYALTY PAYABLE TO PIERIS

For [***], except [***], Zydus shall pay Pieris a [***] tiered royalty as described in Section 7(3)(c) on all Net Sales sold by Zydus and its Affiliates (x) in the Zydus Territory [***], or (y) in the Pieris Territory, in case Pieris opts out and Zydus elects to continue under Section 4(4); provided, however, that, in the Pieris Territory, the [***]% tiered royalty will [***]. All royalty payments due under this Section 7(3)(a) ("Zydus' Royalty Obligation") shall be made on a quarterly basis (i.e., within thirty (30) days after 31st March, 30th June, and 30th September and 31st December). For clarity, [***].

b) ROYALTY PAYABLE TO ZYDUS

For [***], except [***], [***], Pieris shall pay Zydus a [***]% tiered royalty as described in Section 7(3)(c) on all Net Sales sold by Pieris and its Affiliates (x) in the Pieris Territory [***], or (y) in the Zydus Territory, in case Zydus opts out and Pieris elects to continue under Section 4(4); provided, however, that, in the Pieris Territory, the [***] tiered royalty will [***]. All royalty payments due under this Section 7(3)(b) ("Pieris' Royalty Obligation") shall be made on a quarterly basis (i.e,. within thirty (30) days after 31st March, 30th June, and 30th September and 31st December). For clarity, [***].

c) TIERED ROYALTY RATES

Net-Sales (USD)	**Royalty rate**
[***]	[***]%
[***]	[***]%
[***]	[***]%

4) PAYMENT CONDITIONS.

The payment obligation of the Parties hereunder shall accrue as and when a Party or its respective Affiliates (as applicable) first receives any such amounts that bear (i) the Royalty Obligations on Net Sales set forth in Section 7(3) or (ii) the Revenue Obligations set forth in Section 7(1) ((i) and (ii) as applicable), respectively (each a "Payment Obligation"). Notwithstanding the foregoing, the Payment Obligation of one Party shall be subject to the following conditions, as may be applicable:

a) [***];

b) [***];

c) [***];

d) [***].

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

e) [***].

5) PAYMENT TERM. One Party's Royalty Obligation under Section 7(3)will terminate upon the date which is the later of: (i) [***]; or (ii) [***] provided that, [***].

6) REPORTS. Following (x) the accrual of a Party's payment obligations arising from Sections 7(1), 7(2) and/or 7(3) above (hereafter "Payment Obligations") and (y) until this Agreement expires or is terminated under Article 11 (the duration between (x) and (y) is hereafter referred as the "Reporting Period"), such Party, on behalf of itself, its Affiliates and Sublicensees, shall furnish to the other Party a written report on [***] basis [***], accounting for the Net Sales of the Product subject to royalty obligations sold by it and/or its Affiliates in its Territory during the Reporting Period and any Pieris Revenue or Zydus Revenue, as the case may be, subject to the Payment Obligations, received by it and/or its Affiliates during the Reporting Period, and detailing the Payment Obligations under this Agreement. Each such report shall state, separately for such Party and each Affiliate, the number, description, and aggregate Pieris Revenues or Zydus Revenues, as the case may be, and aggregate Net Sales, on a [***] basis during the calendar quarter during which a Payment Obligation is payable. The reports required pursuant to this Section 7(6) shall be provided to the other Party contemporaneously with the payment of the Payments Obligations hereunder. All sums due under this Agreement shall be made by the due date, failing which a Party may charge the other Party interest on any outstanding amount on a [***] basis at a rate [***].

7) MAINTENANCE OF RECORDS. The Parties shall keep and maintain (and cause to be kept and maintained) complete and accurate records of the Net Sales and Pieris Revenues and Zydus Revenues, as the case may be, by such Party and/or their respective Affiliates and Sublicensees. The Parties shall retain such records for [***] years after the close of any Calendar Year.

8) FINANCIAL AUDITS.

(a) Upon [***] days' prior written notice, no more frequently than [***] in each period of [***] months and no later than [***] years following the applicable period of time, an independent certified public accounting firm of nationally recognized standing, reasonably acceptable to the Parties, at the expense of the Party initiating such request, shall have access during normal business hours to such of the records of the other Party and its Affiliates, as applicable, as may be reasonably necessary to verify the accuracy of the Revenue/royalty reports (as applicable) hereunder in relation to Net Sales as applicable, and any royalties or other payments due thereon. The accounting firm shall be under a duty to keep confidential any other information obtained from such reports. Each Party shall cooperate with the audit. The results of any audit shall be shared by the auditing Party with the audited Party. The fees charged by such accounting firm shall be paid by the Party initiating such request; provided, however, that if there is a discrepancy of an underpayment of more than [***] in the Royalty/Revenue amounts, the Party initiating the request may (i) charge the other Party interest on any outstanding amount on a [***] basis at a rate equivalent to [***], and (ii) [***].

(b) If such accounting firm concludes that additional payments were owed during such period, the Party so owing the payment shall pay the additional payments within [***] days of the date the other Party delivers to the Party owing the payment, such accounting firm's written report so correctly concluding; provided, however, that [***], [***].

(c) Each Party shall include in each sublicence granted by it pursuant to this Agreement a provision requiring its respective Sublicensees to make reports to it, to keep and maintain records of sales made pursuant to such sublicence and to grant access and audit rights to such records by the mutually selected independent accountant.

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

(d) The Parties shall treat all financial information subject to review under this Article 7 or under any sublicence agreement, in accordance with the confidentiality provisions of this Agreement, and shall cause the accounting firm to enter into a reasonably acceptable confidentiality agreement with the concerned Party obligating it to retain all such financial information in confidence pursuant to such confidentiality agreement.

9) PAYMENT CURRENCY AND EXCHANGE RATE. All payments to be made by either Party to the other Party under this Agreement shall be made in U.S. dollars (USD) and shall be paid by bank wire transfer to such bank account designated in writing by the other Party from time to time. In the case of sales/revenues which are invoiced/recorded in a foreign currency exchange, conversion of such sales into USD will be made on a [***] basis and shall be made at the rate of exchange [***].

10) INCOME TAX WITHHOLDING. Where any sum due to be paid to Pieris/Zydus (as applicable) hereunder shall be subject to any withholding tax, the Parties shall use all reasonable efforts to do all such acts and things and to sign all such documents as will enable them to take advantage of any applicable taxation treaty or agreement. In the event there is no applicable taxation treaty or agreement, or if an applicable taxation treaty or agreement reduces but does not eliminate such withholding or similar tax, the concerned Party shall pay such withholding or similar tax to the appropriate Governmental Authority, deduct the amount paid from the amount due to Pieris/Zydus (as applicable), and secure and send to Pieris/Zydus (as applicable) the best available evidence of such payment sufficient to enable Pieris/Zydus (as applicable) to obtain a deduction for such withheld taxes or obtain a refund thereof including, without limitation, when received, a copy of the official tax receipt evidencing payment of such tax to the appropriate taxing authority.

ARTICLE 8

CONFIDENTIALITY

1) CONFIDENTIALITY

Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, the Recipient agrees that, for the Term and for [***] years thereafter, it shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement (which includes the exercise of any rights or the performance of any obligations hereunder) any Confidential Information furnished to it by the Discloser pursuant to this Agreement except for that portion of such Information that the Recipient can demonstrate by competent written proof:

(a) was already known to the Recipient or any of its Affiliates, other than under an obligation of confidentiality to the Disclosing Party, at the time of disclosure by the Discloser;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Recipient;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the Recipient in breach of this Agreement;

(d) is subsequently disclosed to the Recipient or any of its Affiliates by a Third Party without obligations of confidentiality to the Discloser with respect thereto; or

(e) is subsequently independently discovered or developed by the Recipient or its Affiliate without the aid, application, or use of Confidential Information of the Discloser.

2) AUTHORIZED DISCLOSURE

Each Party may disclose Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary in the following situations:

(a) filing or prosecuting Patents in accordance with Article 10;

(b) subject to Section 8(3), regulatory filings and other filings with Governmental Authorities (including Regulatory Authorities), including filings with the FDA, as necessary for the Development or Commercialization, as required in connection with any filing, application or request for Regulatory Approval; provided, however, that reasonable measures will be taken to assure confidential treatment of such information;

(c) prosecuting or defending litigation;

(d) complying with Applicable Law, including regulations promulgated by securities exchanges;

(e) subject to Section 8(3), complying with Applicable Laws, including regulations promulgated by securities exchanges;

(f) disclosure to its Affiliates, Authorized Persons, independent contractors, licensors and any Sublicensees (including prospective Sublicensees), but only on a need-to-know basis and solely in connection with the performance of this Agreement, provided that each aforementioned disclosee must be bound by obligations of confidentiality and non-use at least as equivalent in scope as and no less restrictive than those set forth in this Article 8 prior to any such disclosure;

(g) disclosure of the material terms of this Agreement to any bona fide potential or actual investor, stockholder, investment banker, acquirer, merger partner or other potential or actual financial partner; provided that each aforementioned disclosee must be bound by obligations of confidentiality and

non-use at least as equivalent in scope as and no less restrictive than those set forth in this Article 8 prior to any such disclosure;

(h) disclosure of the stage of Development of Products under this Agreement to any bona fide potential or actual investor, stockholder, investment banker, acquirer, merger partner or other potential or actual financial partner; provided that each aforementioned disclosee must be bound by obligations of confidentiality and non-use at least as equivalent in scope as and no less restrictive than those set forth in this Article 8 prior to any such disclosure;

(i) disclosure of any blinded data generated under this Agreement to any bona fide potential or actual investor, stockholder, investment banker, acquirer, merger partner or other potential or actual financial partner; provided that each aforementioned disclosee must be bound by obligations of confidentiality and non-use at least as equivalent in scope as and no less restrictive than those set forth in this Article 8 prior to any such disclosure; and

(j) disclosure pursuant to Section 5(3)).

Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party's Confidential Information pursuant to Sections 8(2)(a), 8(2)(b), 8(2)(c) or 8(2)(d), it will, except where impracticable, give reasonable advance notice to the other Party of such disclosure and use reasonable efforts to secure confidential treatment of such information. In any event, the Parties agree to take all reasonable action to avoid disclosure of Confidential Information hereunder.

3) PUBLICITY; TERMS OF AGREEMENT

(a) The Parties agree that the material terms of this Agreement are the Confidential Information of both Parties, only subject to the special authorized disclosure provisions set forth in Section 8(2) and this Section 8(3). The Parties agree to make a joint public announcement of the execution of this Agreement substantially in the form of the press release attached as Schedule 6 on or after the Effective Date.

(b) After issuance of such joint press release, if either Party desires to make a public announcement concerning the material terms of this Agreement, such Party shall give reasonable prior advance notice of the proposed text of such announcement to the other Party for its prior review and approval (except as otherwise provided herein), such approval not to be unreasonably withheld in light of the intent and purposes of this Agreement, except that in the case of a press release or governmental filing required by Applicable Laws (where reasonably advised by the disclosing Party's counsel), the disclosing Party shall provide the other Party with such advance notice as it reasonably can and shall not be required to obtain approval therefor. A Party commenting on such a proposed press release shall provide its comments, if any, within [***] days (or within three (3) business days in the event that one Party (or its Affiliate) is a public reporting company) after receiving the press release for review and the other Party shall give good faith consideration to same. Neither Party shall be required to seek the permission of the other Party to repeat any information regarding the terms of this Agreement that have previously been publicly disclosed by such Party, or by the other Party, in accordance with this Section 8(3). For clarity, [***].

(c) The Parties acknowledge that either or both Parties may be obligated to file under Applicable Laws a copy of this Agreement with the Government Authorities of country where each Party is domiciled or has a public listing. Each Party shall be entitled to make such a required filing, provided that it requests confidential treatment of at least the financial terms and sensitive technical terms hereof and thereof to the extent such confidential treatment is reasonably available to such Party. In the event of any such filing, each Party will provide the other Party with a copy of this Agreement marked to show provisions for which such Party intends to seek confidential treatment not less than five (5) Business Days prior to such filing (and any revisions to such portions of the proposed filing a reasonable time prior

to the filing thereof), and shall reasonably consider the other Party's comments thereon to the extent consistent with the legal requirements, with respect to the filing Party, governing disclosure of material agreements and material information that must be publicly filed, and shall only disclose Confidential Information which it is advised by counsel or the applicable Governmental Authority is legally required to be disclosed. No such notice shall be required under this Section 8(3)(c) if the substance of the description of or reference to this Agreement contained in the proposed filing has been included in any previous filing made by either Party hereunder or otherwise approved by the other Party.

(d) Each Party shall require each of its Affiliates and private investors to which Confidential Information of the other Party is disclosed as permitted hereunder to comply with the covenants and restrictions set forth in this Article 8 as if each such Affiliate and each such investor were a Party to this Agreement and shall be fully responsible for any breach of such covenants and restrictions by any such Affiliate or investor.

4) PUBLICATIONS

(a) Neither Party shall publicly present or publish results of studies carried out under this Agreement (each such presentation or publication a "Publication") without the opportunity for prior review by the other Party, except to the extent otherwise required by Applicable Law, in which case Section 8(3) shall apply with respect to disclosures required by the SEC and/or for regulatory filings. The submitting Party shall provide the other Party the opportunity to review any proposed Publication at least [***] days prior to the earlier of its presentation or intended submission for publication. The submitting Party agrees, upon request by the other Party, not to submit or present any Publication until the other Party has had [***] days to comment on any material in such Publication. The submitting Party shall consider the comments of the other Party in good faith, but will retain the sole authority to submit the manuscript for Publication; provided that the submitting Party agrees to delay such Publication as necessary to enable the Parties to file a Patent if such Publication might adversely affect such Patent. The submitting Party shall provide the other Party a copy of the Publication at the time of the submission or presentation. Notwithstanding the foregoing, Zydus shall not have the right to publish or present Pieris' Confidential Information without Pieris' prior written consent, and Pieris shall not have the right to publish or present Zydus' Confidential Information without Zydus' prior written consent. Each Party agrees to acknowledge the contributions of the other Party, and the employees of the other Party, in all publications as scientifically appropriate.

(b) Nothing contained in this Section 8(4) shall prohibit the inclusion of information in a patent application claiming, and in furtherance of, the manufacture, use, sale or formulation of a Product, provided that the non-filing Party is given a reasonable opportunity to review, comment upon and/or approve the information to be included prior to submission of such patent application, where and to the extent required by Article 10 hereof.

(c) Notwithstanding Article 10, the Parties recognize that independent investigators have been engaged, and will be engaged in the future, to conduct clinical trials of Products. The Parties recognize that such investigators operate in an academic environment and may release information regarding such studies in a manner consistent with academic standards; provided that each Party will use reasonable efforts (e.g. through contractual relationship with said investigators) to prevent publication prior to the filing of relevant patent applications and to ensure that no Confidential Information of either Party is disclosed.

5) TERMINATION OF PRIOR CDA AND PRIOR MTA.

This Agreement terminates, as of the Effective Date, the Prior CDA as well as the Prior MTA. All Information exchanged between the Parties under the Prior CDA as well as the Prior MTA and/or obtained by either Party under the Prior MTA shall be deemed Confidential Information of the corresponding Party under this Agreement and shall be subject to the terms of this Article 8.

ARTICLE 9

WARRANTIES AND INDEMNITIES

1) PIERIS WARRANTIES

Pieris warrants, represents and undertakes to Zydus that, to the best of Pieris' knowledge, on and before the Effective Date:

I. It is a corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement, including the right to grant the licenses granted by it hereunder;

II. It has the full corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder. It has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered on behalf of Pieris, and constitutes a legal, valid, and binding obligation of Pieris that is enforceable against it in accordance with its terms;

III. It is not a party to any agreement, outstanding order, judgment or decree of any court or Governmental Authority that would prevent it from granting the rights granted to Zydus under this Agreement or performing its obligations under this Agreement;

IV. It has not, and will not, after the Effective Date and during the Term, grant any right to any Third Party that would conflict with the rights granted to Zydus hereunder;

V. Pieris is [***].

VI. Schedule 1 contains a complete listing of all Pieris Patents [***] as of the Effective Date;

VII. Pieris has sufficient legal and/or beneficial title, ownership or license under the Pieris Rights to grant the licenses to Zydus as purported to be granted pursuant to this Agreement; and

VIII. There are no written allegations or pending proceedings which assert that the Development, use or sale of a Product infringes or will infringe Third Party rights or which challenge the validity or enforceability of the Pieris Patents.

2) ZYDUS WARRANTIES

Zydus warrants, represents and undertakes to Pieris that, to the best of Zydus' knowledge, as of the Effective Date:

I. It is a company or corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement, including the right to grant the licenses granted by it hereunder;

II. It has the full corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder. It has taken all necessary corporate action on its part required to

authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered on behalf of Zydus, and constitutes a legal, valid, and binding obligation of Zydus that is enforceable against it in accordance with its terms;

III. It is not a party to any agreement, outstanding order, judgment or decree of any court or Governmental Authority that would prevent it from granting the rights granted to Pieris under this Agreement or performing its obligations under this Agreement;

IV. It has not, and will not, after the Effective Date and during the Term, grant any right to any Third Party that would conflict with the rights granted to Pieris hereunder;

V. it is the exclusive legal and beneficial owner of all rights, title and interest in the Zydus Rights, and there are no liens, encumbrances or other charges over any of them;

VI. Zydus [***] upon the terms and conditions of this Agreement [***] under this Agreement;

VII. Zydus will perform its obligations hereunder with reasonable care and skill;

VIII. there are no written allegations or claims that Zydus is not entitled to the Zydus Rights;

IX. it shall make a full and complete disclosure to Pieris of all Zydus relationships with Third Parties which may affect Pieris' complete exercise of rights under this Agreement;

X. in the event of Zydus becoming aware of any information which might affect its ability to give the warranties and representations set out above it shall promptly notify Pieris.

3) MUTUAL INDEMNIFICATION

a) ZYDUS' OBLIGATION. Zydus will defend, indemnify, and hold harmless Pieris from and against any and all liabilities, damages, losses, penalties, fines, costs, interest, and expenses, including, without limitation, reasonable attorneys' fees (collectively, "Damages"), direct or indirect, arising from or occurring as a result of (i) a Third Party's claim, action, suit, judgment, or settlement against Pieris (collectively, "Claims", and each a "Claim") arising out of the Development, preclinical and clinical testing, manufacture, distribution, Commercialization and/or use (including but not limited to product liability claims and claims for infringement of any Third Party intellectual property rights) of any Product, done by Zydus, its Affiliates or Sublicensees, or (ii) any breach by Zydus of an obligation, agreement, condition, covenant, representation, or warranty of Zydus under this Agreement; provided, however, that Zydus will not be obligated to indemnify or hold harmless Pieris from Damages under (i) and (ii) above to the extent that such Damages have resulted from (i) the grossly negligent (or more culpable e.g. willful) act or omission of Pieris or (ii) any breach by Pieris of an obligation, agreement, condition, covenant, representation, or warranty of Pieris under this Agreement or (iii) Pieris' Rights or Joint Arising IP.

b) PIERIS' OBLIGATION. Pieris will defend, indemnify, and hold harmless Zydus from and against any and all liabilities, damages, losses, penalties, fines, costs, interest, and expenses, including, without limitation, reasonable attorneys' fees (collectively, "Damages"), direct or indirect, arising from or occurring as a result of (i) a Third Party's claim, action, suit, judgment, or settlement against Zydus (collectively, "Claims" and each a "Claim")) arising out of the Development, preclinical and clinical testing, manufacture, distribution, Commercialization and/or use (including but not limited to product liability claims and claims for infringement of any Third Party intellectual property rights) of any Product, done by Pieris, its Affiliates or Sublicensees, or (ii) any breach by Pieris of an obligation, agreement, condition, covenant, representation, or warranty of Pieris

under this Agreement; provided, however, that Pieris will not be obligated to indemnify or hold harmless Zydus from Damages under (i) and (ii) above to the extent that such Damages have resulted from (i) the grossly negligent (or more culpable e.g. willful) act or omission of Zydus or (ii) any breach by Zydus of an obligation, agreement, condition, covenant, representation, or warranty of Zydus under this Agreement or (iii) Zydus' Rights or Joint Arising IP.

c) INDEMNIFICATION PROCEDURE. Notwithstanding foregoing, Section 9(3)(a) or Section 9(3)(b) will not apply, unless the following (i), (ii) (iii) and (iv) are all satisfied: (i) when the respective Party (the "Indemnitee") seeks indemnification from the other Party (the "Indemnitor") with respect to any Claim, the Indemnitee shall provide written notice of the Claim to the Indemnitor as soon as reasonably practicable upon becoming aware of the Claim; (ii) the Indemnitor shall be entitled, but shall not be obligated, to participate in or assume the defence of the Claim; provided, however, that if the defence is assumed, the Indemnitor shall, through legal representative chosen by it at its cost, act reasonably, and the Indemnitee shall also have the right, but not the obligation, to employ separate legal representative, in which event the fees and expenses of such second legal representative shall be borne by the Indemnitee; (iii) the Indemnitee shall reasonably cooperate with the Indemnitor and its legal representative in the investigation or defence of such Claim; (iv) no Claim may be settled by the Indemnitor without the prior written consent of the Indemnitee.

4) LIMITATION OF LIABILITY.

NEITHER PARTY WILL BE LIABLE TO THE OTHER PARTY FOR INDIRECT, INCIDENTAL, CONSEQUENTIAL, OR SPECIAL DAMAGES INCLUDING, BUT NOT LIMITED TO, LOST PROFITS ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. HOWEVER, NOTHING IN THIS SECTION IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY HEREUNDER.

ARTICLE 10

INTELLECTUAL PROPERTY

1) OBTAIN AND MAINTAIN THE PATENTS

a) Pieris shall, at its own cost and expense and within its sole discretion, file, maintain and prosecute (i) in the Territories, the Patents claiming the Pieris Rights, the Pieris Arising IP and the Pieris Acquired IP, and (ii) in the Pieris Territory only, the Joint Arising IP. Pieris shall [***].

b) Zydus shall, at its own cost and expense and within its sole discretion, file, maintain and prosecute (i) in the Territory, the Patents claiming the Zydus Rights, the Zydus Arising IP and the Zydus Acquired IP, and (ii) in the Zydus Territory only, the Joint Arising IP. Zydus shall not [***].

c) Notwithstanding foregoing Sections 10(1)(a) and (b), for said Patents, if either Party (the "Ceasing Party") wishes (i) not to file an application in any one of the following jurisdictions: [***], (ii) abandon any such patent application or (iii) not to maintain any such Patent in any one of said jurisdictions, it shall give prior written notice to the other Party at least [***] days before any relevant deadline, then the other Party has the right, exercisable within [***] days exercisable within [***] days of such notice, to take an assignment of the patent application or patent and, at its own expense, control the further prosecution the patent application or maintenance of such Patent. In the event such right is exercised by the other Party, the Ceasing Party shall effectuate said assignment and provide to the other Party all information necessary for the further

prosecution or maintenance. For the avoidance of doubt, any such Patent is part of the other Party's Acquired IP.

d) Notwithstanding foregoing Sections 10(1)(a) and (b), with respect to the filing, maintaining and prosecution of (i) any of Joint Arising IP as well as (ii) any of Pieris Arising IP and Zydus Arising IP, before any action taken by either Party, the Parties will confer first and try to agree on a strategy for drafting and/or prosecuting the respective application. In this regard, each of Zydus and Pieris shall keep the other Party fully informed as to the status of preparation, prosecution and maintenance of the respective application or patent, including, without limitation, (x) providing the other Party the opportunity to fully review and comment on (i) any patent application at least [***] days of the respective filing date and on (ii) any documents which will be filed in any patent office at least [***] days of any relevant deadline, and (y) providing the other copies of any substantive documents that such Party receives from such patent office at least [***] days after receipt, including notice of all interferences, reissues, re-examinations, oppositions or requests for patent term extensions. The other Party shall provide feedback at least [***] days of the respective filing date or the relevant deadline. If the Parties could not agree on such a strategy in good faith upon [***] days of the relevant deadline, Pieris will have the final decision-making authority regarding the filing, maintaining and prosecution of any of (i) [***] and (ii) [***];, while Zydus will have the final decision-making authority regarding the filing, maintaining and prosecution of any of (i) [***] and (ii) [***]; provided, however, that, if [***], [***]. Zydus and Pieris shall reasonably cooperate with and assist each other at their own respective expense in connection with activities referred under this Section 10(1)(d), at the other Party's request.

