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, 2023

OR

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

For the transition period from _____ to _____

Commission file number: 001-37471

PIERIS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Nevada	**EIN 30-0784346**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
225 Franklin Street, 26th Floor Boston, MA United States	
(Address of principal executive offices)	**02110 (Zip Code)**

Registrant's telephone number, including area code
857-246-8998

Securities registered pursuant to Section12(b) of the Exchange Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.001 per share	**PIRS**	**The Nasdaq Stock Market LLC**

Securities registered pursuant to Section12(g) of the 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 Act. Yes ☐ No ☒

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

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

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b). ☐

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant on June 30, 2023, the last business day of the registrant's most recently completed second fiscal quarter, based on the closing price on that date of $0.17, was $11,222,444.

As of March 26, 2024, the registrant had 98,935,025 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required in Part III of this Annual Report on Form 10-K is incorporated from the Registrant's Proxy Statement for the 2024 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission.

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Forward-Looking Statements

This annual report on Form 10-K for the year ended December 31, 2023, or this Annual Report on Form 10-K, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, that involve risks and uncertainties, principally in the sections titled "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 ability to maximize capture of future milestones payments, our workforce reduction and related restructuring activities, our future financial and operating performance, anticipated timing and amounts of milestone and other payments under collaboration agreements, business strategy and plans, objectives of management for future operations, timing and outcome of legal and other proceedings and our ability to finance our operations are forward-looking statements. We have attempted to identify forward-looking statements by using terms such as including "anticipates," "approach," "believes," "can," "contemplate," "continue," "look forward," "ongoing," "could," "estimates," "expects," "intends," "may," "appears," "suggests," "future," "likely," "goal," "plans," "potential," "possibly," "projects," "predicts," "seek," "should," "target," "would" or "will" and other similar words or expressions or the negative of these terms or other comparable terminology. Although we do not make forward-looking statements unless we believe we have a reasonable basis for doing so, we cannot guarantee their accuracy. These statements are only predictions and involve known and unknown risks and uncertainties and other factors that 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. The description of our Business set forth in Item 1, the Risk Factors set forth in Item 1A and our Management's Discussion and Analysis of Financial Condition and Results of Operations set forth in Item 7 as well as other sections in this report, discuss some of the factors that could contribute to these differences. These forward-looking statements include, among other things, statements about:

- *the accuracy of our estimates regarding expenses, future revenues, uses of cash, capital requirements and the need for additional financing;*
- *our workforce reduction and related restructuring activities;*
- *our ability to realize the anticipated benefits of our corporate strategy;*
- *our cash runway and the sufficiency of our financial resources to fund our operations;*
- *the initiation, timing, progress, results, and decisions of our partners' development activities, preclinical studies and clinical trials with respect to our product candidates;*
- *our collaborators' election to pursue or continue research, development and commercialization activities;*
- *our ability to obtain future reimbursement and/or milestone payments from our collaborators;*
- *our ability to obtain and maintain intellectual property protection for our product candidates;*
- *our partners' ability to successfully commercialize our partnered product candidates;*
- *the size and growth of the markets for our partnered product candidates and our partners' ability to serve those markets;*
- *the rate and degree of market acceptance of any future products;*
- *the success of competing drugs that are or may become available;*
- *regulatory developments in the United States and other countries; and*
- *any restrictions on our ability to use our net operating loss carryforwards.*

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. Actual results could differ materially from our forward-looking statements due to a number of factors, including, without limitation, risks related to: our ability to realize the anticipated benefits of our strategy; our ability to achieve anticipated cost savings and capital preservation as a result of our workforce reduction and related restructuring, including implementation of any potential potential changes leadership structure; the early stage of our partnered drug candidates presently under development; our partners' continued progress, if any, in the areas of co-stimulatory bispecifics and the results of their research and development activities including uncertainties relating to the ongoing or planned clinical testing of our partnered product candidates; our potential need for substantial additional funds in order to continue our operations and the uncertainty of whether we will be able to obtain the funding we need; our ability to meet the minimum bid price requirement for our common stock for continued inclusion on the Nasdaq Capital Market or otherwise maintain the listing of our common stock on Nasdaq; the possibility that Nasdaq treats us as a public shell which may lead to delisting of our common stock on Nasdaq; our future financial performance; our ability to protect our intellectual property rights that are valuable to our business, including patent and other intellectual property rights; the success of our collaborations with third parties; our partners' ability to meet milestones; the receipt of royalty and milestone payments provided for in our collaboration agreements; our partners' ability to successfully market and sell our drug candidates in the future as needed; the size and growth of the potential markets for any of our product candidates for which we or our partners may obtain regulatory approval, and the rate and degree of market acceptance of such product candidates; competition in our industry; regulatory developments in the United States and foreign countries, including with respect to the U.S. Food and Drug Administration, or FDA; Servier's ability to advance the phase 1 study for S095012 (also known as PRS-344); Pfizer's ability to continue to advance SGN-BB228 (also known as PRS-346) and the other drug candidates licensed to them; Boston Pharmaceuticals' ability to continue to advance BOS-342 (also known as PRS-342); the expected impact of new accounting standards; and the delays or disruptions due to geopolitical issues, including the conflicts in Ukraine and the Middle East on our company.

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 titled "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 Duocalin®. 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, trade dress or product owner.

As used in this Annual Report on Form 10-K, unless the context indicates or otherwise requires, "our Company", "the Company", "Pieris", "we", "us" and "our" refer to Pieris Pharmaceuticals, Inc., a Nevada corporation, and its consolidated subsidiary, Pieris Pharmaceuticals GmbH (formerly known as Pieris AG), a company organized under the laws of Germany, Pieris Australia Pty Ltd., a company organized under the laws of Australia that is a consolidated subsidiary of Pieris Pharmaceuticals GmbH and Pieris Pharmaceuticals Securities Corporation, a Massachusetts securities corporation, a consolidated subsidiary of Pieris Pharmaceuticals, Inc. Effective as of August 26, 2015 and with notification from the Amtsgericht München as of September 29, 2015, Pieris AG was transformed to Pieris Pharmaceuticals GmbH as a result of a change in the legal entity.

Currency Presentation and Currency Translation

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

The functional currency for our operations is primarily the euro. With respect to our financial statements, the translation from the euro to U.S. dollars is performed for balance sheet accounts using exchange rates in effect at the balance sheet date and for revenue and expense accounts using a weighted average exchange rate during the period. The resulting translation adjustments are recorded as a component of accumulated other comprehensive loss.

Where in this Annual 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. $1.1038 based on Thomson Reuters as of December 31, 2023.

PART I

Item 1. BUSINESS

Corporate History

General

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

Pieris Pharmaceuticals, Inc.’s corporate headquarters is located at 225 Franklin Street, 26th Floor, Boston, Massachusetts 02110. The office of Pieris GmbH is located in Hallbergmoos, Germany. Pieris Australia Pty Ltd., a wholly-owned subsidiary of Pieris GmbH, was formed on February 14, 2014 to conduct research and development activities in Australia. Pieris Pharmaceuticals Securities Corporation, a wholly-owned subsidiary of Pieris Pharmaceuticals, Inc., was formed on December 14, 2016 to buy, sell, deal in, or hold securities on its own behalf and not as a broker, and engages in its activities exclusively for investment purposes.

Business Overview

The Company is a biotechnology company that historically discovered and developed Anticalin® protein-based drugs to target validated disease pathways in unique and transformative ways. On March 27, 2024, the Company implemented measures to maximize its ability to collect potential milestones from its clinical pipeline of partnered drug candidates and maintain its capability to consider other strategic options. The Company's clinical pipeline consists of immuno-oncology, or IO, bispecifics in partnership with collaborators, including S095012 (also referred to as PRS-344) targeting PD-L1 and 4-1BB, SGN-BB228 (also referred to as PRS-346) targeting CD228 and 4-1BB, and BOS-342 (also referred to as PRS-342) targeting GPC3 and 4-1BB. Proprietary to the Company, Anticalin proteins are a novel class of therapeutics validated in the clinic and through partnerships with leading pharmaceutical companies.

Anticalin proteins are a class of low molecular-weight therapeutic proteins derived from lipocalins, which are naturally occurring proteins typically found in human blood plasma and other bodily fluids. Anticalin proteins function similarly to monoclonal antibodies by binding tightly and specifically to a diverse range of targets. An antibody is a large protein used by the immune system to recognize a target molecule, called an antigen. The Company believes Anticalin proteins possess numerous advantages over antibodies in certain applications. For example, Anticalin proteins are relatively small in size and comprised of a single polypeptide chain whereas antibodies are much bigger and comprised of four polypeptide chains. The Anticalin technology is modular, which allows us to design multimeric Anticalin based bi- and multi- specific proteins to bind with specificity to two or more targets at the same time. This multispecificity offers advantages in biological settings where binding to multiple targets can enhance the ability of a drug to achieve its desired effects, such as facilitating the killing of cancer cells.

The Company has intellectual property rights directed to various aspects of the Anticalin technology platform and Anticalin-based drug candidates. The Company believes that its ownership or exclusive license of intellectual property related to the Anticalin platform provides it with a strong intellectual property position.

The core Anticalin technology and platform were developed in Germany, and the Company has collaborations with multiple major pharmaceutical and biotechnology companies, as follows:

- The Company entered into a license and collaboration agreement, or the Servier Collaboration Agreement, with Les Laboratoires Servier and Institut de Recherches Internationales Servier, or Servier, in January 2017 in IO.

- In February 2018, the Company entered into a license and collaboration agreement, or the Pfizer Collaboration Agreement (formerly referenced as the Seagen Collaboration Agreement), with Pfizer Inc. (formerly Seagen Inc.), or Pfizer, in IO. On March 25, 2021, the Company announced an amendment to the Pfizer Collaboration Agreement, or the Amended Pfizer Agreement (formerly referenced as the Amended Seagen Agreement), whereby its option to co-develop and co-commercialize one of the three programs in the collaboration was converted to a co-promotion option for one program in the United States, with Pfizer solely responsible for the development and overall commercialization of that program. Under the co-promotion option, the Company will be entitled to increased royalties from that program in the event that it chooses to exercise the option. As part of this transaction, the Company entered into a subscription agreement pursuant to which we issued to Pfizer 3,706,174 shares of our common stock for a total purchase price of $13.0 million in a private placement transaction. In September 2023, the Company and Pfizer entered into an amendment of the Amended Pfizer Agreement that provides Pfizer with collaboration product licenses with no changes to the amounts achievable under the collaboration agreement. The effect of the September amendment was to transfer responsibility for substantially all activities previously performed by the Company to Pfizer.
- On April 24, 2021, the Company and BP Asset XII, Inc., or Boston Pharmaceuticals, a subsidiary of Boston Pharma Holdings, LLC, entered into an exclusive product license agreement, or the BP Agreement, to develop BOS-342, a GPC3/4-1BB immuno-oncology antibody-Anticalin fusion, or Mabcalin™, bispecific protein, which is now in a phase 1 clinical study.
- On May 19, 2021, the Company and Genentech, Inc., or Genentech, entered into a research collaboration and license agreement, or the Genentech Agreement, to discover, develop and commercialize locally delivered respiratory and ophthalmology therapies that leverage the Company’s proprietary Anticalin technology. In April and May 2023, Genentech and the Company decided to discontinue the discovery-stage programs in ophthalmology and respiratory, respectively, for scientific reasons.

As part of the Company's March 27, 2024 announcement, it indicated it would implement a new strategy along with relevant cost-saving measures that are expected to extend its cash runway into at least 2027, while maximizing its ability to capture the potential milestones from its partnered 4-1BB bispecific Mabcalin protein IO assets. To support the Company's new strategy, it plans to discontinue all of its research and development efforts that it expects will be completed by the middle of 2024, implement a workforce reduction that will impact additional employees and the executive leadership team which is expected to be implemented in the second quarter of 2024, and reduce the size of its Board of Directors, which the Company also expects to have implemented in the second quarter of 2024. This decision follows the Company's strategic transaction review that began in July 2023, under which the Company, with the assistance of its strategic advisor, Stifel, Nicolaus & Company, conducted a robust process to identify and assess various potential strategic transactions. The Company ultimately determined that its new strategy offers the best opportunity to maximize stockholder value, in part by allowing it to maximize its partnered 4-1BB bispecific Mabcalin protein assets, and further preserving its capability to obtain value for its products in prior development, including cinrebafusp alfa as well as proprietary platform capabilities, by pursuing potential out-licensing or sale transactions. The Company may be entitled to aggregate milestones of up to $20 million upon first patient dosed in the phase 2 trials for SGN-BB228, S095012 (formerly PRS-344) and BOS-342, which are all currently in phase 1 clinical development, and aggregated milestones of up to $55 million upon first patient dosed in pivotal clinical trials for SGN-BB228, S095012 (formerly PRS-344) and BOS-342.

The Company has several 4-1BB bispecific Mabcalin IO assets in partnership with other major pharmaceutical and biotechnology companies.

In January 2017, the Company initiated a strategic collaboration with Servier to discover and develop multiple Anticalin-based bispecific therapeutics in IO. S095012, a PD-L1/4-1BB bispecific Mabcalin compound is a clinical-stage program being developed within this alliance. The Company and Servier presented preclinical data and the phase 1/2 study design for S095012 at the American Association for Cancer Research, or AACR, medical meeting in April 2022. The first-in-human phase 1/2 multicenter open-label dose escalation study is being conducted in multiple countries and is designed to determine the safety and preliminary activity of S095012 in patients with advanced and/or metastatic solid tumors. In July 2023, the Company notified Servier that it was opting out of co-development and commercialization of S095012 in the U.S. Servier continues to advance the program. Servier retains exclusive, even as to the Company, worldwide rights to the program including the right to advance development and potential commercialization in the U.S. As a result of the election to opt out, the Company is entitled to increased royalty rates and potential royalties and milestones, if any, for S095012.

In February 2018, the Company initiated a strategic collaboration with Pfizer (formerly Seagen) to discover and develop up to three Anticalin-based tumor-targeted bispecific therapeutics in IO. The first program, SGN-BB228 (also referenced as PRS-346), a CD228/4-1BB bispecific antibody-Anticalin (i.e. Mabcalin™) compound, is currently being advanced in the clinic by Pfizer, which is responsible for further advancement and funding of the asset. In January 2023, the first patient was dosed in a Pfizer-sponsored phase 1 study of SGN-BB228, which triggered a $5.0 million payment from Pfizer to us. Pfizer presented preclinical data for this program at the Society for Immunotherapy of Cancer 37th Annual Meeting in November 2022 and at the American Association for Cancer Research (AACR) Annual Meeting in April 2023. In June 2023, Pfizer presented the study design of the phase 1 study of SGN-BB228 at the American Society of Clinical Oncology (ASCO) Annual Meeting. The Company believes the achievement of a clinical development milestone for this program offers validation our approach in IO bispecifics, complementing the encouraging clinical data seen with cinrebafusp alfa. At the end of 2023, the Company handed over the second and third programs, which were initiated in the third quarter of 2021 and fourth quarter of 2022, respectively, to Pfizer which is responsible for further advancement and funding of these assets. The Company retains a co-promotion option for one of the programs in the United States.

BOS-342 (also referenced as PRS-342) is a GPC3/4-1BB bispecific Mabcalin compound that the Company exclusively licensed to Boston Pharmaceuticals. Boston Pharmaceuticals continues to advance BOS-342 in the clinic. In August 2023, the first patient was dosed in a Boston Pharmaceuticals sponsored phase 1/2 study of BOS-342 in hepatocellular carcinoma (HCC), for which the Company received a $2.5 million milestone payment and is entitled to receive up to approximately $350 million in potential development, regulatory and sales-based milestone payments, and tiered royalties on potential sales of BOS-342.

Formerly the lead IO Anticalin-based drug candidate in its pipeline, cinrebafusp alfa is a bispecific Mabcalin compound comprising a HER2-targeting antibody genetically linked to 4-1BB-targeting Anticalin proteins. Cinrebafusp alfa is designed to drive tumor localized T cell activation through tumor-targeted drug clustering mediated by HER2 expressed on tumor cells. This program was the first 4-1BB bispecific T cell co-stimulatory agonist to enter clinical development. In August 2022, we announced the decision to cease further enrollment in the two-arm, multicenter, open-label phase 2 study of cinrebafusp alfa as part of a strategic pipeline prioritization to focus our resources. Cinrebafusp alfa has demonstrated clinical benefit in phase 1 studies, including single agent activity in a monotherapy setting, and in the phase 2 study in HER2-expressing gastric cancer, providing evidence of clinical activity for our broader 4-1BB franchise. In April 2023, clinical data showing an unconfirmed 100% objective response rate and promising emerging durability profile were presented at the American Association of Cancer Research annual meeting. The Company continues to remain committed to obtaining value for cinrebafusp alfa either through out-licensing or sale transaction.

The Company's clinical pipeline formerly included respiratory assets as well. Elarekibep (previously known as PRS-060/AZD1402) was a clinical stage Anticalin drug candidate being developed in partnership with AstraZeneca under a license and collaboration agreement, or the AstraZeneca Collaboration Agreement, and a non-exclusive Anticalin platform technology license agreement, or AstraZeneca Platform License, and together with the AstraZeneca Collaboration Agreement, the AstraZeneca Agreements, with AstraZeneca AB, or AstraZeneca, which was entered into on May 2, 2017 and became effective on June 10, 2017, following expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976. Elarekibep targets IL-4Rα, a cell surface receptor expressed on immune cells in the lung. IL-4Rα is specific for the cytokine IL-4 and the closely related cytokine IL-13, both key drivers of the immune system. The Company sponsored the phase 1 single ascending dose/multiple ascending dose studies for elarekibep, after which AstraZeneca took responsibility for further clinical development of elarekibep. The phase 2a study was a two-part, multi-center, placebo-controlled clinical study of elarekibep to evaluate elarekibep at three dose levels, 1, 3 and 10 mg, using a dry powder formulation administered via inhalation twice daily.

On June 21, 2023, the Company issued a press release announcing that AstraZeneca had communicated to the Company its decision to discontinue and cease dosing in the ongoing clinical studies of elarekibep. This decision was based on lung findings from a non-clinical 13-week GLP toxicology study in non-human primates with dry powder inhaler-formulated elarekibep, which did not support long-term use and progression to later-stage development. AstraZeneca’s decision was made independent of any data from the phase 2a study. On July 17, 2023, AstraZeneca notified the Company of its intention to terminate the AstraZeneca Agreements, effective October 15, 2023. AstraZeneca’s decision to terminate the AstraZeneca Agreements was based on non-clinical safety findings in a 13-week toxicology study of elarekibep in non-human primates previously disclosed by the Company. With the termination of the AstraZeneca Agreements, there are no more active programs or performance obligations related to the collaboration. Following the Company's review of the data, the Company determined that it would not continue to advance the program for scientific reasons.

The Company's fully proprietary respiratory asset, PRS-220, an orally inhaled Anticalin protein targeting connective tissue growth factor, or CTGF, was being developed as a local treatment for idiopathic pulmonary fibrosis, or IPF, and other fibrotic lung diseases. In August 2023, the Company completed a phase 1 healthy volunteer study in of PRS-220 in healthy volunteers in Australia, which was a randomized, two-part, blinded, placebo-controlled study, designed to assess the safety, tolerability, pharmacokinetics, and immunogenicity of single and multiple ascending doses of PRS-220 when administered by oral inhalation to healthy subjects. CTGF, a matricellular protein, is a driver of fibrotic tissue remodeling and the protein has been found over-expressed in lung tissue from patients suffering from IPF. Data from the single and multiple ascending doses of PRS-220, when administered by oral inhalation to healthy subjects, demonstrated that PRS-220 was safe and generally well tolerated at all administered doses by subjects in this study. With the completion of the phase 1 healthy volunteer study, the Company intends to winddown PRS-220 and does not plan to continue to advance the program for scientific reasons.

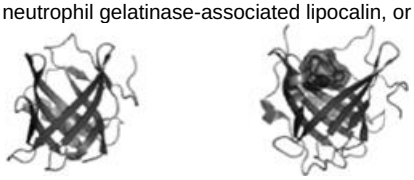
Strategy

On March 27, 2024, we announced the implementation of a new strategy along with relevant cost-saving measures that are expected to extend our cash runway into at least 2027, while maximizing our ability to capture the potential milestones from our partnered 4-1BB bispecific Mabcalin protein IO assets. We may be entitled to aggregate milestones of up to $20 million upon first patient dosed in the phase 2 trials for SGN-BB228, S095012 and BOS-342, which are all currently in phase 1 clinical development, and aggregated milestones of up to $55 million upon first patient dosed in pivotal clinical trials for SGN-BB228, S095012 and BOS-342. To support the new strategy, we plan to discontinue all of our research and development efforts which we expect will be completed by the middle of 2024, implement a workforce reduction that will impact additional employees and the executive leadership team that is expected to be implemented in the second quarter of 2024, and reduce the size of our Board of Directors, which we also expect to have implemented in the second quarter of 2024. In addition to the alliance management activities for our partnered programs, we remain committed to obtaining value for our products in prior development, including cinrebafusp alfa as well as our proprietary platform capabilities, by pursuing potential out-licensing or sales transactions. In addition to these potential transactions, we may also, from time-to-time, consider strategic opportunities that we believe may increase stockholder value.

Anticalin Platform Technology

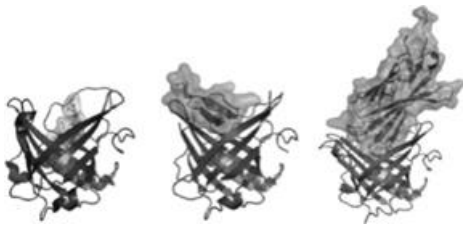
Our platform technology focuses on low molecular-weight Anticalin proteins that can bind tightly and specifically to a diverse range of targets. Anticalin proteins are derived from human proteins called lipocalins, which are naturally occurring low-molecular weight human proteins of approximately 17 to 21 kDa molecular mass typically found in blood plasma and other bodily fluids. The lipocalin class of proteins defines a group of specific extracellular binding proteins that, collectively, exhibit extremely high structural homology, yet have a low amino acid sequence identity (less than 20%), making them attractive “templates” for amino acid diversification. Lipocalins naturally bind to, store and transport a wide spectrum of molecules. The defining attributes of the human lipocalin class and, by extension, Anticalin proteins, engineered from the lipocalin class of proteins, are a rigidly conserved beta-barrel backbone with four flexible loops, which, together, form a cup-like binding pocket.

The graphic below shows the tear lipocalin (left) and neutrophil gelatinase-associated lipocalin, or NGAL (right).



Our Anticalin proteins were developed from two scaffolds, namely the tear lipocalin, found primarily in human tear fluid as well as the lung epithelium, and NGAL, a protein involved in the innate immune system, by selection from diverse libraries with mutations in the genetic code of the ligand binding regions and regions of the proteins that are amenable for amino acid exchanges. These mutations have the potential to lead to highly specific, high-affinity binding proteins for both small and large molecular targets. Mutations are introduced at pre-defined positions, creating exponentially diverse pools of Anticalin proteins, the most potent and well-behaved of which are selected and optimized in a customized manner through *in vitro* selection using techniques such as phage and yeast display, which are successful techniques in antibody-based drug discovery. The ability to generate highly-diverse and high-quality Anticalin libraries and to select for the best binders among the large pool of Anticalin proteins by display technologies gives us the opportunity to select highly specific and high affinity Anticalin proteins for a wide variety of targets. The flexibility inherent in the Anticalin proteins’ cup-like structure allows us to choose both small-molecule targets that are capable of binding inside the ‘cup’ as well as larger protein targets that are predominantly bound by the flexible loop region outside of the ‘cup’. Our prior clinical studies of intravenously-administered Anticalin-based drug candidates, including the phase 1 studies of cinrebafusp alfa, the phase 1 and 2 studies of PRS-080, the phase 1 study of PRS-050, as well as the phase 1 study of a PCSK9-specific Anticalin protein, indicate that these proteins appear to have the potential to exhibit a favorable safety profile.

The below graphic illustrates Anticalin proteins binding to a small molecule (left), a small protein target (hepcidin, center) and a large protein target (CTLA4, right):



To obtain a specific Anticalin protein, we took advantage of the breadth of our proprietary Anticalin libraries, generated through our protein engineering expertise. We created proprietary Anticalin libraries by rationally diversifying certain lipocalin regions, thereby generating Anticalin libraries suitable for identifying binders to different types of targets. By utilizing bacterial and mammalian expression platforms from the earliest stages of drug discovery through current Good Manufacturing Practice, or cGMP, manufacturing, we created seamless platforms that facilitate the selection of high-quality and cost-effective drug candidates. Anticalin-based drug candidates have been proven to be suitable for expression in standard mammalian expression systems. Thus, Anticalin protein manufacturing is not limited to bacterial systems, and the expression system can be selected on a program-by-program basis. See “—Manufacturing” below.

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

- *High specificity to their targets*. Like antibodies, Anticalin proteins can bind their targets without binding other molecules, even molecules with very similar chemical structures or amino acid sequences, allowing for more effective treatments through, for example, minimizing off-target effects.
- *Tight binding and effective biological activity at their targets* . Like antibodies, Anticalin proteins are able to bind their targets at subnanomolar to picomolar affinities. Anticalin proteins can potentially achieve desirable biological effects by inhibiting an undesired or inducing a desired cell activity by binding to cell-surface receptors or their ligands.
- *Scalability for large-scale production*. Like antibodies, Anticalin proteins lend themselves to large-scale production, yet can also be produced in a range of expression systems ranging from prokaryotic (bacterial) to eukaryotic (for example, animal and fungal) cells. Anticalin proteins can take advantage of several well-understood and widely-practiced methods of protein production both in small amounts for preclinical testing and at larger scale for clinical trials and commercial production.

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

- *Small size and biophysical stability*. Anticalin proteins are small in size and consist of one single polypeptide chain. Therefore, we believe Anticalin proteins are generally more biophysically stable than antibodies, which are composed of four polypeptide chains. We believe Anticalin proteins may also be less expensive to manufacture than antibodies due to their lower molecular weight and less bulky structure.
- *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.
- *Flexible formatting facilitates selection of potent T cell engagers* . The molecular architecture of Anticalin proteins as a single polypeptide chain that folds into a stable eight-stranded β-barrel with exposed N- and C-termini, both not part of the binding site, makes them ideal building blocks to generate bispecific and even multispecific fusion proteins offering novel therapeutic modalities. Multispecific Anticalin-based fusion proteins can be used to pursue innovative therapeutic strategies in IO, particularly by addressing the “immunological synapse” that forms at the interface upon contact between an immune cell and a cancer cell. This can drive an efficient activation of tumor-specific T cells in the vicinity of the tumor, thereby avoiding some of the toxicities observed with peripheral T cell activation in healthy tissues. Generally, the formatting flexibility of Anticalin-based biologics offers the ability of modulating valency and geometry of the multispecific compound according to biological needs. For example, Anticalin proteins can be genetically fused to either the N- or C- terminus of the antibody heavy or light chain, thereby resulting in different geometries of the fusion protein with the antibody as well as Anticalin binding sites covering a range of distances with regard to the T cell target on the one hand and the tumor antigen on the other.
- *Platform for higher-order multispecificity and avoidance of cross-linking*. Our Anticalin technology allows for monovalent or multivalent target engagement, including multispecificity within a single protein. We believe that a monovalent “backbone” is an advantage in situations where pure antagonism of certain cellular receptors is desired. The dual-binding nature of antibodies, which have two “arms,” can be a disadvantage 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, or monovalent, Anticalin proteins have only a single binding site and by that do not induce cross-linking. Further, when it is called for by the biology we are addressing, we can create multispecific Anticalin-based proteins that can simultaneously bind (i) two or more different targets or (ii) different epitopes on the same target by genetically linking Anticalin proteins with distinct specificities or by genetic fusion of an Anticalin protein with an antibody. We believe this multispecificity offers advantages in biological settings where binding to multiple targets can enhance the ability of a drug to achieve its desired effects, such as killing cancer cells. Novel Anticalin proteins genetically fused to each other or to existing antibodies for simultaneous target engagement are expressed as a fusion protein without generally compromising on manufacturability.

Implementation of the Anticalin Platform Technology: Our Drug Candidate Pipeline

All of our drug candidates are in the early stage of development with our partners, and we anticipate that it will likely be several years before any of our drug candidates could be commercialized. Our current collaborations include:

Servier Collaboration

S095012 (also known as PRS-344) consists of a PD-L1-targeting antibody and 4-1BB-targeting Anticalin proteins genetically fused to each arm of the C-terminal heavy chain of the antibody, and is currently being developed by Servier under our collaboration agreement with them. The first patient was dosed in November 2021 and the first-in-human study consists of evaluating the safety and tolerability profile of S095012 and determining its maximum tolerated dose, or MTD, and/or the recommended phase 2 dose, or RP2D, in patients with solid tumors. In addition, the PK profile as well as pharmacodynamic effects of S095012 will be characterized in the study and any initial signs of anti-tumoral activity will be correlated to safety and PK and further explored in expansion cohorts.

In July 2023, we notified Servier that we were opting out of co-development and commercialization of S095012 in the U.S. Servier continues to advance the program, and is fully responsible for any further advancement and funding of this program. Servier retains exclusive, even as to us, worldwide rights to the program including the right to advance development and potential commercialization in the U.S. As a result of our election to opt out, we are entitled to increased royalty rates and potential royalties and milestones, if any, for S095012.

Pfizer Collaboration

In addition, our collaboration with Pfizer (formerly Seagen) to discover and develop Anticalin-based tumor-targeted bispecific antibody-Anticalin therapeutics in IO includes three programs.

We achieved a key development milestone for one of the programs, a CD228 x 4-1BB, or SGN-BB228, bispecific tumor-targeted costimulatory agonist, in the Pfizer collaboration in 2020, triggering a $5 million milestone payment. We handed the program over to Pfizer, which is responsible for further advancement and funding of the asset. Pfizer presented preclinical data for this program at the Society for Immunotherapy of Cancer 37th Annual Meeting. In January 2023, we announced that the first patient was dosed in a Pfizer-sponsored phase 1 study of SGN-BB228, which triggered a $5 million milestone payment from Pfizer to us. The program is one of three current programs in the Pfizer alliance.

In March 2021, Pfizer made a $13.0 million equity investment in Pieris as part of an ongoing collaboration between the companies. The companies also amended their existing immuno-oncology collaboration whereby Pieris' option to co-develop and co-commercialize the second of three programs in the collaboration was converted to a co-promotion option for one of the three programs in the United States. During the third quarter of 2021, we initiated the second program, and during the fourth quarter of 2022, we initiated the third program within the collaboration with Pfizer.