2) INFRINGEMENT OF THE PATENTS/INTELLECTUAL PROPERTY RIGHTS

a) During the Term, each Party shall inform the other Party promptly if it becomes aware of any infringement or potential infringement in the Territory of any of the Pieris Rights, the Pieris Arising IP, the Pieris Acquired IP, the Zydus Rights, the Zydus Arising IP, the Zydus Acquired IP or the Joint Arising IP, and the Parties shall consult with each other to decide the best way to respond to such infringement.

b) During the Term, if the Parties fail to agree on a joint program of action, including how the costs of any such action are to be borne and how any damages or other sums received from such action are to be distributed, then the Party (the "Enforcing Party") in whose Territory such infringement has taken place shall be entitled to take action against the applicable Third Party at its sole expense and the other Party (the "Abstaining Party") hereby agrees to be joined by the Enforcing Party in any legal proceeding where the Applicable Law requires the Abstaining Party's participation for the Enforcing Party to initiate and maintain such proceeding. In this regard, the Enforcing Party shall have control over such proceeding and the Abstaining Party shall reasonably cooperate with the Enforcing Party and defer to the Enforcing Party's decisions. The damages or other sums received from such action (the "Receipts") shall be distributed as follows: After deducting its own documented legal costs and reimbursing the other Party for any reasonable expenses incurred in assisting it in such action, the enforcing Party shall pay [***] of all remaining Receipts to the other Party, and shall keep the balance of the remaining Receipts for itself. Notwithstanding the foregoing, during the Term, only the Continuing Party under Section 4(4) can take action against the applicable Third Party in the Territories,

3) INFRINGEMENT OF THIRD PARTY RIGHTS

a) If any warning letter or other notice of infringement is received by a Party, or legal suit or other action is brought against such Party, alleging infringement of Third Party Rights in the practice of its Licence rights hereunder or in the manufacture, use or sale of the Product or use of any Patents, such Party shall promptly provide full details to the other Party, and the Parties shall discuss the best way to respond. The other Party, however, shall not be relieved of any of its

obligations for indemnification, if any, provided for hereinabove, for such infringement.

b) Zydus shall have the right but not the obligation to defend any such suit in the Zydus Territory, and Pieris shall have the right but not the obligation to defend any such suit in the Pieris Territory. The defending Party shall have the right to settle with such Third Party, provided that if any action or proposed settlement involves the making of any statement, express or implied, concerning the validity of any Patent Controlled by the other Party, the consent of the other Party must be obtained before taking such action or making such settlement.

c) Zydus shall be entitled to deduct, from royalties payable to Pieris in any Calendar Year under this Agreement, up to [***] of any sums paid to Third Parties (including, without limitation, damages, payments in settlement of litigation and royalty payments) during the same Calendar Year, based on any alleged or actual infringement of Third Party rights as the result of Zydus' practice of the Pieris Rights pursuant to this Agreement; provided, however, that no such deduction shall exceed [***] of the royalties otherwise payable to Pieris during such Calendar Year. Pieris shall be entitled to deduct, from payments payable to Zydus in any Calendar Year under this Agreement, up to [***] of any sums paid to Third Parties (including, without limitation, damages, payments in settlement of litigation and royalty payments) during the same Calendar Year, based on any alleged or actual infringement of Third Party rights as the result of Pieris' practice of the Zydus Rights pursuant to this Agreement; provided, however, that no such deduction shall exceed [***] of the payments otherwise payable to Zydus during such Calendar Year.

ARTICLE 11

TERM AND TERMINATION

1) TERM

This Agreement shall come into force on the Effective Date and, subject to the terms and conditions herein contained, will remain in effect until both Parties cease to have their respective Payment Obligations hereunder (the "Term"). Upon expiration of a Party's Payment Obligations hereunder, such Party will have a fully paid-up exclusive License as to the Product in its respective Territory from the other Party.

2) TERMINATION

a) Without prejudice to any other right or remedy it may have, either Party may terminate this Agreement at any time by notice in writing to the other Party, upon or after the occurrence of any one of the following:

i. Breach of any material provision of this Agreement by the other Party and if the breaching Party has not cured such breach within the [***] day period following written notice of termination by the non-breaching Party or breach of any provision of this Agreement by the other Party and if the breaching Party has not cured such breach within the [***] day period following written notice of termination by the non-breaching Party; provided, however, that to the extent there is a Dispute as to the existence of such a breach, then prior to any termination under this Section 11(2)(a)(i), the Parties shall resolve such Dispute in accordance with Article 12; and

ii. Insolvency or passing of a winding-up order or going into liquidation of the other Party, or if the other Party ceases to otherwise trade or is unable to pay its debts as and when they

fall due or is otherwise subject to any insolvency or winding-up procedure; or a petition is presented for its winding up or it enters into a composition with its creditors; or has filed against it a petition in bankruptcy; makes any assignment for the benefit of creditors; has appointed a receiver of its property or a substantial portion thereof; or takes advantage of any other law or procedure for the protection of creditors; or the majority of the Party‘s shares are transferred to Third Parties.

Said notice shall take effect on the date as specified in the notice as long as such date is after the occurrence of any of the (i) or (ii) above. For the avoidance of doubt, the non-breach Party is entitled to cease performance of its obligations during the respective period referred above in Section 11(2)(a)(i) until the breaching Party has cured the breach.

b) Either Party shall be permitted to terminate this Agreement with respect to a Product after a conclusion in good faith by the Parties that data generated from IND-enabling studies and/or an ongoing clinical trial preclude further Development of such Product in the Territory (e.g. as decided by the CC in good faith), by providing one thirty (30) days’ prior written notice to the other Party. Once this Agreement is so terminated pursuant to this Section 11(2)(b), either Party shall be solely responsible for any expenses in relation to its activities and/or responsibilities under this Agreement.

3) EFFECTS OF TERMINATION

a) Termination of this Agreement for any reason shall not release either Party hereto from any of its outstanding financial obligations hereunder or any liability which, at the time of such termination, has already accrued to the other Party or which is attributable to a period prior to such termination, nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement.

b) In the event of termination by Pieris pursuant to Section 11(2)(a)(i) or (ii), Pieris shall retain and/or have the exclusive rights to (i) all data generated until the effective date of such termination as well as the Arising IP relating thereto (Pieris Arising IP, Zydus Arising IP and Joint Arising IP) and (ii) to continue the Development and/or Commercialization of Products, whether directly or indirectly (e.g., through a Sublicensee), in a regulatory jurisdiction (e.g. a country or geographical region) within the Territories, without any further financial obligation to Zydus. Zydus agrees to execute one or more assignments necessary to effectuate such grant of rights to Pieris free of charge. Further, the License granted by Pieris to Zydus hereunder shall terminate concurrently, and the License granted by Zydus to Pieris hereunder shall survive such termination and remain in effect, subject to the terms and conditions of this Agreement applicable thereto.

c) In the event of termination by Zydus pursuant to Section 11(2)(a)(i) or (ii), Zydus shall retain and/or have the exclusive rights to all data generated until the effective date of such termination as well as the Arising IP relating thereto (Pieris Arising IP, Zydus Arising IP and Joint Arising IP) and (ii) to continue the Development and/or Commercialization of Products, whether directly or indirectly (e.g., through a Sublicensee), in a regulatory jurisdiction (e.g. a country or geographical region) within the Territories, without any further financial obligation to Pieris. Pieris agrees to execute such as one or more assignments necessary to effectuate such grant of rights to Zydus free of charge. Further, the License granted by Zydus to Pieris hereunder shall terminate concurrently, and the License granted by Pieris to Zydus hereunder shall survive such termination and remain in effect, subject to the terms and conditions of this Agreement applicable thereto.

d) In the event of termination by one Party pursuant to Section 11(2)(b), in term of the Product so terminated, each Party shall retain and/or have the exclusive rights to its Arising IP and the other Party agrees to execute one or more assignments necessary to effectuate such grant of rights to the first-mentioned Party free of charge. The Parties will handle Joint Arising IP pursuant to Article 10. Further, the License granted by one Party to the other Party hereunder shall terminate

concurrently, except that the non-exclusive licenses granted under Section 2(1)(a)(3) and Section 2(1)(b)(3) hereunder shall survive such termination and remain in effect, subject to the terms and conditions of this Agreement applicable thereto. Furthermore, the Parties hereby agree to keep the data in confidence in accordance with Article 8 for the Term and [***] years thereafter.

4) SURVIVAL

The following provisions shall survive the expiration or termination of this Agreement for any reason: Articles 1 and 7 to 13.

ARTICLE 12

GOVERNING LAW [***]

This Agreement shall be governed by and construed in accordance with the then-current substantive law of the state of New York, United States, without regard to the conflict of laws principles thereof. The Parties further agree that any Dispute that cannot be resolved by negotiation between the Parties shall [***].

ARTICLE 13

MISCELLANEOUS

1) FORCE MAJEURE

Neither Party will be held liable or responsible to the other Party nor be deemed to have defaulted under or breached the Agreement for failure or delay in fulfilling or performing any term of the Agreement when such failure or delay is caused by or results from causes beyond such Party's reasonable control including, without limitation, war, fire, accident or other casualty, labor disturbance, strike or other industrial destruction, riots, revolt, acts of war (whether war be declared or not), insurrections, riots, civil commotions, or earthquakes, flood or other natural disasters or Acts of God or the public enemy, (collectively, "Force Majeure"), provided that, however, the Party affected will notify the other Party of such Force Majeure circumstances as soon as reasonably practicable and will make every reasonable effort to mitigate the effects of such Force Majeure circumstances.

2) FURTHER ASSURANCES

The Parties intend that this Agreement contain all consents, licenses and authorizations from one Party to the other necessary to enable each Party to perform its obligations hereunder. In the event any further such consents, licenses or authorizations are necessary, each Party agrees to take such further actions and execute such further agreements as may be reasonably necessary to carry out the intent and purposes of this Agreement.

3) SEVERABILITY

In the event any one or more of the provisions contained in this Agreement should be held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein will not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affect the intent and purposes of this Agreement. The Parties will in such an instance use their diligent efforts to replace the invalid, illegal or unenforceable provision(s) with

valid, legal and enforceable provision(s) which, insofar as practicable, maintains the intent and purposes of this Agreement under this Agreement.

4) NOTICES

All notices which are required or permitted hereunder will be in writing and sufficient if delivered personally, sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier) or sent by nationally-recognized overnight courier addressed as follows:

if to Pieris, to:
Pieris, AG
Lise-Meitner-Straße 30, 85354
Freising, Germany
Attention: CEO
Fax No: 49 (0) 8161 14 11 444

if to Zydus, to:
Zydus Research Centre
Sarkhej-BavlaN.H. No. 8A
Moraiya, Ahmedabad - 382210
Gujarat, India
Attn: Dr. Sanjeev Kumar
Sr. Vice President, Biotechnology
Ph: +91-2717-665555

CC to
Cadila Healthcare Limited
Zydus Tower
Satellite Cross Roads
Ahmedabad - 380 015
India
Attention: Mr. Arun Parikh
Fax No.: +91-79-26868144

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice will be deemed to have been given (i) on the same business day if personally delivered or sent by facsimile or (ii) on the third (3rd) business day after dispatch if sent by nationally-recognized overnight courier.

5) ENTIRE AGREEMENT

This Agreement contains the entire understanding of the Parties with respect to License, Research, Development, manufacture and Commercialization of a Product as well as related financial obligations on either Party. All express or implied agreements and understandings, either oral or written, heretofore made by the Parties on the same subject matter, are expressly superseded by this Agreement. The Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by both Parties hereto.

6) HEADINGS

The captions to the several Articles and Sections hereof are not a part of the Agreement nor affect the interpretation of any of its provisions, but are merely a convenience to assist in locating and reading the several Articles and Sections hereof.

Portions of the exhibit, indicated by the mark "[***],"were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

7) INDEPENDENT CONTRACTORS

It is expressly agreed that Pieris and Zydus will be independent contractors and that the relationship between the two Parties will not constitute a partnership, joint venture or agency. Neither Pieris nor Zydus will have the ability to control the other Party or the authority to make any statements, representations or commitments of any kind, or to take any action, which will be binding on the other, without the prior written consent of the other Party.

8) ASSIGNMENT

This Agreement may not be assigned or otherwise transferred, nor, except as expressly provided hereunder, may any right or obligation hereunder be assigned or transferred by either Party without the prior written consent of the other Party; provided, however, that a Party may make such an assignment or transfer without the other Party's consent to any Affiliate of such Party, provided that (i) such transfer shall not adversely affect the other Party's rights and obligations under this Agreement and that such assigning/transferring Party remains jointly and severally liable with such Affiliate for the performance of this Agreement and/or the assigned obligations, and (ii) that the assigning Party provides written notice to the other Party of such assignment and the assignee shall have agreed in writing to be bound (or is otherwise required by operation of Applicable Laws to be bound) in the same manner as such assigning Party hereunder. Notwithstanding the foregoing, either Party shall have the right to assign this Agreement to a Third Party successor-in-interest or purchaser of all or substantially all of the business or assets of such Party to which this Agreement relates (the "Third Party Assignee"), whether in a merger, combination, reorganization, sale of stock, sale of assets or other transaction; provided, however, that the Third Party Assignee expressly obligates itself in a written instrument delivered to the non-assigning Party, on or before the date of closing such merger, combination, reorganization, sale of stock, sale of assets or other transaction, to fully perform all of the obligations of the assigning Party under this Agreement. In addition, either Party may assign its right to receive proceeds under this Agreement or grant a security interest in such right to receive proceeds under this Agreement to one or more Third Parties providing financing to such Party pursuant to the terms of a security or other agreement related to such financing (i.e., for purposes of a royalty financing arrangement). The rights and obligations of the Parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties. Any attempted assignment not in accordance with this Section 13(8) will be void.

9) WAIVER

The waiver by either Party hereto of any right hereunder, or any failure to perform by the other Party, or any breach by the other Party will not be deemed a waiver of any other right hereunder or of any other breach or failure by said other Party whether of a similar nature or otherwise.

10) NO THIRD PARTY BENEFICIARIES

Except for as referred in Section 13(8), this Agreement is neither expressly nor impliedly made for the benefit of any Person other than the Parties.

11) COUNTERPARTS

The Agreement may be executed in two or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. The counterparts of this Agreement may be executed by one Party with electronic signature and delivered through facsimile or email to the other Party and the receiving Party may rely on the receipt of such counterpart so executed and delivered by as if the original had been received.

12) WAIVER OF RULE OF CONSTRUCTION

Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement will be construed against the drafting Party will not apply.

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

CADILA HEALTHCARE LIMITED

/s/ Nitin Parekh

Name: Nitin Parekh
Title: Chief Financial Officer

/s/ Arun Parikh
Name: Arun Parikh
Title: Sr. V.P. Legal

PIERIS AG

/s/ Stephen S. Yoder

Name: Stephen S. Yoder
Title: Chief Executive Officer

***Portions of the exhibit, indicated by the mark "[***],"* were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.**

EXECUTION COPY

SCHEDULE 1

Pieris Patents:

(a) all patent applications derived from any one of the Patent Cooperation Treaty/PCT applications listed below in this Schedule 1 from i) to vi); (b) all patents issuing from such patent applications (including certificates of invention); (c) all patents and patent applications based on, corresponding to, or claiming priority from any of the foregoing; (d) all reissues, substitutions, confirmations, registrations, validations, re-examinations, additions, continuations, continued prosecution applications, continuations-in-part, or divisions of or to any of the foregoing; and (e) all term extensions, supplementary protection certificates and other governmental action beyond the original patent expiration date.

i) PCT/DE98/02898

ii) PCT/EP2004/009447

iii) PCT/EP2007/057971

iv) PCT/EP2009/051020

v) PCT/EP2010/061436

vi) PCT/EP2013/050158

Portions of the exhibit, indicated by the mark "[***],"were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

EXECUTION COPY

SCHEDULE 2

CC MEMBERS

[***]

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

SCHEDULE 3

Plan

Zydus and Pieris shall plan the activities in the CC meeting and track the progress on a regular basis.

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

EXECUTION COPY

SCHEDULE 4

Zydus Territory (subject to Section 4(3)):

[***]

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

EXECUTION COPY

SCHEDULE 5

[***]

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

EXECUTION COPY

SCHEDULE 6

Press Release

Zydus and Pieris Sign Broad Co-Development Alliance for Novel Anticalin® Therapeutics

—cMet antagonist, PRS-110, to be the flagship program—

Ahmedabad, India; Freising, Germany.

Zydus Cadila, an innovative global pharmaceutical company that discovers, develops, manufactures and markets a broad range of healthcare products, and Pieris AG, a next generation therapeutic protein R&D company, have entered into an alliance for development and commercialization of multiple novel Anticalin®-based protein therapeutics, both companies announced today. The collaboration combines Pieris' drug discovery and early development capabilities with Zydus' expertise in biologics development, regulatory affairs and biologics manufacturing. Under the terms of the agreement, Zydus will take the lead in advancing Anticalin drug candidates through formal pre-clinical development and into clinical development, undertaking drug development in accordance with ICH guidelines. Zydus has been granted exclusive marketing rights in India and several other emerging markets, while Pieris retains exclusive marketing rights in key developed markets.

Mr. Pankaj R. Patel, Chairman and Managing Director, Zydus group said, "Collaborating with established biotech companies on differentiated drug candidates is an important component of Zydus' ongoing transformation into an innovation-led global healthcare provider, and we are pleased to add Anticalins to our novel biologics pipeline". Pieris CEO, Stephen Yoder, added, "With Zydus' state-of-the-art manufacturing facilities and seasoned drug development team, this collaboration will allow Pieris to unlock value on a global scale in a cost-effective manner, significantly expanding the number of proprietary Anticalin programs we can advance into clinical trials."

The most advanced program in the collaboration is PRS-110, an Anticalin specific for cMet, a target becoming increasingly validated across a broad spectrum of tumors. PRS-110, which is a pure antagonist due to its monovalent target engagement, has demonstrated the ability to

—CONTINUES—

***Portions of the exhibit, indicated by the mark "[***],"* were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.**

inhibit both ligand-dependent and -independent cMet signaling in a variety of animal models. Through this unique collaborative model, the companies seek to develop candidates to proof-of-concept and will explore out-licensing opportunities in Pieris' territories at the appropriate time. Licensing revenues would be shared on mutually agreed upon terms.

About Zydus:

Zydus Cadila is an innovative, global pharmaceutical company that discovers, develops, manufactures and markets a broad range of healthcare therapies. The group employs over 15,000 people worldwide and is dedicated to creating healthier communities globally. Zydus is the only Indian pharma company to launch its own patented NCE – Lipaglyn™, the world's first drug to be approved for the treatment of diabetic dyslipidemia. It aims to be a leading global healthcare provider with a robust product pipeline, achieve sales of over $3 billion by 2015 and be a research-based pharmaceutical company by 2020.

The group has been making significant investments in the development and manufacturing of Biologics for more than a decade. Zydus has developed a pipeline of 17 Biosimilar drugs with six such drugs commercialized and others in clinical development. Zydus capitalizes on its in-house drug development and manufacturing strengths to partner in Novel Biologics opportunities and has so far advanced two novel biologic drugs to the clinical trial stage. Zydus has one of the largest Biologics manufacturing facilities in India with scales reaching up to 11,000 L per batch. With a vision to provide high quality Biologics drugs in a cost-effective manner Zydus aspires to be a world leader in the biologics space. For more information, please visit: www.zyduscadila.com

About Pieris & Anticalins

Pieris AG is an independent, clinical-staged biotechnology company advancing its proprietary Anticalin® technology to create differentiated drugs that are safer and more effective than conventional approaches. Exclusive to Pieris, Anticalins promise to address high-unmet medical needs and expand the potential of targeted therapeutics. The company currently has a diverse proprietary pipeline and has, in addition to Zydus, ongoing R&D collaborations with Daiichi Sankyo, the Sanofi Group and Allergan. Privately held, Pieris has been funded by premier biotechnology-focused venture capital, including lead investors OrbiMed Advisors and Global Life Science Ventures. For more information, please visit: www.pieris-ag.com.

Anticalins® are recombinantly engineered versions of human lipocalins, low-molecular weight polypeptides that naturally bind, store and transport a wide spectrum of molecules. To make Anticalins, Pieris makes discrete changes to those lipocalin amino acid positions responsible in endogenous ligand binding, thereby redirecting specificity away from the natural ligand and to virtually any target of interest. By utilizing an endogenous binding protein as a template, Pieris "hijacks" the natural function of the lipocalin to enable diverse therapeutic applications.

—END—

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

For more information, please contact:

Zydus

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+91 (0)9974051180
sujatha.rajesh@zyduscadila.com

Rashmi Nair
+91(0) 9724313237
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Pieris AG

Stephen Yoder, CEO
+49 (0) 8161 1411 400

Gretchen Schweitzer
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media@pieris-ag.com

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

CONFIDENTIAL TREATMENT REQUESTED

CONFIDENTIAL

JOINT DEVELOPMENT & LICENSE AGREEMENT

This Joint Development and License Agreement (this "Agreement") is made as of November 21st, 2013 (the "Effective Date"), by and between Pieris AG, a German stock corporation organized and existing under the laws of Germany, whose principal place of business is at Lise-Meitner-Straße 30, 85354 Freising, Germany ("Pieris"), and Stelis BioPharma Private Limited, formerly known as Agila Biotech Private Limited, a company incorporated under the Companies Act (India), 1956 and having its registered office at Strides House, Bilekahalli, Bannerghatta Road, Bangalore 560 076, India ("Stelis BioPharma"). Pieris and Stelis BioPharma may be referred to individually as a "Party" or together as the "Parties."

BACKGROUND

A. Pieris has certain proprietary technologies and know-how available before the Effective Date (the "Pieris Technology"), which is used to create and develop engineered lipocalin muteins (each, an "Anticalin® Protein");

B. Stelis BioPharma is engaged in the business of manufacturing and supplying therapeutic biological products for research and development and commercial purposes;

C. Pieris and Stelis BioPharma desire to collaborate in the Field with each other, to develop certain therapeutic biological products, comprising Anticalin® Protein(s) made using the Pieris Technology, [***] in accordance with the terms and conditions of this Agreement;

D. Pieris and Stelis BioPharma may establish a joint venture company (the "JVC") to further develop and commercialize one or more such products, after [***], pursuant to a separate Joint Venture Agreement to be entered into by the Parties (the "JVA) as set forth in Article 3.8; and

E. Upon successful completion of the pre-clinical activities in the Territory for such product(s) and the JVC's receipt of all necessary Technology Transfer Documents (TTD), Consents, business licenses and governmental approvals, and contingent upon the Parties' agreement to form the JVC and on a plan and budget for the further development and commercialization of such product(s), such product(s) and all associated data, rights and assets will be transferred to the JVC and the JVC will continue the development and commercialization of such product(s) as further provided in the JVA.

NOW, THEREFORE, in consideration of the mutual covenants and promises herein contained and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged by the Parties, the Parties agree as follows:

Article 1
DEFINITIONS

1.1 "Indian Act" means the Drugs and Cosmetics Act (India), 1940.

1.2 "Additional Product(s)" means [***], named by mutual agreement between the Parties after the Effective Date pursuant to Article 3.11.

1.3 "Acquired Intellectual Property" or "Acquired IP" means all Information, know-how, intellectual property, including Improvements and any and all inventions, patents, copyrights and trademarks and other rights, in each case necessary for the performance of the activities set forth in this Agreement and the applicable Development Plan and over which one Party acquires Control during the Term.

1.4 "Affiliate" means, with respect to a Party, any Person controlling, controlled by or under common control with such Party, for so long as such control exists. For the purposes of this definition, "control" means: (a) to possess, directly or indirectly, the power to direct the management and policies of such Person, whether through ownership of voting securities or by contract relating to voting rights or corporate governance; or (b) ownership of more than fifty percent (50%) of the voting securities in such Person (or such lesser percent as may be the maximum that may be owned pursuant to Applicable Laws of the country of incorporation or domicile, as applicable). For clarity, for purposes of this Agreement, the JVC shall not be deemed an Affiliate of either Party.

1.5 "[***]" means, [***].

1.6 "Applicable Laws" means any laws, statutes, rules, regulations, guidelines, and standards promulgated by any governmental authority of competent jurisdiction applicable to the Parties or the activities contemplated hereunder, together with any judgments, orders, notices, instructions, decisions, standards, guidance and awards, each having the force of law, issued by a court or competent authority or tribunal or a Regulatory Authority to which the applicable Party is subject, including, as applicable, GCP, GLP, GMP, the Indian Act and the Indian Rules.

1.7 "Background Technology" means, with respect to a Party, any and all technology, know-how, technical information and other technical subject matter, and all intellectual property rights therein, in each case Controlled by such Party as of the Effective Date or otherwise conceived or developed by or on behalf of such Party outside the performance of this Agreement, in each case that are necessary for the performance of the activities set forth in this Agreement and the applicable Development Plan.

1.8 "Collaboration Product(s)" means, [***].

1.9 "Consents" means any consent, license, approval, authorization, waiver, permit, grant, concession, agreement, license, certificate, exemption, order or registration, of or with any Person.

1.10 "Control" means the possession (whether by ownership, license or other authorization), as of the Effective Date or during the Term, of (a) with respect to materials, data or information, physical possession or the right to such physical possession of those items, and the right to provide them to others (including the other Party); and (b) with respect to intellectual property rights, the right sufficient to grant the applicable license or sublicense under this Agreement; in each case without violating the terms of any agreement with any Third Party. Notwithstanding anything to the contrary in this Agreement, the following shall not be deemed to be Controlled by

a Party: (i) any materials, data, information or intellectual property owned or licensed by any Acquiring Entity immediately prior to the effective date of merger, consolidation or transfer, and (ii) any materials, data, information or intellectual property that any Acquiring Entity subsequently develops independently, without accessing or practicing Pieris' Background Technology (in the case of an Acquiring Entity of Pieris) or Stelis BioPharma's Background Technology (in the case of an Acquiring Entity of Stelis BioPharma). For the purpose of this Article 1.10, "Acquiring Entity" means, with respect to a Party, a Third Party that merges or consolidates with or acquires such Party, or to which such Party transfers all or substantially all of its assets to which this Agreement pertains. "Controlled" has its corollary meaning.

1.11 "Commercially Reasonable Efforts" means application of expertise and resources that are typical in the pharmaceutical industry in the research, development and commercialization of a product or compound owned by a Third Party or resulting from a Party's own research efforts, which product or compound is [***].

1.12 "Dispute" means any dispute arising from or relating to this Agreement, including, without limitation, the interpretation of any term of this Agreement, the rights and liabilities of the Parties hereto and/or the assessment of a Party's compliance with any of its obligations under this Agreement.

1.13 "Drug Product" or "DP" means the final dosage form, which contains a Collaboration Product in association with other active or inactive ingredients.

1.14 "Drug Substance" or "DS" means any substance or mixture of substances, comprising a Collaboration Product, intended to be used in the manufacture of a Drug Product and that, when used in the production of the Drug Product, becomes the Active Pharmaceutical Ingredient of the Drug Product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body.

1.15 "Facility" means (a) a GMP-compliant facility jointly identified by both Parties for manufacturing (including storing and handling) any Drug Product of Collaboration Product(s) for pre-clinical studies and/or clinical trials, (and (b) [***]), or such other facility as identified by JVA and notified to Pieris, only when all applicable testing and validation of such facility has been successfully completed, and all required Consents have been obtained, and such facility is otherwise ready and available for use in manufacture of Collaboration Products.

1.16 "Field" means (i) with respect to [***], the treatment, palliation and/or prevention of [***] diseases in human; and (ii) with respect to any Additional Product, the treatment, palliation and/or prevention of [***].

1.17 "GCP" means the then-current FDA regulations and guidelines for "Good Clinical Practice," as promulgated by the FDA under 21 CFR Parts 50, 54, 56 and 312, as amended from time to time, or any foreign equivalents thereto (*e.g.*, ICH Guideline for Good Clinical Practice) in the country in which the applicable pre-clinical study or clinical trial is conducted.

1.18 "GMP" means the then-current Good Manufacturing Practices pursuant to the U.S. Food, Drug and Cosmetic Act and any U.S. regulations found in Title 21 of the U.S. Code of Federal

Regulations (including Parts 11, 210 and 211 and the provisions of the Act and the Rules) and comparable laws, rules and regulations applicable to the manufacture, labeling, packaging, handling, storage, supply and transport of any Collaboration Product in any jurisdiction where the applicable Collaboration Product is or may be utilized in humans hereunder.

1.19 "GLP" means the then-current FDA regulations and guidelines for "Good Laboratory Practice," as promulgated by the FDA under Title 21 of the U.S. Code of Federal Regulations Part 58, as amended from time to time, or any foreign equivalents thereto in the country in which research is conducted hereunder.

1.20 "ICH" means the International Conference on Harmonization.

1.21 "Investigational Medical Product" or "IMP" means a pharmaceutical form of a DP or DS being tested in one or more clinical trials.

1.22 "[***]" means, [***].

1.23 "[***]" means [***].

1.24 "[***]" or "[***]" means [***].

1.25 "Marketing Approval" means the act of a Regulatory Authority necessary for the Commercialization of a Product for one or more indications in a regulatory jurisdiction in the Territories, including, without limitation, the approval of an NDA by a Regulatory Authority and satisfaction of all applicable regulatory and notification requirements.

1.26 "New Drug Application" or "NDA" means an application or set of applications (and any other required registrations, notifications, forms, amendments or supplements) for a Marketing Approval for a Product and/or pre-market approval to make and commercialize the Product, filed with a Regulatory Authority including, without limitation, all documents, data and other information concerning a pharmaceutical product which are necessary for gaining the Marketing Approval.

1.27 "[***]" means [***].

1.28 "Person" means any individual, corporation, partnership, limited liability company, trust, business trust, association, joint-stock company, joint venture, pool, syndicate, sole proprietorship, unincorporated organization, government authority or any other form of entity not specifically listed herein.

1.29 "Pieris Technology" means Pieris' proprietary technologies and know-how available before the Effective Date, together with all intellectual property rights therein.

1.30 "Phase I Clinical Trial" means any human clinical trial conducted in healthy volunteers or patients anywhere in the Territory with a Collaboration Product in accordance with GCP to establish an initial safety profile and the pharmacokinetics and/or pharmacodynamics of the Collaboration Product, or otherwise generally consistent with 21 C.F.R. §312.21(a). Phase I

Clinical Trials include Phase Ia Clinical Trials and Phase Ib Clinical (multiple ascending dose) Trials.

1.31 "Phase II Clinical Trial" means any controlled human clinical trial conducted anywhere in the Territory with a Collaboration Product in accordance with GCP to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug. Phase II Clinical Trials s are typically well controlled, closely monitored, and conducted in a relatively small number of patients, or otherwise generally consistent with 21 C.F.R. §312.21(b).

1.32 "Phase III Clinical Trial" means any human clinical trial conducted anywhere in the Territory with a Collaboration Product in accordance with GCP on a sufficient numbers of patients that is designed, if the defined end-points are met, to establish safety and efficacy of a pharmaceutical product in patients with the indication being studied for purposes of filing a Marketing Approval application or to otherwise be a pivotal trial for obtaining a Marketing Approval or label expansion for such pharmaceutical product or otherwise generally consistent with 21 C.F.R. §312.21(c).

1.33 "[***]" means [***]; provided, however, that [***] (i) [***], (ii) [***], and (iii) [***].

1.34 "Raw Materials" means, with respect to any Collaboration Product(s), any and all ingredients, including media, buffers, solvents and other components [***] used in the manufacture of such Collaboration Product hereunder in accordance with the [***] and Specifications for such Collaboration Product.

1.35 "Regulatory Approval" means all approvals, licenses, clearances, registrations or authorizations received from any Regulatory Authority in response to a Regulatory Filing together with all necessary approvals by any regulatory advisory board (e.g. institutional review board and ethics committee).

1.36 "Regulatory Authority" means any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity with authority over the development, manufacture or other commercialization (including the granting of Regulatory Approvals) of any Collaboration Product in any jurisdiction, including the Drugs Controller General of India, European Medicines Agency ("EMA") and the United States Food and Drug Administration ("FDA"), in each case, any successor entity thereto.

1.37 "Regulatory Filings" means any submission made to a Regulatory Authority with respect to a pharmaceutical or medicinal product, including any application necessary to commence or conduct clinical testing of such product in humans, any submission to a regulatory advisory board with respect to such product, and in each case any supplement or amendment to any of the foregoing.

1.38 "[***]" or "[***]" means [***].

1.39 "Indian Rules" means the Drugs and Cosmetic Rules (India), 1945.

1.40 "Results" means any and all data, results and reports from any pre-clinical studies or clinical trials with respect to any Collaboration Product conducted hereunder, including all data, results and reports from all pre-clinical studies (such as Animal Toxicity Studies) as well as from all clinical trials conducted hereunder and all interim reports and the final report generated therefrom.

1.41 "Specifications" means, with respect to a Collaboration Product, those specifications, manufacturing guidelines, control procedures, acceptance criteria, validation protocols, packaging, storage and release requirement or procedures or other similar requirements for the manufacture of such Collaboration Product, as mutually agreed by the Parties and set forth in the applicable Development Plan.

1.42 "Sublicensee" means any Third Party to which either Party grants any right to make, have made, use, sell, have sold, offer for sale and/or import/export a Collaboration Product in the Field anywhere in the Territory. For the avoidance of doubt, a Third Party who is granted only the right to distribute or promote a Collaboration Product (such as a contract sales organization) on behalf of either Party will not be considered a Sublicensee.

1.43 "[***]" means, with respect to [***].

1.44 "Territory" means [***].

1.45 "Technology Transfer Documents" or "TTD" means any and all documents, generated by either Party and pertaining to the Collaboration Product(s), including, but not limited to, selection of Collaboration Product(s), all pre-clinical/ *in vitro* studies carried out on the Collaboration Product(s), all process development studies whether carried out in-house or at a third-party CMO site in connection with the Collaboration Product(s), all CMC studies in connection with the Collaboration Product(s), and all data pertaining to any and all analytical method development activities in connection with the Collaboration Product(s).

1.46 "Third Party" means a Person other than Pieris, Stelis BioPharma and their respective Affiliates, employees and representatives.

1.47 "Third Party Proprietary Technology" means any technology that is Controlled by a Third Party and is not in the public domain.

1.48 "[***]" means [***].

1.49 Additional Defined Terms. Each of the following terms shall have the meaning described in the corresponding Article of this Agreement indicated below:

term	**Article Defined**
Stelis BioPharma Improvements	0
Alliance Manager	2.6
Co-Chair	2.2

term	**Article Defined**
Collaboration Technology	10.3
Confidential Information	9.1
Development Plan	3.1
Indemnitee	13.3
Indemnitor	13.3
JSC	2.1
JVA	Background
JVC	Background
Pieris Improvements	10.4
Pieris Materials and Deliverables	4.1.1
Plan and Budget	3.9
Prior Confidentiality Agreement	9.5
Subcommittee	2.7
Term	11.1

1.50 Interpretation. The captions and headings to this Agreement are for convenience only, and are to be of no force or effect in construing or interpreting any of the provisions of this Agreement. Unless specified to the contrary, references to Articles, Articles or Exhibits means the particular Articles and Articles of or Exhibits to this Agreement, and references to this Agreement include all Exhibits hereto. Unless context clearly requires otherwise, whenever used in this Agreement: (a) the words “include” or “including” shall be construed as incorporating, also, “but not limited to” or “without limitation;” (b) the word “or” shall have its inclusive meaning of “and/or;” (c) the word “day” or “quarter” or “year” means a calendar day or calendar quarter or calendar year unless otherwise specified; (d) the word “notice” shall require notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement; (e) the words “hereof,” “herein,” “hereunder,” “hereby” and derivative or similar words refer to this Agreement (including any Exhibits); (f) provisions that require that a Party or the Parties hereunder “agree,” “consent” or “approve” or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter or otherwise; (g) words of any gender include the other gender; (h) words using the singular or plural number also include the plural or singular number, respectively; (i) references to any specific law, or article, Article or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement thereof; and (j) provisions that refer to Persons acting “under the authority of Pieris” shall include Pieris’ Affiliates or licensees, as applicable, and those Persons acting “under the authority of Stelis BioPharma” shall include Stelis BioPharma’s Affiliates or Sublicensees, as applicable; conversely, those Persons acting “under the authority of Pieris” shall exclude Stelis BioPharma, its Affiliates and Sublicensees, as applicable, and those Persons acting “under the authority of Stelis BioPharma” shall exclude Pieris, its Affiliates and Sublicensees, as applicable.

Article 2
GOVERNANCE

2.1 JSC Establishment. Within [***] days of the Effective Date, the Parties agree to establish a joint steering committee ("JSC") for the overall coordination and oversight of the Parties' activities under this Agreement.

2.2 JSC Membership. The JSC shall be comprised of [***]. Either Party may replace its respective JSC representatives at any time with prior written notice to the other Party, provided that such replacement has comparable authority and scope of functional responsibility within that Party's organization as the individual he or she is replacing. Without limiting the foregoing, each Party shall appoint by notice to the other Party one of its members to the JSC as a co-chair of the JSC (each, a "Co-Chair"). The Co-Chairs shall ensure (a) the orderly conduct of the JSC's meetings (b) attend (subject to below) each meeting of the JSC, The Co-Chairs shall coordinate with the Alliance Manager to (a) prepare the agenda and (b) to prepare and issue minutes of each meeting within [***] days thereafter accurately reflecting the discussions and decisions of the JSC at such meeting. The Parties shall prepare the minutes in an alternating fashion which minutes shall constitute Confidential Information of each Party. Such minutes from each JSC meeting shall not be finalized until each Party has reviewed and approved the accuracy of such minutes in writing. The Alliance Manager shall solicit agenda items from the JSC members and provide an agenda along with appropriate information for such agenda reasonably in advance (to the extent possible) of any meeting. In the event the presiding Co-Chair or another member of the JSC from either Party is unable to attend or participate in any meeting of the JSC, the Party who designated such member may designate a substitute representative for the meeting.

2.3 JSC Responsibilities. The role of the JSC shall be:

2.3.1 to review and approve the Development Plan for any Collaboration Product(s) and any amendment thereto;

2.3.2 to coordinate and oversee the transfer of Pieris Materials and Deliverables to Stelis BioPharma;

2.3.3 to manage and oversee the implementation of the Development Plan for any Collaboration Product(s), including all regulatory activities required or otherwise conducted in accordance therewith;

2.3.4 to monitor each pre-clinical study and clinical trial conducted pursuant to the Development Plan for the respective Collaboration Product(s);

2.3.5 to provide a forum for the Parties to exchange information with respect to matters pertaining to and status of the performance of the Development Plan for any Collaboration Product(s);

2.3.6 to coordinate and oversee the transfer of any Collaboration Product(s) to the JVC pursuant to Article 0 when the Parties enter into the JVA; and

2.3.7 to perform such other functions as appropriate to further the purposes of this Agreement, as expressly set forth hereunder or otherwise agreed in writing by the Parties.

2.4 JSC Meetings.

2.4.1 Conduct. During the Term, the JSC shall hold at least [***] per [***] in accordance with a schedule established in advance [***] or as the JSC otherwise agrees. Meetings of the JSC shall be effective [***] at least [***]. The JSC may meet either (a) in person at either Party's facilities or at such locations as the Parties may otherwise agree; or (b) by audio or video teleconference; provided that at least [***] such meeting per [***]. With the prior consent of the other Party's representatives (such consent not to be unreasonably withheld or delayed), each Party may invite non-member employees to participate in the discussions and meetings of the JSC, provided that such participants shall have no vote and shall be subject to the confidentiality provisions set forth in Article 9 of this Agreement. Additional meetings of the JSC may also be held with the mutual consent of the Parties, or as required under this Agreement, and neither Party will unreasonably withhold or delay its consent to hold any such additional meeting. Each Party shall be responsible for all of its own expenses incurred (e.g. for its representative(s) and employee(s)) in connection with participating in the JSC.

2.4.2 Progress Report. At each meeting of the JSC, each Party shall summarize to the JSC the progress of the activities performed by or under authority of such Party and its Affiliates with respect to each Collaboration Product during the period since the last meeting of the JSC.

2.5 JSC Decision Making. Decisions of the JSC shall be made by [***]. Each Party shall [***] on all matters and act in the general spirit of cooperation and in no event shall either Party unreasonably withhold, condition or delay any approval or other decision of the JSC hereunder. In the event [***], then [***] pursuant to Article 0. For clarity, [***] of this Agreement. It is further understood and agreed that [***].

2.6 Alliance Manager. Promptly after the execution of this Agreement, each Party shall appoint a single individual to act as the primary point of contact between the Parties in connection with the performance of the Development Plans (each, an "Alliance Manager"). Each Party may at any time appoint a different Alliance Manager by written notice to the other Party and may elect, upon mutual agreement by the Parties, to eliminate the responsibilities of the Alliance Managers. The Alliance Managers shall be entitled to attend meetings of the JSC, but shall not have, or be deemed to have, any rights or responsibilities of a member of the JSC, unless also designated as a member of the JSC pursuant to Article 2.2. Each Alliance Manager may bring any matter to the attention of the JSC where such Alliance Manager reasonably believes that such matter requires such attention.

2.7 Subcommittees. Promptly after the establishment of the JSC, the JSC shall establish the following subcommittees (each, a "Subcommittee"): (a) [***]; (b) [***]; (c) [***]; (d) [***]; and (e) [***]. Each Subcommittee shall consist of equal number of representatives of each Party and shall meet with such frequency as the JSC determines is appropriate. Each Subcommittee shall be responsible for day-to-day implementation and operations of the activities under this

Agreement for which it has or is otherwise assigned responsibility, provided that such implementation is not inconsistent with the express terms of this Agreement, the applicable Development Plan or the decisions of the JSC. Each Subcommittee shall operate by [***], with [***] at least [***]. If, with respect to a matter that is subject to a Subcommittee's decision-making authority, the Subcommittee cannot reach unanimity, the matter shall be referred to the Alliance Manager, who shall submit such matter to the JSC for resolution in accordance with Article 0. The various Subcommittees may have overlapping membership and the Parties will attempt to time meetings of the JSC and the various Subcommittees to maximize productivity of the members and minimize costs associated therewith.

Article 3
PRODUCT DEVELOPMENT

3.1 Development Plan. Promptly after the execution of this Agreement, on a Collaboration Product-by-Collaboration Product basis, Pieris and Stelis BioPharma shall jointly prepare a mutually-agreed written work plan for any Collaboration Product(s) that sets out in reasonable detail the development activities to be conducted by each Party and its designees [***] for any Collaboration Product(s), as well as the location, protocol, budget and timelines for completion of various tasks therefor (each, a "Development Plan"); provided, however, that the Development Plan for Product 1 shall be in accordance with the framework plan set forth in Exhibit I. Each Development Plan shall be subject to the JSC's approval. Upon the JSC's approval of a Development Plan, such Development Plan shall be signed by a duly authorized representative from each Party and attached hereto as a part of this Agreement. For the avoidance of doubt, neither Party shall have any obligation with respect to any activity except as set forth in a Development Plan; provided, however, that unless and until the Parties sign a Development Plan, the Parties shall use good faith efforts to prepare and agree on the Development Plan for Product 1 with respect to activities beyond those referred to in Exhibit I within [***] days from the Effective Date. Each Development Plan will be updated and approved semi-annually by the JSC and shall be consistent with the general allocation of responsibilities described in Article 3.2 below. Without limiting the foregoing, any material modifications or additions to any Development Plan shall be first approved by JSC prior to its implementation. Each Party shall perform its obligations allocated to it under each Development Plan in accordance with the terms and conditions of this Agreement (including the diligence requirement set forth in Article 9), the applicable Development Plan and all Applicable Laws.

3.2 General Allocation of Responsibilities.

3.2.1 To Pieris. As further provided in the applicable Development Plan, with respect to each Collaboration Product, Pieris shall be responsible for and shall bear the expenses of: transferring all material, in Pieris' possession, pertaining to the Collaboration Product, including, but not limited to, [***], provided that [***].

3.2.2 To Stelis BioPharma. As further provided in the applicable Development Plan, with respect to each Collaboration Product, Stelis BioPharma shall be responsible for and shall bear the expenses of: [***];

3.3 Development Costs. As between the Parties, each Party shall bear all of the costs and expenses incurred in connection with any of the activities allocated to such Party under this Agreement and each applicable Development Plan, including fees charged and costs and expenses incurred by subcontractor(s) of said Party in connection with the respective Party's responsibilities hereunder this Agreement.

3.4 Subcontractors. Except as set forth in the applicable Development Plan, neither Party may subcontract or otherwise delegate all or any portion of its obligations under this Agreement (including substituting or adding manufacturing or contract research facilities of a Third Party) without JSC's prior written approval. When considering a subcontractor, a Party will advise the JSC, which will establish an audit team comprised of members from each Party to audit or review such subcontractor to ensure that the subcontractor meets the qualifications necessary and has complied with Applicable Laws with respect to the subcontracting activities for which such subcontractor is being considered. To the extent such approval is granted, the subcontracting Party shall (a) ensure that each such subcontractor has and maintains all appropriate qualifications and complies with Applicable Laws and that the other Party or its designee has the right to participate in and approve such qualification process; (b) ensure that all such approved subcontractors comply with the provisions of this Agreement; and (c) be responsible for each such subcontractor's performance hereunder (including, without limitation, any breach of this Agreement by such subcontractor), as if such subcontracting Party were itself performing such activities. For clarity, each Party may exercise its rights or perform its obligations under this Agreement through one or more of its Affiliates; provided that each Party shall ensure that each such Affiliate complies with the provisions of this Agreement and be responsible for each such Affiliate's performance hereunder (including, without limitation, any breach of this Agreement).

3.5 Protocols**.** All protocols for any pre-clinical studies or clinical trials to be performed with respect to each Collaboration Product shall be developed by the relevant Subcommittee, in consultation with those relevant scientific/technical representatives from each Party, and submitted to the JSC for its review and approval. Further, any material modification to any such protocol shall subject to the review and approval of the JSC.

3.6 Information Sharing. On an annual basis or as the JSC otherwise determines, during the Term, and without limiting Article 0, each Party shall provide to the other Party the documentation, reports and other data from or relating to any completed or ongoing development activities and the results thereof such as Results (and summaries of any results in English if such documentation and materials are not provided in English) controlled by such Party relating to each Collaboration Product (including documentation relating to Regulatory Filings and Regulatory Approvals, original source data, reports, case report forms (CRFs) and summary literature). Each Party shall have the right to use, and disclose (provided that if such information is the Confidential Information of the other Party, such disclosure shall be subject to confidentiality obligations as set forth in Article 9 of this Agreement) such information to the extent necessary to exercise its rights and fulfill its obligations hereunder.

3.7 Exclusivity of Efforts. On a [***] basis, during the Term, for the applicable Collaboration Product, each Party agrees that, except for its obligations hereunder, neither it nor any of its Affiliates or Sublicensees shall develop, manufacture, supply or commercialize any

Collaboration Product(s) in the Field, or assist any Third Party to perform any such activities with respect to any Collaboration Product(s) in the Field. In addition, [***].

3.8 Optional JVA. [***], and as soon as practicable after the execution of this Agreement, the Parties may discuss and negotiate a JVA, with respect to such Collaboration Product, in the form as substantially set out in Exhibit III of this Agreement. Once the Parties agree to form the JVC, the Parties will mutually agree on and select [***]. The Parties agree to amend the JVA template, when necessary, promptly after the selection of the JVC Venue, to (i) [***], (ii) [***], (iii) [***]; (iv) [***]; and (v) [***].

3.9 Collaboration Product Transfer to the JVC. On a [***] basis, reasonably in advance [***], the Parties shall, through the JSC, discuss and develop a detailed development plan and budget setting forth in reasonable detail the activities to be conducted by the JVC for the further development and commercialization of such Collaboration Product and associated budget and timelines, including the strategy for conducting Clinical Trials for such Collaboration Product, the location for such trials, the contract research organizations to conduct such trials and the budget therefor, as well as the launch strategy for such Collaboration Product and budget therefor (each, a "Plan and Budget"). [***], after the Parties enter into the JVA and after the JVC's receipt of all necessary Technology Transfer Documents (TTD), Consents, business licenses, permits and Regulatory Approvals, and further contingent upon the Parties' agreement on the applicable Plan and Budget and the JVC board of directors' ratification thereof, such Collaboration Product and all associated data, rights and assets will be transferred to the JVC, and the JVC will continue the development and commercialization of such Collaboration Product in accordance with the applicable Plan and Budget as further provided in the JVA.