In September 2023, we and Pfizer entered into an amendment of the Second Pfizer Amendment that provides Pfizer with collaboration product licenses with no changes to the amounts achievable under the collaboration agreement. The effect of the September 2023 amendment was to transfer responsibility for substantially all activities previously performed by the Company to Pfizer. Furthermore, in December 2023, we officially handed over the remaining programs to Pfizer, and it is responsible for any further advancement and funding of these assets.

Boston Pharmaceuticals Collaboration

In April 2021, we and Boston Pharmaceuticals, a subsidiary of Boston Pharma Holdings, LLC, entered into an exclusive product license agreement to develop BOS-342, a GPC3/4-1BB preclinical immuno-oncology bispecific Mabcalin protein.

In August 2023, the first patient was dosed in a Boston Pharmaceuticals sponsored phase 1/2 study of BOS-342 in hepatocellular carcinoma (HCC), for which we received a $2.5 million milestone payment and are entitled to receive up to approximately $350 million in potential development, regulatory and sales-based milestone payments, and tiered royalties on potential sales of BOS-342. Boston Pharmaceuticals is responsible for any further advancement and funding of this asset.

Our drug candidate pipeline formerly included:

Elarekibep Targeting IL-4Rα in Asthma

Elarekibep (previously known as PRS-060/AZD1402) was a clinical stage Anticalin drug candidate targeting IL-4Rα, a cell surface receptor expressed on immune cells in the lung. IL-4Rα is specific for the cytokine IL-4 and the closely related cytokine IL-13, both key drivers of the immune system. Elarekibep was derived from human tear lipocalin, and has a 20 pM affinity for human IL-4Rα. We sponsored the phase 1 single ascending dose/multiple ascending dose studies for elarekibep, after which AstraZeneca took responsibility for further clinical development of elarekibep. The phase 2a study was a two-part, multi-center, placebo-controlled clinical study of elarekibep to evaluate elarekibep at three dose levels, 1, 3 and 10 mg, using a dry powder formulation administered via inhalation twice daily. On June 21, 2023, we announced that AstraZeneca had communicated to us its decision to discontinue and cease dosing in the ongoing clinical studies of elarekibep. This decision was based on lung findings from a non-clinical 13-week GLP toxicology study with dry powder inhaler-formulated elarekibep, which did not support long-term use and progression to later-stage development. AstraZeneca's decision was made independent of any data from the phase 2a study. Following our review of the data, we decided to not continue to advance the program for scientific reasons.

PRS-220 Targeting Connective Tissue Growth Factor (CTGF) in IPF

Our former lead fully proprietary respiratory asset, PRS-220, an orally inhaled Anticalin protein targeting CTGF, was being developed as a local treatment for IPF and other fibrotic diseases, and passed the drug candidate nomination stage in 2021.

We completed the phase 1 clinical study in healthy volunteers in August 2023, and finalized the clinical study report in December 2023. The first-in-human study was a randomized, two-part, blinded, placebo-controlled study, designed to assess the safety, tolerability, pharmacokinetics, and immunogenicity of single and multiple ascending doses of PRS-220 when administered by oral inhalation to healthy subjects. Data from the single and multiple ascending doses of PRS-220, when administered by oral inhalation to healthy subjects, demonstrated that PRS-220 was safe and generally well tolerated at all administered doses by subjects in this study. We received a €14.2 million grant from the Bavarian Ministry of Economic Affairs, Regional Development and Energy supporting research and development of the program. With the completion of the phase 1 healthy volunteer study, we intend to wind down PRS-220 and do not plan to continue to advance the program for scientific reasons.

Manufacturing

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We do not expect that we will manufacture any drug candidates in the future. We have historically relied on third party contract manufacturer organizations, or CMOs, and if we ever decide to manufacture any drug candidates in the future, we expect we will rely on CMOs, for the manufacture of any drug candidates for larger scale preclinical and clinical testing, as well as for commercial quantities of any drug candidates that may be approved for marketing.

We believe that Anticalin-branded drug candidates, including Mabcalin proteins, can be manufactured in reliable and reproducible biologic processes from readily available starting materials as they are produced using mammalian expression systems similar to those systems that are widely used in the industry for the production of antibodies. We believe that the manufacturing process is amenable to scale-up and will not require unusual or expensive equipment. As previously disclosed, our partners are fully responsible for any further advancement and funding of these assets.

Intellectual Property and Exclusivity

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

We seek to protect our exclusive position of Anticalin technologies by, among other means, prosecuting our own international, U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We have established intellectual property protection in relation to our Anticalin technologies in key global markets, including in North America, Europe and Asia. We also rely on trade secrets for confidential know-how, which we generally seek to protect through contractual (for example, confidentiality) agreements with employees and third parties.

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

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

In applicable jurisdictions, such as the United States, we will seek patent term extensions for certain issued patents of ours. If we obtain marketing approval for our drug candidates in the United States or certain jurisdictions outside of the United States, we may be eligible for regulatory protection, such as 4 years of data exclusivity and 12 years of market exclusivity for new biological entities in the United States and as mentioned below, up to five years of patent term extension potentially available in the United States, eight to 11 years of data and marketing exclusivity potentially available for new drugs in the European Union, up to five and a half years of patent extension in Europe (supplemental protection certificate) and eight years of exclusivity, similar to data exclusivity in the United States, potentially available in Japan under its re-examination system. There can be no assurance that we will qualify for any such regulatory exclusivity or that any such exclusivity will prevent competitors from seeking approval solely on the basis of their own studies. See “Government Regulation.”

We hold issued patents and pending patent applications in the United States and other foreign jurisdictions, which patents or patent applications are related to libraries of different scaffolds and consensus sequences such as human NGAL and human tear lipocalin, and are expiring or expected to expire between 2024 and 2043, subject to any patent term adjustments and terminal disclaimers in the United States. We also own a number of patents and patent applications at various stages of prosecution directed towards compositions of matter and in some cases, formulations or methods of use, of our preclinical and clinical drug candidates. Where possible, we will pursue patent term adjustments in the United States and any applicable foreign jurisdictions.

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

We hold a number of issued patents and pending patent applications in the United States and foreign jurisdictions directed to newly-discovered or improved scaffold libraries of lipocalin muteins, compounds derived therefrom (i.e., specific drug candidates) or the uses of such compounds to treat, prevent and mitigate certain diseases and conditions whose pathological development involve the targets of interest as well as to diagnose, prognose and select treatments for the diseases and conditions. We would expect that these patents and any patents that may issue from pending applications would likely expire between 2029 and 2043 without taking into account possible patent term adjustments or other extensions. However, any and all of these pending patent applications may not result in issued patents, and not all issued patents may be maintained in force for their entire term.

In addition to issued patents, we hold trademarks in the United States for the Pieris and Anticalin marks. Similarly, we hold their respective counterparts, as registered trademarks, in a number of foreign jurisdictions.

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 inception, we have entered into several strategic partnerships and other license or option agreements to complement our drug discovery and development. Specifically, we entered into strategic partnerships with Servier, Boston Pharmaceuticals, Pfizer and Genentech, or collectively, the Strategic Partnerships. Under the Strategic Partnerships, we have developed and conducted selection and screening of drug candidates, as well as *in vitro* potency and efficacy testing, using our Anticalin-brand drug discovery platform, our Anticalin libraries and other proprietary methods to generate, identify and characterize drug candidates against certain biological targets associated with several diseases. The Strategic Partnerships as well as the former AstraZeneca collaboration have provided us with approximately $179.7 million in cash from upfront and milestone payments through December 31, 2023. With respect to discontinued agreements, we have no ongoing performance obligations and do not expect to receive any significant additional consideration pursuant to those agreements.

Under our ongoing Strategic Partnerships, our partners are obligated to use commercially reasonable efforts to develop and commercialize drug candidates identified in the course of the collaboration. We are entitled to receive from our partners’ research, development and regulatory milestone payments and, in some cases, including in the Servier, Boston Pharmaceuticals, Pfizer and Genentech collaborations, royalties on net sales for products developed and commercialized under these collaborations. With respect to the Pfizer partnership, we have the option to co-promote one or more therapeutic programs with our partners.

The Strategic Partnerships represent collaborations primarily in IO. Certain terms and conditions of these Strategic Partnerships are summarized below.

Our collaboration with Servier

On January 4, 2017, we entered into the Servier Collaboration Agreement and a non-exclusive Anticalin platform license agreement with Servier, or the Servier Platform License, collectively referred to as the Servier Agreements. Pursuant to the terms of the Servier Agreements, we, along with Servier, initially pursued five bispecific therapeutic programs. Servier has terminated four of the five bispecific therapeutic programs, and is focusing on continued development of the most advanced program, S095012 (also referred to as PRS-344).

In July 2023, we notified Servier that we were opting out of co-development and commercialization of S095012 in the U.S., which Servier continues to advance. Servier retains exclusive, even as to us, worldwide rights to the program including the right to advance development and potential commercialization in the U.S. As a result of our election to opt out, we are entitled to increased royalty rates and potential royalties and milestones, if any, for S095012.

Under the Servier Agreements, we received an upfront payment of €30.0 million (approximately $32.0 million) and have achieved two preclinical milestones related to S095012 as well as one clinical milestone related to S095012 and one preclinical milestone related to PRS-352, which has been discontinued by Servier. We may also receive additional development-dependent and commercial milestone payments for S095012. In addition, we will be entitled to receive tiered royalties up to low double digits on the sales of commercialized products in the Servier territories.

The term of each of the Servier Agreements ends upon the expiration of all of Servier's payment obligations under such Servier Agreement. The Servier Agreements may be terminated by either of us for material breach upon 90 days' or 120 days' notice of a material breach, with respect to the Servier Collaboration Agreement and the Servier Platform License, respectively, provided that the applicable party has not cured such breach by the applicable 90-day or 120-day permitted cure period, and dispute resolution procedures specified in the applicable Servier Agreement have been followed. The Servier Agreements may also be terminated due to the other party's insolvency or for a safety issue, and may in certain instances be terminated on a product-by-product and/or country-by-country basis. The Servier Platform License will terminate upon termination of the Servier Collaboration Agreement, on a product-by-product and/or country-by-country basis.

Our collaboration with Pfizer

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

Under the terms of the Pfizer Agreements, Pfizer paid us a $30 million upfront fee and will pay tiered royalties on net sales up to the low double-digits. Additionally, Pfizer will pay us up to $1.2 billion in total success-based payments, as of December 31, 2023, across three product candidates. The companies will pursue multiple antibody-Anticalin proteins during a research phase, and Pfizer has the option to select up to three therapeutic programs for further development. On March 25, 2021 we announced an amendment to the Pfizer Collaboration Agreement whereby our option to co-develop and co-commercialize the second of three programs in the collaboration was converted to a co-promotion option for one of the three programs in the United States, with Pfizer solely responsible for the development and overall commercialization of that program. We will be entitled to increased royalties in the event that we choose to exercise the co-promotion option for that program. As a result of this amendment, Pfizer will solely develop, fund and commercialize all three programs. Pfizer may also decide to select additional candidates from the initial research phase for further development in return for the payment to us of additional fees, milestone payments and royalties.

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

In June 2020, we and Pfizer entered into amendments to the Pfizer Agreements, or together, the Amendment. The Amendment extended the deadline for Pfizer to nominate a second and third antibody target, both of which have since been nominated, and triggered a $5.0 million milestone payment due from Pfizer as Pfizer made a go decision on SGN-BB228. In January 2023, we announced that the first patient was dosed in SGN-BB228 and Pfizer paid us a $5.0 million milestone fee in connection with this achievement. Additionally, as part of this transaction, we entered into a subscription agreement pursuant to which we agreed to issue to Pfizer 3,706,174 shares of our common stock for a total purchase price of $13.0 million, or $3.51 per share, in a private placement transaction.

Finally, in September 2023, we and Pfizer entered into an amendment of the Pfizer Collaboration Agreement, as amended, that provides Pfizer with collaboration product licenses with no changes to the amounts achievable under the Pfizer Collaboration Agreement, as amended. The effect of the September 2023 amendment was to transfer responsibility for substantially all activities previously performed by the Company to Pfizer. Furthermore, in December 2023, we officially handed over the remaining programs to Pfizer, and it is responsible for any further advancement and funding of these assets.

Our collaboration with Boston Pharmaceuticals

On April 24, 2021, we and BP Asset XII, Inc., or Boston Pharmaceuticals, a subsidiary of Boston Pharma Holdings, LLC, entered into an exclusive product license agreement, or the BP Agreement, to develop BOS-342, a 4-1BB/GPC3 preclinical immuno-oncology Mabcalin bispecific protein.

Under the terms of the BP Agreement, Boston Pharmaceuticals exclusively licensed worldwide rights to BOS-342. We received an upfront payment of $10.0 million and are further entitled to receive up to $352.5 million in development, regulatory and sales-based milestone payments, tiered royalties up to low double-digits on sales of PRS-342 and a percentage of consideration received by Boston Pharmaceuticals in the event of a sublicense of a program licensed under the BP Agreement or a change of control of Boston Pharmaceuticals. We will also contribute up to $4.0 million toward manufacturing activities.

The term of the BP Agreement ends upon the expiration of all of Boston Pharmaceuticals' payment obligations thereunder. The BP Agreement may be terminated by Boston Pharmaceuticals in its entirety for convenience beginning nine months after its effective date upon 60 days' notice or, for any program under the BP Agreement which has received marketing approval, upon 120 days' notice. If any program is terminated by Boston Pharmaceuticals, we will have full rights to continue such program. The BP Agreement may also be terminated by Boston Pharmaceuticals or us for an uncured material breach by the other party upon 180 days' notice (60 days in the case of non-payment of undisputed amounts due and payable), subject to extension for an additional 180 days in certain cases and subject, in all cases, to dispute resolution procedures. The Agreement may also be terminated due to the other party's insolvency. We may also terminate the BP Agreement if Boston Pharmaceuticals challenges the validity of any patents licensed under the BP Agreement, subject to certain exceptions.

We do not have any obligations to assist in the research and development efforts of Boston Pharmaceuticals under the BP Agreement. However, we had an obligation to fund up to $4.0 million in costs, including out-of-pocket costs incurred by Boston Pharmaceuticals, in connection with the manufacture of products under the BP Agreement. The arrangement with Boston Pharmaceuticals provides for the transfer of the following: (i) exclusive license of BOS-342, (ii) non-exclusive Pieris platform license, (iii) initial know-how, (iv) product cell line license, and (v) materials (as each such term is defined under the BP Agreement).

In August 2023, the first patient was dosed in a Boston Pharmaceuticals sponsored phase 1/2 study of BOS-342 in hepatocellular carcinoma (HCC), for which we received a $2.5 million milestone payment and are entitled to receive up to approximately $350 million in potential development, regulatory and sales-based milestone payments, and tiered royalties on potential sales of BOS-342.

Our collaboration with Genentech

On May 19, 2021, we and Genentech, Inc., or Genentech, entered into a Research Collaboration and License Agreement, or the Genentech Agreement, to discover, develop and commercialize locally delivered respiratory and ophthalmology therapies that leverage the Company's proprietary Anticalin technology. Upon signing the Genentech Agreement, Genentech paid the Company a $20 million upfront fee. In addition, the Genentech Agreement provides for us to be eligible to receive additional milestone payments across multiple programs, as well as tiered royalty payments on net sales at percentages ranging from the mid-single to low double-digits, subject to certain standard reductions and offsets.

Under the terms of the Genentech Agreement, we would be responsible for discovery and preclinical development of two initial programs. We would be responsible for research activities following target nomination through the late-stage research go decision. We and Genentech would then collaborate on drug candidate characterization until the development go decision. After the development go decision, Genentech would be responsible for pursuing the preclinical and clinical development of each program, and thereafter, the commercialization efforts. Each party would be responsible for the costs incurred to perform their respective responsibilities. Genentech has an option to expand the collaboration to encompass two additional programs with the payment of a $10 million fee per additional program. If Genentech exercises its option to start additional programs, payment to us of additional fees, milestone payments and royalties would result.

Unless earlier terminated, the term of the Genentech Agreement continues until no royalty or other payment obligations are or will become due under the Genentech Agreement. The Genentech Agreement may be terminated (i) by either party based on insolvency or breach by the other party and such insolvency proceeding is not dismissed or such breach is not cured within 90 days; or (ii) after nine months from the effective date of the Genentech Agreement, by Genentech as a whole or on a product-by-product and/or country-by-country basis upon 90 days' prior written notice before the first commercial sale of a product or upon 180 days' prior written notice after the first commercial sale of a product.

While the Genentech Agreement allows for up to four research programs, only two research programs were initially identified and committed in the Genentech Agreement. To reach a total of up to four research programs, we have granted Genentech options to nominate an additional two collaboration targets of their choosing, subject to the legal availability of the target to be researched. Genentech will have three years after the effective date to nominate the subsequent targets. We have also granted Genentech options to replace any of the collaboration targets identified with another target. However, at no point will there be more than four identified collaboration targets for which there are ongoing research programs. In April and May 2023, Genentech and the Company decided to discontinue the discovery-stage programs in ophthalmology and respiratory, respectively, for scientific reasons.

Our collaboration with AstraZeneca

On May 2, 2017, we entered into the AstraZeneca Collaboration Agreement and a Non-exclusive Anticalin Platform Technology License Agreement with AstraZeneca, or the AstraZeneca Platform License, collectively referred to as the AstraZeneca Agreements, which became effective on June 10, 2017, which were subsequently amended on March 29, 2021. In connection with the amendments, we entered into a Subscription Agreement pursuant to which we agreed to issue to AstraZeneca 3,584,230 shares of our common stock for a total purchase price of $10.0 million in a private placement transaction. In August 2022, we entered into another amendment to the License and Collaboration Agreement.

On July 17, 2023, AstraZeneca notified the Company of its intention to terminate the AstraZeneca Collaboration Agreement and the AstraZeneca Platform License, and the termination became effective October 15, 2023. AstraZeneca's decision to terminate the AstraZeneca Agreements was based on non-clinical safety findings in a 13-week toxicology study of elarekibep in non-human primates previously disclosed by the Company. With the termination of the AstraZeneca Agreements, there are no more active programs or performance obligations related to the collaboration. Since the termination of the AstraZeneca Agreements, the Company has decided it would not pursue further development of the programs from the AstraZeneca Agreements.

In-License Agreements

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

TUM License

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

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

As a result of research efforts to date under the TUM License, we hold a worldwide exclusive license under our agreement with TUM to multiple patents and patent applications related to certain Anticalin proteins and libraries. We bear the costs of filing, prosecution and maintenance of patents assigned or licensed to us under the agreement.

As consideration for the assignments and licenses, we are obliged to pay to TUM license payments on development of our proprietary products claimed by patents assigned or licensed to us by TUM. For each of such proprietary products developed by us, we could be required to pay up to an aggregate of approximately €0.2 million ($0.2 million) in license payments to TUM under the agreement.

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

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

Pieris and TUM initiated discussions in the second quarter of 2018 to clarify, expand and restructure the TUM License, including the parties' obligations under such license agreement. The parties' discussions relate to revised commercial terms and to re-initiating additional collaborations between faculty at TUM and Pieris. While an amended and restated license agreement has not yet been completed, the Company may enter into an amendment reflecting the parties' discussions.

Kelun License Agreement

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

Government Regulation

The research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing, sales, among other things, of drug products are extensively regulated by governmental authorities in the United States and other countries.

U.S. Government regulation of drug and biological products

In the United States, the FDA regulates human drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and in the case of biologics, also under the Public Health Service Act, or the PHSA, and their implementing regulations. Failure to comply with the applicable U.S. requirements may subject an applicant to administrative or judicial sanctions, such as FDA refusal to approve pending new drug applications, or NDAs, or biologics license applications, or BLAs, or the agency's issuance of warning letters, or the imposition of fines, civil penalties, product recalls, product seizures, total or partial suspension of production or distribution, injunctions and/or criminal prosecution brought by the FDA and the U.S. Department of Justice or other governmental entities.

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

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

Preclinical studies

Before testing any drug or biological product candidate in humans, the product candidate must undergo rigorous preclinical testing. The preclinical developmental stage generally involves laboratory evaluations of drug chemistry, formulation and stability, as well as studies to evaluate toxicity in animals and potential for other adverse events, which support subsequent clinical testing and rationale for subsequent therapeutic use.

The Consolidated Appropriations Act for 2023, signed into law on December 29, 2022, (P.L. 117-328) amended both the FDCA and PHSA to specify that nonclinical testing for drugs and biologics, respectively, may, but is not required to, include *in vivo* animal testing. According to the amended language, a sponsor may fulfill nonclinical testing requirements by completing various *in vitro* assays (e.g., cell-based assays, organ chips, or microphysiological systems), *in silico* studies (i.e., computer modeling), other human or non-human biology-based tests (e.g., bioprinting), or *in vivo* animal tests. The sponsor must submit the results of the preclinical studies, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before human clinical trials may begin.

The conduct of preclinical studies is subject to federal regulations and requirements, including good laboratory practices, or GLP, regulations for safety and toxicology studies. Some long-term nonclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after an IND for an investigational drug candidate is submitted to the FDA and human clinical trials have been initiated.

Human clinical trials in support of an NDA or BLA

All clinical trials must be conducted under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing the objectives of the study, the parameters to be used in monitoring the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND. Study subjects must sign an informed consent form before participating in a clinical trial. There are also requirements governing the reporting of on-going clinical trials and clinical trial results to public registries. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence. Clinical holds may also be imposed by the FDA at any time before or during studies due to safety concerns or non-compliance.

In addition, an IRB representing each institution that is participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must thereafter conduct a continuing review and re-approve the trial at least annually. The IRB must review and approve, among other things, the trial protocol and informed consent information to be provided to clinical trial subjects. An IRB must operate in compliance with FDA regulations.

Information about certain clinical trials, including details of the protocol and eventually study results, also must be submitted within specific time frames to the National Institutes of Health, or NIH, for public dissemination on the ClinicalTrials.gov data registry. Information related to the product, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in some cases for up to two years after the date of completion of the trial. Failure to timely register a covered clinical study or to submit study results as provided for in the law can give rise to civil monetary penalties and also prevent the non-compliant party from receiving future grant funds from the federal government. The U.S. Department of Health and Human Services' Final Rule and NIH's complementary policy on ClinicalTrials.gov registration and reporting requirements became effective in 2017, and the government has brought enforcement against clinical trial sponsors that fail to comply with such requirements.

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

- ***Phase 1:*** The product candidate is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, such as cancer, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- ***Phase 2:*** This phase involves studies in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- ***Phase 3:*** Clinical trials are undertaken with an expanded patient population to further evaluate dosage, clinical efficacy and safety in an expanded patient population, often at geographically dispersed clinical study sites. These studies are intended to establish the overall risk-benefit ratio of the product candidate and provide, if appropriate, an adequate basis for product labeling. These trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing.

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

Congress also recently amended the FDCA, as part of the Consolidated Appropriations Act for 2023, in order to require sponsors of a phase 3 clinical trial, or other “pivotal study” of a new drug to support marketing authorization, to design and submit a diversity action plan for such clinical trial. The action plan must include the sponsor’s diversity goals for enrollment, as well as a rationale for the goals and a description of how the sponsor will meet them. Sponsors must submit a diversity action plan to the FDA by the time the sponsor submits the relevant clinical trial protocol to the agency for review. The FDA may grant a waiver for some or all of the requirements for a diversity action plan. It is unknown at this time how the diversity action plan may affect phase 3 trial planning and timing or what specific information FDA will expect in such plans, but if the FDA objects to a sponsor’s diversity action plan, it may delay trial initiation.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events, or SAEs, occur. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the clinical protocol, cGCP, or other IRB requirements or if the drug has been associated with unexpected serious harm to patients.

During the development of a new drug or biological product, sponsors have the opportunity to meet with the FDA at certain points, including prior to submission of an IND, at the end of phase 2, and before submission of an NDA or BLA. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development. Sponsors typically use the end of phase 2 meeting to discuss their phase 2 clinical results with the agency and to present their plans for the pivotal phase 3 studies that they believe will support approval of the new drug or biological product.

Concurrent with clinical trials, companies usually complete additional nonclinical studies and must also develop additional information about the physical characteristics of the drug or biological product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality, potency and purity of the final drug or biological product. For biological products in particular, the PHSA emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined in order to help reduce the risk of the introduction of adventitious agents. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

Marketing application submission and FDA review

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

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

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

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

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

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

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

The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality and purity. The FDA reviews a BLA to determine, among other things whether the product is safe, pure and potent and that the facility (or facilities) in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. The approval process is lengthy and often difficult, and the FDA may refuse to approve an NDA or BLA if the applicable regulatory criteria are not satisfied or may require additional clinical or other data and information. On the basis of the FDA's evaluation of the NDA or BLA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue either an approval letter or a Complete Response Letter, or CRL. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete and the application will not be approved in its present form. A CRL generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. The CRL may require additional clinical or other data, additional pivotal phase 3 clinical trial(s) and/or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a CRL is issued, the applicant may choose to either resubmit the NDA or BLA addressing all of the deficiencies identified in the letter or withdraw the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA or BLA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in response to an issued CRL in either two or six months depending on the type of information included. Even with the submission of this additional information, however, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

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

Fast Track, Breakthrough Therapy and Priority Review Designations

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

To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need by providing a therapy where none exists or a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. Fast track designation provides opportunities for more frequent interactions with the FDA review team to expedite development and review of the product. The FDA may also review sections of the NDA or BLA for a fast track product on a rolling basis before the complete application is submitted, if the sponsor and the FDA agree on a schedule for the submission of the application sections and the sponsor pays any required user fees upon submission of the first section of the NDA or BLA. In addition, fast track designation may be withdrawn by the sponsor or rescinded by the FDA if the designation is no longer supported by data emerging from the clinical trial process.

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

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

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

Accelerated approval pathway

In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval from the FDA and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a drug or biologic when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform post-marketing clinical trials to verify and describe the predicted effect on IMM or other clinical endpoint, and the product may be subject to expedited withdrawal procedures. Drugs and biologics granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

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

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

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint.

In addition, as part of the Consolidated Appropriations Act for 2023, Congress provided FDA additional statutory authority to mitigate potential risks to patients from continued marketing of ineffective drugs previously granted accelerated approval. Under these recent amendments to the FDCA, the agency may require a sponsor of a product granted accelerated approval to have a confirmatory trial underway prior to approval. The sponsor must also submit progress reports on a confirmatory trial every six months until the trial is complete, and such reports will be published on FDA's website.

Failure to conduct required post-approval studies, or to confirm the predicted clinical benefit of the product during post-marketing studies, allows the FDA to withdraw approval of the drug.

Congress also recently amended the FDCA law to give the agency the option of using expedited procedures to withdraw product approval if the sponsor's confirmatory trial fails to verify the claimed clinical benefits of the product.
All promotional materials for product candidates being considered and approved under the accelerated approval program are subject to prior review by the FDA.

Patent term restoration

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

Pediatric exclusivity

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

Reference product exclusivity for biological products

In March 2010, the Patient Protection and Affordable Care Act was enacted in the United States and included the Biologics Price Competition and Innovation Act of 2009, or the BPCIA. The BPCIA amended the PHSA to create an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Since that time, the FDA has approved approximately 40 biosimilars, including the first interchangeable monoclonal antibody biosimilar in 2021. The FDA has also issued several guidance documents outlining its approach to reviewing and approving biosimilars and interchangeable biosimilar, and has created a public database that contains information on all FDA-licensed biological products, including biosimilars, called the Purple Book.

A biosimilar product is defined as one that is highly similar to a reference product notwithstanding minor differences in clinically inactive components and for which there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity and potency of the product. An interchangeable product is a biosimilar product that can be expected to produce the same clinical results as the reference product in any given patient and, for products administered multiple times to an individual, that the product and the reference product may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product without such alternation or switch. Upon licensure by the FDA, an interchangeable biosimilar may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

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

A reference biological product is granted 12 years of market exclusivity from the time of first licensure of the product, and the first approved interchangeable biologic product will be granted an exclusivity period of up to one year after it is first commercially marketed.

As part of the Consolidated Appropriations Act for 2023, Congress amended the PHSA in order to permit multiple interchangeable products approved on the same day to receive and benefit from this one-year exclusivity period.

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

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

Orphan drug designation and exclusivity

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States for that drug. Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process. If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication, except in very limited circumstances, for seven years. Orphan drug exclusivity, however, also could block the approval of one of our products for seven years if a competitor obtains approval of the same drug as defined by the FDA for treatment of the same indication. Recent court cases have challenged FDA's approach to determining the scope of orphan drug exclusivity; however, at this time the agency continues to apply its long-standing interpretation of the governing regulations and has stated that it does not plan to change any orphan drug implementing regulations.

Post-approval requirements

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

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

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

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

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution. The Drug Supply Chain Security Act, or DSCSA, was enacted with the aim of building an electronic system to identify and trace certain prescription drugs distributed in the United States, including most biological products. The DSCSA mandates phased-in and resource-intensive obligations for pharmaceutical manufacturers, wholesale distributors and dispensers over a 10-year period, which culminated in November 2023.
Most recently, the FDA announced a one-year stabilization period to November 2024, giving entities subject to the DSCSA additional time to finalize interoperable tracking systems and to ensure supply chain continuity.
From time to time, new legislation and regulations may be implemented that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA.

For example, FDA released proposed regulations in February 2022 to amend the national standards for licensing of wholesale drug distributors by the states; establish new minimum standards for state licensing third-party logistics providers; and create a federal system for licensure for use in the absence of a state program, each of which is mandated by the DSCSA.

It is impossible to predict whether further legislative or regulatory changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

Regulation outside of the United States

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products outside of the United States. Whether or not we obtain FDA approval for a product candidate, we must obtain approval from the comparable regulatory authorities of foreign countries or economic areas, such as the 27-member European Union, before we may commence clinical trials or market products in those countries or areas. With the United Kingdom withdrawal from the European Union on January 31, 2020, UK licensing decisions were transferred from EMA to The Medicines and Healthcare Products Regulatory Agency, or MHRA, the UK Regulatory Body. For a period of three years following January 1, 2021, the UK continued to adopt decisions taken by the European Commission on the approval of new marketing authorizations. However, companies will be required to submit an identical application to the MHRA upon the Committee for Medicinal Products for Human Use, or CHMP, positive opinion of the application. The MHRA will then wait for the European Commission decision on approval. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly between countries and jurisdictions and can involve additional testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

European Union drug development, review and approval

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

The Clinical Trials Directive 2001/20/EC, the Directive 2005/28/EC on GCP, and the related national implementing provisions of the individual EU Member States previously governed the system for the approval of clinical trials in the European Union. Under this system, an applicant had to obtain prior approval from the competent national authority of the EU Member States in which the clinical trial is to be conducted. Furthermore, the applicant could only start a clinical trial at a specific study site after the competent ethics committee has issued a favorable opinion.