3.10 Development and Commercialization in the absence of the JVA. If a Party does not wish to enter into the JVA pursuant to Article 3.8 with respect to a Collaboration Product, then it shall provide a written notice, accordingly, to the other Party, within [***] ("**Non-Continuation Notice**"), in which case the other Party shall have the option to continue development and commercialization of such Collaboration Product in accordance with terms and conditions set forth in Exhibit II, which option shall be exercisable within [***] days after receipt of the Non-Continuation Notice, and a license agreement consistent with such terms and conditions shall be timely agreed upon between the Parties, comprising a transfer of all Regulatory Approvals obtained or maintained under this Agreement with respect to such Collaboration Product (together with all relevant Regulatory Filings and correspondence with Regulatory Authorities) as well as all Technology Transfer Documents (TTD) pertinent to such Collaboration Product to the continuing Party when applicable. If [***], then [***].

3.11 Additional Product(s).

3.11.1 The Parties may name Additional Product(s) by mutual agreement and agree on the respective Field(s) and the financial rights and obligations for the development of such Additional Product(s). After such nomination, the Parties will use good faith efforts to prepare and agree on a Development Plan in accordance with Article 3.1 for each Additional Product. For clarity, [***].

3.11.2 The Parties shall [***] nominate one Additional Product within [***] months after the Effective Date, taking into consideration the provisions of Section 3.11.1.

Article 4
PIERIS DELIVERABLES

4.1 Delivery and Restrictions.

4.1.1 Delivery. With respect to each Collaboration Product, promptly after Pieris has established (if at all) (a) [***], (b) [***] and (c) [***] for such Collaboration Product, Pieris shall deliver to Stelis BioPharma [***] for the production of such Collaboration Product (all such deliverables together with all modifications or derivatives thereof, based in whole or part on the Pieris Technology, hereafter collectively referred to as the "Pieris Materials and Deliverables"); provided, however, that with respect to Product 1, Pieris is only obliged to deliver (a), (b) and (c) as established as of the Effective Date. Pieris Materials and Deliverables shall be and remain the sole and exclusive property of Pieris; and the physical possession of such Pieris Materials and Deliverables by Stelis BioPharma shall not be (nor be construed as) deemed as a sale, lease, offer to sell or lease, or other transfer of title of such materials to Stelis BioPharma. Except as expressly provided in this Agreement, no licenses or rights shall be deemed as granted to Stelis BioPharma, by implication, estoppel or otherwise, by the transfer of physical possession of any such Pieris Materials and Deliverables to Stelis BioPharma.

4.1.2 Limitations on Use and Transfer. Stelis BioPharma shall not use the Pieris Materials and Deliverables for any purpose other than for the performance of its obligations under this Agreement. Except as otherwise authorized by Pieris in writing, Stelis BioPharma shall not provide the Pieris Materials and Deliverables to any Person other than to approved subcontractors pursuant to Article 0 or those employees of Stelis BioPharma who require access to the Pieris Materials and Deliverables, in each case for the performance of the activities allocated to Stelis BioPharma under any Development Plan. Stelis BioPharma shall only use the Pieris Materials and Deliverables in compliance with all Applicable Laws.

4.1.3 No Modification or Derivation. Except as (a) expressly set forth in the applicable Development Plan, (b) appropriate to further the purposes of this Agreement, and/or (c) allowed with Pieris' prior written consent, Stelis BioPharma shall not attempt to alter or modify the Pieris Materials and Deliverables in any way, or to make any derivatives or modifications thereof and shall not, under any circumstances, attempt, directly or indirectly, to analyze, characterize, reverse engineer or otherwise derive the sequences, or constructs of the Pieris Materials and Deliverables.

4.1.4 Care in Use of the Pieris Materials and Deliverables. Stelis BioPharma acknowledges that the Pieris Materials and Deliverables are experimental in nature and may have unknown characteristics and therefore agrees to use prudence and all reasonable care in the use, handling, storage, containment, transportation and

disposition of the Pieris Materials and Deliverables. Pieris will provide Stelis BioPharma with all information in Pieris' possession with respect to the handling of the Pieris Materials.

4.2 Warranties Regarding Pieris Materials and Deliverables. Pieris hereby represents and warrants to Stelis BioPharma that (a) Pieris owns or has rights to the Pieris Materials and Deliverables; (b) Pieris has the right to provide the Pieris Materials and Deliverables to Stelis BioPharma for use in accordance with this Agreement and (c) the Pieris Materials and Deliverables meet the written Specifications therefor as set forth in the applicable Development Plan(s) at the time of delivery to Stelis BioPharma.

4.3 Acknowledgement. Stelis BioPharma acknowledges that the use or modification of the Pieris Materials and Deliverables other than as permitted under this Agreement could cause irreparable damage to Pieris. As such, Stelis BioPharma agrees that: (a) any breach of this Article 4 shall be considered a material breach of this Agreement; (b) Stelis BioPharma hereby assigns to Pieris all right, title and interest in and to any invention arising from an impermissible modification or use of the Pieris Materials and Deliverables as well as any patent or patent application that contains, discloses or claims any invention arising from an impermissible modification or use of the Pieris Materials and Deliverables, and (c) the remedies set forth in (a) and (b) of this Article 4.3 shall not prejudice Pieris' right to pursue any legal or equitable remedy available to Pieris for any violations of this Article 4. Pieris undertakes that it shall not declare a permitted use or permitted modification as impermissible after having knowledge of such use or modification by Stelis BioPharma and not objecting in writing within a reasonable period of time thereafter.

Article 5
MANUFACTURING OF COLLABORATION PRODUCTS

5.1 General. As between the Parties, Stelis BioPharma shall be solely responsible for manufacturing any Collaboration Product(s) for [***] at its own costs in the Facilities. All Drug Products or IMPs of Collaboration Product(s) supplied by Stelis BioPharma hereunder for use in any Pre-clinical studies and Clinical Trials shall meet the applicable Specifications therefor and shall be manufactured at the Facility in accordance with [***] and all Applicable Laws (including GMP). Stelis BioPharma shall perform quality control procedures reasonably necessary to ensure that any Drug Product or IMP of Collaboration Product(s) for use in any pre-clinical studies and/or clinical trials conform fully to the applicable Specifications.

5.2 Changes. Once established at Stelis BioPharma, neither Party shall make any changes to the [***], Specifications, [***], Facility, Raw Materials or any other item in any manner that would reasonably cause any Drug Product or IMP of a Collaboration Product for use in any clinical studies not to comply with the Specifications therefor or Applicable Laws, without the JSC's prior written approval. If either Party desires any such change, it may request such change through the JSC. All such changes shall be documented in a writing signed by an authorized representative of each of Pieris and Stelis BioPharma.

5.3 Deviations. Without limiting Article 5.2 above, in the event any material deviations occur during the course of the manufacture of any batch of any Drug Product or IMP of a

Collaboration Product for use in any clinical studies under this Agreement, Stelis BioPharma shall immediately provide the JSC with a detailed written description of such deviation. In addition, Stelis BioPharma shall undertake all reasonable and appropriate actions to investigate the cause of such deviation and to correct the same, both at its own costs.

5.4 [***]:

5.4.1 Collaboration Product. All Drug Products or IMPs of Collaboration Product(s) supplied by Stelis BioPharma hereunder shall comply with all Applicable Laws, GMPs and meet all Specifications, and Stelis BioPharma shall perform and document all manufacturing and supply activities contemplated herein in compliance with all Applicable Laws. [***].

5.4.2 Facilities and Equipment. The Facility(ies), all equipment used for the manufacture of each Collaboration Product within the Facility(ies) and the activities contemplated herein complies with all Applicable Laws and Stelis BioPharma shall obtain and maintain all Consents including governmental registrations, permits, licenses and approvals necessary for Stelis BioPharma to manufacture Drug Product(s) or IMP(s) of each Collaboration Product, and otherwise to perform its obligations, under this Agreement.

5.5 Manufacturing Records. Stelis BioPharma shall generate and maintain complete and accurate records and samples as necessary to evidence compliance with this Agreement and all Applicable Laws and other requirements of applicable governmental authorities relating to the manufacture of Drug Product(s) or IMP(s) of each Collaboration Product, including validation data, stability testing data, certificates of analysis, certificates of origin of all raw materials, batch and lot records, quality control and laboratory testing, and any other data required by Applicable Laws. All such records and samples shall be maintained for such periods as may be required by Applicable Law. Upon request by Pieris, Stelis BioPharma shall provide Pieris (or its designee) reasonable access to, and copies and portions of, such records and samples, including all batch and lot records, and any supporting data relating thereto, including written investigations of any deviations that may have been generated from manufacturing, packaging, inspection, or testing processes.

5.6 Inspection. During the Term and such longer period required by Applicable Laws, upon at least [***] days advance notice and at reasonable frequency, Pieris shall have the right to inspect and audit, at its own costs, [***]per[***] during regular business hours: (a) any Facility or any other location at which any of the manufacturing, processing or other activities relating to any Collaboration Product are performed hereunder; and (b) any of the manufacturing and quality control records and all other documentation relating to the manufacturing, processing and other activities with respect to any Collaboration Product (including any internal quality control audits or reviews. Such inspections and audits shall be for the purpose of ascertaining compliance with Applicable Laws, the Specifications and other aspects of this Agreement, reviewing correspondence, reports, filings and other documents from or to Regulatory Authorities to the extent related to the manufacturing, processing and other activities hereunder, approving, where appropriate, all variances from applicable requirements hereunder, and evaluating the implementation of all manufacturing and process changes pursuant to this

Agreement. In performing any such audit or inspection, employees or consultants of Pieris shall: (i) not unreasonably interfere with other activities of Stelis BioPharma being carried out at the location at which such audit or inspection is taking place; and (ii) observe all rules and regulations applicable to visitors and to individuals employed at the Facility which have been communicated by Stelis BioPharma to Pieris in writing. Any information obtained by Pieris through such inspections and audits shall be treated as Confidential Information of Stelis BioPharma in accordance with Article 9 below.

5.7 [***]. Stelis BioPharma will [***].

Article 6
REGULATORY MATTERS

6.1 General. As between the Parties, Stelis BioPharma shall be solely responsible for Regulatory Filings, obtaining and maintaining all necessary Regulatory Approvals for the initiation and performance of the pre-clinical studies [***] and [***]. As between the Parties, Stelis BioPharma shall assume all responsibilities of sponsors and investigators under Applicable Laws for the pre-clinical studies [***]. Upon the transfer of any Collaboration Product to the JVC as provided in Articles 2.3.6 and 3.9, Stelis BioPharma shall assign and deliver, or cause to be assigned and delivered, to the JVC, and the JVC shall assume control of, all Regulatory Filings and approvals (including Regulatory Approvals) and all communications with the applicable Regulatory Authorities with respect thereto obtained and maintained by Stelis BioPharma or its Affiliate in connection with the development of such Collaboration Product(s).

6.2 Meetings with Regulatory Authorities. Stelis BioPharma shall timely inform Pieris as soon as reasonably practicable of any meetings scheduled with any Regulatory Authority concerning any Collaboration Product. As reasonably requested in a timely manner, Stelis BioPharma shall allow representatives from Pieris to participate in such meetings with any Regulatory Authority. Stelis BioPharma shall timely inform Pieris as soon as reasonably practicable of the outcome of any meetings with any Regulatory Authority concerning such Collaboration Product.

6.3 Regulatory Filings. Reasonably in advance of the submission of any Regulatory Filing or material correspondence with applicable Regulatory Authorities for any Collaboration Product, Stelis BioPharma shall provide a copy of such document to Pieris for its review and shall incorporate any reasonable comments and suggestions provided by Pieris with respect thereto. Stelis BioPharma shall make available, directly, or through the JSC, copies of any Regulatory Filing or correspondence with applicable Regulatory Authorities for any Collaboration Product promptly after such Regulatory Filing or correspondence has been submitted to the applicable Regulatory Authority.

6.4 Regulatory Actions. Stelis BioPharma shall permit all applicable Regulatory Authorities to conduct such inspections of the Facility or any other location at which any of the manufacturing or development activities (including pre-clinical or clinical studies) relating to any Collaboration Product are performed, as such Regulatory Authorities may request in accordance with Applicable Laws and shall cooperate with such Regulatory Authorities with respect to such inspections and any related matters. Stelis BioPharma shall give Pieris prompt written notice of

any such inspections, and shall keep Pieris informed about the results and conclusions of each such regulatory inspection, including actions taken by Stelis BioPharma to remedy conditions cited in such inspections. In addition, Stelis BioPharma shall allow Pieris or its representative to assist in the preparation for and be present at such inspections for which it has advanced notice. Stelis BioPharma shall provide Pieris with copies of any written inspection reports issued by any Regulatory Authority and all correspondence between Stelis BioPharma and any Regulatory Authority with respect thereto. Additionally, Stelis BioPharma agrees to promptly notify and provide Pieris copies of any request, directive or other communication of the applicable Regulatory Authority relating to or otherwise that may affect any Collaboration Product or its manufacture or development. Prior to responding to any reports, requests, directive or other communications issued by any Regulatory Authority relating to or otherwise that may affect any Collaboration Product or its manufacture or development, Stelis BioPharma shall provide Pieris a copy of its proposed response for Pieris' review and comments and Stelis BioPharma shall include any reasonable comments or recommendations provided by Pieris with respect thereto prior to submitting such response to the applicable Regulatory Authority. Stelis BioPharma shall provide Pieris a copy of its final response contemporaneously with submitting the response to the Regulatory Authority.

Article 7
RECORDS AND INSPECTIONS

7.1 Record Keeping. Without limiting any other specific record-keeping obligations set forth in this Agreement or any Development Plan, each Party shall generate and maintain, during the Term and such longer period required by Applicable Laws, complete and accurate records related to its performance of its obligations under each Development Plan as necessary to evidence compliance with this Agreement and all Applicable Laws. Upon the transfer of any Collaboration Product to the JVC as provided in Articles 2.3.6 and 0, each Party shall deliver, or cause to be delivered, to the JVC all records (or copies thereof) kept by such Party in accordance with this Article 7.1.

7.2 Inspection. Without limiting any other specific inspection provisions in this Agreement or any Development Plan, during the Term and such longer period required by Applicable Laws, at least [***] business days advance notice by a Party and at reasonable frequency, such Party shall have the right to inspect and audit, during regular business hours, the records kept by the other Party pursuant to Article 7.1. Such inspections and audits shall be for the purpose of ascertaining compliance with this Agreement and Applicable Laws. Any information obtained by the auditing Party through such inspections and audits shall be treated as Confidential Information of the audited Party in accordance with Article 9 below.

Article 8
DILIGENCE

Each Party will use good faith and Commercially Reasonable Efforts, with respect to each objective set forth in this Agreement or otherwise assigned to such Party under any Development Plan, to accomplish such objective including within the corresponding timelines.

Article 9
CONFIDENTIALITY

9.1 Confidential Information. The Parties may from time to time disclose to each other Confidential Information. "Confidential Information" means any information disclosed by one Party to the other Party hereto, which (i) if disclosed in tangible form is marked "confidential" or with other similar designation to indicate its confidential or proprietary nature, (ii) if disclosed orally, is identified as confidential or proprietary by the Party disclosing such information at the time of its initial disclosure and is confirmed in writing as confidential or proprietary by the disclosing Party within forty five (45) days after such initial disclosure, or (iii) is reasonably expected to be treated in a confidential manner based on the nature of such information and the circumstances of its disclosure. For clarity, the terms of this Agreement and all Results shall be deemed Confidential Information of both Parties. Notwithstanding the foregoing or anything herein to the contrary, a receiving Party's obligations under this Article 9 shall not apply to any information that, in each case as demonstrated by written documentation: (a) was already known to the receiving Party, other than under an obligation of confidentiality, at the time of disclosure; (b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party; (c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement; (d) was subsequently lawfully disclosed to the receiving Party by a Person other than the disclosing Party; or (e) was independently developed by the receiving Party without use of or reference to or benefit of any Confidential Information of the disclosing Party.

9.2 Confidentiality. During the Term of this Agreement and for [***] years thereafter without regard to the means of termination (or if the JVA is entered into, then such longer period as required by the JVA), neither Party shall use, for any purpose other than the purposes set out this Agreement (including (i) in connection with the performance of its obligations or exercise of rights granted to such Party in this Agreement and (ii) to the extent such disclosure is reasonably necessary in filing for, prosecuting or maintenance of patents and other intellectual property rights (including applications therefor) in accordance with this Agreement, due diligence exercise for any transaction in connection with the development of any Collaboration Product in accordance with this Agreement, prosecuting or defending litigation, complying with applicable governmental regulations, filing for, conducting preclinical or clinical trials, obtaining and maintaining regulatory approvals, or otherwise required by Applicable Laws or the rules of a recognized stock exchange), reveal or disclose to any Third Party, other than one Party's employees involved in the performance of this Agreement or subcontractors approved under Article 3.4, advisors, consultants, attorneys, investors, prospective investors, acquirers, prospective acquirers, investment bankers, lenders, acquirers lenders or their respective advisors and attorneys who agree to be bound by confidentiality terms substantially similar to this Article 9, Confidential Information and materials disclosed by the other Party (whether prior to or during the Term of this Agreement) without first obtaining the written consent of the other Party. The Parties agree to take all necessary steps to ensure that Confidential Information is securely maintained and to inform those who are authorized to receive such Confidential Information of their obligations under this Agreement and subject to written non-disclosure, non-use requirements consistent with this Article 9. Upon the termination or expiration of this Agreement for any reason (unless the JVA is entered into, then as required in the JVA), the receiving Party

promptly shall, upon request by the disclosing Party, return all such Confidential Information, and any copies or reproductions thereof, to the disclosing Party and agrees to make no further use of such Confidential Information, except it may retain one copy thereof solely for use in complying with any record keeping and other obligations within such Party's jurisdiction.

9.3 Reasonable Precautions. The Parties shall take all reasonable precautions to prevent the use or disclosure of such Confidential Information of the other Party without first obtaining the written consent of the other Party, except in accordance with Article 0.

9.4 Publicity Review.

9.4.1 Press Releases and Public Announcements. Neither Party shall issue any press release or other publicity materials, or make any public presentation with respect to this Agreement, the terms or conditions of this Agreement, or any Results without the prior written consent of the other Party (such consent not to be unreasonably withheld, conditioned or delayed). The restrictions provided in this Article 0 shall not apply to disclosures required by Applicable Law, including as may be required in connection with any filings made with the Securities and Exchange Commission or similar non-U.S. regulatory authority, or by the disclosure policies of a major stock exchange; provided that each Party shall use good faith efforts to provide any such disclosure at least [***] days prior to such disclosure (to the extent practicable) for the other Party's review and comment.

9.4.2 Use of Names. Neither Party shall utilize the name or trademarks of the other Party or make any disclosures concerning this Agreement, without the other Party's prior written consent, provided that such use or disclosure shall be permitted if required by Applicable Laws and the Party making such use or disclosure consults with the other Party to the extent practicable not less than [***] days prior the use or disclosure.

9.5 Prior Agreement. This Agreement supersedes the terms and conditions of the Confidentiality Agreement between the Parties dated August 6th, 2012 ("Prior Confidentiality Agreement") with respect to information disclosed thereunder. All information exchanged between the Parties under such Prior Confidentiality Agreement shall be deemed Confidential Information of the disclosing Party and shall be subject to the terms of this Article 9.

Article 10
INTELLECTUAL PROPERTY AND LICENSE

10.1 Background Technology and Acquired IP. Except for the limited licenses granted under Article 10.2 below, as between the Parties, each Party retains full right, title and interest in and to its Background Technology and Acquired IP. Unless otherwise expressly set forth in this Agreement, each Party shall be fully responsible for obtaining and maintaining, at its own expense, ownership of or appropriate license to any technologies (and intellectual property rights therein) that are necessary for its performance of its obligations under each Development Plan. Without limiting the generality of the foregoing, both Parties shall be responsible for developing or acquiring (including licensing or acquiring rights or assets from any Third Party), subject to the oversight and consent of the JSC, any Third Party Proprietary Technology [***] that may be necessary for the development of a Collaboration Product, as provided in the applicable

Development Plan. Both Parties shall share all licensing costs associated with the development or acquisition of any such Third Party Proprietary Technology, except that any royalty, payable to a Third Party upon the sale of any Collaboration Product(s) in which such Third Party Proprietary Technology are implicated or incorporated, shall be borne by the JVC, or in the event if the JVC does not exist at the time of sale of the Collaboration Product(s), then such cost-sharing shall be discussed in good faith by both Parties herein in accordance with the provisions of Article 3.10 and Exhibit II hereof.

10.2 License Grant

10.2.1 License to Stelis BioPharma. Pieris hereby grants to Stelis BioPharma (i) a [***] license, in the Field, during the Term, under Pieris' Background Technology and Acquired IP, any Collaboration Technology solely owned by Pieris pursuant to this Article 10 such as Pieris Improvements, and Pieris' interests in any Collaboration Technology jointly owned by the Parties pursuant to this Article 10, together with all intellectual property rights therein, with the right to grant sublicenses to subcontractors approved under Article 3.4, solely to the extent necessary for Stelis BioPharma to perform the activities allocated to it under this Agreement and the applicable Development Plan, and (ii) a [***] license under any Collaboration Technology solely owned by Pieris pursuant to this Article 10 and Pieris' interests in any Collaboration Technology jointly owned by the Parties pursuant to this Article 10, together with all intellectual property rights therein, with the right to grant sublicenses, to exploit Stelis BioPharma's know-how and intellectual property available at Stelis BioPharma before the Effective Date in a manner consistent with the terms and conditions of this Agreement.

10.2.2 License to Pieris. Stelis BioPharma hereby grants to Pieris (i) a [***] license, in the Field, during the Term, under Stelis BioPharma's Background Technology and Acquired IP, any Collaboration Technology solely owned by Stelis BioPharma pursuant to this Article 10 such as Stelis BioPharma Improvements, and Stelis BioPharma's interests in any Collaboration Technology jointly owned by the Parties pursuant to this Article 10, together with all intellectual property rights therein, with the right to grant sublicenses to subcontractors approved under Article 3.4, solely to the extent necessary for Pieris to perform the activities allocated to it under this Agreement and the applicable Development Plan, and (ii) a [***] license under any Collaboration Technology solely owned by Pieris pursuant to this Article 10 and Stelis BioPharma's interests in any Collaboration Technology jointly owned by the Parties pursuant to this Article 10, together with all intellectual property rights therein, with the right to grant sublicenses, to exploit Pieris' know-how and intellectual property available at Pieris before the Effective Date in a manner consistent with the terms and conditions of this Agreement.

10.2.3 The rights described in the preceding paragraphs of this Article 10.2 are referred as the "License" hereunder this Agreement. Pieris shall not exploit or sublicense any patents in any manner that would conflict with License. Stelis BioPharma shall not exploit or sublicense any patents in any manner that would conflict with License.

10.2.4 No Other Right. All rights and licenses granted under this Agreement are limited to the scope expressly granted. Accordingly, except for the rights expressly granted

under this Agreement, no right, title, or interest of any nature whatsoever is granted whether by implication, estoppel, reliance, or otherwise, by either Party to the other Party.

10.3 Collaboration Technology. Except as provided in Articles 0 and 0 and subject to Article 0, as between the Parties all right, title and interest to inventions and other subject matter (together with all intellectual property rights therein) conceived or created or first reduced to practice in connection with the exercise of rights or performance of obligations under this Agreement (collectively, "Collaboration Technology") (i) by or under the authority of Pieris or its Affiliates, independently of Stelis BioPharma and its Affiliates, shall be owned by Pieris, (ii) by or under the authority of Stelis BioPharma or its Affiliates, independently of Pieris and its Affiliates, shall be owned by Stelis BioPharma, and (iii) by personnel of Pieris or its Affiliates and Stelis BioPharma or its Affiliates shall be jointly owned by Pieris and Stelis BioPharma. Except as expressly provided otherwise in this Agreement, neither Party shall have any obligation to obtain any approval of the other Party for, nor pay the other Party any share of the proceeds from or otherwise account to the other Party for, the practice, enforcement, licensing, assignment or other exploitation of such jointly owned Collaboration Technology, and each Party hereby waives any right it may have under the Applicable Laws of any country to require such approval, sharing or accounting. Except as otherwise expressly provided hereunder, the Party that owns any particular Collaboration Technology shall, as between the Parties, have the sole and exclusive right to control the filing for, prosecution, maintenance and enforcement of any intellectual property rights therein in its sole discretion and any jointly owned Collaboration Technology will be prosecuted, maintained and enforced as determined by the intellectual property Subcommittee in accordance with the procedures set forth in Article 2.

10.4 Pieris Improvements. Notwithstanding Article 0 above, all Pieris Improvements will be the sole and exclusive property of Pieris, and Stelis BioPharma hereby assigns to Pieris all Pieris Improvements. Stelis BioPharma will promptly disclose to Pieris any and all Pieris Improvements and take such other reasonable actions at Pieris' request and expense to effectuate such assignment. As used herein, "Pieris Improvements" means: (i) [***] as well as (ii) [***]; provided however, which (i) and (ii) [***],.

10.5 Stelis BioPharma Improvements. Notwithstanding Article 0 above, all Stelis BioPharma Improvements will be the sole and exclusive property of Stelis BioPharma. As used herein, "Stelis BioPharma Improvements" means [***].

10.6 Assignment to JVC. Upon the transfer of any Collaboration Product to the JVC pursuant to Articles Articles 2.3.6 and 0, each Party shall assign, or cause to be assigned, to the JVC, all of its right, title and interest in and to any Collaboration Technology (but excluding any Pieris Improvement) arising from the performance of the applicable Development Plan and the JVC shall have the sole and exclusive right to control the filing for, prosecution, maintenance and enforcement of any intellectual property rights in such Collaboration Technology in its sole discretion. Each Party shall grant to the JVC appropriate licenses to its Background Technology and Acquired IP to enable the JVC to exclusively develop and commercialize said Collaboration Product in the Field.

10.7 Disclosure and Cooperation. Each Party shall promptly disclose to the other Party any Collaboration Technology generated hereunder. The Parties shall at all times fully cooperate in

order to reasonably implement the provisions of this Article 10. Such cooperation may include the execution of necessary legal documents, coordinating prosecution to avoid or mitigate any patentability issues, and the provision of any other assistance reasonably requested by the other Party at such other Party's expenses.

10.8 Prosecution of Intellectual Property Rights.

a) Pieris shall, at its own cost and expense and within its sole discretion, file, maintain and prosecute in the Territory, the patents claiming (i) Pieris' Background Technology and Acquired IP and (ii) any Collaboration Technology solely owned by Pieris pursuant to this Article 10 such as Pieris Improvements.

b) Stelis BioPharma shall, at its own cost and expense and within its sole discretion, file, maintain and prosecute in the Territory, the patents claiming (i) Stelis BioPharma's Background Technology and Acquired IP and (ii) any Collaboration Technology solely owned by Stelis BioPharma pursuant to this Article 10 such as Stelis BioPharma Improvements.

c) Notwithstanding foregoing Articles 10(8)(a) and (b), for the patents claiming any Collaboration Technology solely owned by one Party pursuant to this Article 10 such as Pieris Improvements or Stelis BioPharma Improvements, if either Party (the "Ceasing Party") wishes (i) not to file a patent application in any one of the following jurisdictions: [***], (ii) abandon any such patent application or (iii) not to maintain any such Patent in any one of said jurisdictions, it shall give prior written notice to the other Party at [***] days before any relevant deadline, then the other Party has the right, exercisable within [***] exercisable within [***] days of such notice, to take an assignment of the patent application or patent and, at its own expense, control the further prosecution the patent application or maintenance of such Patent. In the event such right is exercised by the other Party, the Ceasing Party shall effectuate said assignment and provide to the other Party all information necessary for the further prosecution or maintenance. For the avoidance of doubt, any such Patent is part of the other Party's Acquired IP.

d) With respect to the filing, maintaining and prosecution of patents claiming any Collaboration Technology jointly owned by the Parties pursuant to this Article 10, before any action taken by either Party, the Parties will confer first and try to agree on a strategy for drafting and/or prosecuting the respective patent application. In this regard, each of Stelis BioPharma and Pieris shall keep the other Party fully informed as to the status of preparation, prosecution and maintenance of the respective patent application or patent, including, without limitation, (x) providing the other Party the opportunity to fully review and comment on (i) any patent application at least [***] days of the respective filing date and on (ii) any documents which will be filed in any patent office at least [***] days of any relevant deadline, and (y) providing the other copies of any substantive documents that such Party receives from such patent office at least [***] days after receipt, including notice of all interferences, reissues, re-examinations, oppositions or requests for patent term extensions. The other Party shall provide feedback at least [***] days of the respective filing date or the relevant deadline. If the Parties could not agree on such a strategy in good faith upon [***] days of the relevant deadline; provided, however, that, if

either Party wishes to keep any Collaboration Technology jointly owned by the Parties pursuant to this Article 11 as trade secret before the filing of the respective patent application, the other Party will keep such Collaboration Technology in confidence in accordance with Article 9. Stelis BioPharma and Pieris shall reasonably cooperate with and assist each other at their own respective expense in connection with activities referred under this Article 10.8(d), at the other Party's request.

Article 11
TERM AND TERMINATION

11.1 Term. The term of this Agreement shall commence on the Effective Date and shall continue on a Collaboration Product-by-Collaboration Product basis until (i) the Parties enter into a JVA for the applicable Collaboration Product(s), (ii) a Party who receives a Non-Continuation Notice timely exercises the option referred in Article 3.10, or (iii) the Parties agree in good faith on how to dispose of such Collaboration Product(s) in the event that neither Party wishes to enter into the JVA pursuant to Article 3.8, whichever is later in time ("Term"); provided, however, that the Term for such Collaboration Product shall automatically end no later than one (1) year after the completion of the first Phase I Trial for such Collaboration Product unless extended by the Parties' mutual agreement.

11.2 Termination for Material Breach. If either Party materially breaches this Agreement, the non-breaching Party shall have the right to terminate this Agreement, with respect to any Collaboration Product that is subject to such material breach, by written notice to the breaching Party specifying the breach and referencing this Article 0, if such breach is not cured within [***] days after written notice is given by the non-breaching Party to the breaching Party specifying the breach; provided, however, that in the event of a good faith dispute with respect to the existence of a material breach, this Agreement or the applicable Development Plan shall not be terminated, unless it is finally determined pursuant to Article 0 that such material breach has occurred, and the breaching Party fails to cure such breach within [***] days after such determination.

11.3 Termination for Insolvency. Each Party shall have the right to terminate this Agreement in its entirety upon delivery of written notice to the other Party in the event that (i) such other Party files in any court or agency pursuant to any statute or regulation of any jurisdiction a petition in bankruptcy or insolvency or for reorganization or similar arrangement for the benefit of creditors or for the appointment of a receiver or trustee of such other Party or its assets, (ii) such other Party is served with an involuntary petition against it in any insolvency proceeding and such involuntary petition has not been stayed or dismissed within [***] days of its filing, or (iii) such other Party makes an assignment of substantially all of its assets for the benefit of its creditors in the absence of a legitimate business transaction.

11.4 Effects of Expiration or Termination.

11.4.1 Expiration or termination of this Agreement (in its entirety or with respect to any Collaboration Product) for any reason shall not release either Party of any obligation or

liability which, at the time of such expiration or termination, has already accrued to such Party or which is attributable to a period prior to such expiration or termination.

11.4.2 Intellectual Property Rights and License.

a. In the event of expiration or termination of this Agreement as a result of that neither Party wishes to enter into the JVA pursuant to Article 3.8, unless otherwise stipulated by the Parties in a separate agreement after the Effective Date, all rights and licenses to any technology and intellectual property rights therein granted by either Party to the other Party (such as the License), under this Agreement or with respect to the applicable terminated Collaboration Product, as applicable, shall terminate and revert back to the Party granting such rights or licenses; provided, however, that licenses granted under Articles 10.2.1(ii) and 10.2.2(ii) shall survive the expiration or termination.

b. In the event of termination by Pieris pursuant to Article 11.2 or Article 11.3, Pieris shall retain and/or have the exclusive rights, with respect to any Collaboration Product that is subject to such material breach under Article 11.2 or with respect to all Collaboration Products when Stelis BioPharma is insolvent under Article 11.3, to (i) all Results generated until the effective date of such termination as well as Collaboration Technology solely owned by either Party and Collaboration Technology jointly owned by the Parties, together with all intellectual property rights therein, and (ii) to continue to develop and/or commercialize Products, whether directly or indirectly (e.g., through a Sublicensee), in any regulatory jurisdiction (including any country or geographical region therein) within the Territory, without any further financial obligation to Stelis BioPharma. Stelis BioPharma hereby agrees to execute one or more assignments necessary to effectuate such grant of rights to Pieris free of charge. Further, the License granted by Pieris to Stelis BioPharma hereunder shall terminate concurrently, and the License granted by Stelis BioPharma to Pieris hereunder shall survive such termination and remain in effect.

c. In the event of termination by Stelis BioPharma pursuant to Article 11.2 or Article 11.3, Stelis BioPharma shall retain and/or have the exclusive rights, with respect to any Collaboration Product that is subject to such material breach under Article 11.2 or with respect to all Collaboration Products when Pieris is insolvent under Article 11.3, to (i) all Results generated until the effective date of such termination as well as Collaboration Technology solely owned by either Party and Collaboration Technology jointly owned by the Parties, together with all intellectual property rights therein, and (ii) to continue to develop and/or commercialize Products, whether directly or indirectly (e.g., through a Sublicensee), in any regulatory jurisdiction (including any country or geographical region therein) within the Territory, without any further financial obligation to Pieris. Pieris hereby agrees to execute one or more assignments necessary to effectuate such grant of rights to Stelis BioPharma free of charge. Further, the License granted by Stelis BioPharma to Pieris hereunder shall terminate concurrently, and the License granted by Pieris to Stelis BioPharma hereunder shall survive such termination and remain in effect.

11.4.3 Upon termination of this Agreement or with respect to any Collaboration Product(s), each Party shall cease all work under this Agreement or the applicable

Development Plan, as applicable, except for activities as necessary for an orderly wind-down of the performance of this Agreement or the applicable Development Plan, and return to the other Party all Confidential Information of the other Party and unused materials provided to it by the other Party under this Agreement or the applicable Development Plan, as applicable, and all copies and embodiments thereof, except that each Party may retain one copy of the other Party's written Confidential Information in its confidential files solely for archival purposes. Without limiting the generality of the foregoing, upon termination of this Agreement (in its entirety or with respect to any Collaboration Product), Stelis BioPharma shall immediately cease any use or practice of Pieris Materials and Deliverables provided under this Agreement or under the applicable Development Plan, as applicable, and return all remaining Pieris Materials and Deliverables in Stelis BioPharma's possession, including all embodiments or derivatives thereof.

11.4.4 Upon expiration of this Agreement with respect to any Collaboration Product(s), in the event such Collaboration Product(s) is transferred to the JVC as provided in Article 0, each Party shall fully cooperate with each other to facilitate a smooth, orderly and prompt transfer of such Collaboration Product(s) to the JVC. Without limiting the generality of the foregoing, (i) Stelis BioPharma shall assign or cause to be assigned to the JVC all Regulatory Filings and Regulatory Approvals and all communications with the applicable Regulatory Authorities obtained or maintained by or on behalf of Stelis BioPharma under this Agreement with respect to such Collaboration Product(s), (ii) each Party shall assign all of its right, title and interest in and to any Collaboration Technology [***] to the JVC, and (iii) each Party shall transfer to the JVC all records, reports and other work products generated during its performance of the applicable Development Plan.

11.4.5 Without affecting Article 3.10, upon expiration or termination of this Agreement with respect to any Collaboration Product, in the event such Collaboration Product(s) is not transferred to the JVC as provided in Article 0, unless otherwise mutually agreed by the Parties, each Party shall return to the other Party all Confidential Information of the other Party and unused materials provided to it by the other Party (including Pieris Materials and Deliverables provided to Stelis BioPharma) under this Agreement or the applicable Development Plan, as applicable, and all copies and embodiments thereof, except that each Party may retain one copy of the other Party's written Confidential Information in its confidential files solely for archival purposes.

11.5 Survival. The provisions of Articles 1, 7, 9, 13 and 14, and Articles 4.1.2-4.1.4, 4.3, 5.5, 5.6, 5.7, 10.1, 10.3-10.5, 10.7, 11.4, 11.5, and 12.3 shall survive the expiration or termination of this Agreement for any reason. All other rights and obligations of the Parties shall cease upon termination of this Agreement. Except as otherwise expressly provided in this Article 0, all other rights and obligations of the Parties shall terminate upon expiration or termination of this Agreement.

Article 12
REPRESENTATIONS AND WARRANTIES

12.1 Mutual Representations and Warranties. Each Party represents and warrants to the other Party that: (a) as of the Effective Date, it has the power and authority to enter into this Agreement and to perform its obligations hereunder and to grant to the other Party the rights granted to such other Party under this Agreement; (b) as of the Effective Date, it has obtained all necessary corporate and other approvals to enter into and execute this Agreement; and (c) it is not, as of the Effective Date, a party to, nor will it enter into or assume during the Term, any contract or other obligation with a Third Party that would in any way limit the performance of its obligations under this Agreement (d) this Agreement will, when executed, constitute valid and binding obligations on the Parties; and (e) entry into and performance by it of this Agreement will not (i) breach any provision of its bylaws or equivalent constitutional documents; or (ii) result in a breach of any Applicable Laws in its jurisdiction of incorporation or of any order, decree or judgment of any court or any Regulatory Authority, where any such breach would affect to a material extent its ability to enter into or perform its obligations under this Agreement.

12.2 No Debarment. Each Party further represents and warrants that neither it, nor any of its Affiliates, nor any of their respective employees or contractors involved in the performance of this Agreement have been "debarred" by the FDA pursuant to 21 U.S.C. § 335a or subject to a similar sanction from any Regulatory Authority in any other jurisdiction, nor have debarment or similar proceedings against such Party, any of its Affiliates, or any of their respective employees or contractors involved in the performance of this Agreement been commenced. Each Party will promptly notify the other Party in writing if any such proceedings are commenced or if such Party, any of its Affiliates, or any of their respective employees or contractors involved in the performance of this Agreement are debarred or similarly sanctioned by any Regulatory Authority.

12.3 DISCLAIMERS.

12.3.1 GENERAL. EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY WARRANTIES (EXPRESS, IMPLIED, STATUTORY OR OTHERWISE) WITH RESPECT TO THE SUBJECT MATTER HEREOF (SUCH AS PIERIS MATERIALS AND DELIVERABLES) AND EACH PARTY EXPRESSLY DISCLAIMS ANY SUCH ADDITIONAL WARRANTIES WITH RESPECT TO THE SUBJECT MATTER HEREOF (SUCH AS PIERIS MATERIALS AND DELIVERABLES), INCLUDING ANY IMPLIED WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE, MERCHANTABILITY OR NONINFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS.

12.3.2 PIERIS MATERIALS AND DELIVERABLES. EXCEPT AS PROVIDED IN ARTICLE 0, THE PIERIS MATERIALS AND DELIVERABLES ARE PROVIDED "AS-IS."

12.3.3 LIMITATION OF LIABILITY. NEITHER PARTY WILL BE LIABLE TO THE OTHER PARTY FOR INDIRECT, INCIDENTAL, CONSEQUENTIAL, OR

SPECIAL DAMAGES INCLUDING, BUT NOT LIMITED TO, LOST PROFITS ARISING FROM OR RELATING TO THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. HOWEVER, NOTHING IN THIS ARTICLE IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY UNDER ARTICLE 13.

Article 13
INDEMNIFICATION

13.1 Pieris. Pieris shall indemnify, defend and hold harmless Stelis BioPharma, its directors, officers, employees, agents, successors and assigns from and against any liabilities, expenses or costs (including reasonable attorneys' fees and court costs) arising out of any claim, complaint, suit, proceeding or cause of action against any of them by a Third Party resulting from: (a) the negligent or intentionally wrongful acts or omissions of Pieris, its Affiliates and subcontractors during the performance of any Development Plan or (b) any breach by Pieris of its representations and warranties under this Agreement; in each case, subject to the requirements set forth in Article 0 below. Notwithstanding the foregoing, Pieris shall have no obligations under this Article 13 for any liabilities, expenses or costs arising out of or relating to claims to the extent covered under Article 0 below.

13.2 Stelis BioPharma. Stelis BioPharma shall indemnify, defend and hold harmless Pieris, its directors, officers, employees, agents, successors and assigns from and against all liabilities, expenses, and costs (including reasonable attorneys' fees and court costs) arising out of any claim, complaint, suit, proceeding or cause of action against any of them by a Third Party resulting from: (a) the negligent or intentionally wrongful acts or omissions of Stelis BioPharma, its Affiliates and subcontractors during the performance of any Development Plan or (b) any breach by Stelis BioPharma of any of its representations and warranties under this Agreement; in each case, subject to the requirements set forth in Article 0 below. Notwithstanding the foregoing, Stelis BioPharma shall have no obligations under this Article 13 for any liabilities, expenses or costs arising out of or relating to claims to the extent covered under Article 0 above.

13.3 Indemnification Procedure. Any Party seeking indemnification under this Article 13 (the "Indemnitee") shall: (a) promptly notify the indemnifying Party (the "Indemnitor") of such claim; (b) agree to the Indemnitor sole control over the defense or settlement thereof; and (c) at the Indemnitor's request and expense, provide full information and reasonable assistance to Indemnitor with respect to such claims. Without limiting the foregoing, with respect to claims brought under Article 0 or 0 above the Indemnitee, at its own expense, shall have the right to participate with counsel of its own choosing in the defense or settlement of any such claim. The indemnification under this Article 13 shall not apply to amounts paid in settlement of any claim if such settlement is effected without the consent of the Indemnitor.

13.4 Insurance. Each Party will procure and maintain, at its own expense, insurance, with a financially sound and reputable insurer, reasonably sufficient to cover such Party's activities and its obligations under this Agreement with minimum coverage amounts customary for the activities of such Party hereunder in the jurisdiction(s) where such activities are performed.

Article 14
GENERAL PROVISIONS

14.1 Affiliates. Each Party may perform any obligations and exercise any rights hereunder through any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and will cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement will be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

14.2 Assignment. Each Party agrees that its rights and obligations under this Agreement may not be assigned or otherwise transferred to a Third Party without the prior written consent of the other Party hereto. Notwithstanding the foregoing, either Party may transfer or assign its rights and obligations under this Agreement to (a) an Affiliate, subject to the prior notice to the other Party and the assigning Party remaining responsible for such Affiliate's performance or (b) a successor to all or substantially all of its business or assets relating to this Agreement whether by sale, merger, operation of law or otherwise, without the prior written consent of the other Party; provided that such assignee or transferee has agreed to be bound by the terms and conditions of this Agreement. Subject to the foregoing, this Agreement shall be binding upon and inure to the benefit of the Parties hereto, their successors and assigns.

14.3 Severability. If any clause, provision, or Article of this Agreement attached hereto, shall, for any reason, be held illegal, invalid or unenforceable, the Parties shall negotiate in good faith and in accordance with reasonable standards of fair dealing, a valid, legal, and enforceable substitute provision or provisions that most nearly reflect the original intent of the Parties under this Agreement in a manner that is commensurate in magnitude and degree with the changes arising as a result of any such substitute provision or provisions. All other provisions in this Agreement shall remain in full force and effect and shall be construed in order to carry out the original intent of the Parties as nearly as possible (consistent with the necessary reallocation of benefits) and as if such invalid, illegal, or unenforceable provision had never been contained herein. In performing this Agreement, the Parties shall comply with all Applicable Laws. Nothing in this Agreement shall be construed so as to require the violation of any law, and wherever there is any conflict between any provision of this Agreement and any law the law shall prevail, but in such event the affected provision of this Agreement shall be affected only to the extent necessary to bring it within the Applicable Laws.

14.4 Merger of Understandings; Amendment. This Agreement (and the Exhibits attached hereto) constitute the entire agreement between the Parties regarding the subject matter hereof and all prior negotiations and understandings between the Parties are deemed to be merged into this Agreement. No agreement or understanding varying or extending this Agreement shall be binding upon either Party hereto, unless set forth in a writing which specifically refers to the Agreement signed by duly authorized officers or representatives of the respective Parties, and the provisions hereof not specifically amended thereby shall remain in full force and effect.

14.5 Waiver. Any waiver of the terms and conditions hereof must be explicitly in writing and executed by a duly authorized officer of the Party waiving compliance. The waiver by either of

the Parties of any breach of any provision hereof by the other shall not be construed to be a waiver of any succeeding breach of such provision or a waiver of the provision itself. The delay or failure of any Party at any time to require performance of any provision of this Agreement shall in no manner affect such Party's rights at a later time to enforce the same.

14.6 Notices. Any notice, report or other communication required or permitted to be given by either Party under this Agreement shall be given in writing and may be delivered by hand, reputable international 3- or 4-day courier service or by mailing if mailed by registered or certified mail, postage prepaid and return receipt requested (or the international equivalent), or by email or fax (with printed confirmation of transmission and with confirmation copy forwarded by reputable international 3- or 4-day courier service), addressed to each Party as follows. Such information may be updated by a Party upon written notice to the other Party. A notice shall be deemed delivered upon receipt, unless the notice is received on a day other than a business day in the jurisdiction of the recipient or after 5:30 p.m. at the location of delivery, in which case delivery shall be deemed to be the next business day after receipt (as determined in the jurisdiction of recipient).

For Pieris:	Pieris AG Lise-Meitner-Straße 30, 85354 Freising, Germany Attention: CEO Fax: +49 8161 14 11 444
For Stelis BioPharma:	Stelis BioPharma Private Limited Strides House, Bilekahalli Bannergahtta Road, Bangalore 560 076, INDIA Attention: Legal Department Fax: + 91 80 6784 0700 / 800

14.7 Force Majeure. Neither of the Parties shall be liable for any default or delay in performance of any obligation under this Agreement caused by any of the following: Act of God, war, terrorism, riot, fire, explosion, accident, flood, sabotage, compliance with governmental requests, laws, regulations, orders or actions, national defense requirements or any other event beyond the reasonable control of such Party, or labor trouble, strike, lockout or injunction, provided that neither of the Parties shall be required to settle a labor dispute against its own best judgment, (collectively, "Force Majeure"). The Party invoking the provisions of this Article 0 shall give the other Party written notice and full particulars of such force majeure event. Both Pieris and Stelis BioPharma shall use reasonable business efforts to resolve or at least mitigate the effects of any force majeure on their respective part.

14.8 Relationship of the Parties. The relationship of Pieris and Stelis BioPharma is strictly one of independent contractors and the Parties acknowledge that this Agreement does not create a joint venture, partnership, or the like, between them. Pieris and Stelis BioPharma shall always remain independent contractors in its performance of this Agreement. Neither Party shall have any authority to employ any individual as an employee or agent for or on behalf of the other

Party to this Agreement for any purpose, and neither Party, nor any person performing any duties or engaging in any work at the request of such Party, shall be deemed to be an employee or agent of the other Party.

14.9 Choice of Law. This Agreement shall be governed by and construed in accordance with the then-current substantive law of England and Wales, without regard to the conflict of laws principles thereof, and shall not be governed by the United Nations Convention on Contracts for the International Sale of Goods.

14.10 Dispute Resolution.

14.10.1 General. Either Party should first try to resolve a Dispute amicably before resorting to the arbitration proceeding referred in Article 14.10.2. In this regard, either Party may, by written notice to the other Party, have a Dispute referred to the Chief Executive Officers of Parties for attempted resolution by good faith negotiations. Promptly after such notice is received, each Party shall cause its Chief Executive Officers to meet (face-to-face or by teleconference) and be available to attempt to resolve such issue. If the Parties are able to resolve such a Dispute, a written document such as a letter or memorandum setting forth the Parties' agreement will be prepared and signed by both Parties if requested by either Party. The Parties shall cooperate in an effort to limit the issues for consideration in such manner as narrowly as reasonably practicable in order to resolve the Dispute.

14.10.2 [***]. In the event that the Parties are unable to resolve a Dispute in the manner referred in Article 0 within [***] days from the date such dispute was referred to the Chief Executive Officers of the Parties, then either Party may [***]. [***].