In 2014, the new Clinical Trials Regulation, (EU) No 536/2014, Clinical Trials Regulation, was adopted and it became effective on January 31, 2022. The Clinical Trials Regulation is directly applicable in all of the EU Member States, as it repealed the Clinical Trials Directive 2001/20/EC. The extent to which ongoing clinical trials will be governed by the Clinical Trials Regulation depends on when the Clinical Trials Regulation became applicable and on the duration of the individual clinical trial. If a clinical trial continues for more than three years from the day on which the Clinical Trials Regulation became applicable, the Clinical Trials Regulation will at that time begin to apply to the clinical trial.

The Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the European Union. The main characteristics of the regulation include: a streamlined application procedure via a single entry point, the "EU portal" or Clinical Trial Information System, or CTIS; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is assessed by the competent authorities of all EU Member States in which an application for authorization of a clinical trial has been submitted (Member States concerned). Part II is assessed separately by each Member State concerned. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the concerned EU Member State. However, overall related timelines will be defined by the Clinical Trials Regulation. Use of the CTIS became mandatory for new clinical trial application submissions as of February 1, 2023.

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

Centralized procedure

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

National authorization procedures

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

- Decentralized procedure. Using the decentralized procedure, an applicant may apply for simultaneous authorization in more than one EU country of medicinal products that have not yet been authorized in any EU country and that do not fall within the mandatory scope of the centralized procedure.
- Mutual recognition procedure. In the mutual recognition procedure, a medicine is first authorized in one EU Member State, in accordance with the national procedures of that country. Following this, further marketing authorizations can be sought from other EU countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

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

Conditional approval

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

Pediatric studies

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

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

European Union regulatory exclusivity

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

European Union orphan designation and exclusivity

The criteria for designating an orphan medicinal product in the European Union, are similar in principle to those in the United States. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five in 10,000 persons in the European Union when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the European Union to justify investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the European Union, or if such a method exists, the product will be of significant benefit to those affected by the condition, as defined in Regulation (EC) 847/2000. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to ten years of market exclusivity for the approved therapeutic indication. The application for orphan designation must be submitted before the application for marketing authorization. The applicant will receive a fee reduction for the marketing authorization application if the orphan designation has been granted, but not if the designation is still pending at the time the marketing authorization is submitted. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

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

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

PRIME designation

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

Periods of authorization and renewals

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

Rest of the world regulation

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

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

Coverage, pricing and reimbursement

Sales of pharmaceutical products approved by the FDA will depend in significant part on the availability of third-party coverage and reimbursement for the products. Third-party payors include government healthcare programs in the United States such as Medicare and Medicaid, managed care providers, private health insurers and other organizations. These third-party payors are increasingly challenging the price and examining the cost-effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication. We may need to conduct expensive pharmacoeconomic studies to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Moreover, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Third-party reimbursement may not be sufficient to maintain price levels high enough to realize an appropriate return on investment in product development. Our product candidates may not be considered cost-effective. It is time consuming and expensive to seek reimbursement from third-party payors. Reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of our product candidate to currently available therapies (so-called health technology assessment, or HTA) in order to obtain reimbursement or pricing approval. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Other member states allow companies to fix their own prices for drug products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally tend to by significantly lower.

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

In the United States, President Biden signed into the law the Inflation Reduction Act (IRA) in August 2022. Among other things, the IRA has multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the U.S. Starting in 2023, a manufacturer of drugs or biological products covered by Medicare Parts B or D must pay a rebate to the federal government if their drug product's price increases faster than the rate of inflation. This calculation is made on a drug product by drug product basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a drug product that is paid for by Medicare Parts B or D. Additionally, starting for payment year 2026, the Centers for Medicare & Medicaid Services (CMS) will negotiate drug prices annually for a select number of single source Part D drugs without generic or biosimilar competition. CMS will also negotiate drug prices for a select number of Part B drugs starting for payment year 2028. If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease. CMS has begun to implement these new authorities
and entered into the first set of agreements with pharmaceutical manufacturers to conduct price negotiations in October 2023. However, the IRA's impact on the pharmaceutical industry in the United States remains uncertain, in part because multiple large pharmaceutical companies and other stakeholders (e.g., the U.S. Chamber of Commerce) have initiated federal lawsuits against CMS arguing the program is unconstitutional for a variety of reasons, among other complaints. Those lawsuits are currently ongoing.

Other U.S. health care laws and regulations

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

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

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

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

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are not able to maintain regulatory compliance, we may lose any marketing approval that we otherwise may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

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

In addition to the IRA's drug price negotiation provisions summarized above, President Biden's Executive Order 14087, issued in October 2022, called for the CMS Innovation Center to prepare and submit a report to the White House on potential payment and delivery modes that would complement IRA, lower drug costs, and promote access to innovative drugs.

In February 2023, CMS published its report which described three potential models focusing on affordability, accessibility and feasibility of implementation for further testing by the CMS Innovation Center. As of December 31, 2023, the CMS Innovation Center's testing of the proposed models is still in progress.

We expect that future changes or additions to the Affordable Care Act, the Medicare and Medicaid programs, and changes stemming from other health care reform measures, especially with regard to health care access, financing or other legislation in individual states, could have a material adverse effect on the health care industry in the United States.

There also has been heightened governmental scrutiny in recent years over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for pharmaceutical and biologic products. For example, the 2021 Consolidated Appropriations Act signed into law on December 27, 2020 incorporated extensive health care provisions and amendments to existing laws, including a requirement that all manufacturers of drug products covered under Medicare Part B report the product's average sales price to CMS beginning on January 1, 2022, subject to enforcement via civil money penalties.

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

For example, in recent years, several states have formed prescription drug affordability boards (PDABs). Much like the IRA's drug price negotiation program, these PDABs have attempted to implement upper payment limits (UPLs) on drugs sold in their respective states in both public and commercial health plans. For example, in August 2023, Colorado's PDAB announced a list of five prescription drugs that would undergo an affordability review. The effects of these efforts remain uncertain pending the outcomes of several federal lawsuits challenging state authority to regulate prescription drug payment limits. In December 2020, the U.S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate pharmacy benefit managers, or PBMs, and other members of the health care and pharmaceutical supply chain, an important decision that appears to be leading to further and more aggressive efforts by states in this area.

In mid-2022, the Federal Trade Commission also launched sweeping investigations into the practices of the PBM industry that could lead to additional federal and state legislative or regulatory proposals targeting such entities' operations, pharmacy networks, or financial arrangements. Significant efforts to change the PBM industry as it currently exists in the U.S. may affect the entire pharmaceutical supply chain and the business of other stakeholders, including biopharmaceutical developers like us.

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

Corporate Information

On December 17, 2014, Pieris, Pieris GmbH and the former stockholders of Pieris GmbH entered into an acquisition agreement, or the Acquisition Agreement. Pursuant to the Acquisition Agreement, the stockholders of Pieris GmbH contributed all of their equity interests in Pieris GmbH to Pieris in exchange for shares of Pieris common stock, which resulted in Pieris GmbH becoming a wholly-owned subsidiary of Pieris, which we refer to as the Acquisition. Upon the closing of the Acquisition on December 17, 2014, Pieris ceased to be a "shell company" under applicable rules of the Securities and Exchange Commission, or the SEC.

Rule 12b-2 of the Exchange Act establishes a class of company called a "smaller reporting company," which effective September 10, 2018, was amended to include companies with a public float of less than $250 million as of the last business day of their most recently completed second fiscal quarter or, if such public float is less than $700 million, had annual revenues of less than $100 million during the most recently completed fiscal year for which audited financial statements are available. For the year ended December 31, 2023, we qualify as a smaller reporting company.

As a smaller reporting company, we are eligible to and have taken advantage of certain extended accounting standards and exemptions from various reporting requirements that are not available to public reporting companies that do not qualify for those classifications. These exemptions include, but are not limited to, reduced disclosure obligations regarding executive compensation in our periodic and annual reports, exemption from the requirement to provide a compensation discussion and analysis describing compensation practices and procedures, and reduced financial statement disclosure in our registration statements, which must include two years of audited financial statements rather than the three years of audited financial statements that are required for other public reporting companies. Smaller reporting companies are also eligible to provide such reduced financial statement disclosure in annual reports on Form 10-K.

For as long as we continue to be a smaller reporting company, we expect that we will take advantage of the reduced disclosure obligations available to us as a result of this classification. We will remain a smaller reporting company until we have (i) a public float of more than $700 million as of the last business day of our most recently completed second fiscal quarter, if we have annual revenues of less than $100 million during the most recently completed fiscal year, or (ii) a public float of $250 million or more as of the last business day of our most recently completed second fiscal quarter, if we have annual revenues of at least $100 million during the most recently completed fiscal year, and we could retain our smaller reporting company status indefinitely depending on the size of our public float.

Employees and Human Capital Resources

On July 18, 2023, our Board of Directors approved a reduction in our workforce by approximately 70%. Since July of 2023, and through December 31, 2023, we took additional steps to reduce our operating footprint including terminating our remaining lease obligations in Germany and winding down our proprietary inhaled respiratory programs. We also opted out of and terminated programs where possible to reduce operating costs. Further reductions in the workforce have occurred based upon these actions. In connection with our announcement on March 27, 2024, we intend to conduct a workforce reduction, which would impact additional employees and the current executive leadership team, and would be implemented in the second quarter of 2024.

As of December 31, 2023, we had 46 full-time employees and 4 permanent part-time employees. None of our employees are represented by a labor union or covered by a collective bargaining agreement. Our corporate headquarters is located in Boston, MA and we have offices located in Hallbergmoos, Germany. As such, 6, or 12%, of our employees were located in the United States and 44, or 88%, of our employees were located in Germany. We also utilize the services of consultants, clinical research organizations and other third parties from locations across the world.

Available Information

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

Item 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, together with the other information contained in this Annual Report on Form 10-K, including our consolidated financial statements and the related notes, before making any decision to invest in shares of our common stock. This Annual Report on Form 10-K contains forward-looking statements. If any of the events discussed in the risk factors below occurs, our business, prospects, results of operations, financial condition and cash flows could be materially harmed. If that were to happen, the trading price of our common stock could decline, and you could lose all or part of your investment. The risks and uncertainties described below are not the only ones we face. Additional risks not currently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.

Following is a summary of our Risk Factors:

- Our business strategy depends substantially upon our ability to receive future contingent milestone and royalty payments from our partnered programs.
- 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 may need to raise additional capital to operate our business.
- We could be subject to product liability lawsuits based on the use of our drug candidates in clinical testing or, if obtained, following our products' marketing approval and commercialization. If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to cease clinical testing or limit commercialization of our drug candidates.
- We are heavily dependent on the successful development of our partnered drug candidates and we cannot be certain that our partners will receive regulatory approvals or be able to successfully commercialize our partnered drug candidates even if they receive regulatory approvals.
- Preclinical and clinical testing of our drug candidates that has been conducted to date or will be conducted in the future may not have been or may not be performed in compliance with applicable regulatory requirements, which could lead to increased costs or material delays for their further development.
- We may be treated as a "public shell" company which could have negative consequences, including potential Nasdaq delisting of our common stock.
- Disagreements with respect to the commercial terms of our sales, licensing, purchase or manufacturing agreements may limit our commercial success.
- We depend on third parties and intend to continue to license or collaborate with third parties, and events involving these strategic partners or any future collaboration could delay or prevent us from developing or commercializing products.
- Our success depends on the efforts of our current collaborators, who will likely have substantial control and discretion over the continued development and commercialization of drug candidates that are the subject of our collaborations.
- We may not receive any further milestone, royalty or license payments under our current collaborations.
- If we breach any of the agreements under which we license from third parties the intellectual property rights or commercialization rights to our drug candidates, particularly our license agreements with TUM and Kelun, we could lose license rights that are important to our business and our operations could be materially harmed.
- We have broad discretion in how we use our cash, cash equivalents and investments, including the net proceeds from our collaborations, public and private securities offerings, and may not use these financial resources effectively, which could affect our results of operations and cause our stock price to decline.
- We have had and have previously reported material weaknesses in our internal controls over financial reporting. If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, our ability to operate our business and investors' views of us.
- Our shares of common stock could be delisted from the Nasdaq Capital Market, which could result in, among other things, a decline in the price of our common stock and less liquidity for holders of shares of our common stock.
- 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.

A detailed discussion of the above Risk Factors follows below.

Risks Related to our Corporate Strategy

Our business strategy depends substantially upon our ability to receive future contingent milestone and royalty payments.

Our business strategy depends substantially upon our ability to receive future milestone and royalty payments from Pfizer (formerly Seagen), Boston Pharmaceuticals, and Servier. On March 27, 2024, we announced a strategy to maximize our ability to capture the potential milestones from licensing and collaboration agreements with our partners, including Pfizer, Boston Pharmaceuticals, and Servier, while maintaining the capability to consider other strategic options. Our Board of Directors implemented a series of measures designed to extend our cash runway into at least 2027 and maximize our ability to capture the potential milestone payments. These measures include discontinuing research and development activities, which is expected to be completed in the middle of 2024, conducting further workforce reduction that affect additional employees and the executive leadership team, which is expected to be implemented in the second quarter of 2024, and reducing the size of our Board of Directors, which is also expected to be implemented in the second quarter of 2024.

We do not have any ongoing research or development activities. Any failure to achieve such milestones or a perception that the milestones may not be achieved will materially and adversely affect the company and the value of the common stock.

Even if some or all of the milestones or royalties set forth in the Pfizer Agreement, Boston Pharmaceuticals Agreement, or Servier Agreement are achieved, it may take significantly longer than we anticipate and could require us to raise additional funding in order to maintain our ability to receive payment for such milestones.

Achievement of the milestones set forth in the Pfizer Agreement, the Boston Pharmaceuticals Agreement, and the Servier Agreement are not guaranteed and there is significant risk that some or all of such milestones will not be achieved when anticipated, if at all. If achievement of the milestones is delayed beyond what we currently anticipate, it could require us to raise additional funds in order to maintain our ability to receive payment for the potential future achievement of such milestones. Sources of funds may not be available or, if available, may not be available on terms satisfactory to us. Raising additional funds could be dilutive or otherwise disadvantageous to our stockholders. Any delay in receipt of the potential benefit to the company or our stockholders resulting from achievement of such milestones, in addition to any additional uncertainty as to whether such milestones will be achieved at all, would materially and adversely affect the company and the value of the common stock.

Time and costs associated with winding down our research and development activities and any return of cash to stockholders may be significant.

There are significant costs associated with winding down our normal historic operations, such as separation of employees, termination of contracts and engagement of external consultants, all of which have and may in the future reduce our cash resources. Additionally, if our Board of Directors decide to issue any cash dividends to our stockholders in the future, we may incur third party costs associated with the distribution of such dividends, all of which would reduce our cash resources.

If some or all of our partners terminate our partnerships for which we may be entitled to milestone payments, our board of directors may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

There can be no assurance or guarantee that we will realize all or some of the milestone payments in connection with our licensing and collaboration agreements, and in the event our partners terminate their respective licensing and collaboration agreements, our board of directors may decide to pursue a dissolution and liquidate. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision and, with the passage of time the amount of cash available for distribution will be reduced as we continue to fund our operations. In addition, if our board of directors were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation, we would be required under Nevada corporate law to pay our outstanding debts and other obligations prior to making any distributions in liquidation to our stockholders. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations and the timing of any such resolution is uncertain. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation. If a dissolution and liquidation were pursued, our board of directors, in consultation with our advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up.

We may rely on external consultants for the execution of our business strategy.

In connection with our March 27, 2024 announcement, we disclosed an additional reduction in force impacting additional employees and our executive leadership team, which is expected to be implemented in the second quarter of 2024. We expect that as the number of employees is reduced, we may become reliant on a limited number of external consultants for the operation of our company, any of whom may terminate their consultancy with us at any time. The loss of some or all of our consultants could delay or inhibit our ability to run our operations or consummate any divestitures of our remaining assets or could interfere with our ability to receive and distribute any potential milestones from Pfizer, Boston Pharmaceuticals, Servier, or any other future partner.

While we have announced that we remain open to considering other strategic opportunities that might arise, there is no assurance that we would be successful in pursuing any such strategic opportunities.

Since we announced in July 2023 that we intend to explore engaging in one or more strategic transactions, our strategic review process has focused on maximizing stockholder value, which includes the maximization of potential milestone payments we are eligible to receive. Management and the Board of Directors evaluated a broad spectrum of potential options, including asset in-licensing, out-licensing, royalty monetization, strategic transactions (including reverse mergers, strategic mergers, and sale), and liquidation. With the assistance of our retained strategic advisor, Stifel, Nicolaus & Company, more than 500 companies were contacted regarding a strategic transaction, and we underwent a robust process to identify and negotiate with a select number of final candidates. We entered into extended exclusivity with one party contemplating a strategic merger, which centered on that party's interest in developing our clinical-stage asset cinrebafusp alfa, but after extensive diligence and negotiations, that counterparty was unable to secure adequate capitalization and offer acceptable terms. On March 27, 2024, we announced a strategy that would maximize our ability to capture potential milestones from our licensing and collaboration agreements while maintaining the capability to consider other strategic opportunities, which we believe offers the best opportunity to maximize stockholder value. Despite remaining open to considering other strategic opportunities that might arise, there can be no assurance that we will be successful in pursuing any opportunity or that any opportunity, if pursued, will be completed on attractive terms or at all. we may rely on the support of consultants and external advisors to assist in the review of strategic opportunities which may be costly. Additionally, there can be no assurance that any particular course of action, strategy to capture potential milestones or other strategy, business arrangement or transaction, or series of transactions, will be successfully pursued, consummated or lead to increased stockholder value. Such other strategies, business arrangement or transaction, or series of transactions could lead to increased costs, dilution to our existing stockholders' percentage of ownership, or assumption of debt and liabilities.

We may be treated as a "public shell" company which could have negative consequences, including potential Nasdaq delisting of our common stock.

Our common stock is currently listed on the Nasdaq Capital Market, or Nasdaq. We have no current plans to delist our common stock from Nasdaq. However, following the discontinuation of historical research and development efforts, we may be treated as a "public shell" company under the Nasdaq rules and the Securities Act of 1933, as amended, or the Securities Act, or the Exchange Act. Although Nasdaq evaluates whether a listed company is a public shell company based on a facts and circumstances determination, a Nasdaq-listed company with 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 is generally considered to be a public shell company. Listed companies determined to be public shell companies by Nasdaq may be subject to delisting proceedings or additional and more stringent listing criteria.

In addition, among other requirements, a minimum $1.00 per share bid price requirement for continued inclusion on the Nasdaq pursuant to Nasdaq Listing Rule 5550(a)(2), or the Bid Price Requirement. The closing bid price for our common stock must remain at or above $1.00 per share to comply with the Bid Price Requirement for continued listing. As previously disclosed, on May 15, 2023, we received a deficiency letter, or the Notice, from the Nasdaq Listing Qualifications Department, or the Staff, notifying us that because the closing bid price of our common stock had fallen below $1.00 per share for 30 consecutive business days, we no longer met the Bid Price Requirement.

Pursuant to Nasdaq Listing Rule 5810(c)(3)(A), or the Compliance Period Rule, we had an initial period of 180 calendar days, or until November 13, 2023, or the Compliance Date, to regain compliance with the Bid Price Requirement. To regain compliance, the closing bid price of our common stock must meet or exceed $1.00 per share for a minimum of 10 consecutive business days as required under the Compliance Period Rule (unless the Staff exercises its discretion to extend this ten-day period pursuant to Nasdaq Listing Rule 5810(c)(3)(H)). However, if during the compliance period our common stock has a closing bid price of $0.10 or less for 10 consecutive trading days, Nasdaq will issue a Staff Delisting Determination with the potential opportunity for us to appeal that determination.

Since the closing bid price of our common stock has not met or exceeded $1.00 per share for a minimum of 10 consecutive business days prior to the Compliance Date, we requested an additional 180 calendar day compliance period on November 6, 2023 in which to regain compliance, in which we provided written notice to Nasdaq of our intention to cure the deficiency during the second compliance period, by effecting a reverse stock split, if necessary. On November 14, 2023, we received a second notice from Nasdaq providing us with the additional 180 calendar days to regain compliance. If the Staff concludes that we will not be able to cure the deficiency, or if we do not regain compliance with the Bid Price Requirement within such additional 180 calendar day compliance period, the Staff will provide written notification to us that our common stock will be subject to delisting. At that time, we may appeal the Staff's delisting determination to a Nasdaq Listing Qualifications Panel, or the Panel. However, there can be no assurance that, if we receive a delisting notice and appeal the delisting determination by the Staff to the Panel, such appeal would be successful.

If our common stock is delisted from Nasdaq, whether because Nasdaq determines we are a "public shell", we fail to regain compliance with the bid price requirement, or otherwise, or if in the future we determine to delist our common stock, we would expect that such securities would qualify for trading over-the-counter, or OTC, in the United States on a market colloquially referred to as the "Pink Sheets." Securities quoted OTC are generally subject to lesser requirements than securities listed for trading on a U.S. national stock exchange, such as Nasdaq, including reduced corporate governance and public reporting standards. If Nasdaq should delist our common stock from trading, or if in the future we determine to delist our common stock, a reduction in some or all of the following may occur, each of which could have a material adverse effect on holders of our common stock: the liquidity of our common stock; the market price of the common stock; the number of institutional and general investors that will consider investing in the common stock; the number of investors in general that will consider investing in the common stock; the number of market makers in our common stock; the availability of information concerning the trading prices and volume of the common stock; and the number of broker-dealers willing to execute trades in our common stock. In addition to the foregoing, there are certain consequences under the Securities Act of being a public shell company, including the unavailability of Rule 144 thereunder for the resale of restricted securities and the inability to utilize Form S-8 for the registration of employee benefit plan securities.

We may become involved in litigation, including securities class action litigation, that could divert management 's attention and harm the company's business, and insurance coverage may not be sufficient to cover all costs and damages.

In the past, litigation, including securities class action litigation, has often followed certain significant business transactions, such as the sale of a company or announcement of any other strategic transaction, or the announcement of negative events, such as negative results from clinical trials. These events may also result in investigations by the SEC. We may be exposed to such litigation even if no wrongdoing occurred. Litigation is usually expensive and diverts management's attention and resources, which could adversely affect our business and cash resources and our ability to execute our strategy to capture potential milestones from licensing and collaboration agreements while maintaining the ability to consider other strategic opportunities.

Any potential changes to our leadership structure as a result of our workforce reduction and restructuring could adversely affect our business.

As a result of our decision to conduct a workforce reduction and additional restructuring, we may implement changes to our leadership and governance structure. Any personnel transition that may result could be difficult and inherently cause some loss of institutional knowledge and skills, which could negatively affect our results of operations and financial condition. Our ability to execute our business strategies may be adversely affected by the uncertainty associated with these transitions and changes to leadership and governance structures, and the time and attention of the board and management dedicated to such changes and transitions could disrupt our business. Further, we cannot guarantee that we will not face other transitions in the future. Although we generally enter into employment agreements with our executives, our executive officers may terminate their employment relationship with us at any time, and we cannot ensure that we will be able to retain the services of any of them. Our leadership's knowledge of our business and industry could be difficult to replace, and management turnover could negatively affect our business, growth, financial conditions, results of operations and cash flows.

Risks Related to Our Business, Financial Position, Capital Requirements, Managing our Growth and Other Legal Compliance Matters

We have incurred significant losses since our inception and anticipate that we will continue to incur losses for the foreseeable future. We currently have no product revenues and no approved products and will rely on our partnered IO programs to generate revenue.

We are a clinical-stage biopharmaceutical company. To date, we have not generated any commercial sales revenue, are not profitable, and have incurred losses since our inception in 2001. For the years ended December 31, 2023 and 2022, we reported net losses of $24.5 million and $33.3 million, respectively. As of December 31, 2023, we had an accumulated deficit of $315.0 million. We expect to continue to incur losses for the foreseeable future.

We have collaborations with Servier, Pfizer, and Boston Pharmaceuticals in IO. Our IO partnered programs include S095012 (PRS-344) in partnership with Servier, SGN-BB228 (PRS-346) in partnership with Pfizer, and BOS-342 (PRS-342) in partnership with Boston Pharmaceuticals, which are all currently in phase 1 studies.

In July 2023, AstraZeneca notified us of its intention to terminate the AstraZeneca Collaboration Agreement and the AstraZeneca Platform License, which terminations became effective October 15, 2023. AstraZeneca's decision to terminate these agreements was based on non-clinical safety

findings in a 13-week toxicology study of elarekibep in non-human primates. If our research and development efforts, including preclinical studies or clinical trials for any of our partnered drug candidates fail or produce unsuccessful results and those drug candidates do not gain regulatory approval, or if any of our drug candidates, if approved, fail to achieve market acceptance, we may never become profitable. In addition, the failure of one drug candidate or program may have an adverse impact on other drug candidates and programs within our class of Anticalin-based therapies. 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.

On March 27, 2024, we announced a strategy to maximize our ability to collect potential milestones from our licensing and collaboration agreements while maintaining the ability to consider other strategic opportunities. We are not developing and commercializing products and do not anticipate seeking to develop any new products with any of our existing cash or any future milestone payments we may receive. Our failure to achieve these potential milestone payments would depress the value of our company. A decline in the value of our company could also cause our stockholders to lose all or part of their investment.

In the event we determine to pursue any future product development efforts, we will need substantial additional funding to continue our operations. In that case, if we are unable to raise capital when needed, we would be forced to delay, reduce, or eliminate such product development programs or commercialization efforts.

Our operations have consumed substantial amounts of cash since our inception. Although we are not developing any drug product candidates and do not have any current plans to do so, if we determine to pursue any future product development efforts, we expect that we would incur significant research and development expenses and will need substantial additional funding.

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

To date, we have financed our operations through a mix of equity investments from private and public investors, the incurrence of debt, grant funding and the receipt of up-front and milestone payments due under our various collaboration agreements, and we may require additional financing to fund operations in order to execute our current business strategy and maintain our ability to receive some or all of the milestones from our IO partnered programs. Additional funding may not be available when or in the amounts needed, on acceptable terms, or at all.

As of the filing of this Annual Report on Form 10-K, we will be subject to the SEC general instructions of Form S-3 known as the "baby shelf rules." Under these instructions, the amount of funds we can raise through primary public offerings of securities in any 12-month period using our registration statement on Form S-3 is limited to one-third of the aggregate market value of the shares of our common stock held by non-affiliates. Therefore, we will be limited in the amount of proceeds it is able to raise by selling shares of our common stock using our Form S-3, including under the ATM Program, until such time as our public float exceeds $75 million. Furthermore, if we are deemed to be a shell company, the baby shelf rules, and therefore our Form S-3, would not be available to us.

Our ability to secure additional funding could be significantly impacted by a multitude of events that are beyond our control, including, but not limited to, changes in the macroeconomic environment and other events affecting the stock market, including the availability of research and other information, favorable or unfavorable, published by securities or industry analysts and news agencies.

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

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

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

Due to our operations outside of the United States, we are exposed to market risk related to changes in foreign currency exchange rates. Changes in the relative values of currencies occur regularly and, in some instances, could materially adversely affect our business, our financial condition, the results of our operations or our cash flows. Our operating results may be affected by volatility in currency exchange rates and our ability to effectively manage our currency transaction risks. Our reporting currency is the U.S. dollar, however, 81% of our operating expenses and all of our revenues are recorded in non-U.S. entities. As such, our financial statements are translated for reporting purposes as follows: (1) asset and liability accounts at year-end rates, (2) income statement accounts at weighted average exchange rates for the year and (3) stockholders' equity accounts at historical rates. Corresponding translation gains or losses are recorded in stockholders' equity.

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

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

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

We are subject to anti-corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures and legal expenses, which could adversely affect our business, results of operations and financial condition.

Our operations are subject to anti-corruption laws, including the FCPA, and other anti-corruption laws that apply in countries where we do business and may do business in the future. The FCPA and these other laws generally prohibit us, our officers, and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. We may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the FCPA or local anti-corruption laws.

There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the FCPA, or other legal requirements, including Trade Control laws. If we are not in compliance with the FCPA and other anti-corruption laws or Trade Control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. Likewise, any investigation of any potential violations of the FCPA, other anti-corruption laws or Trade Control laws by U.S. or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition.

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

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

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

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

As of December 31, 2023, we had net operating loss carryforwards for United States federal income tax purposes of $43.4 million and net operating loss carryforwards for state income tax purposes of $46.7 million. Tax loss carryforwards that were generated prior to December 31, 2017 expire through 2037; U.S. federal tax loss carryforwards generated after that date do not expire. State loss carryforwards expire starting in 2035. In the United States, utilization of the net operating loss carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, and similar state provisions due to ownership change limitations that have occurred previously or that could occur in the future. These ownership changes may limit the amount of net operating loss carryforwards that can be utilized annually to offset future taxable income and tax, respectively. If we were to lose the benefits of these loss carryforwards, our future earnings and cash resources would be materially and adversely affected. We completed a Section 382 study through December 31, 2020. Based on the study, we underwent an ownership change for Section 382 purposes which occurred in February 2018. As a result of the ownership change, our net operating loss and tax credit carryforwards as of the ownership change dates are subject to limitation under Section 382; however, these limitations are not expected to result in any of the impacted net operating loss and tax credit carryforwards to expire unutilized. Any net operating losses or tax credits generated after the February 2018 change are not subject to this annual limitation. However, subsequent ownership changes, as defined by Section 382, may potentially further limit the amount of net operating loss and tax credit carryforwards that could be utilized to offset future taxable income and tax.

As of December 31, 2023, we had German corporate income tax and trade tax net operating loss carryforwards of approximately $187.6 million and $183.7 million, respectively, which may be used to reduce our future taxable income in Germany. Under current German laws, tax loss carryforwards may only be used to offset any relevant later assessment period (calendar year) by $1.2 million plus 60% of the exceeding taxable income and trade profit of such period and do not expire. In addition, certain transactions, including transfers of shares or interest in the loss holding entity, may result in the partial or total forfeiture of tax losses existing at that date. Partial or total forfeiture of tax losses may further occur in corporate reorganizations of the loss holding entity.