14.11 Headings. Headings herein are for convenience of reference only and shall in no way affect interpretation of this Agreement.

14.12 Counterparts. This Agreement may be executed in any number of counterparts with the same effect as if all Parties had signed the same document. All such counterparts shall be deemed an original, shall be construed together and shall constitute one and the same instrument.

14.13 Exhibits. The appended Exhibits and any modifications or amendments thereof form an integral part of this Agreement.

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

IN WITNESS WHEREOF, the Parties hereto have caused their duly authorized representatives to execute this Agreement as of the Effective Date.

PIERIS AG

By: /s/ Stephen S. Yoder

Name: Stephen S. Yoder

Title: CEO

WITNESS

By: /s/ Shane Olwill

Name: Shane Olwill

Title: VP Development

STELIS BIOPHARMA PRIVATE LIMITED

By: /s/ Anand Iyer

Name: Dr. Anand Iyer

Title: CEO

WITNESS

By: /s/ Winny

Name: Winny Singh

Title: Team Leader

***Portions of the exhibit, indicated by the mark "[***],"* were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.**

CONFIDENTIAL TREATMENT REQUESTED

Exhibit I

Development Plan

[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**
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Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

CONFIDENTIAL TREATMENT REQUESTED

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CONFIDENTIAL TREATMENT REQUESTED

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Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

CONFIDENTIAL TREATMENT REQUESTED

CONFIDENTIAL

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CONFIDENTIAL

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Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Exhibit II

(Each initially-capitalized term has the meaning
as defined in the Joint Development and License Agreement)

When a Party timely exercises the option under Article 3.10 of the Joint Development and License Agreement for a Collaboration Product, the other Party shall grant the first-mentioned Party an exclusive (event to the granting Party), royalty-bearing, world-wide license under the granting Party's Background Technology and Acquired IP, any Collaboration Technology solely owned by the granting Party pursuant to Article 10 of the Joint Development and License Agreement, and the granting Party's interests in any Collaboration Technology jointly owned by the Parties pursuant to said Article 10, together with all intellectual property rights therein, with the right to grant sublicenses, to use, make, have made, sell, have sold, offer for sale and/or have offered for sale such Collaboration Product in the Field; provided, however, that the Parties shall negotiate and agree in good faith on financial terms, wherein [***], as well as on other customary terms and conditions.

CONFIDENTIAL TREATMENT REQUESTED

CONFIDENTIAL

Exhibit III

JOINT VENTURE AGREEMENT

[***]

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Exhibit 10.10

CONFIDENTIAL TREATMENT REQUESTED

RESEARCH AND LICENSING AGREEMENT

between

Technische Universität München
(Munich Technical University),
represented by its President,

Executory:
Prof. Dr. Arne Skerra
Chair of Biochemistry
An der Saatzucht 5
D-85350 Freising/Weihenstephan

(hereinafter referred to as the **UNIVERSITY**)

and

Pieris AG

Lise-Meitner-Str. 30

D-85354 Freising

(hereinafter referred to as **PIERIS**)

***Portions of the exhibit, indicated by the mark "[***],"* were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.**

PREAMBLE

The Parties are jointly conducting research aimed at gaining fundamental insights in the realm of anticalins and lipocalins. To that effect the Parties signed a Research and Licensing Agreement on 26 June / 04 July 2003[***].

The UNIVERSITY, Chair of Biochemistry, Prof. Skerra, maintains cooperative research relations on the subject of this Agreement [***] who, inter alia, [***], while under this Agreement, against payment of licence fees, UNIVERSITY grants licences or assigns to PIERIS patent rights to be obtained or already secured by UNIVERSITY in connection with this research activity. PIERIS endeavours to commercially exploit the knowledge thus acquired and patents granted.

Both Parties understand that, before the object of this Agreement can be marketed, PIERIS will have to expend substantial future research efforts and financial means above and beyond this Agreement.

§ 1
OBJECT OF THE AGREEMENT

1.1 The object of this Agreement is a joint research effort aimed at optimising the anticalin technology developed by Prof. Skerra for deployment in therapeutic, prophylactic and diagnostic applications and as research reagents and, beyond that, at gaining fundamental insights in the realm of anticalins and lipocalins. For the purpose of this research, the Parties are conducting joint research projects (hereinafter the “PROJECTS”), initially defined in more detail in Appendix 1 and subject to updates as a function of the progress of the project.

1.2 As set forth in § 4, PIERIS shall provide UNIVERSITY with funding for the execution of the PROJECTS.

§ 2
COOPERATION BETWEEN UNIVERSITY AND PIERIS

2.1 The Parties to this Agreement concur that the success of the project depends in large measure on cooperation in mutual trust and on a regular exchange of information. Both Parties therefore agree to vigorously promote the project by discussing their activities and exchanging their experiences.

2.2 The Parties to the Agreement concur that it is necessary to adhere as much as possible to the PROJECTS, described in some detail in Appendix 1, both in terms of substance and schedules, but that they must remain flexibly adjustable in view of the dynamics of the development. Such adjustments shall be made in the course of periodic progress meetings on the occasion of which the next project steps shall also be determined. The results shall be defined in dated, consecutively numbered minutes, signed by both Parties and integrated as updates to Appendix 1 of this Agreement. On the part of the UNIVERSITY, such updates shall be within the purview of Prof. Dr. Arne Skerra.

§ 3
THE UNIVERSITY'S CONTRIBUTION

3.1 For subject research under this Agreement, the UNIVERSITY, Chair of Biochemistry, Prof. Skerra, shall cooperate [***] throughout the duration of the project, collaboration with non-commercial parties excepted. Within the scope of this cooperation the UNIVERSITY shall make everything available that is required for the research hereunder and for the fulfilment of this Agreement, in particular the necessary equipment as well as the findings and insights gained to date.

3.2 The UNIVERSITY commits itself to having the PROJECTS carried out by at least [***] or, alternatively, by [***]. The extent of the activities will be determined by the respective update to Appendix 1.

3.3 These activities shall be supervised by Prof. Dr. Arne Skerra, Chair of Biochemistry at the Technical University in Freising/Weihenstephan. Prof. Skerra will perform his activities within the scope of the research project without basing it on any employment status with PIERIS. [***].

3.4 The UNIVERSITY and its associates shall make every effort, in due consideration of the latest scientific findings, to advance the project to the best of their ability.

3.5 On at least [***] basis the UNIVERSITY shall prepare a written summary of the project status attained, indicating the deployment of personnel and materials, and submit these reports to PIERIS.

3.7 Both Parties concur that the data, MATERIALS or patents conveyed by UNIVERSITY to PIERIS within the scope of this Agreement shall [***] in accordance with [***]. In the event of [***] UNIVERSITY shall [***]. Independent thereof, UNIVERSITY shall [***].

§ 4
PIERIS' CONTRIBUTION

4.1 As its contribution to the funding of the cost of personnel and materials incurred by Prof. Skerra's work group in connection with the PROJECTS, PIERIS shall allocate to the UNIVERSITY the total amount of EUR[***] for PROJECT [***] during the period [***], [***] EUR[***] at the [***]. PIERIS shall remit all payments, identified by an accounting entry code to be provided by the UNIVERSITY in each case and with the annotation "Chair of Biochemistry, Prof. Dr. Skerra", into account number [***]. The payee and owner of that account is [***].

4.2 The Parties to this Agreement concur that the PROJECTS described in more detail in Appendix 1 hereto shall be adhered to as much as possible in terms of substance and target dates. PIERIS expressly abstains from committing [***] extending beyond the term of this Agreement. PIERIS is aware, however, of the fact that [***]. In the event of a premature cancellation of this Agreement brought about by PIERIS, PIERIS shall [***] stated under 4.1.

4.3 To the extent that within the scope of the PROJECTS and as agreed with PIERIS, joint work sessions or the support services to be provided by the UNIVERSITY involve travel expenses, PIERIS shall reimburse the UNIVERSITY [***].

§ 5

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

CONFIDENTIALITY

5.1 Each Party to this Agreement agrees to treat as confidential vis-à-vis third parties all documentation and other data received from the respective other Party as well as the results achieved within the scope of this project and the MATERIAL made available by the respective other Party and developed MATERIAL (information), subject to the provisions of § 5.3 and § 5.4, and to publish them only with the prior consent of the respective other Party to this Agreement. The Parties to the Agreement shall limit the dissemination of data to the group of persons participating in the project. This obligation shall not apply if the information was (i) verifiably available to the recipient prior to the date of this Agreement, was in the public domain or was generally accessible prior to the publication; or (ii) essentially corresponds to data disclosed or made accessible to the recipient at any given time by an authorised third party; or (iii) the data are verifiably based on an independent development made by the recipient.

5.2 Each Party to this Agreement shall make certain that the persons engaged in this project, including in particular Prof. Skerra, are made aware of, and consent to, the conditions of this Agreement, especially with regard to the confidentiality obligation. Each Party hereto agrees to have all persons involved in the project sign a corresponding confidentiality undertaking (Appendix 2), providing the respective other Party with a copy thereof prior to the inception of the project.

5.3 For PIERIS the confidentiality-related provisions of this § 5 shall not be applicable to the extent that the information-related MATERIAL had been turned over to PIERIS or the information-related patents were transferred to PIERIS by way of assignment or licensing or if the release of the information to potential or current investors is desirable or otherwise customary. PIERIS may share the information with sub-licensees or collaborative partners only if these commit to the customary extent of confidentiality or if the UNIVERSITY waives the confidentiality requirement.

5.4 UNIVERSITY shall not pass on to third parties biological material previously or subsequently given to it by PIERIS or any biological material generated within the scope of this Agreement. UNIVERSITY shall bring this obligation to the attention of its co-workers who are involved in the research project under this Agreement. The exceptional release of biological material to third parties by UNIVERSITY shall require a written consent via a Material Transfer Agreement, attached hereto as Appendix 4. Upon request by PIERIS, the transfer of biological material from PIERIS to UNIVERSITY shall also be documented in writing by way of a Material Transfer Agreement. In that case, clause 6

of the Material Transfer Agreement per Appendix 4 shall not apply to the relationship between UNIVERSITY and PIERIS with regard to material which was transferred during the PROJECT PHASE per § 8.1. Per mutual consent, both Parties shall be able to modify Appendix 4 in individual cases or to waive the use of Appendix 4.

§ 6
PUBLICATIONS

6.1 The Parties concur that the objective of their cooperation consists in the development of exploitable inventions and their protection through patents or other intellectual property rights. Patent protection, however, can only be obtained if at the time the application is filed the novel realisations have not yet been published. On the other hand, the UNIVERSITY and its participating co-workers have an interest in publishing the results achieved and scientific knowledge gained at the University during the cooperative activity. Nevertheless, patent applications planned by PIERIS or the UNIVERSITY on the object of the research or this Agreement must not be jeopardised by prepublications prejudicial to novelty.

6.2 UNIVERSITY agrees that, when publishing scientific papers including dissertations, it will take PIERIS' interests into account. Therefore, [***] prior to such publication, UNIVERSITY shall submit to PIERIS the text of the intended publication or dissertation. Upon request by PIERIS, both Parties shall deliberate a wording that satisfies the interests of both Parties.

6.3 PIERIS agrees to review the proposed publications (manuscripts) with regard to prepublication [***] within [***] and to correspondingly advise UNIVERSITY of its position. If after expiration of [***] UNIVERSITY has not received a written position statement from PIERIS, PIERIS's consent regarding publication shall be deemed to have been given, provided PIERIS has at least acknowledged to UNIVERSITY, in writing, the receipt of the publication proposal. After the expiration of [***] from its submittal to PIERIS, the manuscript may be published irrespective of any consent by PIERIS. Dissertations, however, may in any event be published after expiration of [***] from submittal to PIERIS.

6.4 If so requested by it, publications shall name PIERIS as a co-initiator and sponsor of the study.

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

§ 7
USE RIGHTS, INTELLECTUAL PROPERTY RIGHTS

7.1 In accordance with this § 7, UNIVERSITY shall assign to PIERIS the property as well as the right to use all material results of its work (MATERIAL). MATERIAL as defined for the purpose of this Agreement shall include all biological and other materials, records, laboratory books, data and other relevant activity results, the reports and documents generated as well as the copyrights on these, derived within the scope of the PROJECTS per 1.1. To the extent that UNIVERSITY is required by law to store or archive parts of the MATERIALS, PIERIS grants UNIVERSITY proprietary rights restricted to that purpose.

7.2 In addition, UNIVERSITY assigns the right to use all non-patentable expertise, know-how and all other intangible results generated within the framework of the projects.

7.3 The Parties concur that (i) in the course of the PROJECTS, inventions and thus rights to patents (intellectual property rights) may be generated and that (ii) the Parties shall be entitled to these rights as follows:

(a) PIERIS INVENTIONS

Inventions made exclusively by PIERIS employees (hereinafter “PIERIS INVENTIONS”) shall belong exclusively to PIERIS;

(b) JOINT INVENTIONS

Inventions made by both PIERIS employees and UNIVERSITY personnel (including Prof. Dr. Arne Skerra) with at least [***] inventive contribution by PIERIS employees (hereinafter “JOINT INVENTIONS”) shall be exclusively credited to PIERIS. To that effect, under this § 7, the UNIVERSITY hereby assigns in advance its proportional rights in such JOINT INVENTIONS to PIERIS.

(c) UNIVERSITY INVENTIONS

Inventions made exclusively by UNIVERSITY personnel or inventions in which the inventive contribution by PIERIS employees is [***] (hereinafter “UNIVERSITY INVENTIONS”) are credited to the UNIVERSITY with the proviso

that, by advance assignment per this § 7, the UNIVERSITY grants PIERIS exclusive rights to use these UNIVERSITY INVENTIONS.

In the event that controversies regarding the proportional inventive contribution cannot be resolved, the case shall be decided by an arbitration tribunal according to § 11.3.

7.4 In exchange for participation in accordance with the licensing model per § 9 under the Research and Licensing Agreement of [***], extended and modified by the Amended and Continued Agreement of [***] and incorporated in this present Agreement, UNIVERSITY has legally assigned to PIERIS the rights to patent [***], already applied for by PIERIS, retroactively to [***] and to [***] (see Appendix 5.1). In addition, in exchange for participation in accordance with the licensing model per § 9, UNIVERSITY is hereby assigning the patent rights, already applied for by PIERIS, to "[***]" (see Appendix 5.1). For these rights, PIERIS has defrayed all application, maintenance and internal administrative costs in the past and shall cover them in the future as well. Furthermore, in exchange for participation in accordance with the licensing model per § 9 of this Agreement, the University hereby grants PIERIS an exclusive licence, unlimited in time and geography, and revocable only per §§ 8.2, 8.3, sub-licensable and freely transferable, for the use of the patent rights under "[***]" (see Appendix 5.2), with the proviso that the rights of [***] project, derived from the [***]", especially with regard to [***], shall be protected and shall take precedence over this present Agreement.

7.5 In accordance with this § 7, UNIVERSITY shall inform PIERIS of additional inventions and developments within the scope of the PROJECTS, granting PIERIS an exclusive licence, unlimited in time and geography, and revocable only per §§ 8.2, 8.3, sub-licensable and freely transferable, on new UNIVERSITY INVENTIONS per § 7.3 c). In addition, UNIVERSITY shall assign to PIERIS the entirety of its share in JOINT INVENTIONS per § 7.3.b). In exchange, PIERIS shall pay royalties per § 9.

7.6 On licensed UNIVERSITY INVENTIONS and assigned JOINT INVENTIONS, PIERIS shall grant the UNIVERSITY and its participating co-workers a free, non-transferable, non-exclusive research and teaching licence subject to the provisions of the confidentiality undertaking (co-worker declaration) and, to the same extent, the right to use all activity results. This precludes the right to perform contract research for third parties as well as any research projects and cooperative research activities that would involve the transfer of research results to commercial third parties.

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

7.7 The MATERIAL generated by the UNIVERSITY in the course of the PROJECTS shall be disclosed to PIERIS as soon as possible, completely and comprehensively, handed over in its original form or copies thereof, and made over, along with the use rights necessary for its exploitation. Within its legal possibilities, UNIVERSITY shall make certain by appropriate measures that the employees report inventions in compliance with Employee Inventions Act § 5.

7.8 For JOINT INVENTIONS and UNIVERSITY INVENTIONS per § 7.3.b) and c), UNIVERSITY shall promptly inform PIERIS of reports submitted in compliance with Employee Inventions Act § 5, indicating the date of the invention report and the names of the persons involved. PIERIS shall promptly send to the University a written acknowledgment indicating the date the information was received.

7.9 PIERIS shall advise the University whether it is interested in these inventions. PIERIS shall provide a corresponding written statement within a maximum of [***] after having received the information from UNIVERSITY. After a positive assessment by PIERIS, UNIVERSITY shall claim unrestricted ownership of the invention. UNIVERSITY shall ensure compensation of its employed inventors in accordance with the Employee Inventions Act. If within the stated time limit PIERIS does not assess or positively assess a reported invention, the UNIVERSITY shall have exclusive rights to the invention concerned or to the corresponding share in the invention.

7.10 The patent rights, once claimed, shall be listed in Appendix 5.

7.11 The exclusive licence for UNIVERSITY INVENTIONS includes the right to file a patent or utility-patent application for such UNIVERSITY INVENTIONS in the name of the UNIVERSITY and to use them for research, development as well as any commercial or other exploitation.

7.12 “Exploitation” as defined for the purpose of this Agreement includes the use, manufacture, out-sourced manufacture, sub-licensing, advertising, marketing, selling, renting, leasing and any other paid-for utilisation of the JOINT INVENTIONS and/or UNIVERSITY INVENTIONS. Paid-for utilisation also includes valuable consideration generated by PIERIS or its sub-licensees through the use of the contractual patent rights in connection with cross-licensing, arm’s-length agreements and all other contracts with third parties which contain a negative or positive licence or which are secured on the basis of court proceedings (before a court of justice and/or an arbitration tribunal) and in judicial and/or extrajudicial adjustment procedures. Any exploitation should take place under standard commercial conditions. Valuable consideration does not include R&D expenses paid by third parties to PIERIS.

Portions of the exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

7.13 The Parties to this Agreement shall inform each other of any patent infringements of which they become aware and, in the event of an infringement and/or nullity suit, to compare notes on a

suitable approach. Neither Party shall have the obligation to take action against infringing persons. Should UNIVERSITY prefer not to take action against infringers, PIERIS shall be free, at its own expense, to take action against infringements of the patent rights. In that case, PIERIS shall promptly inform UNIVERSITY ahead of its action and UNIVERSITY shall immediately provide PIERIS with all necessary information, carrying out measures of its own, declarations and actions only as instructed by PIERIS.

7.14 [***] shall assume all reasonable or generally customary costs, [***], in connection with the patent application ([***]), defence and enforcement including all attorneys' fees verifiably paid or payable in connection with patents to which PIERIS has been granted exclusive rights, or if PIERIS itself pursues the assigned patent rights or has given its written consent to having an attorney handle the application and follow-up on the exclusively licensed patent rights. The selection of appropriate attorneys shall be made by [***]. [***] shall fully exempt the attorneys from the confidentiality obligation while requiring them to keep [***] informed.

7.15 If because of the use of intellectual property rights either Party is sued for the infringement of the rights of a third party, it shall immediately notify the respective other Party hereto. The respective other Party shall in any such case have the right to join in the legal dispute.

7.16 Should one of the Parties to this Agreement choose not to continue pursuing a patent, it shall so advise the respective other Party hereto early enough to enable the other Party to further pursue the patent concerned within a time limit of [***]. The Party concerned shall offer the respective other Party the assignment of the patent rights concerned under simultaneous recognition of a free, non-exclusive right to use the inventions/patent rights for its own research purposes (not including contract research for third parties nor exploitation per § 7.12) while, if applicable, providing the other Party hereto with the documentation needed for further pursuing the patent and submitting any other additionally required explanations. In the event of an assignment of the patent rights the receiving Party hereto shall exempt the other Party from its obligations vis-à-vis the latter's employed inventors. If the offer is accepted, the accepting Party shall defray the cost of maintaining the patent rights assigned to it. In addition, in the event of a reverse assignment, UNIVERSITY shall cover the investments made by PIERIS toward the development of the patent rights as well as all costs and fees incurred as of that date in connection with the patent, with UNIVERSITY only having to make these payments out of royalty income and other payments received from third parties relative to the patent, as well as out of

its own net proceeds analogously defined in § 9.5.4. The costs incurred by the UNIVERSITY for continuing the patent rights as well as a reasonable risk allowance shall be deducted from these payments.

§ 8
TERM OF THIS AGREEMENT

8.1 The individual PROJECT PHASES extend over a period of 24 months, to wit: PROJECT PHASE 1 from 1 March 2003 through 28 February 2005, PROJECT PHASE 2 from 1 March 2005 through 28 February 2007, and PROJECT PHASE 3 from 1 March 2007 through 28 February 2009. If PIERIS intends to extend the Research Agreement, it shall so inform the UNIVERSITY by 31 December 2008 at the latest. Thereupon, by 31 January 2009, UNIVERSITY shall advise in writing whether it agrees to an extension. 8.2 The licensing provisions of this Agreement set forth in §§ 7 and 9 shall remain in effect until the patent concerned expires or at least for as long as royalties have to be paid according to § 9, unless this Agreement is prematurely cancelled in its entirety or for individual patents. The stipulations regarding publication and confidentiality per §§ 5 and 6 shall become void five years after the expiration of the specific PROJECT PHASE concerned.

8.3 The Parties to this Agreement may prematurely cancel the licensing arrangements for cause only. On the part of the UNIVERSITY, such cause exists if, a written reminder and a reasonable deadline notwithstanding, PIERIS has failed twice to pay the fees due according to the Agreement. The notice of cancellation must be in writing and delivered via registered mail. PIERIS may cancel the Licensing Agreement for individual and/or all licensed patent rights at 3 months' notice as of the end of a month. No such right to cancel exists with regard to patents assigned to PIERIS, but PIERIS shall have the right to offer such patents per 7.16 for reverse assignment to the UNIVERSITY.

§ 9
License Fees

9.1 In exchange for the assignment or licensing of shares in JOINT INVENTIONS and/or UNIVERSITY INVENTIONS by UNIVERSITY to PIERIS, a remuneration along a licence model per §§ 9.3 – 9.6 shall be payable. To the extent that it relates to UNIVERSITY INVENTIONS, the licence model shall apply in full. In the case of JOINT INVENTIONS, the license fee amounts shown shall be prorated according to the proportion of the invention contributed by UNIVERSITY.

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

9.2 The payments required per §§ 9.3 – 9.6 shall not begin until the time of the first patent application and end upon expiration of the longest-running patent.

9.3 If a licensed or assigned patent is legally declared null and void, no further license fee payments shall be due for that particular patent. PIERIS cannot require repayment of fees paid per § 9.

9.4 For all patents covered under this Agreement, PIERIS shall make the following [***] license fee payment in the year concerned (all amounts shown below are in Euros), if no other income has been or is being generated through sales revenues or other valuations, the total of which results in an income for UNIVERSITY that exceeds the respective annually payable minimum license fee according to the following table (if the total amount of such other income is higher than the minimum license fee for a given year, the excess amount shall be applied toward the minimum license fee for the subsequent years):

[***]		
[***]		
[***]		
[***]		
[***]	[***] Euros	[***]
[***]	[***] Euros	[***]
[***]	[***] Euros	[***]
[***]	[***] Euros	[***]
[***]	[***] Euros	[***]
[***]	[***] Euros	[***]
[***]	[***] Euros	[***]
[***]	[***] Euros	[***]

9.5 For [***] the following amounts shall be paid:

9.5.1 If the development of an anticalin is based on one or several patents covered by this Agreement, the following [***] license fees shall be payable in each case of [***] of an anticalin [***]:

[***] Euros

[***] Euros

[***] Euros

[***] Euros

[***] Euros

An [***]" as defined for the purpose of this provision is [***]. A "[***]" as defined herein refers to [***].

9.5.2 In addition, a [***] payment of EUR [***] Euros [***] shall be due for [***] based on one or several patents covered by this Agreement and shall be payable after a [***].

9.5.3 If [***] are based on one or more patents covered by this Agreement are [***], a royalty of [***] of the

[***].

9.5.4 The term [***] as defined in this Agreement refers to [***].

9.6 In case of [***], PIERIS shall pay the following amounts:

In each case of [***] per § 7.12 [***], PIERIS shall make a payment in the amount of [***]) of [***] to PIERIS as the [***] to the UNIVERSITY, but at least [***] of the [***] which the UNIVERSITY would receive as a result in the case of [***] by PIERIS according to art. 9.5 and 9.8, limited, however, to a maximum of [***] of the total annual revenue achieved by PIERIS in a [***].

9.7 In [***] per art. 7.12, PIERIS shall pay [***] of the [***] thereby achieved or, in the event of some other exploitation, of the pecuniary-value benefits derived via a [***].

9.8 If in the case of [***] per § 7.12 PIERIS has to pay a total in excess of [***] in [***] to third parties, unrelated to [***], the UNIVERSITY shall receive [***] according to the table below. In any such case of [***] PIERIS shall pay an amount of [***] (see definition below) of the [***] of the [***] as [***] to the UNIVERSITY, but at least [***] of the license fee which the UNIVERSITY would receive as a result of [***]. [***], not exceeding, however, a maximum of [***] of [***] PIERIS would achieve in [***]. However, that license fee shall never be less than [***]. PIERIS shall provide the UNIVERSITY with [***] of the amount of [***] or it shall [***].

In the event of [***] [***], the payment to UNIVERSITY shall be calculated as follows:

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

A = The [***] payable by PIERIS to the UNIVERSITY shall be [***] to PIERIS.

B = For [***] covered by this Agreement, PIERIS shall pay [***].

B	A
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

9.9 If and to the extent that, within the framework of joint research during PROJECT [***], public or otherwise sponsored projects are carried out, the rights of the [***] concerned as well as the obligations of the Parties under [***] shall [***].

9.10 Should PIERIS close down its business operation or face insolvency procedures, it shall immediately notify the UNIVERSITY in writing. In the event a petition in bankruptcy is filed, the UNIVERSITY shall have the first right of refusal on all patents, proportional patent rights and patent applications assigned to PIERIS.

9.11 As of [***] of each consecutive year, PIERIS shall [***] covered by this Agreement. In the case of [***], PIERIS shall [***]. An account statement prepared by [***] shall be made available to the UNIVERSITY. [***], the UNIVERSITY may appoint an independent, sworn auditor who will review the information provided by PIERIS, or, if [***], examine the business records of PIERIS to obtain [***] covered by this Agreement. PIERIS shall be required to provide the auditor with all data and materials needed for verification of the information. In the case of [***], PIERIS shall [***] to permit an audit by the auditor appointed by PIERIS. If the [***], PIERIS shall absorb the cost of the audit, otherwise the UNIVERSITY shall absorb it. [***]

All payments shall be made within [***] from the payment due date. Payments per § 9, including the applicable value-added tax, shall be remitted

into a bank account to be named by the UNIVERSITY.

The remittance shall be in EUR[***] and with indication of the bank ID number to be provided by the UNIVERSITY.

§ 10
Liability

10.1 PIERIS develops and markets products, developed on the basis of this Agreement, for its own account and without the right of participation or opposition on the part of the UNIVERSITY. Accordingly, PIERIS [***]. When marketing products that are also based on patents owned by UNIVERSITY, PIERIS shall provide to the UNIVERSITY, by [***], proof of customary product liability insurance by submitting a copy of the respectively valid insurance policy for the products manufactured and marketed by PIERIS.

10.2 PIERIS shall [***].

10.3 The Parties hereto assume no guarantee or liability for the patentability and the commercial exploitability of the rights that constitute the subject matter of this Agreement. Nor do the Parties hereto assume any guarantee or liability to the effect that the use of the patent rights under this Agreement would not interfere with industrial patents, copyrights or other rights of third parties nor lead to losses on the part of the licensee or of third parties.

10.4 The above disclaimers of liability shall be invalid in cases of malicious intent and gross negligence on the part of the Parties or their employees.

§ 11
MISCELLANEOUS

11.1 This Agreement in its present wording definitively governs the relations between the Parties with regard to the object of the Agreement. Collateral parol evidence does not exist or is voided. A notice of cancellation, any amendments and additions as well as a rescission of this Agreement must be in writing. Documentation supporting the content of this Agreement as well as any waiver of this written-form requirement must be in writing.

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

11.2 Should one or more of the provisions of this Agreement be or become invalid, the Parties shall be obligated to replace the invalid provisions with other, valid provisions the financial result of which comes so close to that of the invalid provisions that the Parties can be reasonably expected to have signed the Agreement with that clause as well.

If such a solution cannot be found, the invalidity of one or several provisions of the Agreement shall not affect the validity of this Agreement in its entirety unless the significance of the invalid provisions is such that the Parties could be reasonably expected not to have signed this Agreement without the invalid stipulations.

11.3 Any disputes arising in connection with this Research and Licensing Agreement, its interpretation or execution or its validity, relating in particular to proprietary rights to the inventions per § 7, shall be negotiated and finally decided in the German language, admitting of no legal appeal, by an arbitration tribunal with three arbitrators, in accordance with the Arbitration Rules of the Deutsche Institution für Schiedsgerichtbarkeit e.V. (DIS) [German Institute for Arbitral Jurisdiction]. The arbitration tribunal may also make a binding decision on the validity of this arbitration clause. The venue of arbitration shall be Munich. The governing law shall be that of Germany.

11.4 Appendices 1 – 5 to this Agreement including the separately signed addenda to Appendices 1 and 5 constitute an essential, integral part of this Agreement.

11.5 By having the respective project director sign the research-project declaration form per Appendix 3, each Party hereto shall ensure that the project director concerned is made aware of the provisions of this Agreement and commits to abiding by these.

11.6 This Agreement shall also be binding on successors in title of both Parties. Specifically, a change in the corporate or ownership structure of the Parties shall not justify a cancellation of this Agreement for cause.

Freising, 26/6/2003

/s/ Martin Pöhlchen

PIERIS Proteolab AG

Freising, 04/07/2003

/s/ Arne Skerra

Technische Universität München

(stamp: TECHNISCHE UNIVERSITÄT MÜNCHEN)
Contract Management & Legal Services

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

APPENDICES

Appendix 1	**Project Description**
Appendix 2	**Confidentiality Agreement / Co-Worker's Declaration**
Appendix 3	**Project Director's Countersignature**
Appendix 4	**Material Transfer and Confidentiality Agreement**
Appendix 5	**Patent Rights**
	I. Assigned Patent Rights
	II. Patent Rights exclusively licensed to PIERIS Proteolab AG

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

CONFIDENTIAL TREATMENT REQUESTED

APPENDIX 1

PROJECT DESCRIPTION

[***]

[***]

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

CONFIDENTIAL TREATMENT REQUESTED

APPENDIX 2

CO-WORKER'S DECLARATION

On the Research Project titled: Advancement of the Anticalin Technology

between:

Technische Universität München
Study Group: Prof. Skerra
Chair of Biochemistry
Freising/Weihenstephan

and:

PIERIS Proteolab AG, Freising/Weihenstephan

Name of Co-Worker: Mr./Ms. _____

As a co-worker participating in the above Research Project undertaken by the Parties named, I hereby pledge to PIERIS to treat as confidential the objective of this Research Project, the data received from PIERIS and the results of the work performed under the joint research and development programme. I have been informed of the confidentiality exception clauses with regard to publication per § 6 of the Agreement on which this Research Project is based. I have also been advised that materials transferred by PIERIS to the University or generated in the course of this cooperation must not be made available to third parties. I have understood these instructions and I pledge to comply with them.

_____

Place, Date and Co-Worker's Signature

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

CONFIDENTIAL TREATMENT REQUESTED

APPENDIX 3

To
Technische Universität München
Central Department 6 – Legal Affairs
ZA 6 – Dept. 62
Arcisstr. 21

80333 München

Re-Research Project: Advancement of the Anticalin Technology

Declaration regarding the Research Project

I am aware that outside grants provided at my request and incorporated in the budget of the University are subject to the rules of budget compliance, unless the Grant Agreement contains different stipulations. I have taken note that [***]% of the project funding will be going to the University as a contribution to its infrastructure.

In order to permit compliance with the obligations stated in the aforementioned Agreement, I shall bind all participants in the research project, whether or not in the employ of the University, through a signed pledge to observe the conditions of the Agreement and to take all actions necessary for the University to fulfil its obligations under the Agreement. All inventions generated within the scope of the research project will be promptly reported to the University Administration in a manner satisfying the requirements of Employee Invention Act § 5 sec. 1 and 2.

In addition, I shall take appropriate measures to ensure that all other conditions of the aforementioned Agreement as well can be properly fulfilled and that no consequential costs or other detriments arise to the University or to the Free State of Bavaria. Any additional expenditures incurred during or upon completion of the research project can be covered out of the outside funding granted to that effect or out of the institute's / department's budget.

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

(seal)

Signature of Prof. Dr. Arne Skerra, Department Chair

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

APPENDIX 4

MATERIALS TRANSFER AND CONFIDENTIALITY AGREEMENT

[***]

[***]
[***]

[***]
[***]
[***]

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Attachment A

Description of Research Project:

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

CONFIDENTIAL TREATMENT REQUESTED

APPENDIX 5

1) Patent Rights assigned by the UNIVERSITY to PIERIS [***]

2) Patents exclusively licensed to PIERIS [***]

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

PIERIS PHARMACEUTICALS, INC.

CORPORATE CODE OF CONDUCT AND ETHICS AND WHISTLEBLOWER POLICY

INTRODUCTION

This Corporate Code of Conduct and Ethics and Whistleblower Policy, referred to as the "Code," is intended to provide our associates, as defined below, with a clear understanding of the principles of business conduct and ethics that are expected of them and to aid them in making ethical and legal decisions when conducting the company's business and performing day-to-day duties. The standards set forth in the Code apply to us all. Every associate of the company must acknowledge his or her review of, and agreement to comply with, the Code as a condition of his or her relationship with the company (see Appendix A attached hereto). The term "associate" as used throughout the Code means (i) every full and part-time employee of the company and its subsidiaries, (ii) all members of the company's senior management, including the company's Chief Executive Officer and Chief Financial Officer, and (iii) every member of the company's Board of Directors, even if such member is not employed by the company.

REPORTING VIOLATIONS UNDER THE CODE; ANTI-RETALIATION PLEDGE

It is our responsibility to conduct ourselves in an ethical business manner and also to ensure that others do the same. If any one of us violates these standards, he or she can expect a disciplinary response, up to and including termination of any employment or other relationship with the company, and possibly other legal action. If you are aware of any breach of the Code, you are obligated to report violations to the Corporate Compliance Officer, to any member of the Compliance Committee, or to the anonymous Hotline that the company has retained to receive such reports, as described in more detail below. Through establishing a confidential and anonymous option to accept and process such reports, we ensure that the good faith efforts of all of us to comply with the Code are not undermined.

The Code contains a clear anti-retaliation pledge, meaning that if you in good faith report a violation of the Code by the company, or its agents acting on behalf of the company, to the Hotline, the Corporate Compliance Officer or another member of the Compliance Committee, the company will undertake to protect you from being fired, demoted, reprimanded or otherwise harmed for reporting the violation, even if the violation involves you, your supervisor, or senior management of the company. Note, however, that while you will not be disciplined for reporting a violation, you may be subject to discipline with respect to the underlying conduct or violation. You are entitled to make the report on a confidential and anonymous basis. To the extent an investigation must be initiated, the company will keep confidential any report you make to the Corporate Compliance Officer or another member of the Compliance Committee to the extent required by applicable law.

COMPLYING WITH THE CODE

The ultimate responsibility for maintaining our Code rests with each of us. As individuals of personal integrity, we can do no less than to behave in a way that will continue to bring credit to ourselves and our company. Applying these standards to our business lives is an extension of the values

by which we are known as individuals and by which we want to be known as a company. To that end, the company has made the Code publicly available on its web site. It is our responsibility to conduct ourselves in an ethical business manner and also to ensure that others do the same. If any one of us violates these standards, he or she can expect a disciplinary response, up to and including termination of any employment or other relationship with the company, and possibly other legal action.

While it is impossible for this Code to describe every situation that may arise, the standards explained in this Code are guidelines that should govern our conduct at all times. If you are confronted with situations not covered by this Code, or have questions regarding the matters that are addressed in the Code, you are urged to consult with the Corporate Compliance Officer, a member of the Compliance Committee, or another member of management. Furthermore, the policies set forth in this Code are in addition to other policies of the company that associates must comply with, including those set forth in **[the company's Employee Handbook and the other policies referenced in the Code]**. Copies of these other policies are available from the Human Resources Department or on the company's Intranet.

The provisions of the Code regarding the actions the company will take are guidelines which the company intends to follow. There may be circumstances, however, that in the company's judgment require different measures or actions and in such cases it may act accordingly while still attempting to fulfill the principles underlying this Code. In the case of any inconsistency between the provisions set out in this Code and the rules contained in any mandatory text, laws or interpretive case law applicable to the company and its associates, the latter prevail. In no instance should this Code be interpreted as modifying, amending or otherwise changing any legal text and related legal precedents that apply to the company and its associates.

Table of Contents

I. WHISTLEBLOWER POLICY

A. Obligation to Report Violations or Suspected Violations

Any associate of the company having any information or knowledge regarding the existence of any violation or suspected violation of the Code has a duty to report the violation or suspected violation to the Whistleblower Hotline (the contact details for which are below), the Corporate Compliance Officer, or any other member of the Compliance Committee. Associates are also encouraged to raise any issues or concerns regarding the company's business or operations. Failure to report suspected or actual violations is itself a violation of the Code and may subject the associate to disciplinary action, up to and including termination of employment or legal action. Reports may be made on a completely confidential and anonymous basis. To the extent any investigation is necessitated by a report, the company will endeavor to keep the proceedings and the identity of the reporting associate confidential to the fullest extent required by applicable law.

Associates are encouraged to pursue all internal reporting channels through completion and reasonably await and consider the results of all internal investigations prior to reporting matters outside of the company. We have instituted the procedures described in this Code, including procedures to make anonymous submissions (a form of internal report), to facilitate the use of internal investigations.

Individuals should also consider leaving, but are not required to leave, their name or a contact number when submitting a report. Such information may facilitate a more thorough and efficient investigation. The Corporate Compliance Officer will strive to maintain the integrity and confidentiality of all compliance-related communications. However, in certain circumstances, the identity of the person reporting the issue may become known or may need to be revealed, particularly if federal or state enforcement authorities become involved in the investigation. The company cannot guarantee confidentiality when material evidence of a violation of the law is disclosed or if the person is identified during the normal course of an investigation.

B. Whistleblower Compliance Hotline for Confidential and Anonymous Reporting

If you are aware of any breach of the Code, you are obligated to report violations to the Corporate Compliance Officer, to any member of the Compliance Committee, or to the anonymous Whistleblower Compliance Hotline (the "Hotline"). The Hotline is operated by a third party service provider, which the company has retained to receive such reports, the contact details for which are below. **You may make such reports on a completely anonymous and confidential basis by contacting the Hotline**. Associates may report to the Hotline any concerns an associate may have with respect to the company, including, but not limited to, concerns with the company's business or operations, suspected violations of the Code, securities or antifraud laws, accounting issues, any law relating to fraud against shareholders, or any other issue concerning the company and their employment with the company. Reports made to the Hotline will, in turn, be provided directly to the Audit Committee on an anonymous and confidential basis. The Hotline may be reached 24 hours a day, 7 days a week at the following toll-free number and internet address:

Contact Information for the Whistleblower Compliance Hotline:

Toll-Free Telephone Number	**[number]**
Hotline E-mail Address	**[email]**
Hotline Internet Address	**[website]**

C. Anti-Retaliation Pledge

Any associate who in good faith reports a suspected violation under the Code by the company, or its agents acting on behalf of the company, or who in good faith raises issues or concerns regarding the company's business or operations, to the Hotline, the Corporate Compliance Officer or any other member of the Compliance Committee, may not be fired, demoted, reprimanded or otherwise harmed for, or because of, the reporting of the suspected violation, issues or concerns, regardless of whether the suspected violation involves the associate, the associate's supervisor or senior management of the company.

In addition, any associate who in good faith reports a suspected violation under the Code which the associate reasonably believes constitutes a violation of a federal statute by the company, or its agents acting on behalf of the company, to a federal regulatory or law enforcement agency, may not be reprimanded, discharged, demoted, suspended, threatened, harassed or in any manner discriminated against in the terms and conditions of the associate's employment for, or because of, the reporting of the suspected violation, regardless of whether the suspected violation involves the associate, the associate's supervisor or senior management of the company.

II. IMPLEMENTATION OF THE CODE

The following questions and answers address the company's implementation of the Code. The company has attempted to design procedures that ensure maximum confidentiality, anonymity, and, most importantly, freedom from the fear of retaliation for complying with and reporting violations under the Code. In addition, each associate shall sign the Associate's Agreement to Comply with the Code in substantially the form attached as Appendix A hereto.

Q: Who is responsible for administering, updating and enforcing the Code?

A: The company's Board of Directors has appointed a Corporate Compliance Officer and a Compliance Committee that includes the Corporate Compliance Officer and at least one additional member to administer, update and enforce the Code. Ultimately, the Board of Directors of the company must ensure that the Corporate Compliance Officer and the Compliance Committee fulfill their responsibilities.

The Corporate Compliance Officer has overall responsibility for overseeing the implementation of the Code. Specific responsibilities of the position are to:

- Develop the Code based on legal requirements, regulations and ethical considerations that are raised in the company's operations;

- Ensure that the Code is distributed to all associates and that all associates acknowledge the principles of the Code;
- Work with the company's Audit Committee to provide a reporting mechanism so that associates have a confidential and anonymous method of reporting not only suspected violations of the Code but concerns regarding federal securities or antifraud laws, accounting issues, or any federal law relating to fraud against shareholders;
- Implement a training program to ensure that associates are aware of and understand the Code;
- Audit and assess compliance with the Code;
- Serve as a point person for reporting violations and asking questions under the Code; and
- Revise and update the Code as necessary to respond to detected violations and changes in the law.

The Compliance Committee is comprised of the Corporate Compliance Officer, and at least one additional member selected from a representative from the Human Resources Department, a representative from the Finance Department, a representative from the Legal Department and/or a member of the executive management team. The primary responsibilities of the Compliance Committee are to:

- Assist the Corporate Compliance Officer in developing and updating the Code;
- Develop internal procedures to monitor and audit compliance with the Code;
- Serve as point persons for reporting violations and asking questions under the Code;
- Set up a mechanism for anonymous reporting of suspected violations of the Code by associates and refer, when appropriate, such reports to the Audit Committee;
- Conduct internal investigations, with the assistance of counsel, of suspected compliance violations;
- Evaluate disciplinary action for associates who violate the Code;
- In the case of more severe violations of the Code, make recommendations regarding disciplinary action to the Board of Directors or a committee thereof; and
- Evaluate the effectiveness of the Code and improve the Code.

The Compliance Committee will provide a summary of all matters considered under the Code to the Board of Directors or a committee thereof at each regular meeting thereof, or sooner if warranted by the severity of the matter. All proceedings and the identity of the person reporting will be kept confidential to the extent required by applicable law.

Q: How can I contact the Corporate Compliance Officer and the Compliance Committee?

A: The names and phone numbers of the Corporate Compliance Officer and each member of the Compliance Committee are listed below. Any one of these individuals can assist you in answering questions or reporting violations or suspected violations under the Code.

[name] **[number]**
Corporate Compliance Officer
[name] [title] **[number]**
Compliance Committee Member

The members of the Compliance Committee may change from time to time. You are encouraged to consult the copy of the Code that is included on the company's website to obtain the most current membership of the Compliance Committee.

III. GENERAL REQUIREMENTS

Each associate of the company is expected to be honest, fair, and accountable in all business dealings and obligations, and to ensure:

- the ethical handling of conflicts of interest between personal and professional relationships;
- full, fair, accurate, timely and understandable disclosure in the reports required to be filed by the company with the Securities and Exchange Commission and in other public communications made by the company; and
- compliance with applicable governmental laws, rules and regulations.

IV. CONFLICTS OF INTEREST

Associates should avoid any situation that may involve, or even appear to involve, a conflict between their personal interests and the interests of the company. In dealings with current or potential customers, suppliers, contractors, and competitors, each associate should act in the best interests of the company to the exclusion of personal advantage. Immediate family members of associates, executive officers and directors are also covered in certain circumstances. For purposes of this section, a "significant" amount or interest shall be deemed to be any amount in excess of $**[**120,000**]** and an "immediate family member" in respect of any person means any child, stepchild, parent, stepparent, spouse, sibling, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law of such person, and any person (other than a tenant or employee) sharing the household of such person.

Associates and, in certain circumstances, their immediate family members, are prohibited from any of the following activities which could represent an actual or perceived conflict of interest:

- No associate or immediate family member of an associate shall have a significant financial interest in, or obligation to, any outside enterprise which does or seeks to do business with the company or which is an actual or potential competitor of the company, without prior approval of the Compliance Committee, or in the case of executive officers or members of the Board of Directors, the full Board of Directors or a committee thereof; provided however, that this provision shall not prevent any

associate from investing in any mutual fund or owning up to 1% of the outstanding stock of any publicly traded company.

- No associate shall conduct a significant amount of business on the company's behalf with an outside enterprise which does or seeks to do business with the company if an immediate family member of the associate is a principal or officer of such enterprise, or an employee of such enterprise who will play a significant role in the business done or to be done between the company and such enterprise, without prior approval of the Compliance Committee, or in the case of executive officers or members of the Board of Directors, the full Board of Directors or a committee thereof.
- No executive officer or employee, or an immediate family member of an executive officer or an employee, shall serve as a director, officer or in any other management or consulting capacity of any actual competitor of the company.
- No director, or an immediate family member of a director, shall serve as a director, officer or in any other management or consulting capacity of any actual competitor of the company, without the prior approval of the full Board of Directors or a committee thereof.
- No associate shall use any company property or information or his or her position at the company for his or her personal gain.
- No associate shall engage in activities that are directly competitive with those in which the company is engaged.
- No associate shall divert a business opportunity from the company to such individual's own benefit. If an associate becomes aware of an opportunity to acquire or profit from a business opportunity or investment in which the company is or may become involved or in which the company may have an existing interest, the associate should disclose the relevant facts to the Corporate Compliance Officer or a member of the Compliance Committee. The associate may proceed to take advantage of such opportunity only if the company is unwilling or unable to take advantage of such opportunity as notified in writing by the Compliance Committee.
- No associate or immediate family member of an associate shall receive any loan or advance from the company, or be the beneficiary of a guarantee by the company of a loan or advance from a third party, except for customary advances or corporate credit in the ordinary course of business or approved by the Compliance Committee. Please see Section V.E. below, "Corporate Advances", for more information on permitted corporate advances.

In addition, the Audit Committee of the Board of Directors will review and approve, in advance, all related-person transactions, as required by the Securities and Exchange Commission, The Nasdaq Stock Market or any other regulatory body to which the company is subject.

Each associate should make prompt and full disclosure in writing to the Corporate Compliance Officer or a member of the Compliance Committee of any situation that may involve a conflict of interest. Failure to disclose any actual or perceived conflict of interest is a violation of the Code.

V. PROTECTION AND PROPER USE OF COMPANY ASSETS

Proper protection and use of company assets and assets entrusted to it by others, including proprietary information, is a fundamental responsibility of each associate of the company. Associates must comply with security programs to safeguard such assets against unauthorized use or removal, as well as against loss by criminal act or breach of trust. The provisions hereof relating to protection of the company's property also apply to property of others entrusted to it (including proprietary and confidential information).

A. Proper Use of Company Property

The removal from the company's facilities of the company's property is prohibited, unless authorized by the company. This applies to furnishings, equipment, and supplies, as well as property created or obtained by the company for its exclusive use – such as client lists, files, personnel information, reference materials and reports, computer software, data processing programs and data bases. Neither originals nor copies of these materials may be removed from the company's premises or used for purposes other than the company's business without prior written authorization from the Compliance Committee.

The company's products and services are its property; contributions made by any associate to their development and implementation are the company's property and remain the company's property even if the individual's employment or directorship terminates.

Each associate has an obligation to use the time for which he or she receives compensation from the company productively. Work hours should be devoted to activities directly related to the company's business.