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

Despite the implementation of security measures, our internal computer systems and those of our contractors and consultants are vulnerable to damage from computer viruses, hacking, ransomware, cyber-attacks, unauthorized access as well as telecommunication and electrical failures. Our information technology and other internal infrastructure systems, including corporate firewalls, servers, leased lines and connection to the Internet, face the risk of systemic failure that could materially disrupt our operations. Although we have invested significant resources to enhance the security of our computer systems, there can be no assurances we will not experience unauthorized intrusions into our computer systems, or those of our CROs, vendors, contractors and consultants, that we will successfully detect future unauthorized intrusions in a timely manner or that future unauthorized intrusions will not result in material adverse effects on our financial condition, reputation or business prospects.

While we have not experienced any such material 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 impact on our business. In addition certain data security breaches must be reported to affected individuals and the government, and in some cases to the media, under provisions of HIPAA, other U.S. federal and state law and requirements of non-U.S. jurisdictions, and financial penalties may also apply. 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.

We are also vulnerable to accidents, electrical blackouts, labor strikes, terrorist activities, war, natural disasters, adverse public health events and other events beyond our control, and we have not undertaken a systematic analysis of the potential consequences to our business as a result of all of such events and do not have an applicable recovery plan in place. Any disruption to our operations or the operations of our collaborators from these kinds of events would likely impact our operating results and financial condition.

Although we carry insurance to protect us against some losses or damages resulting from certain types of disasters, the extent of that insurance is limited in scope and amount, and we cannot assure you that our insurance coverage will be sufficient to satisfy any damages and losses. Any business interruption may have a material adverse effect on our business, financial position, results of operations, and prospects.

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

We are subject to data protection laws and regulations that address privacy and data security. The legislative and regulatory landscape for data protection continues to evolve, and there has been an increasing focus on privacy and data security issues with the potential to affect our business. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws and federal and state consumer protection laws govern the collection, use, disclosure and protection of health-related and other personal information. Failure to comply with data protection laws and regulations could result in government enforcement actions, which could include civil or criminal penalties, private litigation and/or adverse publicity and could negatively affect our operating results and business. For example, California enacted the California Consumer Privacy Act, or CCPA, which went into effect in January 2020. The CCPA creates data privacy obligations for covered businesses and establishes data privacy rights for California residents, including the right to opt out of certain disclosures of their information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches. Additionally, California voters passed the California Privacy Rights Act, or CPRA, which became effective January 1, 2023. The CPRA significantly amends the CCPA, and imposes additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive personal information. The CPRA also established a new regulatory authority, the California Privacy Protection Agency, which is tasked with enacting new regulations under the CPRA and will have expanded enforcement authority, which may result in increased privacy and information security enforcement in California. In addition to California, more U.S. states are enacting similar consumer privacy legislation, increasing compliance complexity and increasing risks of failures to comply. As of 2023, Virginia, Colorado, Connecticut and Utah enacted similar comprehensive data protection laws. Additional consumer privacy laws have also been enacted in Delaware, Indiana, Iowa, Montana, New Jersey, Oregon, Tennessee, and Texas, which laws will take effect over the next three years.

Numerous other countries have, or are developing, laws governing the collection, use and transmission of personal information as well. For example, the European Union's General Data Protection Regulation, or GDPR, which took effect in 2018, imposed a broad data protection framework that expanded the scope of data protection law across the European Union and European Economic Area ("EEA") and can apply to non-EU entities that process, or control the processing of, personal data relating to individuals located in the EEA, including clinical trial data. The GDPR sets out a number of requirements that must be complied with when handling the personal data of EEA-based data subjects, including: providing expanded disclosures about how their personal data will be used; higher standards for organizations to demonstrate that they have obtained valid consent or have another legal basis to justify their data processing activities; the obligation to appoint data protection officers in certain circumstances; new rights for individuals to be "forgotten" and rights to data portability; an expansion of data subject rights with respect to access and control over their personal data (e.g., access requests); requirements for demonstrating compliance through policies, procedures, training and audit; and a new mandatory data breach reporting and notification regime. In particular, medical or health data, genetic data and biometric data are all classified as "special category" data under the GDPR and are therefore subject to additional compliance obligations. Further, EEA member states have a broad right to impose additional conditions—including restrictions—on these data categories in connection with permitted derogations from the requirements of the GDPR mainly in regard to specific processing situations (including special category data and processing for scientific or statistical purposes). We are subject to the GDPR and the German federal data privacy law, the Bundesdatenschutzgesetz, and we are subject to the regulatory authority of the Bavarian data protection authority, the BayLDA. As the EU states continue to reframe their national legislation to harmonize with the GDPR, we will monitor compliance with all relevant EU member states' laws and regulations, including where permitted derogation from the GDPR are introduced.

We are also subject to evolving EU laws on data export since we transfer data to countries outside of the EEA, including the United States and United Kingdom, to ourselves or third parties. The GDPR only permits exports of data outside of the EEA where there is a suitable data transfer mechanism in place to safeguard personal data (e.g., the EU Commission approved Standard Contractual Clauses). On July 16, 2020, the Court of Justice of the EU, or the CJEU, issued a landmark opinion in the case Maximilian Schrems vs. Facebook (Case C-311/18) (Schrems II). This decision calls into question certain data transfer mechanisms as between the EU member states and the US. The CJEU is the highest court in Europe and the Schrems II decision heightens the burden on data importers to assess U.S. national security laws on their business and to evaluate risks of potential fines and penalties and/or data transfers from the EU being halted. On July 10, 2023, the EU Commission adopted an adequacy decision for a new mechanism for transferring data from the EU to the United States – the EU-US Data Privacy Framework (the "Framework"). The Framework provides EU individuals with several new rights, including the right to obtain access to their data, or obtain correction or deletion of incorrect or unlawfully handled data. The adequacy decision followed the signing of an executive order introducing new binding safeguards to address the points raised in the Schrems II decision. Notably, the new obligations were geared to ensure that data can be accessed by US intelligence agencies only to the extent necessary and proportionate and to establish an independent and impartial redress mechanism to handle complaints from Europeans concerning the collection of their data for national security purposes. The EU Commission will continually review developments in the US along with its adequacy decision. Adequacy decisions can be adapted or even withdrawn in the event of developments affecting the level of protection in the applicable jurisdiction. Future actions of EU data protection authorities are difficult to predict. Reliance on the Framework to enable cross-border transfers without certain contractual and other representations is dependent upon certification to the Framework, which we have not yet done.

If we have to rely on third parties to carry out services for us, including processing personal data on our behalf, we are required under GDPR to enter into contractual arrangements to help ensure that these third parties only process such data according to our instructions and have sufficient security measures in place. Any security breach or non-compliance with our contractual terms or breach of applicable law by such third parties could result in enforcement actions, litigation, fines and penalties or adverse publicity and could harm consumer confidence in us, which would have an adverse impact on our reputation and business. Any contractual arrangements requiring the processing of personal data from the EEA to us in the United States will require greater scrutiny and assessments as required under Schrems II and may have an adverse impact on cross-border transfers of personal data, or increase costs of compliance. The GDPR provides an enforcement authority to impose large penalties for noncompliance, including the potential for fines of up to €20 million or 4% of total global turnover from the preceding fiscal year of the noncompliant company, whichever is greater.

Applicable data privacy and data protection laws may conflict with each other, and by complying with the laws or regulations of one jurisdiction, we cannot be assured of compliance with the laws or regulations of another jurisdiction. Despite our efforts, we may not have fully complied in the past and may not in the future. That could require us to incur significant expenses, which could significantly affect our business. Failure to comply with data protection laws may expose us to risk of enforcement actions taken by data protection authorities or other regulatory agencies, private rights of action in some jurisdictions, and potential significant fines and penalties if we are found to be non-compliant.

Furthermore, the number of government investigations related to data security incidents and privacy violations continues to increase and government investigations typically require significant resources and generate negative publicity, which could harm our business and reputation.

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

We are subject to income and other taxes in the United States and foreign jurisdictions. Changes in laws and policy relating to taxes or trade may have an adverse effect on our business, financial condition and results of operations. This Annual Report on Form 10-K does not discuss any such tax legislation or changes to tax laws and regulations, or the manner in which it might affect us or purchasers of our securities. We urge our investors to consult with their legal and tax advisors with respect to such legislation and the potential tax consequences of investing in our securities.

We are also subject to different tax regulations in each of the jurisdictions where we conduct our business or where our management is located. We expect the scope and extent of regulation in the jurisdictions in which we conduct our business, or where our management is located, as well as regulatory oversight and supervision, to generally continue to increase. Generally, future changes in applicable U.S. or foreign tax laws and regulations, or their interpretation and application could have an adverse effect on our business, financial conditions and results of operations.

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

We could be subject to product liability lawsuits if any drug candidate we develop allegedly causes injury or is found to be otherwise unsuitable for human use during product testing, manufacturing, marketing or sale. Any such product liability claim may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities. Even successful defense would require significant financial and management resources.

Regardless of merit or eventual outcome, liability claims may result in, among other things, reduced resources of our management to pursue our business strategy, injury to our reputation and significant negative media attention, significant costs to defend the related litigation, substantial monetary awards to clinical trial participants or patients, and increased insurance costs.

While we currently carry insurance in an amount and on terms and conditions that are customary for similarly situated companies and that are satisfactory to our board of directors, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer.

Risks Related to the Development and Commercialization of Our Drug Candidates

Although we have in the past depended heavily on the success of our drug candidates and programs, we do not have any product candidates currently in active development. Future clinical trials, if any, may not be successful and we cannot be certain that we will receive regulatory approvals or be able to successfully commercialize our products even if we receive regulatory approvals.

We currently have no products that are approved for commercial sale, and do not have plans to independently develop any drug product candidates. All of our IO drug candidates are being developed in partnership with our collaborators. Accordingly, our business is currently substantially dependent on the successful development, clinical testing, regulatory approval and commercialization of our partnered programs, which may never occur. For example, in July 2023 AstraZeneca notified us of its intention to terminate the AstraZeneca Collaboration Agreement and the AstraZeneca Platform License, which terminations became effective October 15, 2023. AstraZeneca's decision to terminate these agreements was based on non-clinical safety findings in a 13-week toxicology study of elarekibep in non-human primates.

In order for us to achieve potential milestones or royalties from our partnered programs, our partners must complete some or all of the following activities, any one of which may not be successfully completed:

- conduct additional preclinical and clinical development with successful outcomes;
- manage preclinical, manufacturing and clinical activities;
- obtain regulatory approval from the FDA and other comparable foreign regulatory authorities;
- establish manufacturing relationships for the clinical and post-approval supply of the applicable drug candidate in compliance with all regulatory requirements;
- build a commercial sales and marketing team, either internally or by contract with third parties;
- establish and maintain patent and trade secret protection or regulatory exclusivity for our product candidates;
- develop and implement marketing strategies for successful commercial launch of our product candidates, if and when approved;
- secure acceptance of our products, if and when approved, by patients, from the relevant medical communities and from third-party payors;
- compete effectively with other therapies;
- establish and maintain adequate health care coverage and reimbursement;
- ensure continued compliance with any post-marketing requirements imposed by regulatory authorities, including any required post-marketing clinical trials or the elements of any post-marketing REMS that may be required by the FDA or comparable requirements in other jurisdictions to ensure the benefits of the product outweigh its risks;
- maintain continued acceptable safety profile of the product candidates following approval; and
- invest significant additional cash in each of the above activities.

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

Clinical testing of our IO partnered programs is ongoing, while clinical testing for other IO programs, for example the preclinical programs with Pfizer, have not yet commenced, and the results of any future clinical trials or preclinical studies of these programs, if unsuccessful, could lead to abandonment of the development of those drug candidates. If studies of these drug candidates produce unsuccessful results and our partners are forced or elect to cease their development, our business and prospects could be substantially harmed.

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

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

We have entered into license, partnership and option arrangements, such as with Servier, Pfizer, and Boston Pharmaceuticals, relating to certain drug candidates and we may continue to do so in the future. Under some of these arrangements, the development of some of those drug candidates has been, or in the future may be, conducted wholly by such partners or third parties with which the partners contract. As a result, we have not been or may not be closely involved with or have any control over those development activities. Although some of our partners have provided information regarding those drug candidates and the related studies conducted to date, including data that has been included in our Annual Reports on Form 10-K, we have not received and may not receive in the future, comprehensive information regarding all of those development activities, including the raw data from certain studies that have been conducted, information regarding the design, procedural implementation and structure and information regarding the manufacture of the drug candidates used in the studies. Because we may have limited or no input on the development of these drug candidates, we may discover that all or certain elements of the trials and studies our partners have performed have not been, or may not in the future be, in compliance with applicable regulatory standards or have otherwise been or may be deficient, and that advancement of the development of these drug candidates on the basis of those trials and studies is not warranted.

Further, the majority of our development activities for each of our drug candidates, and any future clinical trials, have been, are being or may in the future be conducted in whole or in part outside of the United States, including in Europe, Australia or Asia. Our partners may also conduct future development activities in other countries or regions. As a result, although those studies may meet the standards of applicable foreign regulatory bodies, the structure and design of those clinical trials and preclinical studies may not meet applicable FDA requirements and also may not meet the requirements of the applicable regulatory authorities in other foreign countries in which we desire to pursue marketing approval.

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

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

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

For example, in June 2023, AstraZeneca communicated to us its decision to discontinue and cease dosing in the ongoing clinical studies of elarekibep. This decision was based on lung findings from a non-clinical 13-week GLP toxicology study with dry powder inhaler-formulated elarekibep, which did not support long-term use and progression to later-stage development. The 13-week non-human primate study included three active dose cohorts. AstraZeneca concluded that there were no clinical observations across any of the doses but that there were respiratory tract pathology findings. These findings included inflammation-mediated lung tissue damage, which did not appear to be dose related. AstraZeneca's decision was made independent of any data from the Phase 2a study. In July 2023, AstraZeneca notified us of its intention to terminate the AstraZeneca Collaboration Agreement and the AstraZeneca Platform License, which terminations became effective October 15, 2023. AstraZeneca's decision to terminate these agreements was based on non-clinical safety findings in a 13-week toxicology study of elarekibep in non-human primate.

Clinical trials may also be delayed, suspended or prematurely terminated for a variety of other reasons, such as:

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

Further, our partners may also encounter delays if a clinical trial is suspended or terminated by us, by any IRB or ethics committee, by a Data Safety Monitoring Board, or DSMB, or by the FDA, EMA, MHRA, or other regulatory authority. A suspension or termination may occur 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, MHRA or other regulatory authorities, exposing participants to health risks caused by unforeseen safety issues or adverse side effects, development of previously unseen safety issues, failure to demonstrate a benefit from using a drug candidate or changes in governmental regulations or administrative actions. We cannot predict with any certainty the schedule for commencement or completion of any currently ongoing, planned or future clinical trials.

If our partners 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 ability to and ability to realize milestones or royalties. The occurrence of any of these events could harm our business, financial condition, results of operations and prospects significantly.

Risks Related to Our Dependence on Third Parties

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-based technology are governed by the licensing and collaboration agreements we enter into with those partners. Our collaborators may include assumptions, understandings or agreements that are not included in our agreements with them, or that are inaccurately or incompletely represented by their terms. In addition, key terms in such agreements may be misunderstood or contested, even when we and the other party previously believed that we both had a mutual understanding of such terms.

Any differences in interpretation or misunderstandings between us and other parties may result in substantial costs, and may negatively impact our revenues and operating results. Partners may fail to develop the drug candidates with the diligence or under the timeline or in the manner we anticipated, and results may differ from the terms upon which we had agreed. 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.

We depend on third parties and may to continue to license or collaborate with third parties, and events involving these strategic partners or any future collaboration could delay or prevent development or commercialization of drug products.

Our business strategy, along with our short- and long-term operating results, depend in part on our ability to execute on existing strategic collaborations and to license or partner with new strategic partners. We have entered into and may in the future to enter into collaborative arrangements with both U.S.-based and foreign pharmaceutical and drug development companies, which will lead or otherwise collaborate with us or assist us in the development, manufacturing and marketing of our drug products. We believe collaborations allow us to leverage our resources and technologies and we may derive some revenues from research and development fees, license fees, milestone payments, and royalties from our collaborative partners.

Our prospects, therefore, may depend to some extent upon our ability to attract and retain collaborative partners. We have limited control over the amount and timing of resources that our current collaborators or any future collaborators devote to our collaborations or potential products, in particular with respect to our collaborations with Servier for the development of S095012, with Boston Pharmaceuticals for the development of BOS-342, with Pfizer for the development of SGN-BB228 and other programs. These collaborators may breach or terminate their agreements with us or otherwise fail to conduct their collaborative activities successfully and in a timely and reasonable manner. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new, amended or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology. Further, our collaborators may not develop or commercialize products that arise out of our collaborative arrangements or devote sufficient resources to the development, manufacturing, marketing or sale of these products. In addition, our collaborative partners may have the right to guide strategy regarding prosecution of relevant patent applications, abandon research projects and/or terminate applicable agreements, including funding obligations, prior to or upon the expiration of the agreed-upon research terms.

Our collaborators may also decide to terminate these agreements based on findings in our clinical trials. For example, in July 2023, AstraZeneca notified us of its intention to terminate the AstraZeneca Collaboration Agreement and the AstraZeneca Platform License, effective October 15, 2023. AstraZeneca's decision to terminate the AstraZeneca Agreements was based on non-clinical safety findings in a 13-week toxicology study of elarekibep in non-human primates.

By entering into such collaborations, we may forego opportunities to collaborate with other third parties who do not wish to be associated with our existing third-party strategic partners. In the event of termination of a collaboration agreement, termination negotiations may result in less than favorable terms.

There can be no assurance that we will be successful in establishing collaborative arrangements on acceptable terms or at all, that collaborative partners will not terminate funding before the completion of projects, that our collaborative arrangements will result in successful product commercialization, or that we will derive any revenues from such arrangements. Potential collaborators may reject collaborations based upon their assessment of our financial, regulatory or intellectual property position and our internal capabilities. Additionally, the negotiation, documentation and implementation of collaborative arrangements are complex and time-consuming. Any discussions with potential collaborators may not lead to new collaborations on favorable terms and may have the potential to provide collaborators with access to our key intellectual property rights.

Our success depends in part on the efforts of our current and possible future collaborators, who will likely have substantial control and discretion over the continued development and commercialization of drug candidates that are the subject of our collaborations.

Our current collaborators and future collaborators will have significant discretion in determining the effort and amount of resources that they dedicate to our collaborations. Our collaborators may determine not to proceed with clinical development or commercialization of a particular drug candidate for a number of reasons that are beyond our control, even under circumstances where we might have continued such a program, currently including BOS-342, SGN-BB228 and S095012. In addition, our rights to receive milestone payments and royalties from our collaborators will depend in part on our collaborators' abilities to establish the safety and efficacy of our drug candidates, obtain regulatory approvals and achieve market acceptance of products developed from our drug candidates. We may also depend on our collaborators to manufacture clinical scale quantities of some of our drug candidates and, possibly, for commercial scale manufacture, distribution, marketing and sales. Our collaborators may not be successful in manufacturing our drug candidates or successfully commercializing them.

We face additional risks in connection with our existing and future collaborations, including the following:

- our collaborators may develop and commercialize, either alone or with others, products that are similar to or competitive with the products that are the subject of the collaboration with us;
- our collaborators may underfund, not commit sufficient resources to, or conduct in an unsatisfactory manner the development, testing, marketing, distribution or sale of our drug candidates;
- our collaborators may not properly maintain or defend our intellectual property rights or utilize our proprietary information in such a way as to invite litigation that could jeopardize or potentially invalidate our intellectual property or proprietary information or expose us to potential liability;
- our collaborators may encounter conflicts of interest, changes in business strategy or other business issues that could adversely affect their willingness or ability to fulfill their obligations to us (for example, pharmaceutical and biotechnology companies historically have re-evaluated their priorities following mergers and consolidations, which have been common in recent years in these industries);
- we do not control the conduct and communications of our collaborators, and, thus, we are subject to the risk that their actions may negatively impact our reputation and potentially harm our business;
- disputes may arise between us and our collaborators delaying or terminating the research, development, manufacture or commercialization of our drug candidates, resulting in significant litigation or arbitration that could be time-consuming and expensive, or causing collaborators to act in their own self-interest and not in the interest of our stockholders;
- we might not have the financial or human resources to meet our obligations or take advantage of our rights under the terms of our existing and future collaborations; and
- our existing collaborators may exercise their respective rights to terminate their collaborations with us without cause, in which event, we do not currently expect to be able to complete development and commercialization of such drug candidates on our own.

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

Part of our strategy is to partner with, or out-license selective products to, other pharmaceutical companies in order to mitigate the cost of developing a drug through clinical trials to commercialization. For example, in July 2023, AstraZeneca notified us of its intention to terminate the AstraZeneca Collaboration Agreement and the AstraZeneca Platform License, effective October 15, 2023. AstraZeneca's decision to terminate the AstraZeneca Agreements was based on non-clinical safety findings in a 13-week toxicology study of elarekibep in non-human primates. If our collaboration with other similar partners is not successful, our future revenues and business will be harmed.

We may not receive any further milestone, royalty or license payments under our current collaborations.

Although we have received upfront, milestone and other payments to date under our current drug development collaborations, we may not receive any royalty payments or additional license and milestone fees under such agreements. In general, our receipt of milestone, royalty or license payments depends on many factors, including whether our collaborators want and are able to continue to pursue potential drug candidates, intellectual property issues, the approval of biosimilars, unforeseen complications in the development or commercialization process, and the ultimate commercial success of the drugs.

Risks Related to Our Intellectual Property

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

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

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

We and TUM initiated discussions in the second quarter of 2018, and may enter into an amendment to our license agreement in the future, to clarify, expand and restructure the TUM License, including the parties' obligations under such license agreement. The contemplated amendment relates to revised commercial terms. We recorded the probable expected impact of the amendment in research and development expense in 2019, although the final expense could be different than what we currently have recorded.

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

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

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

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

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

- the degree and range of protection any patents will afford us against competitors, including whether third parties will find ways to make, use, sell, offer to sell or import competitive products without infringing our patents;
- if and when patents will be issued;
- how laws in the various jurisdictions, such as the USPTO or the European Patent Office, or the EPO, will change thus affecting our ability to obtain patents or maintain and enforce existing patents;
- whether or not others will obtain patents claiming inventions similar to those covered by our patents and patent applications; or
- whether we will need to initiate litigation or administrative proceedings (for example, at the USPTO or the EPO) in connection with patent rights, which may be costly whether we win or lose.

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

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

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

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

Our partnered drug candidates, may infringe or be accused of infringing a patent or other form of intellectual property under which we do not hold a license or other rights. Third parties may assert that we are employing their proprietary technology without authorization.

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

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

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

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

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

Competitors may infringe our patents or the patents of our current or potential licensors. To attempt to stop infringement or unauthorized use, we may need to enforce one or more of our patents, which can distract our management and divert our limited time and resources. Our standing to enforce such patents may sometimes be dependent on the licensor joining such suit, and a licensor's failure to join such suit may prevent us from enforcing the patent. If we pursue any litigation, a court may decide that a patent of ours or any of our licensors' is not valid or is unenforceable or may refuse to stop the other party from using the relevant technology on the grounds that our patents do not cover the technology in question. Further, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, which could reduce the likelihood of success of, or the amount of damages that could be awarded resulting from, any infringement proceeding we pursue in any such jurisdiction. An adverse result in any infringement litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing, which could limit our ability to exclude competitors from directly competing with us in those jurisdictions.

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

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

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

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

Furthermore, issued patents and pending applications require regular maintenance. Failure to maintain our portfolio may result in loss of rights that may adversely impact our intellectual property rights, such as rendering issued patents unenforceable or terminating pending applications prematurely.

In addition, under the European Union regulation on classification, labeling and packaging of substances and mixtures, and under other regulations in the United States or other countries related to the clinical development of our drug candidates (including, for example, submissions to regulatory authorities such as the FDA and EMA as well as submissions related to obtaining a non-proprietary, or INN and USAN, name for our clinical drug candidates to the World Health Organization, and United States Adopted Name Council, or the USAN Council), we or our partners may be required to publicly disclose the composition of our proprietary products or substances, which may facilitate infringement or avoidance of our intellectual property by third parties and may potentially reduce the margin we are able to charge for our products by allowing competitors to more accurately determine our production costs. Future development of these regulations may have a further negative impact on our revenues and a substantial negative impact on our business.

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

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

Risks Related to Our Personnel

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

We continue to rely on a limited number of employees and may rely on external consultants in the future for the operation of the company. Any of these employees or external consultants may terminate their relationship with us at any time. We may not be able to attract and retain consultants on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. Any future consultant or advisor may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. We do not maintain “key person” insurance on any of our employees or consultants.

In addition, our industry tends to experience a high rate of turnover of management personnel and our employees are generally able to terminate their relationships with us on short notice. Pursuant to German employment law, our employment arrangements with employees of Pieris GmbH are governed by employment contracts, which provide certain defined terms for either party to terminate the employment relationship.

Furthermore, to the extent we pursue any strategic opportunities, our ability to consummate such opportunities depends upon our ability to retain our employees and consultants required to consummate such a transaction, the loss of whose services may adversely impact the ability to consummate such transaction.

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

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

In contrast, in Germany, there is no analogous doctrine of “employment at will.” By law, German employees must have written employment contracts that reflect the key aspects of the employment relationship. Our relations between German employers and employees are extensively regulated under German labor and employment laws and regulations. Employment relationships may be terminated for cause without observing the ordinary notice period. If terminated without cause, the applicable ordinary notice period must be observed. German employees have special protection against dismissals provided the employee has been employed by a company for more than six months and such company employs more than 10 full-time employees.

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

- the employer must observe the applicable notice period, which is ordinarily determined by law (between four weeks and seven months, depending upon the length of employment, though it is possible for the notice period to be two weeks, if a probationary period, lasting up to the first six months of employment, is agreed upon), if a longer period is not otherwise agreed by the parties, and has to deliver a written notice of termination to the employee;
- for companies with more than 10 full-time 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 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 30 calendar day period, prior written notification to the German employment office is required.

In July 2023, we conducted a reduction in force that impacted 70% of our employees, and in March 2024 we announced additional measures that would result in a further reduction in workforce that is intended to be implemented in the second quarter of 2024. In this regard, if we downsize for any reason and fail to adhere to the complex requirements articulated by the employee protection law, we could face legal actions brought by affected employees or former employees, and, as a result, we may incur operational or financial losses and divert the attention of our executive officers from managing our business.

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

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

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

Our employees, independent contractors, principal investigators, CROs, consultants, or vendors 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 that our employees, independent contractors, principal investigators, contract research organizations, or CROs, consultants, or vendors may engage in fraudulent or other illegal activity. Misconduct by any of these parties could include intentional, reckless, and/or negligent conduct that may include failures to comply with FDA, MHRA, EMA or other foreign jurisdiction regulations, provide accurate information to the FDA, MHRA, EMA or their comparable foreign equivalents, 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 and other third-party 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 misconduct by our employees and other third parties, and the precautions and procedures we currently take or may establish in the future as our operations and employee and third-party 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 to be in compliance 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 civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid, and other federal healthcare programs, contractual damages, reputational harm, diminished potential profits and future earnings, and curtailment of our operations.

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

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

Risks Related to the Ownership of Our Common Stock

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

Market prices for shares of biotechnology companies such as ours are often volatile. Thus, the quoted price of our common stock has been, and is likely to continue 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 timing and amount of potential milestone payments that we may receive from Pfizer, Boston Pharmaceuticals, and Servier;
- additions or departures of key scientific or management personnel;
- changes in laws or regulations applicable to our drug candidates, including without limitation clinical trial requirements for approvals;
- the perception of the pharmaceutical and biotechnology industry by the public, legislatures, regulators and the investment community;
- disputes or other developments relating to patents and other proprietary rights and our ability to obtain patent protection for our drug candidates;
- significant lawsuits, including patent and stockholder class action litigation;
- our potential inability to maintain the listing of our common stock on the Nasdaq Capital Market;
- actual or anticipated variations in quarterly operating results;
- failure to meet or exceed the estimates and projections of the investment community;
- overall performance of the equity markets and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies;
- conditions or trends in the biotechnology and biopharmaceutical industries;
- introduction of new products by our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- issuances of debt or equity securities;
- execution, cost and timing of our reduction in force and operations;
- sales of our common stock by us or our stockholders in the future, or the perception that such sales could occur;
- trading volume of our common stock;
- ineffectiveness of our internal control over financial reporting or disclosure controls and procedures;
- general political and economic conditions;
- effects of natural or man-made catastrophic events; and
- other events or factors, many of which are beyond our control.

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

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

Our management has considerable discretion in the application of our cash, cash equivalents and investments, including the fees and milestone payments from our collaborations and the net proceeds of our securities offerings. As a result, investors will be relying upon management's judgment with only limited information about our specific intentions for the use of the cash, cash equivalents and investments. We may use the cash, cash equivalents and investments for purposes that do not yield a significant return or any return at all for our stockholders. In addition, pending their use, we may invest the financial resources from our collaborations and securities offerings in a manner that does not produce income or that loses value. We may also use the cash to pay out dividends to stockholders if we determine that there is sufficient cash and investments to achieve our near and long-term objectives.

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. If only a few securities or industry analysts commence coverage of our company, the trading price for our stock would likely be negatively affected and there can be no assurance that analysts will provide favorable coverage. If securities or industry analysts who initiate coverage downgrade our stock or publish inaccurate or unfavorable research about our business or our market, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and any trading volume to decline.

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

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting. However, as we remain a smaller reporting company with less than $100 million in revenue, we are not currently required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm.

If we cannot favorably assess 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.

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

We were previously deemed a "shell company" under applicable SEC rules and regulations, prior to the reverse merger transaction in which we became a public company, 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. Sales of the restricted securities of a former shell company, such as us, are not permitted pursuant to Rule 144 of the Securities Act, unless at the time of a proposed sale, (i) we are subject to the reporting requirements of Section 13 or 15(d) of the Exchange Act; and (ii) we have filed all reports and other materials required to be filed by Section 13 or 15(d) of the Exchange Act, as applicable, during the preceding 12 months, other than current reports on Form 8-K. Additionally, our previous status as a shell company could also limit our use of our securities to pay for any acquisitions we may seek to pursue in the future. The lack of liquidity of our securities as a result of the inability to sell under Rule 144 for a longer period of time than a non-former shell company could cause the market price of our securities to decline.