B. Confidential Information

The company provides its associates with confidential information relating to the company and its business with the understanding that such information is to be held in confidence and not communicated to anyone who is not authorized to see it, except as may be required by law. The types of information that each associate must safeguard include (but are not limited to) the company's plans and business strategy, unannounced products and/or contracts, sales data, significant projects, customer and supplier lists, patents, patent applications, trade secrets, manufacturing techniques and sensitive financial information, whether in electronic or paper format. These are costly, valuable resources developed for the exclusive benefit of the company. No associate shall disclose the company's confidential information to an unauthorized third party or use the company's confidential information for his or her own personal benefit.

C. Accurate Records and Reporting

Under law, the company is required to keep books, records and accounts that accurately and fairly reflect all transactions, dispositions of assets and other events that are the subject of specific regulatory record keeping requirements, including generally accepted accounting principles and other applicable rules, regulations and criteria for preparing financial statements and for preparing periodic reports filed with the Securities and Exchange Commission. All company reports, accounting records, sales reports, expense accounts, invoices, purchase orders, and other documents must accurately and clearly represent the relevant facts and the true nature of transactions. Reports and other documents should state all material facts of a transaction and not omit any information that would be relevant in interpreting such report or document. Under no circumstance may there be any unrecorded liability or fund of the company, regardless of the purposes for which the liability or fund may have been intended, or any improper or inaccurate entry knowingly made on the books or records of the company. No payment on behalf of the company may be approved or made with the intention, understanding or awareness that any part of the payment is to be used for any purpose other than that described by the documentation supporting the payment. In addition, intentional accounting misclassifications (e.g., expense versus capital) and improper acceleration or deferral of expenses or revenues are unacceptable reporting practices that are expressly prohibited.

The company has developed and maintains a system of internal controls to provide reasonable assurance that transactions are executed in accordance with management's authorization, are properly recorded and posted, and are in compliance with regulatory requirements. The system of internal controls within the company includes written policies and procedures, budgetary controls, supervisory review and monitoring, and various other checks and balances, and safeguards, such as password protection to access certain computer systems.

The company has also developed and maintains a set of disclosure controls and procedures to ensure that all of the information required to be disclosed by the company in the reports that it files or submits under the Securities Exchange Act is recorded, processed, summarized and reported within the time periods specified by the Securities and Exchange Commission's rules and forms.

Associates are expected to be familiar with, and to adhere strictly to, these internal controls and disclosure controls and procedures.

Responsibility for compliance with these internal controls and disclosure controls and procedures rests not solely with the company's accounting personnel, but with all associates involved in approving transactions, supplying documentation for transactions, and recording, processing, summarizing and reporting of transactions and other information required by periodic reports filed with the Securities and Exchange Commission. **Because the integrity of the company's external reports to shareholders and the Securities and Exchange Commission depends on the integrity of the company's internal reports and record-keeping, all associates must adhere to the highest standards of care with respect to our internal records and reporting. The company is committed to full, fair, accurate, timely, and understandable disclosure in the periodic reports required to be filed by it with the Securities and Exchange Commission, and it expects each associate to work diligently towards that goal.**

Any associate who believes the company's books and records are not in accord with these requirements should immediately report the matter to the Hotline, the Corporate Compliance Officer or a member of the Compliance Committee. The company has adopted explicit anti-retaliation policies with respect to these matters, as described in Section I above.

D. Document Retention

Numerous federal and state statutes require the proper retention of many categories of records and documents that are commonly maintained by companies. In consideration of those legal requirements and the company's business needs, all associates must maintain records in accordance with these laws and, if any, the company's document retention policy.

Any record, in paper or electronic format, relevant to a threatened, anticipated or actual internal or external inquiry, investigation, matter or lawsuit may not be discarded, concealed, falsified, altered, or otherwise made unavailable, once an associate has become aware of the existence of such threatened, anticipated or actual internal or external inquiry, investigation, matter or lawsuit.

When in doubt regarding retention of any record, an associate must not discard or alter the record in question and should seek guidance from the Corporate Compliance Officer or a member of the Compliance Committee. Associates should also direct all questions regarding document retention and related procedures to the Corporate Compliance Officer or a member of the Compliance Committee.

E. Corporate Advances

Under law, the company may not loan money to associates except in limited circumstances. It shall be a violation of the Code for any associate to advance company funds to any other associate or to himself or herself except for usual and customary business advances for legitimate corporate purposes which are approved by a supervisor or pursuant to a corporate credit card for usual and customary, legitimate business purposes. It is the company's policy that any advance to an associate not meeting the forgoing criteria be approved in advance by the Compliance Committee.

Company credit cards are to be used only for authorized, legitimate business purposes. An associate will be responsible for any unauthorized charges to a company credit card.

VI. FAIR DEALING WITH CUSTOMERS, SUPPLIERS, COMPETITORS, AND ASSOCIATES

The company does not seek to gain any advantage through the improper use of favors or other inducements. Good judgment and moderation must be exercised to avoid misinterpretation and adverse effect on the reputation of the company or its associates. Offering, giving, soliciting or receiving any form of bribe to or from an employee of a customer or supplier to influence that employee's conduct is strictly prohibited.

A. Giving Gifts

Cash or cash-equivalent gifts must not be given by an associate to any person or enterprise. Gifts, favors and entertainment may be given to non-governmental employees if what is given:

- is consistent with customary business practice;
- is not excessive in value and cannot be construed as a bribe or pay-off;
- is not in violation of applicable law or ethical standards; and
- will not embarrass the company or the associate if publicly disclosed.

See also subsection E below for considerations relating to gifts to foreign officials and Section VII. B below for considerations relating to gifts to government employees.

B. Receiving Gifts

Gifts, favors, entertainment or other inducements may not be accepted by associates or members of their immediate families from any person or organization that does or seeks to do business with, or is a competitor of, the company**,** except as common courtesies usually associated with customary business practices. If the gift is of more than token value, the Compliance Committee must approve its acceptance.

An especially strict standard applies when suppliers are involved. If a gift unduly influences or makes an associate feel obligated to "pay back" the other party with business, receipt of the gift is unacceptable.

It is never acceptable to accept a gift in cash or cash equivalent. Even cash gifts of token value must be declined and returned to the sender.

C. Unfair Competition

Although the free enterprise system is based upon competition, rules have been imposed stating what can and what cannot be done in a competitive environment. The following practices can lead to liability for "unfair competition" and should be avoided. They are violations of the Code.

Disparagement of Competitors. It is not illegal to point out weaknesses in a competitor's service, product or operation; however, associates may not spread false rumors about competitors or make misrepresentations about their businesses. For example, an associate may not pass on anecdotal or unverified stories about a competitor's products or services as the absolute truth (e.g., the statement that "our competitors' diagnostic testing procedures have poor quality control").

Disrupting a Competitor's Business. This includes bribing a competitor's employees, posing as prospective customers or using deceptive practices such as enticing away employees in order to obtain secrets or destroy a competitor's organization. For example, it is not a valid form

of “market research” to visit a competitor’s place of business posing as a customer.

Misrepresentations of Price and Product. Lies or misrepresentations about the nature, quality or character of the company’s services and products are both illegal and contrary to company policy. An associate may only describe our services and products based on their documented specifications, not based on anecdote or his or her belief that our specifications are too conservative.

D. Antitrust Concerns

Federal and state antitrust laws are intended to preserve the free enterprise system by ensuring that competition is the primary regulator of the economy. Every corporate decision that involves customers, competitors, and business planning with respect to output, sales and pricing raises antitrust issues. Compliance with the antitrust laws is in the public interest, in the interest of the business community at large, and in our company’s interest.

Failing to recognize antitrust risk is costly. Antitrust litigation can be very expensive and time-consuming. Moreover, violations of the antitrust laws can, among other things, subject you and the company to the imposition of injunctions, treble damages, and heavy fines. Criminal penalties may also be imposed, and individual associates can receive heavy fines or even be imprisoned. For this reason, antitrust compliance should be taken seriously at all levels within the company.

A primary focus of antitrust laws is on dealings between competitors. In all interactions with actual or potential competitors all associates must follow these rules:

- Never agree with a competitor or a group of competitors to charge the same prices or to use the same pricing methods, to allocate services, customers, private or governmental payor contracts or territories among yourselves, to boycott or refuse to do business with a provider, vendor, payor or any other third party, or to refrain from the sale or marketing of, or limit the supply of, particular products or services.
- Never discuss past, present, or future prices, pricing policies, bundling, discounts or allowances, royalties, terms or conditions of sale, costs, choice of customers, territorial markets, production quotas, allocation of customers or territories, or bidding on a job with a competitor.
- Be careful of your conduct. An “agreement” that violates the antitrust laws may be not only a written or oral agreement, but also a “gentlemen’s agreement” or a tacit understanding. Such an “agreement” need not be in writing. It can be inferred from conduct, discussions or communications of any sort with a representative of a competitor.
- Make every output and sales-related decision (pricing, volume, etc.) independently, in light of costs and market conditions and competitive prices.

- Carefully monitor trade association activity. These forums frequently create an opportunity for competitors to engage in antitrust violations.

Another focus of antitrust law is how a company deals with customers, suppliers, contractors and other third parties. The following practices could raise issues, and associates should always consult with the Corporate Compliance Officer or the Compliance Committee before doing any of the following:

- Refuse to sell to any customers or prospective customer;
- Enter into any new distribution or supply agreement which differs in any respect from those previously approved;
- Condition a sale on the customer's purchasing another product or service, or on not purchasing the product of a competitor;
- Agree with a customer on a minimum or maximum resale price of our products;
- Impose restrictions on the geographic area to which our customers may resell our products;
- Require a supplier to purchase products from the company as a condition of purchasing products from that supplier;
- Enter into an exclusive dealing arrangement with a supplier or customer; or
- Offer different prices, terms, services or allowances to different customers who compete or whose customers compete in the distribution of commodities.

If our company has a dominant or potentially dominant position with respect to a particular product or market, especially rigorous standards of conduct must be followed. In these circumstances, all associates should:

- Consult with the Corporate Compliance Officer or the Compliance Committee before selling at unreasonably low prices or engaging in any bundling practices; and
- Keep the Corporate Compliance Officer or the Compliance Committee fully informed of competitive strategies and conditions in any areas where the company may have a significant market position.

Finally, always immediately inform the Corporate Compliance Officer or the Compliance Committee if local, state or federal law enforcement officials request information from the company concerning its operations.

E. Unfair Practices in International Business

Under the Foreign Corrupt Practices Act ("FCPA"), associates of the company are prohibited from making certain gifts to foreign officials. "Foreign officials" include not only persons acting in an official capacity on behalf of a foreign government, agency, department or instrumentality, but also representatives of international organizations, foreign political parties and candidates for foreign public office. The gift is "corrupt" under the FCPA if it is made for the purpose of:

- influencing any act or decision of a foreign official in his official capacity;
- inducing a foreign official to do or omit to do any act in violation of his lawful duty;
- inducing a foreign official to use his position to affect any decision of the government; or
- inducing a foreign official to secure any "improper advantage."

A gift is still "corrupt" even when paid through an intermediary. Any associate who has any questions whatsoever as to whether a particular gift might be "corrupt" under the FCPA, please contact the Corporate Compliance Officer or any member of the Compliance Committee.

VII. GOVERNMENT RELATIONS

Associates must adhere to the highest standards of ethical conduct in all relationships with government employees and must not improperly attempt to influence the actions of any public official.

A. Government Procurement and Funding

The U.S. government, governments of other countries and many state, regional and local governments have adopted comprehensive laws and regulations governing the purchase of products from private contractors or the provision of funds to the private sector for research and development. These laws and regulations are intended to assure that governmental entities receive pricing, terms, and/or conditions equivalent to those granted to the company's most favored commercial counterparties and that there is full and open competition in contracting.

When selling products or services to, or seeking funding from, government agencies, the company is accountable for complying with all applicable laws, regulations, and requirements. Certifications to, and contracts with, government agencies are to be signed by a company associate authorized by the Board of Directors to sign such documents, based upon knowledge that all requirements have been fully satisfied.

B. Payments to Officials

Payments or gifts shall not be made directly or indirectly to any government official or associate if the gift or payment is illegal under the laws of the country having jurisdiction over the transaction, or if it is for the purpose of influencing or inducing the recipient to do, or omit to do, any act in violation of his or her lawful duty. Under no circumstances should gifts be given to any government employees.

C. Political Contributions

Company funds, property or services may not be contributed to any political party or committee, or to any candidate for or holder of any office of any government. This policy does not preclude, where lawful, company expenditures to support or oppose public referendum or separate ballot issues, or, where lawful and when reviewed and approved in advance by the Compliance Committee, the formation and operation of a political action committee.

VIII. COMPLIANCE WITH LAWS, RULES AND REGULATIONS

A. Insider Trading Policy

The company expressly forbids any associate from trading on material non-public information or communicating material non-public information to others in violation of the law. This conduct is frequently referred to as “insider trading.” This policy applies to every associate of the company and extends to activities both within and outside their duties to the company, including trading for a personal account.

The concept of who is an “insider” is broad. It includes officers, directors and employees of a company. In addition, a person can be a “temporary insider” if he or she enters into a special confidential relationship in the conduct of a company’s affairs and as a result is given access to information solely for the company’s purpose. A temporary insider can include, among others, a company’s investment advisors, agents, attorneys, accountants and lending institutions, as well as the employees of such organizations. An associate may also become a temporary insider of *another company* with which our company has a contractual or other relationship.

Trading on inside information is not a basis for liability unless the information is material. This is information that a reasonable investor would consider important in making his or her investment decisions, or information that is likely to have a significant effect on the price of a company’s securities.

Information is non-public until it has been effectively communicated to the marketplace. Tangible evidence of such dissemination is the best indication that the information is public. For example, information found in a report filed with the Securities and Exchange Commission or appearing in a national newspaper would be considered public.

Each associate should be familiar with and abide by the company’s Insider Trading Policy. A copy of this policy is given to all new associates of the company and is available from the Corporate Compliance Officer.

B. Equal Employment Opportunity

The company makes employment-related decisions without regard to a person's race, color, religious creed, age, sex, sexual orientation, marital status, national origin, ancestry, present or past history of mental disorder, mental retardation, learning disability or physical disability, including, but not limited to, blindness and genetic predisposition, or any other factor unrelated to a person's ability to perform the person's job. "Employment decisions" generally mean decisions relating to hiring, recruiting, training, promotions and compensation, but the term may encompass other employment actions as well.

The company encourages its associates to bring any problem, complaint or concern regarding any alleged employment discrimination to the attention of the Corporate Compliance Officer or any member of the Compliance Committee**.** Associates who have concerns regarding conduct they believe is discriminatory should also feel free to make any such reports to the Corporate Compliance Officer, a member of the Compliance Committee, or the Hotline.

C. Sexual Harassment Policy

The company is committed to maintaining a collegial work environment in which all individuals are treated with respect and dignity and which is free of sexual harassment. In keeping with this commitment, the company will not tolerate sexual harassment of associates by anyone, including any supervisor, co-worker, vendor, client or customer, whether in the workplace, at assignments outside the workplace, at company-sponsored social functions or elsewhere.

Each associate should be familiar with and abide by the company's Sexual Harassment Policy. A copy of this policy is given to all associates of the company and is available from the Corporate Compliance Officer.

D. Health, Safety & Environment Laws

Health, safety, and environmental responsibilities are fundamental to the company's values. Associates are responsible for ensuring that the company complies with all provisions of the health, safety, and environmental laws of the United States and of other countries where the company does business.

The penalties that can be imposed against the company and its associates for failure to comply with health, safety, and environmental laws can be substantial, and include imprisonment and fines.

IX. QUESTIONS UNDER THE CODE AND WAIVER PROCEDURES

Associates are encouraged to consult with the Corporate Compliance Officer and Compliance Committee about any uncertainty or questions they may have under the Code.

If any situation should arise where a course of action would likely result in a violation of the Code but for which the associate thinks that a valid reason for the course of action exists, the

associate should contact the Corporate Compliance Officer or a member of the Compliance Committee to obtain a waiver **prior to the time the action is taken. No waivers will be granted after the fact for actions already taken.** Except as noted below, the Compliance Committee will review all the facts surrounding the proposed course of action and will determine whether a waiver from any policy in the Code should be granted.

Waiver Procedures for Executive Officers and Directors. Waiver requests by an executive officer or member of the Board of Directors shall be referred by the Compliance Committee, with its recommendation, to the Board of Directors or a committee thereof for consideration. If either (i) a majority of the independent directors on the Board of Directors, or (ii) a committee comprised solely of independent directors agrees that the waiver should be granted, it will be granted. The company will disclose the nature and reasons for the waiver on a Form 8-K to be filed with the Securities and Exchange Commission within four business days or as otherwise permitted by the rules of the Securities and Exchange Commission and The Nasdaq Stock Market**.** If the Board denies the request for a waiver, the waiver will not be granted and the associate may not pursue the intended course of action.

It is the company's policy only to grant waivers from the Code in limited and extraordinary circumstances.

X. FREQUENTLY ASKED QUESTIONS (FAQ'S) REGARDING REPORTING VIOLATIONS UNDER THE CODE, WHISTLEBLOWER POLICY AND HOTLINE

The following questions and answers address each associate's obligation to comply with the Code. The company has attempted to design procedures that ensure maximum confidentiality and, most importantly, freedom from the fear of retaliation for complying with and reporting violations under the Code.

Q: Do I have a duty to report violations under the Code?

A: Yes, participation in the Code and its compliance program is mandatory. You must immediately report any suspected or actual violation of the Code to the Hotline, the Corporate Compliance Officer or a member of the Compliance Committee. The company will keep reports confidential to the fullest extent required by applicable law. Failure to report suspected or actual violations is itself a violation of the Code and may subject you to disciplinary action, up to and including termination of employment or legal action.

Q: I'm afraid of being fired for raising questions or reporting violations under the Code. Will I be risking my job if I do?

A: The Code contains a clear anti-retaliation pledge, meaning that if you in good faith report a violation of the Code by the company, or its agents acting on behalf of the company, to the Hotline, the Corporate Compliance Officer or another member of the Compliance Committee, the company will undertake to protect you from being fired, demoted, reprimanded or otherwise harmed for reporting the violation, even if the violation involves you, your supervisor, or senior

management of the company. Note, however, that while you will not be disciplined for reporting a violation, you may be subject to discipline with respect to the underlying conduct or violation. You are entitled to make the report on a confidential and anonymous basis. To the extent an investigation must be initiated, the company will keep confidential any report you make to the Corporate Compliance Officer or another member of the Compliance Committee to the extent required by applicable law.

In addition, if you in good faith report a suspected violation under the Code which you reasonably believe constitutes a violation of a federal statute by the company, or its agents acting on behalf of the company, to a federal regulatory or law enforcement agency, you may not be reprimanded, discharged, demoted, suspended, threatened, harassed or in any manner discriminated against in the terms and conditions of your employment for reporting the suspected violation, regardless of whether the suspected violation involves you, your supervisor or senior management of the company.

Associates are encouraged to pursue all internal reporting channels through completion and reasonably await and consider the results of all internal investigations prior to reporting matters outside of the company. We have instituted the procedures described in this Code, including procedures to make anonymous submissions (a form of internal report), to facilitate the use of internal investigations.

Individuals should also consider leaving, but are not required to leave, their name or a contact number when submitting a report. Such information may facilitate a more thorough and efficient investigation. The Corporate Compliance Officer will strive to maintain the integrity and confidentiality of all compliance-related communications. However, in certain circumstances, the identity of the person reporting the issue may become known or may need to be revealed, particularly if federal or state enforcement authorities become involved in the investigation. The company cannot guarantee confidentiality when material evidence of a violation of the law is disclosed or if the person is identified during the normal course of an investigation.

Q: How are suspected violations investigated under the Code?

A: When a suspected violation is reported to the Hotline, the Corporate Compliance Officer or a member of the Compliance Committee, the Compliance Committee will gather information about the allegation by interviewing the associate reporting the suspected violation, the associate who is accused of the violation and/or any co-workers or associates of the accused associates to determine if a factual basis for the allegation exists. The reporting associate’s immediate supervisor will not be involved in the investigation if the reported violation involved that supervisor. The company will keep the identity of the reporting associate confidential to the fullest extent required by applicable law.

If the report is not substantiated, the reporting associate will be informed and at that time will be asked for any additional information not previously communicated. If there is no additional information, the Corporate Compliance Officer will close the matter as unsubstantiated.

If the allegation is substantiated, the Compliance Committee will make a judgment as to the degree of severity of the violation and the appropriate disciplinary response. In more severe cases, the Compliance Committee will make a recommendation to the Board of Directors of the company for its approval. The Board's decision as to disciplinary and corrective action will be final. In the case of less severe violations, the Corporate Compliance Officer may refer the violation to the individual's supervisor, the Human Resources Department, the Corporate Compliance Officer or any member of the Compliance Committee for appropriate disciplinary action.

The Compliance Committee shall provide a summary of all matters considered under the Code to the Board of Directors or a committee thereof at each regular meeting thereof, or sooner if warranted by the severity of the matter.

Q: Do I have to participate in any investigation under the Code?

A: Your full cooperation with any pending investigation under the Code is a condition of your continued relationship with the company. The refusal to cooperate fully with any investigation is a violation of the Code and grounds for discipline, up to and including termination.

Q: What are the consequences of violating the Code?

A: As explained above, associates who violate the Code may be subject to discipline, up to and including termination of employment. Associates who violate the Code may simultaneously violate federal, state, local or foreign laws, regulations or policies. Such associates may be subject to prosecution, imprisonment and fines, and may be required to make reimbursement to the company, the government or any other person for losses resulting from the violation. They may be subject to punitive or treble damages depending on the severity of the violation and applicable law.

Q: What if I have questions under the Code or want to obtain a waiver under any provision of the Code?

A: The Corporate Compliance Officer and any member of the Compliance Committee can help answer questions you may have under the Code. Particularly difficult questions will be answered with input from the Compliance Committee as a whole. In addition, Section IX of the Code provides information on how you may obtain a waiver from the Code; waivers will be granted only in very limited circumstances. You should never pursue a course of action that is unclear under the Code without first consulting the Corporate Compliance Officer or the Compliance Committee, and if necessary, obtaining a waiver from the Code.

APPENDIX A

ASSOCIATE'S AGREEMENT TO COMPLY

I have read the Pieris Pharmaceuticals, Inc. Corporate Code of Conduct and Ethics (the "Code"). I have obtained an interpretation of any provision about which I had a question. I agree to abide by the provisions of the Code. Based on my review, I acknowledge that

_____ To the best of my knowledge, I am not in violation of, or aware of any violation by others of, any provision contained in the Code;

OR

_____ I have made a full disclosure on the reverse side of this acknowledgement of the facts regarding any possible violation of the provisions set forth in the Code.

In addition, I understand that I am required to report any suspected or actual violation of the Code, and that I may make such reports on a fully anonymous basis through the mechanisms described in this Code. I understand that I am required to cooperate fully with the company in connection with the investigation of any suspected violation. I understand that my failure to comply with the Code or its procedures may result in disciplinary action, up to and including termination.

By: _____ Date: _____

Name (Please print):
Department/Location:

Exhibit 31.1

CERTIFICATIONS UNDER SECTION 302

I, Stephen S. Yoder, certify that:

1. I have reviewed this annual report on Form 10-K of Pieris Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 27, 2015

/s/ Stephen S. Yoder

Stephen S. Yoder
Title: Chief Executive Officer and President
(principal executive officer)

Exhibit 31.2

CERTIFICATIONS UNDER SECTION 302

I, Darlene Deptula-Hicks, certify that:

1. I have reviewed this annual report on Form 10-K of Pieris Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 27, 2015

/s/ Darlene Deptula-Hicks

Darlene Deptula-Hicks
Title: Acting Chief Financial Officer
(principal accounting and financial officer)

Exhibit 32.1

CERTIFICATIONS UNDER SECTION 906

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), the undersigned officer of Pieris Pharmaceuticals, Inc. a Nevada corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The Annual Report for the year ended December 31, 2014 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 27, 2015

/s/ Stephen S. Yoder

Stephen S. Yoder
Title: Chief Executive Officer and President
(principal executive officer)

Exhibit 32.2

CERTIFICATIONS UNDER SECTION 906

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), the undersigned officer of Pieris Pharmaceuticals, Inc. a Nevada corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The Annual Report for the year ended December 31, 2014 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 27, 2015

/s/ Darlene Deptula-Hicks

Darlene Deptula-Hicks
Title: Acting Chief Financial Officer
(principal accounting and financial officer)