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

Our Amended and Restated Articles of Incorporation authorize the issuance of up to 300,000,000 shares of our common stock and up to 10,000,000 shares of preferred stock with the terms, limitations, voting rights, relative rights and preferences and variations of each series that our Board of Directors may determine from time to time. Possible business and financial uses for our authorized capital stock include, without limitation, equity financing, future stock splits, acquiring other companies, businesses or products in exchange for shares of our capital stock, issuing shares of our capital stock to partners or other collaborators in connection with strategic alliances, attracting and retaining employees by the issuance of additional securities under our equity compensation plan, or other transactions and corporate purposes that our Board of Directors deems are in the interests of our company. Furthermore, issuances of shares of our capital stock could have the effect of delaying or preventing changes in control or our management. Any future issuances of shares of our capital stock may not be made on favorable terms or at all, they may have rights, preferences and privileges that are superior to those of our common stock and may have an adverse effect on our business or the trading price of our common stock. The issuance of any additional shares of our common stock will reduce the book value per share and may contribute to a reduction in the market price of the outstanding shares of our common stock. Additionally, any such issuance will reduce the proportionate ownership and voting power of all of our current stockholders.

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

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. As of December 31, 2023, a total of 98,935,025 shares of our common stock were outstanding. Any sales of those shares or any perception in the market that such sales may occur could cause the trading price of our common stock to decline.

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

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

The sale, or availability for sale, of our common stock in the public market may adversely affect the prevailing market price of our common stock and may impair our ability to raise additional equity capital. Pursuant to registration statements filed with the SEC, we previously registered for resale shares of our common stock, which included all of the shares of our common stock issued in our private placements and in connection with the closing of the reverse merger transaction in which we became a public company. For example, in March 2021, we registered for resale 3,706,174 shares of common stock in connection with a private placement transaction with Pfizer, and 3,584,320 shares of common stock in connection with a private placement transaction with AstraZeneca. The resale registration statements permit the resale of these shares at any time without restriction.

The resale of a substantial number of shares of our common stock in the public market could adversely affect the market price for our common stock and make it more difficult for investors to sell shares of our common stock at times and prices that investors feel are appropriate. Furthermore, because there are a large number of shares registered pursuant to the resale registration statements, we may continue to offer shares covered by the resale registration statements for a significant period of time, the precise duration of which cannot be predicted. Accordingly, the adverse market and price pressures resulting from an offering pursuant to the resale registration statement may continue for an extended period of time and continued negative pressure on the market price of our common stock could have a material adverse effect on our ability to raise additional equity capital, if we seek to do so in the future.

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.

If we seek to raise capital in the future, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner, in which we may determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors in a prior transaction may be materially diluted. Additionally, new investors could gain rights, preferences and privileges senior to those of existing holders of our common stock. Further, any future sales of our common stock by us or resales of our common stock by our existing stockholders could cause the market price of our common stock to decline.

As of December 31, 2023, there were 9,284,808 shares reserved for future issuance under our equity compensation plans, and 14,803,071 shares reserved for issuance upon the exercise of outstanding equity awards. Pursuant to our 2023 Employee Stock Purchase Plan, we are authorized to sell 750,000 shares to our employees. Any future grants of options, warrants or other securities exercisable or convertible into our common stock, or the exercise or conversion of such shares, and any sales of such shares in the market, could have an adverse effect on the market price of our common stock.

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

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

These provisions provide, among other things:

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

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

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

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

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

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

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

We believe the choice-of-forum provision in our Amended and Restated Articles of Incorporation will help provide for the orderly, efficient and cost-effective resolution of Nevada-law issues affecting us by designating courts located in the State of Nevada (our state of incorporation) as the exclusive forum for cases involving such issues. However, this provision may limit a stockholder's ability to bring a claim in a judicial forum that it believes to be favorable for disputes with us or our directors, officers, employees or agents, which may discourage such actions against us and our directors, officers, employees and agents. While we are not aware of any Nevada case law addressing the enforceability of this type of provision, Nevada courts have on prior occasion found persuasive authority in Delaware case law in the absence of Nevada statutory or case law specifically addressing an issue of corporate law. The Court of Chancery of the State of Delaware ruled in June 2013 that choice-of-forum provisions of a type similar to those included in our Amended and Restated Articles of Incorporation are not facially invalid under corporate law and constitute valid and enforceable contractual forum selection clauses. However, if a court were to find the choice-of-forum provision in our Amended and Restated Articles of Incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition or results of operations.

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

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

Our Board of Directors may, at their sole discretion, elect to pay cash dividends on our capital stock .

We have never declared or paid any cash dividends on our common stock. We may pay out dividends to stockholders if it is determined that there is sufficient cash and investments to achieve our near and long-term objectives. We may choose to retain all future earnings to fund strategic opportunities in the future. Any future payment of cash dividends 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.

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

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

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

We have in the past issued, and we may at any time in the future issue, shares of preferred stock. In connection with our June 2016 private placement, we issued 4,963 shares of our Series A convertible preferred stock to certain affiliates of Biotechnology Value Fund, L.P., or BVF, each share of which is convertible into 1,000 shares of our common stock, subject to certain ownership restrictions. In January 2019, we entered into an exchange agreement with BVF to exchange 5,000,000 shares of our common stock previously held by BVF for 5,000 shares of our Series B convertible preferred stock, each share of which is convertible into 1,000 shares of our common stock, subject to certain ownership restrictions. In connection with our November 2019 private placement, we issued 3,522 shares of our Series C convertible preferred stock to certain affiliates of BVF each share of which is convertible into 1,000 shares of our common stock, subject to certain ownership restrictions. In March 2020, we entered into another exchange agreement with BVF to exchange 3,000,000 shares of our common stock previously held by BVF for 3,000 shares of our Series D convertible preferred stock, each share of which is convertible into 1,000 shares of our common stock, subject to certain ownership restrictions. In May 2021, we entered into another exchange agreement with BVF to exchange 5,000,000 shares of our common stock previously held by BVF for 5,000 shares of our Series E convertible preferred stock, each share of which is convertible into 1,000 shares of our common stock, subject to certain ownership restrictions. If the holders of our shares of preferred stock convert their shares into common stock, existing holders of our common stock will experience dilution.

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

As a public company, we are subject to the reporting requirements of the Exchange Act and the Sarbanes-Oxley Act. The Exchange Act requires the filing of annual, quarterly and current reports with respect to a public company's business and financial condition. The Sarbanes-Oxley Act requires, among other things, that a public company establish and maintain effective internal control over financial reporting. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased and will continue to negatively impact our legal and financial compliance costs and will make some activities more time-consuming and costly.

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

Under Rule 12b-2 of the Exchange Act, a "smaller reporting company" is a company that is not an investment company, an asset-backed issuer or a majority-owned subsidiary of a parent company that is not a smaller reporting company, and had a public float of less than $250 million as of the last business day of its most recently completed second fiscal quarter or, if such public float is less than $700 million, had annual revenues of less than $100 million during the most recently completed fiscal year. Smaller reporting companies are permitted to provide simplified executive compensation disclosure in their filings; and they have certain other decreased disclosure obligations in their SEC filings, including, among other things, only being required to provide two years of audited financial statements in annual reports. We qualify as a smaller reporting company. For as long as we continue to be a smaller reporting company, we expect that we will take advantage of the reduced disclosure obligations available to us as a result of those respective classifications. Decreased disclosure in our SEC filings as a result of our having availed ourselves of scaled disclosure may make it harder for investors to analyze our results of operations and financial prospects.

Item 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

Item 1C. CYBERSECURITY

We recognize the critical importance of maintaining the trust and confidence of our patients, employees, and business partners toward our business and are committed to protecting the confidentiality, integrity and availability of our business operations and systems. Our audit committee of the board of directors is actively involved in oversight of our risk management activities, and cybersecurity represents an important element of our overall approach to risk management. We have taken into account recognized frameworks established by the National Institute of Standards and Technology, or NIST, when developing cybersecurity policies, standards, processes and practices among other considerations. In general, we seek to address cybersecurity risks through a comprehensive, cross-functional approach that is focused on preserving the confidentiality, security and availability of the information that we collect and store by identifying, preventing and mitigating cybersecurity threats and effectively responding to cybersecurity incidents when they occur.

Cybersecurity Risk Management and Strategy; Effect of Risk

We face risks related to cybersecurity such as unauthorized access, cybersecurity attacks and other security incidents, including as perpetrated by hackers and unintentional damage or disruption to hardware and software systems, loss of data, and misappropriation of confidential information. To identify and assess material risks from cybersecurity threats, we maintain a comprehensive cybersecurity program to ensure our systems are effective and prepared for information security risks, including regular oversight of our programs for security monitoring for internal and external threats to ensure the confidentiality and integrity of our information assets. We consider risks from cybersecurity threats alongside other company risks as part of our overall risk assessment process. We employ a range of tools and services, including phishing training, regular network and endpoint monitoring, audits, vulnerability assessments, to inform our risk identification and assessment. As discussed in more detail under “Cybersecurity Governance; Management” below, our audit committee provides oversight of our cybersecurity risk management and strategy processes, which are led by the General Counsel and third-party information technology and security providers who act as our information technology team.

We also identify our cybersecurity threat risks by comparing our processes to standards set by NIST. To provide for the availability of critical data and systems, maintain regulatory compliance, manage our material risks from cybersecurity threats, and protect against and respond to cybersecurity incidents, we undertake the following activities:

- monitor emerging data protection laws and implement changes to our processes that are designed to comply with such laws;
- through our policies, practices and contracts (as applicable), require employees, as well as third parties that provide services on our behalf, to treat confidential information and data with care and enter into confidentiality agreements, and enter into data processing agreements with third parties that are processing personal data we control;
- employ technical safeguards that are designed to protect our information systems from cybersecurity threats, including physical security measures to prevent access to data processing systems, firewalls, intrusion prevention and detection systems, email security controls, anti-malware functionality and access controls, endpoint detection and response systems, all of which are evaluated and improved through internal and external vulnerability assessments and cybersecurity threat intelligence;
- provide mandatory training and notifications for our employees and contractors regarding cybersecurity threats as a means to equip them with effective tools to understand, identify and address cybersecurity threats, and to communicate our evolving information security policies, standards, processes and practices;
- conduct mandatory annual phishing training and regular phishing email simulations for all employees and contractors with access to our email systems to enhance awareness and responsiveness to possible threats;
- utilize pseudonymized data for patients and use other encryption methods to ensure security of personal data;
- leverage procedures informed by appropriate incident handling frameworks to help us identify, protect, detect, respond and recover when there is an actual or potential cybersecurity incident; and
- carry information security risk insurance that provides protection against the potential losses arising from a cybersecurity incident.

Our incident response plan coordinates the activities we take to prepare for, detect, respond to and recover from cybersecurity incidents, which include processes to triage, assess severity for, escalate, contain, investigate and remediate the incident, as well as to comply with potentially applicable legal obligations and mitigate damage to our business and reputation.

As part of the above processes, we engage with third parties, including annually having a qualified third-party review our incident response plan and our cybersecurity measures to help identify areas for continued focus, improvement and compliance.

Our processes also address cybersecurity threat risks associated with our use of third-party service providers, including those who have access to patient and employee data or our systems. In addition, cybersecurity considerations affect the selection and oversight of our third-party service providers. We perform diligence on third parties that have access to our systems, data or facilities that house such systems or data, and assess cybersecurity threat risks identified through such diligence. Additionally, we generally require those third parties that could introduce significant cybersecurity risk to us to agree by contract to manage their cybersecurity risks in specified ways, for example, by engaging with known, reputable vendors, and requiring they have industry standard safeguards and notification procedures. We may also ask vendors associated with increased cybersecurity risk to complete a periodic questionnaire regarding their security practices for ongoing vendor management purposes.

We describe whether and how risks from identified cybersecurity threats, including as a result of any previous cybersecurity incidents, have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition, under the heading "Significant disruptions of information technology systems or security breaches could adversely affect our business" in Item 1A, Risk Factors, which disclosures are incorporated by reference herein.

In the last three fiscal years, we have not experienced any material cybersecurity incidents and the expenses we have incurred from cybersecurity incidents were immaterial. We also have not been subject to any penalties or settlements.

Cybersecurity Governance; Management

Cybersecurity is an important part of our risk management processes and an area of focus for our board of directors and management. In general, our board of directors oversees risk management activities designed and implemented by our management, and considers specific risks, including, for example, risks associated with our strategic plan, business operations, and capital structure. Our board of directors executes its oversight responsibility for risk management both directly and through delegating oversight of certain of these risks to its committees, and our board of directors has authorized our audit committee to oversee risks from cybersecurity threats.

At least quarterly, our audit committee receives an update from management of our cybersecurity threat risk management and strategy processes covering topics such as data security posture, results from third-party assessments, our incident response plan, and material cybersecurity threat risks or incidents and developments, as well as the steps management has taken to respond to such risks. In such sessions, our audit committee generally receives materials that include discussions of current and emerging general material cybersecurity threat risks, including our particular cyber risk situation, and describing our ability and strategy to mitigate those risks and may discuss such matters with our Information Technology team or General Counsel. Our audit committee also receives prompt and timely information regarding any cybersecurity incident that meets reporting thresholds, as well as ongoing updates regarding any such incident until it has been addressed.

Members of our audit committee are also encouraged to regularly engage in conversations with management on cybersecurity-related news events and discuss any updates to our cybersecurity risk management and strategy programs. Material cybersecurity threat risks are also considered during separate board meeting discussions of important matters like enterprise risk management, operational budgeting, business continuity planning, mergers and acquisitions, and other relevant matters.

Our cybersecurity risk management and strategy processes, which are discussed in greater detail above, are led by our external Information Technology team, an Information Technology council composed of various management and senior level employees, and the General Counsel. Such individuals have collectively over 10 years of prior work experience in various roles involving managing information security, developing cybersecurity strategy, implementing effective information and cybersecurity programs, as well as several relevant degrees. These management team members are informed about and monitor the prevention, mitigation, detection, and remediation of cybersecurity incidents through their management of, and participation in, the cybersecurity risk management and strategy processes described above, including the operation of our incident response plan. As discussed above, these management team members report to the audit committee of our board of directors about cybersecurity threat risks, among other cybersecurity related matters, at least annually.

Item 2. PROPERTIES

In October 2018, Pieris GmbH entered into a lease initially comprising of approximately 96,400 square feet of mixed laboratory and office space in Hallbergmoos, Germany, which became our location for all German operations in February 2020. This agreement, or the Lease Agreement, provides for an initial term of 150 months, commencing on the date the lessor first delivers the leased property to Pieris GmbH as agreed under the Lease Agreement, which occurred in February 2020. On December 15, 2023, the Lease Agreement was terminated effective December 31, 2023. As consideration for the lessor's agreement to terminate the Lease Agreement, Pieris GmbH paid a fee of approximately €9.7 million. The Company will continue to occupy a limited portion of the office space through June 2024.

Our corporate headquarters continues to be located in Boston, Massachusetts, but we now generally conduct our operational functions remotely.

Item 3. LEGAL PROCEEDINGS

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

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Market Information

Our common stock is listed on The Nasdaq Stock Market LLC under the symbol "PIRS" and on June 30, 2015 our common stock began trading on The Nasdaq Capital Market.

Stockholders

As of March 26, 2024, there were 31 and 4 stockholders of record of our common stock and preferred stock, respectively. Because many of our shares are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of beneficial holders represented by these record holders.

Dividends

We have never paid dividends but may elect to pay out dividends to stockholders if it is determined that there is sufficient cash and investments to achieve our near and long-term objectives.

Unregistered Sales of Securities

None.

Issuer Purchases of Equity Securities

None.

Item 6. [RESERVED]

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

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

Overview

We are a biotechnology company that historically discovered and developed Anticalin® protein-based drugs to target validated disease pathways in unique and transformative ways. Proprietary to us, Anticalin proteins are a novel class of therapeutics validated in the clinic and through partnerships with leading pharmaceutical companies, including Servier, Pfizer (formerly Seagen), and Boston Pharmaceuticals in immuno-oncology, or IO. Our clinical pipeline consists of IO bispecifics in partnership with collaborators, including S095012 (also referred to as PRS-344) targeting PD-L1 and 4-1BB, SGN-BB228 (also referred to as PRS-346) targeting CD228 and 4-1BB, and BOS-342 (also referred to as PRS-342) targeting GPC3 and 4-1BB.

On March 27, 2024, we announced an update on our review of strategic alternatives, and our decision to implement measures that are expected to extend our cash runway into at least 2027, while maximizing our ability to collect potential milestones from our clinical pipeline of partnered drug candidates, potentially obtain value for cinrebafusp alfa and other proprietary platform capabilities, and explore other strategic opportunities. As part of this strategy, we intend to discontinue all of our research and development efforts that we expect will be completed by the middle of 2024, reduce our workforce, which is expected to affect additional employees and the executive leadership and be implemented in the second quarter of 2024, and reduce the size of our Board of Directors, which is also expected to be implemented in the second quarter of 2024. We remain eligible to receive potential contingent milestone and royalty payments from its partnered 4-1BB bispecific Mabcalin protein franchise from Pfizer, Boston Pharmaceuticals, and Servier. These include aggregated milestones of approximately $20 million in connection with dosing a first patient in the phase 2 trials for SGN-BB228, S095102, and BOS-342, and aggregated milestones of approximately $55 million in connection with dosing a first patient in the pivotal clinical trials for SGN-BB228, S095102, and BOS-342. Our strategy announced in March 2024 follows from our July 2023 announcement where we stated our intention to explore one or more strategic transactions with the assistance of our advisors, Stifel, Nicolaus & Company, and also announced a reduction in our workforce by approximately 70% in light of decision to reduce our operating footprint and expenses by opting out of and terminating programs.

Discovery and Development Programs

We currently have several IO drug candidates, both proprietary and partnered with major biopharmaceutical companies and are at varying stages of development:

- Our IO partnered portfolio includes the following drug candidates that are multi-specific Anticalin-based fusion protein drug candidates designed to engage immunomodulatory targets, in partnership with Pfizer (formerly Seagen), Boston Pharmaceutics, and Servier.

    - In the Pfizer collaboration, SGN-BB228 (also referenced as PRS-346), a CD228 x 4-1BB bispecific antibody-Anticalin compound, was previously handed over to Pfizer, which is responsible for further advancement and funding of the asset. In January 2023, the first patient was dosed in a Pfizer-sponsored phase 1 study of SGN-BB228, upon which we achieved a $5.0 million milestone. Pfizer, as they were referred to at the time, presented preclinical data for this program at the Society for Immunotherapy of Cancer 37th Annual Meeting in November 2022 and at the American Association for Cancer Research (AACR) Annual Meeting in April 2023, Pfizer presented the study design of the phase 1 study of SGN-BB228 at the American Society of Clinical Oncology (ASCO) Annual Meeting in June 2023. The program is one of three programs in the Pfizer alliance, and we believe the previous achievement of a key development milestone for this program validates our approach in IO bispecifics, complementing the encouraging clinical data seen with cinrebafusp alfa. We transferred the second and third programs to Pfizer at the end of 2023, and retain a co-promotion option for one program in the Pfizer collaboration in the United States.

    - BOS-342 (also referenced as PRS-342) is a GPC3 x 4-1BB bispecific Mabcalin compound that we have exclusively licensed to Boston Pharmaceuticals. In August 2023, the first patient was dosed in a Boston Pharmaceuticals sponsored phase 1/2 study of BOS-342 in hepatocellular carcinoma (HCC), for which we received a $2.5 million milestone payment and are entitled to receive up to approximately $350 million in potential development, regulatory and sales-based milestone payments, and tiered royalties on potential sales of BOS-342.

    - S095012 (also referenced as PRS-344) is a bispecific Mabcalin compound comprising a PD-L1-targeting antibody genetically linked to 4-1BB-targeting Anticalin proteins being developed by Servier on a worldwide basis. The first-in-human phase 1/2 multicenter open-label dose escalation study is designed to determine the safety and preliminary activity of S095012 in patients with advanced and/or metastatic solid tumors. In July 2023, we notified Servier that we were opting out of co-development and commercialization of S095012 in the U.S. Servier retains exclusive, even as to us, worldwide rights to the program including the right to advance development and potential commercialization in the U.S. As a result of our election to opt out, we are entitled to increased royalty rates and potential royalties and milestones, if any, for S095012.

- In May 2021, we also entered into a multi-program research collaboration and license agreement with Genentech, a member of the Roche Group, to discover, develop and commercialize locally delivered respiratory and ophthalmology therapies. In April and May 2023, the ophthalmology and respiratory programs were jointly discontinued, respectively.

Cinrebafusp alfa is a bispecific Mabcalin compound comprising a HER2-targeting antibody genetically linked to 4-1BB-targeting Anticalin proteins. Cinrebafusp alfa is designed to drive tumor localized T cell activation through tumor-targeted drug clustering mediated by HER2 expressed on tumor cells. This program was the first 4-1BB bispecific T cell co-stimulatory agonist to enter clinical development.

    - In July 2022, we received fast track designation from FDA for cinrebafusp alfa. In August 2022, we announced the decision to cease further enrollment in the two-arm, multicenter, open-label phase 2 study of cinrebafusp alfa as part of a strategic pipeline prioritization to focus our resources. Cinrebafusp alfa has demonstrated clinical benefit in phase 1 studies, including single agent activity in a monotherapy setting, and in the phase 2 study in HER2-expressing gastric cancer, giving the Company confidence in its broader 4-1BB franchise. In April 2023, clinical data showing an unconfirmed 100% objective response rate and promising emerging durability profile were presented at the American Association of Cancer Research annual meeting. This data provided encouraging evidence of clinical activity for this program. The Company continues to remain committed to obtaining value for cinrebafusp alfa.

Our former drug candidates include:

- *Elarekibep*, a former respiratory program that was partnered with AstraZeneca for the treatment of asthma, was a drug candidate that antagonizes IL-4Rα, thereby inhibiting the downstream action of IL-4 and IL-13, two cytokines known to be key mediators in the inflammatory cascade that drive the pathogenesis of asthma and other inflammatory diseases.
    - In June 2023, AstraZeneca communicated to us its decision to discontinue and cease dosing in the phase 2 clinical studies of elarekibep. This decision was based on lung findings from a non-clinical 13-week GLP toxicology study with dry powder inhaler-formulated elarekibep, which did not support long-term use and progression to later-stage development. The 13-week non-human primate study included three active dose cohorts. AstraZeneca concluded that there were no clinical observations across any of the doses but that there were respiratory tract pathology findings. These findings included inflammation-mediated lung tissue damage, which did not appear to be dose related. AstraZeneca's decision was made independent of any data from the phase 2a study.
    - In July 2023, AstraZeneca notified us of its intention to terminate the AstraZeneca Collaboration Agreement and the AstraZeneca Platform License, which terminations became effective October 15, 2023. AstraZeneca's decision to terminate these agreements was based on the non-clinical safety findings in a 13-week toxicology study of elarekibep in non-human primates previously disclosed by us. Based upon our review, we have determined to discontinue the program for scientific reasons.
- *PRS-220* is an orally inhaled Anticalin protein targeting connective tissue growth factor, or CTGF, that was being developed as a local treatment for idiopathic pulmonary fibrosis, or IPF, and other forms of fibrotic lung diseases. CTGF, a matricellular protein, has been demonstrated to be a driver of fibrotic tissue remodeling and the protein has been found over-expressed in lung tissue from patients suffering from IPF.
    - In 2021, we received a €14.2 million grant from the Bavarian Ministry of Economic Affairs, Regional Development and Energy supporting research and development of the PRS-220 program. We conducted a phase 1 study of PRS-220 in healthy volunteers in Australia, which we completed in August 2023. The study was a randomized, two-part, blinded, placebo-controlled study, designed to assess the safety, tolerability, pharmacokinetics, and immunogenicity of single and multiple ascending doses of PRS-220 when administered by oral inhalation to healthy subjects. The clinical study report was finalized at the end of December 2023. Data from the single and multiple ascending doses of PRS-220, when administered by oral inhalation to healthy subjects, demonstrated that PRS-220 was safe and generally well tolerated by subjects in this study at all administered doses. With the completion of the phase 1 clinical studies, we have decided to discontinue further development of the program for strategic and scientific reasons.

Since inception, we have devoted nearly all of our efforts and resources to our research and development activities and have incurred significant net losses. For the years ended December 31, 2023 and 2022, we reported net losses of $24.5 million and $33.3 million, respectively. As of December 31, 2023, we had an accumulated deficit of $315.0 million. We expect to continue incurring substantial losses as we devote time and resources into exploring strategic transactions. Our operating expenses have historically been comprised of research and development expenses and general and administrative expenses.

We have not generated any revenues from product sales to date, and we do not expect to generate revenues from product sales for the foreseeable future. Our revenues for the fiscal years ended December 31, 2023 and 2022 were from license and collaboration agreements with our partners.

A significant portion of our operations are conducted in countries other than the United States. Since we conduct our business in U.S. dollars, our main exposure, if any, results from changes in the exchange rates between the euro and the U.S. dollar. At each period end, we remeasure assets and liabilities to the functional currency of that entity (for example, U.S. dollar payables recorded by our subsidiary, Pieris Pharmaceuticals GmbH). Remeasurement gains and losses are recorded in the statement of operations line item 'Other income (expense), net'. All assets and liabilities denominated in euros are translated into U.S. dollars at the exchange rate on the balance sheet date. Revenues and expenses are translated at the weighted average rate during the period. Equity transactions are translated using historical exchange rates. All adjustments resulting from translating foreign currency financial statements into U.S. dollars are included in accumulated other comprehensive income (loss).

Key Financial Terms and Metrics

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

Revenues

We have not generated any revenues from product sales to date and we do not expect to generate revenues from product sales for the foreseeable future. Our revenues for the last two years have been from the license and collaboration agreements with AstraZeneca, Servier, Pfizer, Genentech and Boston Pharmaceuticals.

The revenues from AstraZeneca, Servier, Pfizer, Genentech and Boston Pharmaceuticals have been comprised primarily of upfront payments, research and development services and milestone payments. For additional information about our revenue recognition policy, see "Note 2-Summary of Significant Accounting Policies".

Research and Development Expenses

The process of researching and developing drugs for human use is lengthy, unpredictable, and subject to many risks. Historically, we incurred substantial expenses as we continued to develop our clinical and preclinical drug candidates and programs. Also included in research and development costs in 2023 were severance costs associated with the workforce reduction announced in July of that year. In the third quarter of 2023, we had stopped or taken actions to wind down research and development costs related to all proprietary programs. On March 27, 2024, we announced that we would be discontinuing all of our research and development activities. We have no further spending obligations related to our partnered IO programs. We expect research and development costs to be significantly lower than historical amounts.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, employee benefits, equity compensation, and other personnel-related costs associated with executive, administrative and other support staff. Other significant general and administrative expenses include the costs associated with professional fees for accounting, auditing, insurance costs, consulting and legal services, along with facility and maintenance costs attributable to general and administrative functions. Included in general and administrative costs in 2023 were severance costs associated with the workforce reduction announced in July of that year. On March 27, 2024, we announced a reduction in workforce that would impact additional employees and the executive leadership team and is expected to be implemented in the second quarter of 2024. We expect general and administrative costs to be significantly lower than historical amounts given the leaner organization and elimination of research and development spending going forward.

Results of Operations

Comparison of Years Ended December 31, 2023 and December 31, 2022

The following table sets forth our revenues and operating expenses for the fiscal years ended December 31, 2023 and 2022 (in thousands):

	Years ended December 31,	
	2023	2022
Revenues	$ 42,810	$ 25,902
Research and development expenses	41,801	52,982
General and administrative expenses	16,853	16,394
Asset impairment	13,912	—
Total operating expenses	72,566	69,376
Interest income	1,851	721
Grant income	3,612	8,173
Other (expense) income , net	(250)	1,303
Loss before income taxes	(24,543)	(33,277)
Benefit for income tax	—	—
Net loss	$ (24,543)	$ (33,277)

Revenues

The following table provides a comparison of revenues for the years ended December 31, 2023 and 2022 (in thousands):

	Year Ended December 31,		
	2023	2022	Increase/(Decrease)
Customer revenue	$ 38,711	$ 25,469	$ 13,242
Collaboration revenue	4,099	433	3,666
Total Revenue	$ 42,810	$ 25,902	16,908

- The $13.2 million increase in customer revenue for the year ended December 31, 2023 compared to the year ended December 31, 2022 is driven by the following:
  - Revenue for the year ended December 31, 2023 is primarily due to event-driven revenue recognized for the discontinuation of programs or termination of agreements with both the Genentech ($12.5 million) and AstraZeneca ($7.4 million), revenue recognized due to the Pfizer collaboration amendment driving acceleration of program handover ($10.1 million) and the milestone achieved for the Phase 1 first patient dose under the Boston Pharmaceuticals collaboration ($2.5 million) in the year ended December 31, 2023. These increases were partially offset by event-driven revenue recognized in the prior year for the discontinuation of two early-stage programs under the AstraZeneca collaboration ($9.2 million), completion of the performance obligation related to the material right for S095025 (PRS-352) ($4.9 million), milestone revenue recorded under the Pfizer collaboration ($5.0 million) and completion of the performance obligation related to the expiration of the target swap for the second program under the Pfizer collaboration ($1.5 million).
- Collaboration revenue increased by $3.7 million in the year ended December 31, 2023 compared to the year ended December 31, 2022. The increase is primarily due to event-driven revenue recognized upon the opt-out co-development for S095012 (PRS-344) ($4.6 million), offset partially by higher Servier efforts and expenses for S095012 (PRS-344) that are reductions of our portion of revenue for activities managed by us under the Servier collaboration.

Research and Development Expenses

The following table provides a comparison of the research and development expenses for the years ended December 31, 2023 and 2022 (in thousands):

	Year Ended December 31,		
	2023	2022	Increase/(Decrease)
Immuno-oncology	$ 6,982	$ 13,743	$ (6,761)
Respiratory	11,511	12,845	(1,334)
Other R&D activities	23,308	26,394	(3,086)
Total	$ 41,801	$ 52,982	(11,181)

- The $6.8 million decrease in our immuno-oncology program spending period-over-period is due primarily to a decrease in clinical and manufacturing costs for both cinrebafusp alfa and S095012 (PRS-344) as well as lower professional services and consulting fees for S095012 (PRS-344).
- The $1.3 million decrease for our respiratory program spending period-over-period is due generally to PRS-220 and PRS-400, and the changing stage of development for these programs year-over-year. PRS-220 incurred lower preclinical and manufacturing costs in 2023, which was partially offset by higher clinical and consulting costs as the program moved from pre-clinical stage in 2022 to clinical stage in 2023. PRS-400 incurred higher manufacturing and pre-clinical costs in 2023 as compared to 2022 as we were planning for IND-enabling activities prior to stopping this program in the middle of the year after our strategic announcement in July 2023.
- The $3.1 million decrease in other research and development activities expenses is driven by lower overall personnel costs due to lower headcount, facility, software and travel expenses, all of which was partially offset higher severance costs after the mid-year strategic announcement.

General and Administrative Expenses

General and administrative expenses were $16.9 million for the year ended December 31, 2023 as compared to $16.4 million for the year ended December 31, 2022. The period-over-period increase was driven primarily by severance expense along with higher audit and tax costs recorded in the current period, offset partially by lower salary and related costs (prior to severance costs), lower facilities, software, legal, travel and insurance costs.

Asset Impairment

During the third quarter of 2023, as part of our strategic process for maximizing the value of assets, we committed to a plan to prepare and sell all property and equipment. As a result of this decision, we incurred impairment expenses totaling $13.9 million, of which $1.8 million was related to impairment of our right-of-use asset under the Hallbergmoos Lease for which we and the landlord terminated the lease in December 2023.

Other income (expense), net

Our other income was $5.2 million for the year ended December 31, 2023 as compared to a other expense of $10.2 million for the year ended December 31, 2022. The decrease year over year was primarily due to lower grant income and unrealized losses. Lower grant income was a result of reaching the threshold for reimbursable costs in 2023. Lower unrealized losses in the current period were due to an overall weakening U.S. dollar on a year to date basis as compared to the prior comparable period. This was partially offset by higher interest income on investment in the current period as a result of higher interest rates.

Liquidity and Capital Resources

On March 27, 2024, we announced an update on our review of strategic alternatives, and our decision to implement measures that are expected to extend our cash runway into at least 2027, while maximizing our ability to collect potential milestones and royalties from our clinical pipeline of partnered drug candidates, potentially obtain value for cinrebafusp alfa and other proprietary platform capabilities, and explore other strategic opportunities. As part of this strategy, we intend to discontinue all of our research and development efforts, reduce our workforce, which is expected to affect additional employees and the executive leadership, and be substantially implemented in the second quarter of 2024, and reduce the size of our Board of Directors. This follows our July 2023 announcement in which we stated our intention to explore one or more strategic transaction, and in which we further announced a reduction in our workforce by approximately 70%.

Through December 31, 2023, we have funded our operations with $553.8 million of cash that has been obtained from the following main sources: $303.0 million from sales of equity; $225.2 million in total upfront and milestone payments received under license and collaboration agreements and $25.6 million from government grants.

As of December 31, 2023, we had a total of $26.4 million in cash, cash equivalents and investments. We have incurred losses in every period since inception including the years ended December 31, 2023 and 2022, respectively, and have a total accumulated deficit of $315.0 million as of December 31, 2023. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. We expect to continue to incur operating losses for at least the next several years.

We have historically devoted substantially all of our financial resources and efforts to research and development and general and administrative expenses to support such research and development.

We expect cash necessary to fund operations will continue to decrease significantly in the near term as we have taken measures to preserve cash, including conducting a further workforce reduction which is expected to impact approximately 60% of the remaining employees, discontinuing our research and development projects. and opting out of co-development of PRS-344/S095012 in the U.S..

The following table provides a summary of operating, investing, and financing cash flows for the years ended December 31, 2023 and 2022 respectively (in thousands):

	Year Ended December 31,	
	2023	2022
Net cash used in operating activities	$ (53,819)	$ (59,932)
Net cash provided by (used in) investing activities	12,002	(21,236)
Net cash provided by financing activities	19,795	7,214

Net cash used in operating activities for the year ended December 31, 2023 and 2022 was $53.8 million and $59.9 million, respectively. Cash used in operations in the year ended December 31, 2023 is impacted by lower deferred revenue, primarily driven by higher revenue recognized across all of our collaborations, lower lease liability due to lease termination payment, lower accounts payable, and lower accrued expenses. These changes are offset partially by lower accounts receivable and lower overall prepaid and other assets. This compares to the impact of lower deferred revenue, primarily driven by higher revenue recognized for AstraZeneca, Servier and Pfizer out of the deferred balance, lower accounts payable and accrued expenses and higher accounts receivable and prepaid expenses in the prior period.

The change in net cash provided by investing activities for the year ended December 31, 2023 compared to net cash used in investing activities in 2022 is solely attributable to the impact of net investments changes (more maturities in the current period versus more purchases of investments in the comparable prior year period).

Financing activities for the year ended December 31, 2023 and 2022 provided cash of $19.8 million and $7.2 million, respectively. The increase in net cash provided by financing activities is due to an increase in sales under the ATM program.

In August 2021, we established the ATM Program under a sales agreement with Jefferies LLC, pursuant to which we may offer and sell shares of our common stock, from time to time, up to an aggregate amount of gross sales proceeds of $50.0 million. In November 2022, the sales agreement was amended to provide for an increase in the aggregate offering amount, such that under the ATM Program, as amended, we may offer and sell shares of our common stock, from time to time, up to an aggregate amount of gross sales proceeds of $75.0 million. The ATM Program, as amended, is offered under a shelf registration statement on Form S-3 that was filed with and declared effective by the SEC in August 2021. For the year ended December 31, 2023, we sold 24.3 million shares for gross proceeds of $20.3 million under the ATM Program at an average stock price of $0.84 per share. For the year ended December 31, 2022, we sold 2.1 million shares for gross proceeds of $7.2 million under the predecessor ATM program at an average stock price of $3.46.

As of the filing of this Annual Report on Form 10-K, we will be subject to the SEC general instructions of Form S-3 known as the “baby shelf rules.” Under these instructions, the amount of funds we can raise through primary public offerings of securities in any 12-month period using our registration statement on Form S-3 is limited to one-third of the aggregate market value of the shares of our common stock held by non-affiliates. Therefore, we will be limited in the amount of proceeds we are able to raise by selling shares of our common stock using our Form S-3, including under the ATM Program, until such time as our public float exceeds $75 million.

We have historically devoted substantially all of our financial resources and efforts to research and development and general and administrative expenses to support such research and development. We expect cash necessary to fund operations will continue to decrease significantly as we have decided to discontinue all research and development activities and implement a further workforce reduction that will effect additional employees and the executive leadership team and is expected to be implemented in the second quarter of 2024.

We believe that our currently available funds will be sufficient to fund our remaining limited operations through at least the next 12 months from the issuance of this Annual Report on Form 10-K. As part of our March 27, 2024 strategic update, as discussed above, we decided to implement measures to reduce discretionary expenditures and other fixed or variable personnel costs as we discontinue all remaining research and development obligations and activities, and conduct a further workforce reduction.

Future investments could be reevaluated if we identify and explore any strategic opportunity that our Board of Directors believes will increase stockholder value. Our belief with respect to our ability to fund operations is based on estimates that are subject to these and other risks and uncertainties.

If we seek to raise additional capital to fulfill our operating and capital requirements through public or private equity financings, utilization of our current ATM Program, strategic collaborations, licensing arrangements, government grants and/or the achievement of milestones under our collaborative agreements, there is no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all, and the terms of any future financing may adversely affect the holdings or the rights of our stockholders.

Off-Balance Sheet Arrangements

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

Critical Accounting Policies and Estimates

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

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

Revenue Recognition

Pieris has entered into several licensing agreements with collaboration partners for the development of Anticalin therapeutics against a variety of targets. The terms of these agreements provide for the transfer of multiple goods or services which may include: (i) licenses, or options to obtain licenses, to Pieris' Anticalin technology and/or specific programs and (ii) research and development activities to be performed on behalf of or with a collaborative partner. Payments to Pieris under these agreements may include upfront fees (which include license and option fees), payments for research and development activities, payments based upon the achievement of certain milestones, and royalties on product sales. There are no performance, cancellation, termination or refund provisions in any of the arrangements that could result in material financial consequences to Pieris.

The Company accounts for revenue recognition pursuant to FASB ASC Topic 606, Revenue Recognition, or ASC 606. The standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services.

Collaborative Arrangements

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

Revenue from Contracts with Customers

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

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

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

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

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

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

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

When a performance obligation is satisfied, revenue is recognized for the amount of the transaction price, excluding estimates of variable consideration that are constrained, that is allocated to that performance obligation on a relative standalone selling price basis. Significant management judgment is required in determining the level of effort required under an arrangement and the period over which we are expected to complete its performance obligations under an arrangement.

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

Milestones and Royalties

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

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

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

Contract Balances

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

Contingencies

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

Research and Development Expense

Research and development costs are charged to expense as incurred in performing research and development activities. Research and development expenses are comprised of costs incurred in performing research and development activities, including salaries and benefits, facilities costs, pre-clinical and clinical costs, contract services, consulting, depreciation and amortization expense, and other related costs. Costs associated with acquired technology, in the form of upfront fees or milestone payments, are charged to research and development expense as incurred.

Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, and operating losses and tax credit carry forwards. Deferred tax assets and liabilities are measured using enacted statutory tax rates expected to apply to taxable income in the jurisdictions and years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

We evaluate the realizability of our net deferred tax assets, including considering the level of historical operating results and projections of taxable income for the future. We record a full valuation allowance to reduce our net deferred tax assets when it is determined that it is more likely than not that our net deferred tax assets will not be realized.

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

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

Recently Issued Accounting Pronouncements

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

Smaller Reporting Company Status

Currently, we qualify as a smaller reporting company.

As a smaller reporting company, we are eligible and have taken advantage of certain exemptions from various reporting requirements that are not available to public reporting companies that do not qualify for this classification, including, but not limited to:

- An opportunity for reduced disclosure obligations regarding executive compensation in our periodic and annual reports, including exemption from the requirement to provide a compensation discussion and analysis describing compensation practices and procedures,
- An opportunity for reduced financial statement disclosure in registration statements and in annual reports on Form 10-K, which only requires two years of audited financial statements rather than the three years of audited financial statements that are required for other public companies,
- An opportunity for reduced audit and other compliance expenses as we are not subject to the requirement to obtain an auditor's report on internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act of 2002, and
- An opportunity to utilize the non-accelerated filer time-line requirements

For as long as we continue to be a smaller reporting company, we expect that we will take advantage of both the reduced internal control audit requirements and the disclosure obligations available to us as a result of this classification.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our Consolidated Financial Statements required by this Item are as set forth in Item 15 beginning on page F-3 of this Annual Report on Form 10-K.

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

Not applicable.

Item 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management is responsible for establishing and maintaining “disclosure controls and procedures” as such term is defined in Rule 13a-15(e) of the Exchange Act, as well as for establishing and maintaining “adequate internal control over financial reporting” as such term is defined in Rule 13a-15(f) under the Exchange Act. Our system of internal controls over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the consolidated financial statements in accordance with generally accepted accounting principles.

Because of the inherent limitations surrounding internal controls over financial reporting, our disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

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

Our management, under the supervision of and with the participation of our principal executive officer and principal financial officer, assessed the effectiveness of our internal control over financial reporting and disclosure controls and procedures as of December 31, 2023. In making this assessment, management used the updated criteria set forth in 2013 by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in Internal Control-Integrated Framework.

Based on our assessment under the COSO Internal Control-Integrated Framework, management believes that, as of December 31, 2023, our disclosure controls and procedures and internal control over financial reporting were effective.

Management, including our principal executive officer and principal financial officer, has concluded that the financial statements and other financial information included in this Annual Report on Form 10-K fairly present in all material respects our financial condition, results of operations and cash flows as of, and for, the periods presented.

Changes in Internal Control over Financial Reporting

There have been no changes in internal control over financial reporting identified in connection with the evaluation of such internal control required by Rules 13a-15(d) and 15d-15(d) under the Exchange Act that occurred during the fourth quarter of 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. OTHER INFORMATION

Not applicable.

Item 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

Item 10. MANAGEMENT AND CORPORATE GOVERNANCE

The information required by this Item 10 is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2023.

Item 11. EXECUTIVE OFFICER AND DIRECTOR COMPENSATION

The information required by this Item 11 is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2023.

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

The information required by this Item 12 is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2023.

Item 13. CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

The information required by this Item 13 is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2023.

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this Item 14 is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2023.

PART IV

Item 15. **EXHIBIT AND FINANCIAL STATEMENT SCHEDULES**

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

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

Item 15(a)(3) Exhibits

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

Exhibit Number	Exhibit Description		Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File / Registration Number
2.1	Acquisition Agreement, dated as of December 17, 2014, by and among the Registrant, Pieris AG and the former stockholders of Pieris AG named therein		Form 8-K (Exhibit 2.1)	December 18, 2014	333-190728
3.1	Amended and Restated Articles of Incorporation of the Registrant		Form 8-K (Exhibit 3.1)	December 18, 2014	333-190728
3.2	Certificate of Designation of Series A Convertible Preferred Stock		Form 10-Q (Exhibit 3.1)	August 11, 2016	001-37471
3.3	Certificate of Designation of Series B Convertible Preferred Stock		Form 8-K (Exhibit 3.1)	February 4, 2019	001-37471
3.4	Certificate of Designation of Series C Convertible Preferred Stock		Form 8-K (Exhibit 3.1)	November 4, 2019	001-37471
3.5	Certificate of Designation of Series D Convertible Preferred Stock		Form 8-K (Exhibit 3.1)	April 6, 2020	001-37471
3.6	Certificate of Designation of Series E Convertible Preferred Stock		Form 8-K (Exhibit 3.1)	May 21, 2021	001-37471
3.7	Amended and Restated Bylaws of the Registrant		Form 8-K (Exhibit 3.2)	December 18, 2014	333-190728
3.8	Amendment to the Amended and Restated Bylaws of the Registrant		Form 8-K (Exhibit 3.1)	September 3, 2019	001-37471
4.1	Form of Common Stock certificate		Form 8-K (Exhibit 4.1)	December 18, 2014	333-190728
4.2	Form of Common Stock certificate		Form 10-K (Exhibit 4.2)	March 23, 2016	001-37471
4.3	Description of Registered Securities		Form 10-K (Exhibit 4.3)	March 13, 2020	001-37471
10.1	2014 Employee, Director and Consultant Equity Incentive Plan	#	Form 8-K (Exhibit 10.1)	December 18, 2014	333-190728
10.2	Form of Stock Option Award Agreement under the Registrant's 2014 Employee, Director and Consultant Equity Incentive Plan	#	Form 8-K (Exhibit 10.2)	December 18, 2014	333-190728
10.3	2016 Employee, Director and Consultant Equity Incentive Plan	#	Form 8-K (Exhibit 10.1)	July 1, 2016	001-37471
10.4	Form of Stock Option Award Agreement under the Registrant's 2016 Employee, Director and Consultant Equity Incentive Plan	#	Form 10-K (Exhibit 10.4)	March 30, 2017	001-37471
10.5	2018 Employee, Director and Consultant Equity Incentive Plan	#	Form 8-K (Exhibit 10.1)	July 26, 2018	001-37471

10.6	Form of Stock Option Award Agreement under the Registrant's 2018 Employee, Director and Consultant Equity Incentive Plan	#	Form S-8 (Exhibit 10.2)	August 9, 2018	333-226733
10.7	Form of Stock Option Award Agreement under the Registrant's 2020 Employee, Director and Consultant Equity Incentive Plan	#	Form S-8 (Exhibit 10.2)	August 5, 2021	333-258502
10.8	2018 Employee Stock Purchase Plan	#	Form 8-K (Exhibit 10.2)	July 26, 2018	001-37471
10.9	2023 Employee Stock Purchase Plan	#	Form 10-Q (Exhibit 10.2)	August 10, 2023	001-37471
10.10	2019 Employee, Director and Consultant Equity Incentive Plan	#	Form 8-K (Exhibit 10.1)	July 31, 2019	001-37471
10.11	2020 Employee, Director and Consultant Equity Incentive Plan	#	Form 8-K (Exhibit 10.1)	June 29, 2020	001-37471
10.12	2020 Employee, Director and Consultant Equity Incentive Plan, as amended	#	Form 8-K (Exhibit 10.1)	June 29, 2021	001-37471
10.13	2020 Employee, Director and Consultant Equity Incentive Plan, as amended	#	Form 8-K (Exhibit 10.1)	June 27, 2022	001-37471
10.14	2020 Employee, Director and Consultant Equity Incentive Plan, as amended	#	Form 8-K (Exhibit 10.1)	June 26, 2023	001-37471
10.15	Research and Licensing Agreement by and between Pieris AG and Technische Universität München, dated as of July 26, 2007	+	Form 10-K (Exhibit 10.10)	March 30, 2015	333-190728
10.16	Collaboration Agreement by and among the Registrant, Pieris Pharmaceuticals GmbH, Les Laboratoires Servier and Institut de Recherches Internationales Servier, dated as of January 4, 2017	+	Form 10-K/A (Exhibit 10.15)	April 26, 2018	001-37471
10.17	Non-Exclusive Anticalin Platform Technology License Agreement by and among the Registrant, Pieris Pharmaceuticals GmbH, Les Laboratoires Servier and Institut de Recherches Internationales Servier, dated as of January 4, 2017	+	Form 10-K/A (Exhibit 10.16)	April 26, 2018	001-37471
10.18	First Amendment to the License and Collaboration Agreement by and between Les Laboratoires Servier, Institut de Recherches Internationales Servier, Pieris Pharmaceuticals, Inc. and Pieris Pharmaceuticals GmbH, effective as of June 16, 2017	+	Form 10-Q/A (Exhibit 10.4)	April 26, 2018	001-37471
10.19	Letter Amendment to the License and Collaboration Agreement by and between Les Laboratoires Servier, Institut de Recherches Internationales Servier, Pieris Pharmaceuticals, Inc. and Pieris Pharmaceuticals GmbH, effective as of January 3, 2020	+	Form 10-K (Exhibit 10.16)	March 13, 2020	001-37471

10.20	License & Collaboration Agreement by and between Pieris Pharmaceuticals Inc., Pieris Pharmaceuticals GmbH & Pieris Australia Pty. Limited and AstraZeneca AB, dated as of May 2, 2017	+	Form 10-Q/A (Exhibit 10.1)	April 26, 2018	001-37471
10.21	Amendment No. 2, dated March 29, 2021, to the License & Collaboration Agreement by and between the Registrant and AstraZeneca AB	+	Form 10-Q (Exhibit 10.4)	May 17, 2021	001-37471
10.22	Amendment No. 3, dated June 9, 2022, to the License & Collaboration Agreement by and between the Registrant and AstraZeneca AB	+	Form 10-Q (Exhibit 10.2)	August 4, 2022	001-37471
10.23	Amendment No. 4, dated June 30, 2022, to the License & Collaboration Agreement by and between the Registrant and AstraZeneca AB	+	Form 10-Q (Exhibit 10.3)	August 4, 2022	001-37471
10.24	Amendment No. 5, dated August 1, 2022, to the License & Collaboration Agreement by and between the Registrant and AstraZeneca AB	+	Form 10-Q (Exhibit 10.2)	November 4, 2022	001-37471
10.25	Non-Exclusive Anticalin® Platform Technology License Agreement, by and between Pieris Pharmaceuticals Inc., Pieris Pharmaceuticals GmbH and Pieris Australia Pty. Limited and AstraZeneca AB, dated as of May 2, 2017	+	Form 10-Q/A (Exhibit 10.2)	April 26, 2018	001-37471
10.26	Amendment No. 1, dated March 29, 2021, to the Non-Exclusive Anticalin® Platform Technology License Agreement, dated May 2, 2017, by and between the Registrant and AstraZeneca AB	+	Form 10-Q (Exhibit 10.5)	May 17, 2021	001-37471
10.27	Subscription Agreement, dated March 29, 2021, by and between the Registrant and AstraZeneca AB	+	Form 10-Q (Exhibit 10.6)	May 17, 2021	001-37471
10.28	License and Collaboration Agreement by and among the Registrant, Pieris GmbH and Seagen, Inc., dated February 8, 2018	+	Form 10-Q (Exhibit 10.1)	May 10, 2018	001-37471
10.29	Amendment No. 1 to License and Collaboration Agreement by and among the Registrant, Pieris GmbH and Seagen, Inc., dated June 2, 2020		Form 10-Q (Exhibit 10.2)	August 10, 2020	001-37471
10.30	Amended and Restated License and Collaboration Agreement, dated March 24, 2021, by and between the Registrant and Seagen Inc.	+	Form 10-Q (Exhibit 10.1)	May 17, 2021	001-37471
10.31	Amendment No. 1, dated September 12, 2023, to the Amended and Restated License and Collaboration Agreement by and between the Registrant and Seagen Inc	+	Form 10-Q (Exhibit 10.3)	November 14, 2023	001-37471
10.32	Subscription Agreement, dated March 24, 2021, by and between the Registrant and Seagen Inc.		Form 10-Q (Exhibit 10.3)	May 17, 2021	001-37471
10.33	Non-Exclusive Anticalin Platform Technology License Agreement by and among the Registrant, Pieris Pharmaceuticals GmbH and Seagen, Inc., dated February 8, 2018	+	Form 10-Q (Exhibit 10.2)	May 10, 2018	001-37471
10.34	Amendment No. 1 to Non-Exclusive Anticalin Platform Technology License Agreement by and among the Registrant, Pieris Pharmaceuticals GmbH and Seagen, Inc., dated June 2, 2020		Form 10-Q (Exhibit 10.3)	August 10, 2020	001-37471
10.35	Exclusive Product License Agreement, dated April 24, 2021, by and among the Registrant, Pieris Pharmaceuticals GmbH and BP Asset XII, Inc.		Form 10-Q (Exhibit 10.1)	August 5, 2021	001-37471

10.36	Research Collaboration and License Agreement, dated May 19, 2021, by and among the Registrant, Pieris Pharmaceuticals GmbH and Genentech, Inc.		Form 10-Q (Exhibit 10.3)	August 5, 2021	001-37471
10.37	Form of Indemnification Agreement by and between the Registrant and each of its current directors and executive officers	#	Form 8-K (Exhibit 10.10)	December 18, 2014	333-190728
10.38	Employment Agreement by and between the Registrant and Stephen S. Yoder, dated as of December 17, 2014	#	Form 8-K (Exhibit 10.15)	December 18, 2014	333-190728
10.39	Employment Agreement by and between the Registrant and Ahmed Mousa, dated as of October 7, 2021	#	Form 10-Q (Exhibit 10.1)	November 2, 2021	001-37471
10.40	Employment Agreement by and between the Registrant and Tom Bures, dated as of October 7, 2021	#	Form 10-Q (Exhibit 10.2)	November 2, 2021	001-37471
10.41	Non-Employee Director Compensation Policy, as amended	#	Form 10-K (Exhibit 10.38)	March 31, 2023	001-37471
10.42	Lease Agreement by and between Pieris GmbH and Hallbergmoos Grundvermögen GmbH, dated October 24, 2018		Form 10-K (Exhibit 10.30)	March 18, 2019	001-37471
10.43	Amendment No. 1 to Lease Agreement by and between Pieris GmbH and Hallbergmoos Grundvermögen GmbH, dated May 21, 2019 (English translation)		Form 10-K (Exhibit 10.31)	March 13, 2020	001-37471
10.44	Amendment No. 2 to Lease Agreement by and between Pieris GmbH and Hallbergmoos Grundvermögen GmbH, dated February 13, 2020 (English translation)		Form 10-K (Exhibit 10.32)	March 13, 2020	001-37471
10.45	Amendment No. 3 to Lease Agreement by and between Pieris GmbH and Hallbergmoos Grundvermögen GmbH, dated May 19, 2020 (English translation)	*			
10.46	Amendment No. 4 to Lease Agreement by and between Pieris GmbH and Hallbergmoos Grundvermögen GmbH, dated December 15, 2023 (English translation)	*			
10.47	Form of Securities Purchase Agreement, dated December 17, 2014, by and among the Registrant and the Purchasers		Form 8-K (Exhibit 10.1)	December 23, 2014	333-190728
10.48	Form of Registration Rights Agreement, dated December 17, 2014, by and among the Registrant and the investors party thereto		Form 8-K (Exhibit 10.2)	December 23, 2014	333-190728
10.49	Form of Warrant to Purchase Common Stock, dated December 17, 2014, issued by the Registrant		Form 8-K (Exhibit 10.3)	December 23, 2014	333-190728
10.50	Securities Purchase Agreement, dated June 2, 2016, by and among the Registrant and the Investors named therein		Form 8-K (Exhibit 10.1)	June 6, 2016	001-37471
10.51	Registration Rights Agreement, dated June 2, 2016, by and among the Registrant and the Investors named therein		Form 8-K (Exhibit 10.3)	June 6, 2016	001-37471
10.52	Form of Warrant to purchase Common Stock, dated June 2, 2016, issued by the Registrant		Form 8-K (Exhibit 10.2)	June 6, 2016	001-37471

10.53	Securities Purchase Agreement, dated November 2, 2019, by and among the Company and the Investors named therein		Form 8-K (Exhibit 10.1)	November 4, 2019	001-37471
10.54	Registration Rights Agreement, dated November 2, 2019, by and among the Company and the Investors named therein		Form 8-K (Exhibit 10.3)	November 4, 2019	001-37471
10.55	Form of Warrant to purchase Common Stock, dated November 2, 2019, issued by the Registrant		Form 8-K (Exhibit 10.2)	November 4, 2019	001-37471
10.56	Exchange Agreement, dated January 30, 2019, by and among the Registrant and Biotechnology Value Fund, L.P., Biotechnology Value Fund II, L.P., and Biotechnology Value Trading Fund OS, L.P.		Form 8-K (Exhibit 10.1)	February 4, 2019	001-37471
10.57	Exchange Agreement, dated March 31, 2020, by and among the Registrant and Biotechnology Value Fund, L.P., Biotechnology Value Fund II, L.P., and Biotechnology Value Trading Fund OS, L.P.		Form 8-K (Exhibit 10.1)	April 6, 2020	001-37471
10.58	Exchange Agreement by and among the Registrant and Biotechnology Value Fund, L.P., Biotechnology Value Fund II, L.P., Biotechnology Value Trading Fund OS, L.P., and MSI BVF SPV, L.L.C., dated as of May 20, 2021		Form 8-K (Exhibit 10.1)	May 21, 2021	001-37471
10.59	Open Market Sale Agreement, dated as of August 9, 2019, by and between Pieris Pharmaceuticals, Inc. and Jefferies LLC		Form 10-Q (Exhibit 10.1)	August 9, 2019	001-37471
10.60	Amendment No. 1 to Sales Agreement, dated November 4, 2022, by and between Pieris Pharmaceuticals, Inc. and Jefferies LLC		Form 8-K (Exhibit 1.1)	November 4, 2022	001-37471
10.61	Consulting Agreement by and between the Registrant and Ahmed Mousa, dated as of September 11, 2023.	#	Form 10-Q (Exhibit 10.2)	November 14, 2023	001-37471
10.62	Amendment No. 1, dated December 11, 2023, to Consulting Agreement by and between the Registrant and Ahmed Mousa	#*			
10.63	Non-Qualified Stock Option Agreement by and between the Registrant and Hitto Kaufmann, Ph.D., dated as of August 30, 2019	#	Form 10-Q (Exhibit 10.3)	November 12, 2019	001-37471
10.64	Separation Agreement by and between the Registrant and Hitto Kaufmann, Ph.D., dated as of July 26, 2023.	#	Form 10-Q (Exhibit 10.1)	November 14, 2023	001-37471
10.65	Employment Agreement by and between Pieris GmbH and Shane Olwill, Ph.D. dated May 9, 2011	#*			
10.66	Amendments to the Employment Agreement by and between Pieris GmbH and Shane Olwill, Ph.D., dated between 2012-2021	#*			
10.67	Retention Letter by and between Pieris GmbH and Shane Olwill, Ph.D., dated February 22, 2024	#*			
21.1	List of Subsidiaries	*			
23.1	Consent of Ernst & Young LLP	*			
31.1	Certification of Stephen S. Yoder, Chief Executive Officer and President, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	*			
31.2	Certification of Thomas Bures, 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 Thomas Bures, Chief Financial Officer, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350	**			
97	Pieris Pharmaceuticals, Inc. Clawback Policy	*#			
101.INS	Inline XBRL Instance Document	*			
101.SCH	Inline XBRL Taxonomy Extension Schema Document	*			
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	*			
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	*			
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	*			
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	*			
104	Cover Page Interactive Data File (embedded within the Inline XBRL document and contained in Exhibit 101)	*			

* Filed herewith

** Furnished herewith

\+ Portions of the exhibit are omitted pursuant to Regulation S-K Item 601(b)(10)(iv). Copies of the unredacted exhibit will be furnished to the SEC upon request.

\# Indicates a management contract or compensatory plan

Item 16. FORM 10-K SUMMARY

We may voluntarily include a summary of information required by Form 10-K under this Item 16. We have elected not to include such summary information.

SIGNATURES

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

PIERIS PHARMACEUTICALS, INC.

March 29, 2024

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

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

Signature	Title	Date
/s/ Stephen S. Yoder Stephen S. Yoder	President, Chief Executive Officer and Director *(Principal Executive Officer)*	March 29, 2024
/s/ Thomas Bures Thomas Bures	Chief Financial Officer *(Principal Financial Officer and Principal Accounting Officer)*	March 29, 2024
/s/ James Geraghty James Geraghty	Chairman of the Board of Directors	March 29, 2024
/s/ Michael Richman Michael Richman	Director	March 29, 2024
/s/ Maya R. Said, Sc.D. Maya R. Said, Sc.D.	Director	March 29, 2024
/s/ Peter Kiener, D.Phil. Peter Kiener, D.Phil.	Director	March 29, 2024
/s/ Christopher Kiritsy Christopher Kiritsy	Director	March 29, 2024
/s/ Ann Barbier, M.D., Ph.D. Ann Barbier, M.D., Ph.D.	Director	March 29, 2024
/s/ Matthew L. Sherman, M.D. Matthew L. Sherman, M.D.	Director	March 29, 2024

PIERIS PHARMACEUTICALS, INC.

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Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Pieris Pharmaceuticals, Inc. (the Company) as of December 31, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2023, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting 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.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Accrued and Prepaid Clinical Trial Expenses

Description of the Matter	As discussed in Note 2 to the consolidated financial statements, the Company records research and development expenses, which include expenses related to clinical trials, as incurred. The Company's determination of clinical trial costs incurred, as well as the related accrued and prepaid expenses at each reporting period incorporates judgment and utilizes various assumptions. Such judgments and assumptions include an evaluation of the information provided to the Company by third parties on actual costs incurred but not yet billed, estimated project timelines and patient enrollment. Payments for these activities are based on the terms of the individual arrangements, which differ from the pattern of costs incurred. Auditing the Company's accrued and prepaid clinical trial expenses was especially challenging due to the large volume of information received from multiple sources that perform service on the Company's behalf. While the Company's estimates of accrued and prepaid clinical trial expenses are primarily based on information received related to each study from its vendors, the Company may need to make an estimate for additional costs incurred based on management judgment. Additionally, due to the duration of the work performed under clinical trials and the timing of invoices received from vendors, the actual amounts incurred are not typically known at the time the financial statements are issued.
How We Addressed the Matter in Our Audit	To evaluate the accrued and prepaid clinical trial expenses, our audit procedures included, among others, testing the accuracy and completeness of the underlying data used in the estimates and evaluating the significant assumptions that are used by management to estimate the recorded accruals and prepayments. We corroborated the progress of research and development activities associated with clinical trials through discussion with the Company's research and development personnel that oversee the research and development activities. We inspected the Company's third-party contracts, amendments, and any pending change orders to assess the impact on amounts recorded. We also reviewed information received by the Company directly from vendors, which indicated the vendors' estimate of costs incurred to date. In addition, we performed analytics over fluctuations in accruals and prepaids by vendor throughout the period subject to audit and compared subsequent invoices received from third parties to amounts accrued.

/s/ Ernst & Young LLP
We have served as the Company's auditor since 2016.
Boston, Massachusetts
March 29, 2024

PIERIS PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 17,396	$ 38,635
Short term investments	8,970	20,534
Accounts receivable	572	5,810
Receivable from public grants	3,141	4,771
Other receivables	2,326	462
Assets held for sale, property and equipment	2,188	—
Prepaid expenses and other current assets	4,087	3,212
Total current assets	38,680	73,424
Property and equipment, net	—	16,992
Operating lease right-of-use assets, non-current	—	3,705
Other non-current assets	—	1,369
Total assets	$ 38,680	$ 95,490
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,372	$ 4,154
Operating lease liabilities, current	—	859
Accrued expenses and other current liabilities	8,550	10,746
Deferred revenues, current portion	—	20,824
Total current liabilities	11,922	36,583
Deferred revenue, net of current portion	—	18,734
Operating lease liabilities, non-current	—	12,244
Total liabilities	11,922	67,561
Commitments and Contingencies		
Stockholders' equity:		
Convertible preferred stock, $0.001 par value per share, 10,000,000 shares authorized and 15,617 shares issued and outstanding at December 21, 2023 and 2022	—	—
Common stock, $0.001 par value per share, 300,000,000 shares authorized and 98,935,025 and 74,519,103 shares issued and outstanding at December 21, 2023 and 2022, respectively	98	74
Additional paid-in capital	341,596	318,530
Accumulated other comprehensive income	28	(254)
Accumulated deficit	(314,964)	(290,421)
Total stockholders' equity	26,758	27,929
Total liabilities and stockholders' equity	$ 38,680	$ 95,490

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

PIERIS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except per share data)

	Year Ended December 31,	
	2023	**2022**
Revenue		
Customer revenue	$ 38,711	$ 25,469
Collaboration revenue	4,099	433
Total revenue	42,810	25,902
Operating expenses		
Research and development	41,801	52,982
General and administrative	16,853	16,394
Asset impairment	13,912	—
Total operating expenses	72,566	69,376
Loss from operations	(29,756)	(43,474)
Other income (expense)		
Interest income	1,851	721
Grant income	3,612	8,173
Other (expense) income	(250)	1,303
Net loss	$ (24,543)	$ (33,277)
Other comprehensive (loss) income:		
Foreign currency translation	208	(1,010)
Unrealized gain (loss) on available-for-sale securities	74	(73)
Comprehensive loss	$ (24,261)	$ (34,360)
Net loss per share		
Basic and diluted	$ (0.27)	$ (0.45)
Weighted average number of common shares outstanding		
Basic and diluted	90,064	74,172

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

PIERIS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

(In thousands)

	Preferred shares		Common shares		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total Stockholders' equity
	No. of shares	Share capital	No. of shares	Share capital				
Balance as of January 1, 2022	16	$ —	72,222	$ 72	$ 306,998	$ 829	$ (257,144)	$ 50,755
Net loss	—	—	—	—	—	—	(33,277)	(33,277)
Foreign currency translation adjustment	—	—	—	—	—	(1,010)	—	(1,010)
Unrealized loss on investments	—	—	—	—	—	(73)	—	(73)
Stock based compensation expense	—	—	—	—	4,402	—	—	4,402
Issuance of common stock resulting from exercise of stock options	—	—	46	—	95	—	—	95
Issuance of common stock resulting from purchase of employee stock purchase plan shares	—	—	182	—	197	—	—	197
Issuance of common stock pursuant to ATM offering program, net of $0.3 million in offering costs	—	—	2,069	2	6,838	—	—	6,840
Balance at December 31, 2022	16	$ —	74,519	$ 74	$ 318,530	$ (254)	$ (290,421)	$ 27,929
Net loss	—	—	—	—	—	—	(24,543)	(24,543)
Foreign currency translation adjustment	—	—	—	—	—	208	—	208
Unrealized gain on investments	—	—	—	—	—	74	—	74
Stock based compensation expense	—	—	—	—	3,349	—	—	3,349
Issuance of common stock resulting from purchase of employee stock purchase plan shares	—	—	155	—	66	—	—	66
Issuance of common stock pursuant to ATM offering program, net of $0.7 million in offering costs	—	—	24,261	24	19,651	—	—	19,675
Balance at December 31, 2023	16	$ —	98,935	$ 98	$ 341,596	$ 28	$ (314,964)	$ 26,758

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

PIERIS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Year Ended December 31,	
	2023	**2022**
Operating activities:		
Net loss	$ (24,543)	$ (33,277)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization (accretion)	1,904	2,770
Right-of-use asset (accretion) amortization	(123)	10
Stock-based compensation	3,349	4,402
Asset impairment	13,912	—
Realized investment gains	(53)	(376)
Other non-cash transactions	(124)	(91)
Changes in operating assets and liabilities:		
Accounts receivable	5,307	(2,624)
Prepaid expenses and other assets	1,018	(1,358)
Deferred revenue	(39,967)	(20,185)
Accounts payable	(789)	(4,208)
Accrued expenses and other current liabilities	(2,336)	(4,005)
Lease liability, prior to operating lease termination	(868)	(990)
Change in lease liability due to termination of operating lease	(10,506)	—
Net cash used in operating activities	(53,819)	(59,932)
Investing activities:		
Purchases of property and equipment	(171)	(1,041)
Proceeds from maturity of investments	35,008	28,200
Purchases of investments	(22,835)	(48,395)
Net cash provided by (used in) investing activities	12,002	(21,236)
Financing activities:		
Proceeds from exercise of stock options	—	95
Proceeds from employee stock purchase plan	66	197
Proceeds from issuance of common stock resulting from ATM sales, net of $ 0.7 million and $0.3 million in transaction costs, respectively	19,729	6,922
Net cash provided by financing activities	19,795	7,214
Effect of exchange rate change on cash and cash equivalents	783	(5,175)
Net decrease in cash and cash equivalents	(21,239)	(79,129)
Cash and cash equivalents at beginning of period	38,635	117,764
Cash and cash equivalents at end of period	$ 17,396	$ 38,635
Supplemental cash flow disclosures:		
Net unrealized gain (loss) on investments	$ 74	$ (73)
Property and equipment included in accounts payable	$ —	$ 193

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., or the Company or Pieris, was founded in May 2013, and acquired 100% interest in Pieris Pharmaceuticals GmbH (formerly Pieris AG, a German company which was founded in 2001) in December 2014. Pieris Pharmaceuticals, Inc. and its wholly-owned subsidiaries, hereinafter collectively Pieris, or the Company, is a biopharmaceutical company that, prior to July of 2023, discovered and developed Anticalin-based drugs to target validated disease pathways in unique and transformative ways. Pieris' clinical pipeline consists of immuno-oncology, or IO, programs partnered with several major multi-national pharmaceutical companies. Pieris' corporate headquarters is located in Boston, Massachusetts. Pieris also maintains office space in Hallbergmoos, Germany.

The Company's core Anticalin technology and platform was developed in Germany.

On July 18, 2023, the Company announced its intention to explore engaging in one or more strategic transactions, including mergers, reverse mergers, acquisitions, other business combinations or sales of assets, or other strategic transactions. This decision was related to events that impacted the Company's inhaled respiratory franchise, based upon AstraZeneca's discontinuation of enrollment of the Phase 2a study for elarekibep, an inhaled IL-4Rα antagonist Anticalin protein to treat uncontrolled asthma. As part of this initiative, the Company engaged Stifel, Nicolaus & Company, Incorporated to serve as its advisor in its review of strategic transactions.

Also on July 18, 2023, the Company's board of directors approved a reduction in the Company's workforce by approximately 70%. Since July of 2023, and through December 31, 2023, the Company took additional steps to reduce its operating footprint including terminating its remaining lease obligations in Germany and winding down its proprietary inhaled respiratory programs. The Company also has opted out and terminated programs where possible to reduce operating costs. Further reductions in the workforce have occurred based upon these actions. As a result, the Company has incurred approximately $7.5 million of severance costs and other related termination benefits in 2023 as the service period to earn such benefits is considered complete. The Company expects termination benefits to be paid through the end of 2024.

On March 27, 2024, the Company announced the implementation of a new strategy along with relevant cost-saving measures that are expected to extend its cash runway into at least 2027, while maximizing its ability to capture the potential milestones from its partnered 4-1BB bispecific Mabcalin protein IO assets. The Company may be entitled to aggregate milestones of up to $20 million upon first patient dosed in the phase 2 trials for SGN-BB228, S095012 (formerly PRS-344) and BOS-342, which are all currently in phase 1 clinical development, and up to $55 million upon first patient dosed in pivotal clinical trials for SGN-BB228, S095012 and BOS-342. To support this new strategy, the Company plans to discontinue all of its research and development efforts which it expects to complete by the middle of 2024, implement a workforce reduction that will impact additional employees and the executive leadership team which is expected to be implemented in the second quarter of 2024, and reduce the size of its Board of Directors, which is also expected to have implemented in the second quarter of 2024. In addition to the alliance management activities for its partnered programs, the Company remains committed to obtaining value for its products in prior development, including cinrebafusp alfa, as well as its proprietary platform capabilities by pursuing potential out-licensing or sales transactions. In addition to these potential transactions, the Company may also, from time-to-time, consider strategic opportunities that it believes may increase stockholder value.

As of December 31, 2023, cash, cash equivalents, and investments were $26.4 million. The Company's net loss was $24.5 million and $33.3 million for the years ended December 31, 2023 and 2022, respectively. The Company has incurred net losses since inception and had an accumulated deficit of $315.0 million as of December 31, 2023. Net losses and negative cash flows have had, and will continue to have, an adverse effect on the Company's stockholders' equity and working capital. The Company expects to continue to incur operating losses for the foreseeable future.

The Company has historically devoted substantially all of its financial resources and efforts to research and development and general and administrative expenses to support the discovery and development of Anticalin-based drugs. Going forward, as part of the Company's decision to implement measures to maximize its ability to capture potential milestones from its partnered programs with Pfizer, Boston Pharmaceuticals, and Servier, the Company plans to discontinue all research and development efforts and reduce discretionary expenditures and other fixed or variable personnel costs. The Company believes that its currently available funds will be sufficient to fund its operations through at least the next twelve months from the issuance of this Annual Report on Form 10-K. The Company's belief with respect to its ability to fund operations is based on estimates that are subject to risks and uncertainties. If actual results are different from management's estimates, the Company may need to seek additional funding.

2. Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

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

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

Foreign Currency Translation

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

Realized and unrealized gains and losses resulting from foreign currency transactions denominated in currencies other than the functional currency are reflected as other (expense) income, net in the consolidated statements of operations. Foreign currency gains and losses on available-for-sale investment transactions are recorded to other comprehensive income (loss) on the Company's balance sheet per Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 830, *Foreign Currency Matters.*

Cash, Cash Equivalents and Investments

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

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

The Company reviews investments for other-than-temporary impairment whenever the fair value of an investment is less than the amortized cost and evidence indicates that an investment's carrying amount is not recoverable within a reasonable period of time. To determine whether an impairment is other-than temporary, the Company considers its intent to sell, or whether it is more likely than not that the Company will be required to sell the investment before recovery of the investment's amortized cost basis. Evidence considered in this assessment includes reasons for the impairment, the severity and the duration of the impairment, and changes in value subsequent to period end.

Concentration of Credit Risk and Off-Balance Sheet Risk

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

Fair Value Measurement

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

- Level 1 inputs are quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date.
- Level 2 utilizes quoted market prices in markets that are not active, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency.
- Level 3 inputs are unobservable inputs for the asset or liability in which there is little, if any, market activity for the asset or liability at the measurement date.

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

Financial instruments measured at fair value on a recurring basis include cash equivalents and investments, if any (*Note 5*).

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

Fair Values of Financial Instruments

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

Accounts Receivable

Accounts receivable are recorded net of allowances for credit losses and represent amounts due from strategic partners. The Company monitors and evaluates collectability of receivables on an ongoing basis and considers whether an allowance for credit losses is necessary. The Company determined that no such reserve is needed as of December 31, 2023 and 2022. Historically, the Company has not had collectability issues.

Property and Equipment

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

Asset Classification	Estimated useful life (in years)
Leasehold improvements	shorter of useful life or remaining life of the lease
Laboratory furniture and equipment	8-14
Office furniture and equipment	5-13
Computer and equipment	3 - 7

If the criteria in *ASC 360 Property, Plant and Equipment* are met, a long-lived asset is classified as held for sale. The long-lived asset is reported at the lower of its carrying value or fair value less cost to sell beginning in the period the held for sale criteria are met. The carrying amount of the asset will be adjusted each reporting period for subsequent changes in fair value less cost to sell. A loss is recognized for any subsequent write-down to fair value less cost to sell. A gain is recognized for any subsequent increase in fair value less cost to sell, but not in excess of the cumulative loss previously recognized. Once classified as held for sale, depreciation and amortization are no longer recorded for any long-lived assets included in the disposal group.

Impairment of Long-lived Assets

The Company reviews its long-lived assets to be held and used for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. The Company evaluates the realizability of its long-lived assets based on profitability and cash flow expectations for the related asset. Any write-downs are treated as permanent reductions in the carrying amount of the assets.

Revenue Recognition

Pieris has entered into several licensing agreements with collaboration partners for the development of Anticalin therapeutics against a variety of targets. The terms of these agreements provide for the transfer of multiple goods or services which *may* include: (i) licenses, or options to obtain licenses, to Pieris' Anticalin technology and/or specific programs and (ii) research and development activities to be performed on behalf of or with a collaborative partner. Payments to Pieris under these agreements *may* include upfront fees (which include license and option fees), payments for research and development activities, payments based upon the achievement of certain milestones, and royalties on product sales. There are *no* performance, cancellation, termination or refund provisions in any of the arrangements that could result in material financial consequences to Pieris. As the Company's intellectual property assets are considered to be located in Germany, the Company records all consolidated revenue in its subsidiary, Pieris Pharmaceuticals, GmbH.

Collaborative Arrangements

The Company considers the nature and contractual terms of an arrangement and assesses whether the arrangement involves a joint operating activity pursuant to which it is an active participant and exposed to significant risks and rewards with respect to the arrangement. If the Company is an active participant and exposed to the significant risks and rewards with respect to the arrangement, it accounts for these arrangements pursuant to ASC 808, *Collaborative Arrangements*, or ASC 808, and applies a systematic and rational approach to recognize revenue. The Company classifies payments received as revenue and payments made as a reduction of revenue in the period in which they are earned. Revenue recognized under a collaborative arrangement involving a participant that is not a customer is presented as Collaboration Revenue in the Statement of Operations.

Revenue from Contracts with Customers

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

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

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

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

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

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

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

When a performance obligation is satisfied, revenue is recognized for the amount of the transaction price, excluding estimates of variable consideration that are constrained, that is allocated to that performance obligation on a relative standalone selling price basis. Significant management judgment is required in determining the level of effort required under an arrangement and the period over which the Company is expected to complete its performance obligations under an arrangement.

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

Revenue recognized under an arrangement involving a participant that is a customer is presented as Customer Revenue.

Milestones and Royalties

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

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

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

The Company calculates the maximum amount of potential milestones achievable under each collaboration agreement and discloses such potential future milestones for all current collaborations using such a maximum calculation.

Contract Balances

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

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

Costs to Obtain and Fulfill a Contract with a Customer

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

Research and Development

Research and development expenses are charged to the statement of operations as incurred. Research and development expenses are comprised of costs incurred in performing research and development activities, including salaries and benefits, facilities costs, pre-clinical and clinical costs, contract services, consulting, depreciation and amortization expense, and other related costs. Costs associated with acquired technology, in the form of upfront fees or milestone payments, are charged to research and development expense as incurred.

Income Taxes

The Company applies ASC Topic 740 *Income Taxes*, which established financial accounting and reporting requirements for the effects of income taxes that result from the Company's activities during the current and preceding years. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, and operating losses and tax credit carry forwards. Deferred tax assets and liabilities are measured using enacted statutory tax rates expected to apply to taxable income in the jurisdictions and years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Where the Company determines that it is more likely than not that some portion or all of the deferred tax assets will not be realized in the future, the deferred tax assets are reduced by a valuation allowance. The Company records interest and penalties related to uncertain tax positions as part of income tax expense.

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

Stock-based Compensation

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

The Company uses the Black-Scholes option pricing model to determine the estimated fair value for stock-based awards. Option-pricing models require the input of various subjective assumptions, including the option's expected life, expected dividend yield, price volatility, risk free interest rate and forfeitures of the underlying stock. Due to the limited operating history of the Company as a public entity and a lack of company specific historical and implied volatility data, the Company has based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. When selecting these public companies on which it has based its expected stock price volatility, the Company selected companies with comparable characteristics to it, including enterprise value, risk profiles, position within the industry, and with historical share price information sufficient to meet the expected term of the stock-based awards. The Company computes historical volatility data using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the stock-based awards. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

Due to the lack of Company specific historical option activity, the Company has estimated the expected term of its employee stock options using the "simplified" method, whereby, the expected term equals the arithmetic average of the vesting term and the original contractual term of the option. The expected term for non-employee awards is the remaining contractual term of the option. The risk-free interest rates are based on the U.S. Treasury securities with a maturity date commensurate with the expected term of the associated award. The Company has never paid dividends, but may elect pay out dividends to stockholders in the future if we determine that there is sufficient cash and investments to achieve our near and long-term objectives.

All excess tax benefits and tax deficiencies are recorded as income tax expense or benefit in the Company's statement of operations and comprehensive loss. For the years ended December 31, 2023 and 2022, the Company did not record an income statement benefit for excess tax benefits as a valuation allowance is also required on these amounts.

Government Grants

The Company recognizes grants from governmental agencies when there is reasonable assurance that the Company will comply with the conditions attached to the grant arrangement and the grant will be received. The Company evaluates the conditions of each grant as of each reporting period to evaluate whether the Company has reached reasonable assurance of meeting the conditions of each grant arrangement and that it is expected that the grant will be received as a result of meeting the necessary conditions. Grants are recognized in the consolidated statements of operations on a systematic basis over the periods in which the Company recognizes the related costs for which the government grant is intended to compensate. Specifically, grant income related to research and development costs is recognized as such expenses are incurred. Grant income is included as a separate caption within Other income (expense), net in the consolidated statements of operations.

Leases

The Company accounts for leases pursuant to ASC 842 *Leases (Topic 842)*, or ASC 842. As a lessee, the Company is required to recognize (i) a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis; and (ii) a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term for all leases (with the exception of short-term leases) at the commencement date.

The Company determines if an arrangement is a lease at inception. The Company's contracts are determined to contain a lease within the scope of ASC 842 when all of the following criteria based on the specific circumstances of the arrangement are met: (1) there is an identified asset for which there are no substantive substitution rights; (2) the Company has the right to obtain substantially all of the economic benefits from the identified asset; and (3) the Company has the right to direct the use of the identified asset. In addition, the Company does not apply the recognition requirements in the lease standard to short-term leases (a lease that at commencement date has a lease term of 12 months or less and does not contain a purchase option that it is reasonably certain to exercise) and does not separate lease and non-lease components for all asset classes. Any variable components of lease costs are excluded from lease payments and are recognized in the period incurred, including increases to rent based on German Consumer Price Index, or CPI.

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

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

Assumptions made by the Company at the commencement date are re-evaluated upon occurrence of certain events, including a lease modification. A lease modification results in a separate contract when the modification grants the lessee an additional right of use not included in the original lease and when lease payments increase commensurate with the standalone price for the additional right of use. When a lease modification results in a separate contract, it is accounted for in the same manner as a new lease.

When a lease is terminated in its entirety, the corresponding lease liability and right-of-use asset are adjusted to zero. Any difference between the carrying amounts of the right-of-use asset and lease liability as compared to the termination payment is recorded in the statement of operations as a gain or loss.

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 evaluated by the chief operating decision maker in making decisions on how to allocate resources and assess performance. The Company operates as a single segment dedicated to the discovery and development of biotechnological applications and the Company's chief operating decision maker, or CODM, makes decisions based on the Company as a whole. The Company has determined that its CODM is its Chief Executive Officer.

Earnings per Share

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

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

Recent Accounting Pronouncements Not Yet Adopted

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

3. Revenue

General

The Company has not generated revenue from product sales. The Company has generated revenue from contracts with customers (option, license and collaboration agreements), which include upfront payments for licenses or options to obtain licenses, payments for research and development services and milestone payments.

During the years ended December 31, 2023 and 2022, respectively, the Company recognized revenue from the following strategic partnerships and other license agreements (in thousands):

	Year Ended December 31,	
	2023	2022
AstraZeneca	$ 8,399	$ 9,117
Pfizer	15,134	8,287
Servier	4,099	5,359
Genentech	12,697	3,139
Boston Pharmaceuticals	2,481	—
Total Revenue	$ 42,810	$ 25,902

Under the Company´s existing strategic partnerships and other license agreements, the Company could receive the following potential milestone payments (in millions) as of December 31, 2023:

	Research, Development, Regulatory & Commercial Milestones	Sales Milestones
Pfizer	$ 759	$ 450
Servier	107	99
Boston Pharmaceuticals	85	265
Total potential milestone payments	$ 951	$ 814

Strategic Partnerships

Genentech

On May 19, 2021, the Company and Genentech, Inc., or Genentech, entered into a Research Collaboration and License Agreement, or the Genentech Agreement, to discover, develop and commercialize locally delivered respiratory and ophthalmology therapies that leverage the Company's proprietary Anticalin technology. Upon signing the Genentech Agreement, Genentech paid the Company a $20 million upfront fee. In addition, the Company may be eligible to receive additional milestone payments across multiple programs, as well as tiered royalty payments on net sales at percentages ranging from the mid-single to low double-digits, subject to certain standard reductions and offsets.

Under the terms of the Genentech Agreement, the Company was responsible for discovery and preclinical development of two initial programs. In April and May 2023, Genentech and the Company decided to discontinue the discovery-stage programs in ophthalmology and respiratory, respectively, for scientific reasons. Pursuant to this decision, the material right performance obligations related to the target swaps for these programs also expired. Based on these decisions, there aren't any active performance obligations remaining under the collaboration and the Company recognized all remaining revenue, or $12.5 million, under the collaboration in the second quarter of 2023.

The Genentech Agreement also provided an option to select additional programs, at Genentech's discretion, for a fee and this option expires in May 2024. If Genentech exercises its option to start additional programs, the Company would be eligible to receive additional milestone payments, as well as tiered royalty payments on net sales, subject to certain standard reductions and offsets. Genentech's options to nominate two additional collaboration targets of their choosing is subject to the legal availability of the target to be researched. As of December 31, 2023, any variable consideration related to the exercise of such options is considered fully constrained.

Boston Pharmaceuticals

On April 24, 2021, the Company and BP Asset XII, Inc., or Boston Pharmaceuticals, a subsidiary of Boston Pharma Holdings, LLC, entered into an Exclusive Product License Agreement, or the BP Agreement, to develop PRS-342, a 4-1BB/GPC3 preclinical immuno-oncology Anticalin-antibody bispecific fusion protein.

Under the terms of the BP Agreement, Boston Pharmaceuticals exclusively licensed worldwide rights to PRS- 342. The Company received an upfront payment of $10.0 million and is further entitled to receive development, regulatory and sales-based milestone payments, tiered royalties up to low double-digits on sales of PRS-342 and a percentage of consideration received by Boston Pharmaceuticals in the event of a sublicense of a program licensed under the BP Agreement or a change of control of Boston Pharmaceuticals. The Company also contributed $4.0 million toward manufacturing activities.

The Company completed all performance obligations in 2021, at which point the revenue was recorded from the upfront payment. In August 2023, the first patient was dosed in the Boston Pharmaceuticals sponsored Phase 1/2 study for BOS-342 in hepatocellular carcinoma, or HCC, for which the Company received a milestone payment.

Pfizer

On February 8, 2018, the Company entered into a license and collaboration agreement, or the Pfizer Collaboration Agreement (formerly the Seagen Collaboration Agreement), and a non-exclusive Anticalin platform technology license agreement, or the Pfizer Platform License (formerly the Seagen Platform License), and together with the Pfizer Collaboration Agreement, the Pfizer Agreements (formerly the Seagen Agreements), with Pfizer (formerly Seagen), pursuant to which the agreed to develop multiple targeted bispecific IO treatments for solid tumors and blood cancers.

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

On March 24, 2021, the Company announced that Pfizer made a strategic equity investment in Pieris, and that the companies had entered into a Second Pfizer Amendment (formerly Second Seagen Amendment), in which their existing immuno-oncology collaboration agreement has been amended relating to joint development and commercial rights for one program in the alliance. Under the Second Pfizer Amendment, Pieris' option to co-develop and co-commercialize one of three programs in the collaboration was converted to a co-promotion option in the United States, with Pfizer solely responsible for the development and overall commercialization of that program. Pieris will also be entitled to increased royalties from that program in the event that it chooses to exercise the co-promotion option. In connection with the agreements described above, the Company and Pfizer entered into a subscription agreement, or the Pfizer Subscription Agreement (formerly the Seagen Subscription Agreement), pursuant to which the Company agreed to issue to Pfizer, and Pfizer agreed to acquire from the Company, 3,706,174 shares of the Company's common stock for a total purchase price of $13.0 million, or $3.51 per share, in a private placement transaction pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended. The Pfizer Subscription Agreement includes a provision to the effect that Pfizer may ask the Company to file a registration statement to register the resale of the shares issued to Pfizer, at any time beginning on the date that is 60 calendar days from the date of issuance of the shares. The Company assessed the ASC 606 implications of the Pfizer Subscription Agreement and concluded that the fair value of the shares on a per share basis was $2.61 per share as of the transaction date. This resulted in a premium paid for the shares of $ 3.3 million, all of which was recorded in deferred revenue upon contract execution and allocated to the remaining performance obligations.

In the second quarter of 2022, the Company recorded approximately $1.5 million in revenue related to completion of the performance obligation for the expiration of the target swap under the second program in the collaboration.

Under the Pfizer Agreements, the Company is eligible to receive various research, development, commercial and sales milestones. There is uncertainty that the events to obtain the research and development milestones will be achieved given the nature of clinical development and the stage of the Company's technology. The Company has thus determined that all research and development milestones will be constrained until it is deemed probable that a significant revenue reversal will not occur, with the exception of the $5.0 million milestone as described in the following paragraph.

In January 2023, the Company achieved a milestone for the first program in the collaboration for $5.0 million. The Company evaluated the recognition of the milestone under ASC 606 and concluded that the constraints on the milestone no longer existed as of December 31, 2022 and therefore recorded the full $5.0 million as revenue for the year ended December 31, 2022.

In September 2023, Pfizer and the Company entered into an amendment of the Second Pfizer Amendment that provides Pfizer with collaboration product licenses and no changes to the amounts achievable under the collaboration agreement. The effect of the September 2023 amendment was to transfer responsibility for substantially all activities previously performed by the Company to Pfizer. Subsequently, in December 2023, the transfer of the programs was fully approved by the combined joint steering committee. Accordingly, the Company recognized revenue of approximately $10.1 million for the delivery on its performance obligations related to the two programs for the year ended December 31, 2023. With this amendment, the Company has satisfied all remaining obligations under the collaboration.

AstraZeneca

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

In addition to the Company's former lead inhaled drug candidate, PRS-060/AZD1402, or the AstraZeneca Lead Product, the Company and AstraZeneca, under the original terms of the AstraZeneca Collaboration Agreement, would also collaborate to progress four additional novel Anticalin proteins against undisclosed targets for respiratory diseases, or the AstraZeneca Collaboration Products, and together with the AstraZeneca Lead Product, the AstraZeneca Products. As of June 2023, the AstraZeneca Lead Product and three of the four AstraZeneca Collaboration Products had been discontinued. The first two discovery-stage programs were previously discontinued in 2022, which led to approximately $9.7 million in revenue recognized due to these discontinuations. Elarekibep and the third discovery-stage program were discontinued in the second quarter of 2023. The discontinuation of the third discovery program led to recognition of $4.0 million of revenue in the quarter ended June 30, 2023, while there was no revenue recognized as a result of the discontinuation of elarekibep.

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

On July 17, 2023, AstraZeneca notified the Company of its intention to terminate the AstraZeneca Collaboration Agreement and the AstraZeneca Platform License, effective October 15, 2023. AstraZeneca's decision to terminate the AstraZeneca Agreements was based on non-clinical safety findings in a 13-week toxicology study of elarekibep in non-human primates previously disclosed by the Company. As a result of this, the remaining amount of current deferred revenue, or $3.5 million, related to the fourth discovery-stage program was recognized in revenue as of September 30, 2023. With the termination of the AstraZeneca Agreements, there are no more active programs or performance obligations related to the collaboration. Following the termination date, the Company determined that it would not continue development of the programs under the AstraZeneca Agreements.

The Company incurred $1.6 million of third-party success fees to obtain the contract with AstraZeneca. Upon adoption of ASC 606, the Company capitalized $1.1 million in accordance with ASC 340. In accordance with the termination of the AstraZeneca Agreements and recognition of remaining revenue, the Company also amortized the remaining deferred transactions costs to obtain the contract, or $0.3 million. Amortization for the year ended December 31, 2022 was $0.3 million.

Servier

In 2017, the Company entered into a license and collaboration agreement, or Servier Collaboration Agreement, and a non-exclusive Anticalin platform license agreement, or Servier Platform License, and together with the Servier Collaboration Agreement, the Servier Agreements with Les Laboratoires Servier and Institut de Recherches Internationales Servier, or Servier, pursuant to which the Company and Servier agreed to initially pursue five bispecific therapeutic programs. The intention of the collaboration and defined programs was to combine antibodies from the Servier portfolio with one or more Anticalin proteins based on the Company's proprietary platform to generate innovative IO bispecific drug candidates, or the Collaboration products.

In the first quarter of 2022, the Company satisfied the performance obligation related to the material right for S095025 (PRS-352), which led to point-in-time recognition of revenue for $4.9 million of revenue previously deferred. In the fourth quarter of 2022, Servier discontinued development of S095025 based upon a strategic portfolio review. Since inception, four of the five initially committed programs have been discontinued by Servier. The Company does not presently intend to continue development of the four discontinued programs but retains full rights to advance the development and commercialization of those products on a world-wide basis in the future.

In July 2023, the Company notified Servier of its decision to opt out of co-development and commercialization of S095012 (PRS-344), a 4- 1BB/PD-L1 bispecific Mabcalin protein, in the U.S. Servier retains exclusive, even as to the Company, worldwide rights to the program, including the right to continue to advance development and potential commercialization of S095012 (PRS-344) in the U.S. As a result of the Company's decision to opt out of co-development, the Company will be entitled to increased royalty rates and potential royalties and milestones, if any, for S095012 (PRS-344) under the terms of the Servier Agreement. With the decision to opt out of co-development of S095012 (PRS-344), the Company recognized the remaining revenue under the collaboration, or $4.7 million, in 2023 and there are no more active co-development programs under the collaboration.

Contract Balances

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

There were no additions to deferred revenue during the year ended December 31, 2023 and reductions to deferred revenue were $ 39.7 million for the year ended December 31, 2023.

4. Grant Income

One of the Company's proprietary respiratory assets is PRS- 220, an oral inhaled Anticalin protein targeting connective tissue growth factor, or CTGF, was being developed as a local treatment for idiopathic pulmonary fibrosis, and other forms for fibrotic lung disorders. In June 2021, the Company received a €14.2 million (approximately $17.0 million) grant from the Bavarian Ministry of Economic Affairs, Regional Development and Energy (the Bavarian Grant) supporting research and development for post-acute sequelae of SARS-CoV-2 infection (PASC) pulmonary fibrosis, or PASC-PF, also known as post-COVID-19 syndrome pulmonary fibrosis, or "long COVID".

The Bavarian Grant provides partial reimbursement for qualifying research and development activities on PRS- 220, including drug manufacturing costs, activities and costs to support an IND filing, and phase 1 clinical trials costs. The Bavarian Grant provides reimbursement of qualifying costs incurred through December 2023, with submission for reimbursements allowed through February 2024, which was successfully completed by the Company. The timing follows the expected development timeline of this program. Qualifying costs incurred may exceed the annual grant funding thresholds.

In addition, the Company is required to communicate if there is a change in control or other event that would impact the continuation of PRS- 220 to the Bavarian project agency, in which case the Company may be required to refund some or all amounts received under the grant.

5. Cash, Cash Equivalents and Investments

As of December 31, 2023, cash, cash equivalents and investments comprised funds in depository, money market accounts and U.S. treasury securities. As of December 31, 2022, cash, cash equivalents and investments comprised funds in depository, money market accounts, U.S. and foreign treasury securities, asset-backed securities and corporate bonds. The following table presents the cash equivalents and investments carried at fair value in accordance with the hierarchy defined in Note 2 at December 31, 2023.

	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
December 31, 2023				
Money market funds, included in cash equivalents	$ 13,224	$ 13,224	$ —	$ —
Investments - US treasuries	8,970	8,970	—	—
Total	$ 22,194	$ 22,194	$ —	$ —

	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
December 31, 2022				
Money market funds, included in cash equivalents	$ 17,618	$ 17,618	$ —	$ —
Investments - US treasuries	3,573	3,573	—	—
Investments - Foreign treasuries	896	896	—	—
Investments - Asset-backed securities	499	—	499	—
Investments - Corporate bonds	15,566	—	15,566	—
Total	$ 38,152	$ 22,087	$ 16,065	$ —

Cash equivalents and marketable securities have been initially valued at the transaction price and subsequently valued, at the end of each reporting period, utilizing third party pricing services or other market observable data. The pricing services utilize industry standard valuation models, including both income and market-based approaches and observable market inputs to determine value. The Company validates the prices provided by its third-party pricing services by reviewing their pricing methods and obtaining market values from other pricing sources, as needed. After completing its validation procedures, the Company did not adjust any fair value measurements provided by the pricing services as of December 31, 2023.

Investments at December 31, 2023 consist of the following (in thousands):

	Contractual maturity (in days)	Amortized Cost	Unrealized gains	Unrealized losses	Fair Value
Investments					
US treasuries	4-51	$ 8,969	$ 1	$ —	$ 8,970
Total		$ 8,969	$ 1	$ —	$ 8,970

The Company recorded realized losses from the maturity of available-for-sale securities of $ 0.1 million and realized gains of $ 0.4 million for the years ended December 31, 2023 and 2022, respectively.

As of December 31, 2023, there were no investments with a fair value that was significantly lower than the amortized cost basis or any investments that had been in an unrealized loss position for a significant period.

6. Assets Held for Sale, Property and Equipment

As of December 31, 2023, assets held for sale are summarized as follows (in thousands):

	December 31, 2023
Laboratory furniture and equipment	$ 1,967
Office furniture and equipment	221
Assets held for sale	$ 2,188

At the end of the third quarter of 2023, as part of the Company's strategic process for maximizing the value of assets, the Company committed to a plan to prepare and sell all property and equipment held at the Hallbergmoos, Germany location. The sale of the assets was deemed probable as a result of management's decision, including the estimated timing of sale which was determined to be within a year of the decision. As a result of this decision, the property and equipment met the criteria for held-for-sale accounting.

The Company recorded impairment charges totaling $13.9 million, of which $1.8 million related to impairment of its right-of-use asset under the Hallbergmoos Lease (see Note 13) with the remaining related to a complete write-off of leasehold improvements and a partial impairment of the Company's other long-lived assets. The remaining $2.2 million in net book value of its long-lived assets represents the Company's best estimate of the fair value less costs to sell that could be recovered related to lab and office equipment and furniture as part of the Company's initiative to monetize all remaining assets. As the estimated selling price less costs to sell are based primarily on unobservable inputs as they relate to the location and condition of the specific lab equipment and furniture, they are classified in Level 3 in the fair value hierarchy. In the first quarter of 2024, the Company conducted an auction, with the assistance of a third party, of its assets held for sale. After the conclusion of the auction, the Company has recovered substantially all of the total net book value of the assets held for sale. The Company has further plans to sell all remaining assets in the second quarter of 2024.

As of December 31, 2022, property and equipment are summarized as follows (in thousands):

	December 31, 2022
Laboratory furniture and equipment	$ 11,970
Office furniture and equipment	1,861
Computer equipment	364
Leasehold improvements	12,444
Property and equipment, cost	26,639
Accumulated depreciation	(9,647)
Property and equipment, net	$ 16,992

Depreciation expense was $1.8 million and $2.3 million for the years ended December 31, 2023 and 2022, respectively. There were no other changes in accumulated depreciation other than the foreign currency impact.

7. Accrued Expenses

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

	Years Ended December 31,	
	2023	2022
Compensation expense	$ 6,448	$ 3,015
Research and development fees	968	5,758
Accrued accounts payable	558	1,245
Other current liabilities	363	483
Accrued license obligations	213	245
Total	$ 8,550	$ 10,746

The compensation expense line item in the above table includes both severance and benefit costs associated with the Company's corporate restructuring actions announced in 2023, inclusive of those employees retained as the service period to earn such benefits is considered complete. The Company recognized restructuring expenses consisting of one-time cash severance payments and other employee-related costs. Severance pay and related costs for certain retained employees are estimated to be paid through the end of 2024. The Company recorded these restructuring charges based on each employee's role to the respective research and development and general and administrative operating expense categories on its consolidated statements of operations and comprehensive loss.

The following table includes a roll forward of the restructuring activity and payments recorded for the year ended December 31, 2023 (in thousands):

	Severance and Benefits Costs
Restructuring expenses	$ 7,523
Cash payments	$ (2,418)
Balance at December 31, 2023	$ 5,105

8. Income Taxes

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

	Years Ended December 31,	
	2023	2022
Domestic	$ (9,818)	$ (11,765)
Foreign	(14,726)	(21,512)
Loss before income taxes	$ (24,544)	$ (33,277)

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

	Years Ended December 31,	
	2023	2022
Current:		
Federal	$ —	$ —
State	—	—
Foreign	—	—
Total current	—	—
Deferred:		
Federal	—	—
State	—	—
Foreign	—	—
Total deferred	—	—
Provision for income taxes	$ —	$ —

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

	2023	2022
Federal income tax rate	21.0%	21.0%
Foreign rate differential	0.7%	5.0%
State tax, net of federal benefit	3.8%	2.0%
Share-based awards compensation	(2.1)%	(2.2)%
Permanent items	(2.1)%	0.3%
Other	(1.0)%	1.0%
Release of uncertain tax position	22.7%	—%
Credits	0.8%	1.2%
Change in valuation allowance	(43.8)%	(28.3)%
Effective income tax rate	—%	—%

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

	Years Ended December 31,	
	2023	2022
Deferred tax assets:		
Net operating loss carryforwards	$ 67,496	$ 54,845
Share-based awards compensation	2,624	3,112
Accrued expenses	461	216
R&D Credits	644	413
Depreciation and other	479	384
Unrealized foreign currency	(377)	359
Capitalized R&D	1,165	952
Lease liability	—	3,541
Total deferred tax assets	72,492	63,822
Deferred tax liabilities:		
Right-of-use asset	—	(3,270)
Accrued expenses	—	—
Total deferred tax liabilities	—	(3,270)
Less: valuation allowance:	(72,492)	(60,552)
Net deferred tax asset	$ —	$ —

The Company operates in multiple jurisdictions. Accordingly, the Company files U.S. federal and state income tax returns as well as returns in multiple foreign jurisdictions. In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax-planning strategies in making this assessment. Management believes it is more likely than not that the results of future operations will not generate sufficient taxable income in the United States or in its foreign jurisdictions to realize the full benefits of its deferred tax assets. As of December 31, 2023, the Company continues to maintain a full valuation allowance against all net deferred tax assets.

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

The increase in the valuation allowance of deferred tax assets of $ 11.9 million for the year ended December 31, 2023 was primarily a result of the operating losses generated in current tax year.

As of December 31, 2023, the Company had net operating loss carryforwards for U.S. federal income tax purposes of $ 43.4 million and net operating loss carryforwards for state income tax purposes of $46.7 million. Federal tax loss carryforwards that were created prior to December 31, 2017 expire through 2037 and federal losses created after that date do not expire. State loss carryforwards expire starting in 2035. Pursuant to Section 382 of the Internal Revenue Code of 1986, or the Code, and similar state tax law, certain substantial changes in the Company's ownership may result in a limitation on the amount of net operating loss and tax credit carryforwards that may be used in future years. Utilization of the net operating loss and tax credit carryforwards may be subject to an annual limitation under Section 382 of the Code due to ownership change limitations that have occurred previously or that could occur in the future. These ownership changes may limit the amount of net operating loss and tax credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. The Company completed a Section 382 study through December 31, 2020. Based on the study, the Company underwent an ownership change for Section 382 purposes which occurred in February 2018. As a result of the ownership change, the Company's net operating loss and tax credit carryforwards as of the ownership change dates are subject to limitation under Section 382; however, these limitations are not expected to result in any of the impacted net operating loss and tax credit carryforwards to expire unutilized. Any net operating losses or tax credits generated after the February 2018 change are not subject to this annual limitation. However, subsequent ownership changes, as defined by Section 382, may potentially further limit the amount of net operating loss and tax credit carryforwards that could be utilized to offset future taxable income and tax. The Company is currently open to examination under the statute of limitations by the Internal Revenue Service and state jurisdictions for the tax years ended 2019 through the current year. Carryforward tax attributes generated in years past may still be adjusted upon future examination if they have or will be used in a future period. The Company is not under examination by the Internal Revenue Service or any other jurisdictions for any tax years.

As of December 31, 2023, the Company had German corporate income tax and trade tax net operating loss carryforwards of approximately $ 187.6 million and $183.7 million respectively. Under current German laws, tax loss carryforwards may only be used to offset any relevant later assessment period (calendar year) of $1.2 million plus 60% of the exceeding taxable income and trade profit of such period and do not expire. In addition, certain transactions, including transfers of shares or interest in the loss holding entity, may result in the partial or total forfeiture of tax losses existing at that date. Partial or total forfeiture of tax losses may further occur in corporate reorganizations of the loss holding entity.

As of December 31, 2023, the Company had gross U.S. federal and state research and development and other tax credit carryforwards of $ 0.5 million and $0.1 million, respectively, which may be available to offset future tax liabilities and begin to expire in 2042 and 2037, respectively. As of December 31, 2022, the Company had gross U.S. federal and state research and development and other tax credit carryforwards of $ 0.3 million and $0.1 million, respectively, which may be available to offset future tax liabilities and begin to expire in 2042 and 2037, respectively.

The Company accounts for uncertain tax positions pursuant to ASC 740, *Income Taxes*, which prescribes a recognition threshold and measurement process for financial statement recognition of uncertain tax positions taken or expected to be taken in a tax return. If the tax position meets this threshold, the benefit to be recognized is measured at the largest amount of benefit that is more likely than not (determined by cumulative probability) of being realized upon ultimate settlement with the taxing authority. The Company recognizes interest and penalties, if any, related to uncertain tax positions in income tax expense. No interest and penalties related to uncertain tax positions were accrued at December 31, 2023 and December 31, 2022.

On December 22, 2017, the Tax Cuts and Jobs Act, or the TCJA, was signed into law. Under the TCJA provisions, effective with tax years beginning on or after January 1, 2022, taxpayers can no longer immediately expense qualified research and development expenditures. Taxpayers are now required to capitalize and amortize these costs over five years for research conducted within the United States or 15 years for research conducted abroad.

The following table sets forth a reconciliation of the beginning and ending amounts of unrecognized tax benefits, excluding the impact of interest and penalties, for the year ended December 31, 2023 (in thousands):

Unrecognized tax benefits at December 31, 2022	$	5,363
Decrease as a result of a lapse of the applicable statute of limitations		(5,363)
Unrecognized tax benefits at December 31, 2023	$	—

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

9. Stockholders' equity

The Company had 300,000,000 shares authorized and 98,935,025 and 74,519,103 shares of common stock issued and outstanding as of December 31, 2023 and December 31, 2022, respectively, with a par value of $ 0.001 per share.

The Company had 10,000,000 shares authorized and 15,617 shares of preferred stock issued and outstanding as of December 31, 2023 and 2022. Preferred stock has a par value of $0.001 per share, and consists of the following tranches:

- Series A Convertible, 85 shares issued and outstanding at December 31, 2023 and 2022
- Series B Convertible, 4,026 shares issued and outstanding at December 31, 2023 and 2022
- Series C Convertible, 3,506 shares issued and outstanding at December 31, 2023 and 2022
- Series D Convertible, 3,000 shares issued and outstanding at December 31, 2023 and 2022
- Series E Convertible, 5,000 shares issued and outstanding at December 31, 2023 and 2022

Common Stock

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

Series A, Series B, Series C, Series D and Series E Preferred Stock rank senior to the Company's common stock; senior to any class or series of capital stock of the Company created after the designation of and specifically ranking by its terms as junior to the five series of Preferred Stock; in parity with each other and with any class or series of capital stock of the Company created after the designation of and specifically ranking by its terms as in parity with the existing five series of Preferred Stock; and junior to any class or series of capital stock of the Company created after the designation of and specifically ranking by its terms as senior to the existing five series of Preferred Stock. In the event of the Company's liquidation, dissolution or winding up, subject to the rights of holders of, holders are entitled to receive a payment equal to $0.001 per share of Preferred Stock pursuant to the rights and preferences discussed above, plus an additional amount equal to any dividends declared but unpaid on such shares. However, if the assets of the Company are insufficient to comply with the preceding sentence, then all remaining assets of the Company shall be distributed ratably to holders of the shares of the existing five series of Preferred Stock.

For each series of Preferred Stock, the Company designated the requisite number of shares of its authorized and unissued preferred stock as a specific series of Preferred Stock and filed a Certificate of Designation with the Nevada Secretary of State.

Shares of Preferred Stock generally have no voting rights, except as required by law and except that the consent of holders of a majority of the then outstanding Preferred Stock is required to amend the terms of the Certificate of Designation for each respective series of Preferred Stock. Holders of Preferred Stock are entitled to receive any dividends payable to holders of the Company's common stock subject to the rights and preferences discussed above, in each case, as to distributions of assets upon the Company's liquidation, dissolution or winding up whether voluntarily or involuntarily and/or the right to receive dividends.

Series A Preferred Stock

In June 2016, the Company entered into a securities purchase agreement for a private placement of the Company's securities with a select group of institutional investors, or the 2016 PIPE. The 2016 PIPE sale transaction, by the Company, consisted of 8,188,804 units at a price of $2.015 per unit for gross proceeds, to the Company, of approximately $16.5 million. After deducting for placement agent fees and offering expenses, the aggregate net proceeds from the private placement was approximately $15.3 million. In connection with the 2016 PIPE, the Company issued 3,225,804 shares of common stock and 4,963 shares of Series A Preferred Stock to the 2016 PIPE investors.

Series B Preferred Stock

On January 30, 2019, the Company and certain entities affiliated with BVF entered into an exchange agreement pursuant to which BVF agreed to exchange an aggregate of 5,000,000 shares of the Company's common stock owned by BVF for an aggregate of 5,000 shares of Series B Preferred Stock.

Series C and 2019 Private Placement

In November 2019, the Company entered into a securities purchase agreement for a private placement, or the Purchase Agreement with a select group of institutional investors, including lead investor BVF as well as existing and new investors, or Investors. The private placement consisted of 9,014,960 units, at a price of $3.55 per unit, or the Financing, for gross proceeds of approximately $ 32.0 million, and net proceeds to the Company of approximately $31.0 million. Each unit consists of (i) one share of the Company's common stock or 0.001 shares of non-voting convertible preferred stock, or Series C Preferred Shares, and together with the Common Shares, or Shares, and (ii) one immediately-exercisable warrant to purchase one share of the Company's common stock with an exercise price of $7.10, or Exercise Price.

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

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

Series D Preferred Stock Conversion

On March 31, 2020, the Company and certain entities affiliated with BVF entered into an exchange agreement pursuant to which, on April 1, 2020, BVF exchanged an aggregate of 3,000,000 shares of the Company’s common stock owned by BVF for an aggregate of 3,000 shares of Series D Preferred Stock.

Series E Preferred Stock Conversion

On May 20, 2021, the Company and certain entities affiliated with BVF entered into an exchange agreement pursuant to which, BVF exchanged an aggregate of 5,000,000 shares of the Company’s common stock owned by BVF for an aggregate of 5,000 shares of Series E Preferred Stock.

Open Market Sales Agreement

In August 2021, the Company established an at-the-market program, or ATM Program, under a sales agreement with Jefferies LLC, pursuant to which the Company may offer and sell shares of its common stock, par value $ 0.001 per share, from time to time, up to an aggregate amount of gross sales proceeds of $50.0 million. In November 2022, the sales agreement was amended to provide for an increase in the aggregate offering amount, such that under the ATM Program, as amended, the Company may offer and sell shares of its common stock, from time to time, up to an aggregate amount of gross sales proceeds of $75.0 million. The ATM Program, as amended, is offered under a shelf registration statement on Form S- 3 that was filed with and declared effective by the SEC in August 2021. For the year ended December 31, 2023, the Company sold 24.3 million shares for gross proceeds of $20.3 million under the ATM Program at an average stock price of $ 0.84. For the year ended December 31, 2022, the Company sold 2.1 million shares for gross proceeds of $7.2 million under the ATM Programs and the predecessor ATM program at an average stock price of $ 3.46.

As of the filing of this Annual Report on Form 10-K, the Company will be subject to the SEC general instructions of Form S- 3 known as the “baby shelf rules.” Under these instructions, the amount of funds the Company can raise through primary public offerings of securities in any 12-month period using its registration statement on Form S-3 is limited to one-third of the aggregate market value of the shares of the Company’s common stock held by non-affiliates. Therefore, the Company will be limited in the amount of proceeds it is able to raise by selling shares of its common stock using its Form S-3, including under the ATM Program, until such time as its public float exceeds $75 million.

10. Net Loss per Share

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

For the years ended December 31, 2023 and 2022, and as calculated using the treasury stock method, approximately 39.4 million and 38.4 million of weighted average shares, respectively, were excluded from the calculation of diluted weighted average shares outstanding as their effect was antidilutive.

11. Stock and Employee Benefit Plans

Employee, Director and Consultant Equity Incentive Plans

At the 2020 Annual Shareholder Meeting, held on June 23, 2020, the stockholders approved the 2020 Employee, Director and Consultant Equity Incentive Plan, or the 2020 Plan. The 2020 Plan originally permitted the Company to issue up to 3,500,000 shares of common stock pursuant to awards granted under the 2020 Plan. Upon approval of the 2020 Plan, the 2019 Employee, Director and Consultant Equity Incentive Plan, or the 2019 Plan, was terminated; all unissued options were canceled and no additional awards will be made thereunder. All outstanding awards under the 2019 Plan will remain in effect and any awards forfeited from the outstanding awards will be allocated back into the 2020 Plan. The 2020 Plan, similar to the 2019 Plan, provided for the grant of stock options, restricted and unrestricted stock awards, and other stock-based awards to employees of the Company, non-employee directors of the Company, and certain other consultants performing services for the Company as designated by either the Board of Directors or the compensation committee of the Board of Directors. At the 2021 Annual Meeting of Stockholders, held on June 25, 2021, the Company's stockholders approved the first amendment to the 2020 Plan to add 2,250,000 shares for issuance under the 2020 Plan, which increased the total permitted for issuance under the 2020 Plan to 5,750,000. At the 2022 Annual Meeting of Stockholders, held on June 22, 2022, the Company's stockholders approved the second amendment to the 2020 Plan to add an additional 3,000,000 shares for issuance under the 2020 Plan. At the 2023 Annual Meeting of Stockholders held on June 21, 2023, the Company's stockholders approved a third amendment to the 2020 Plan to add 6,000,000 shares of common stock for issuance under the 2020 Plan, which increased the total permitted for issuance under the 2020 Plan to 14,750,000. The 2020 Plan permits the Company to issue up to 14,750,000 shares reserved for issuance pursuant to the 2020 Plan and any additional shares which may be issued if awards outstanding under the Company's 2014, 2016, 2018 and 2019 Plans are canceled or expire.

The Company's stock options have a maximum term of 10 years from the date of grant. Stock options granted may be either incentive stock options or nonqualified stock options and the exercise price of stock options must be at least equal to the fair market value of the common stock on the date of grant. The Company's general policy is to issue shares of common stock upon the exercise of stock options.

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

	Years Ended December 31,	
	2023	2022
Risk free interest rate	3.33% - 4.11%	1.43% - 3.39%
Expected term (in years)	5.5 - 5.73	5.5 - 5.73
Dividend yield	—	—
Expected volatility	79.5% - 98.6%	79.9% - 81.1%

The weighted-average fair value of the 3,727,942 and 3,075,282 options granted during the years ended December 31, 2023 and 2022 was $0.85 and $1.96, respectively. As of December 31, 2023, there were 9,284,808 shares available for future grant under the 2020 Plan.

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

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2022	13,430,366	$ 3.21		$ —
Granted	3,727,942	1.22		—
Canceled/Forfeited	2,655,237	2.65		—
Outstanding, December 31, 2023	14,503,071	$ 2.80	5.90	$ —
Vested or expected to vest, December 31, 2023	14,503,071	$ 2.80	5.90	$ —
Exercisable, December 31, 2023	10,292,063	$ 3.21	4.75	$ —

Periodically, the Company grants inducement options, which are awards outside of stockholder-approved stock option plans, and which are awarded as an inducement material to the executive officers or other personnel entering senior leadership roles with the Company. The terms of inducement option awards were substantially the same as those issued under our 2020 Plan. These awards are excluded from the table above. The following table summarizes stock option activity for these inducement options (in thousands):

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2022	300,000	$ 4.65		$ —
Granted	—	$ —		$ —
Canceled/Forfeited	—	$ —		$ —
Outstanding, December 31, 2023	300,000	$ 4.65	5.67	$ —
Vested or expected to vest, December 31, 2023	300,000	$ 4.65	5.67	$ —
Exercisable, December 31, 2023	300,000	$ 4.65	5.67	$ —

Employee Stock Purchase Plans

At the 2023 Annual Meeting of Stockholders, the Company's stockholders approved the 2023 Employee Stock Purchase Plan, or the 2023 ESPP, which replaces the former 2018 Employee Stock Purchase Plan, or 2018 ESPP. The 2023 ESPP provides eligible employees with the opportunity to purchase shares of the Company's common stock at a discount of 85% of the lower closing market price of the common stock at the beginning date or ending date of each purchase period, on a tax-favored basis, through regular payroll deductions in compliance with federal tax regulations. The Company has reserved 750,000 shares of common stock for issuance under the 2023 ESPP.

Total shares purchased under the 2023 ESPP and 2018 ESPP plan were 154,656 and 181,466 for the years ended December 31, 2023 and 2022, respectively.

Total Stock-based Compensation Expense

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

	Years Ended December 31,	
	2023	2022
Research and development	$ 1,190	$ 1,905
General and administrative	2,159	2,497
Total stock-based compensation	$ 3,349	$ 4,402

As of December 31, 2023, the total unrecognized compensation cost related to all non-vested awards was $ 4.3 million. The unrecognized compensation cost would be recognized over a remaining weighted-average period of 2.24 years.

12. License Agreement

TUM License

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

13. Leases

In August 2015, the Company entered into a sublease to lease approximately 3,950 square feet in Boston, Massachusetts, which expired on December 31, 2022. The Company did not extend the sublease. The Company generally conducts its operational functions in the United States remotely.

In October 2018, Pieris Pharmaceuticals GmbH entered into a lease for office and laboratory space located in Hallbergmoos, Germany, or the Hallbergmoos Lease. Pieris GmbH moved its operations to the Hallbergmoos facility in February 2020. The Hallbergmoos Lease was subsequently amended in May 2019 and February 2020. The Hallbergmoos Lease, as amended, provided an initial rental term of 12.5 years, and a rental area of approximately 105,000 square feet.

In December 2023, Pieris Pharmaceuticals GmbH entered into an agreement to terminate the Hallbermoos Lease, or the Lease Termination Agreement. Under the terms of the Lease Termination Agreement, Pieris Pharmaceuticals GmbH terminated the Hallbergmoos Lease in exchange for a termination fee of approximately €9.7 million, and vacated the majority of the premises by December 31, 2023, while continuing to occupy, through June 2024, a limited portion of the office space and using another portion of the former lab space to house its assets being held for sale.

Cash paid for amounts included in the measurement of the lease liabilities were $ 2.2 million and $2.4 million for the years ended December 31, 2023 and 2022, respectively, all of which were incurred prior to the lease termination.

The Hallbergmoos Lease included $11.5 million of tenant improvements allowance for normal tenant improvements which was incurred prior to commencing the lease. The Company capitalized the leasehold incentives which were included in Property and equipment, net on the Consolidated Balance Sheet and were amortized on a straight-line basis over the shorter of the useful life or the remaining lease term. The leasehold improvement were subsequently fully impaired in the third quarter of 2023.

The following table summarizes operating lease costs included in operating expenses (in thousands):

	Year Ended December 31,	
	2023	2022
Operating lease costs	$ 1,169	$ 1,356
Variable lease costs (1)	679	737
Total lease cost	$ 1,848	$ 2,093

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

Exhibit 10.45

Addendum No. 3

to the Rental Agreement dated 16.10./24.10.2018 and Addendum no. 1 dated 21.05.2019 and Addendum no. 2 dated 12./13.02.2020

(re. space in the building Zeppelinstraße 3, 85399 Hallbergmoos)

between the

Hallbergmoos Grundvermögen GmbH
(registered in the Commercial Register of the Local Court of Munich under HRB 220581)
Nördliche Münchner Straße 28, 82031 Grünwald
represented by the person named in the signature line

- hereinafter referred to as the "**Landlord**" -

and

Pieris Pharmaceuticals GmbH
(registered in the Commercial Register of the Local Court of Munich under HRB 221043)
USTIdentNr: DE 813177203
Zeppelinstraße 3, 85399 Hallbergmoos
represented by the managing director, Dr. Hitto Kaufmann

- hereinafter referred to as "**Tenant**" -

- The Landlord and Tenant together are also referred to as the "**parties**".

Preamble:

The parties have entered an agreement for the building Zeppelinstraße 3, 85399 Hallbergmoos - hereinafter referred to as " **property**" - in accordance with the rental agreement dated 16.10./24.10.2018 including addendum no. 1 dated 21.05.2019 and addendum no. 2 dated 12./13.02. - hereinafter referred to as the "**rental agreement**" - for office, laboratory, and technical space as well as parking spaces.

For the rental area acc. To Clause 1.2.e (3rd floor, MB 11), the contractually agreed latest handover date of May 1 st, 2020, cannot be met due to delays in the delivery and construction of the lighting system caused by the COVID-19 pandemic. The parties wish to clarify the resulting changes compared to the rental agreement together with addendum no. 1 and addendum no. 2 with this addendum.

Therefore, the parties agree the following:

1. Handover

1.1 Clause 2.11.4 of the rental agreement is amended to the effect that the latest handover date of the rented space acc. Clause 1, No. 1.2 lit. e) is now June 1st, 2020. Notwithstanding the provisions in Clause 2.11.3, the Landlord is entitled to inform the Tenant of the exact handover date of the rented space pursuant to Clause 1, No. 1.2 lit. e) with a notice period of 7 days in advance.

1.2 In this respect, the parties clarify that, despite the delayed handover, the term of the rental agreement also ends for the areas pursuant to Clause 1, No. 1.2 lit. e) in accordance with § 4.1 of the rental agreement at the end of 13 August 2032.

1.3 All other agreements regarding the rental space remain in full force and effect.

2. General provisions

2.1 The parties are aware that the rental agreement to which this addendum refers requires the statutory written form pursuant to section 126 BGB due to its term of more than one year in accordance with sections 550, 578 (2) BGB. The parties wish to comply with the written form requirement.

a) They therefore mutually undertake, at the request of either party at any time, all actions and make all declarations necessary to comply with the statutory written form requirements.

b) They further will not terminate this rental agreement prematurely on the grounds of non-compliance with the statutory written form.

c) The rights and obligations under lit. a) and lit. b) apply not only to this addendum, but also to the original rental agreement and to all further addenda/amendments and supplementary agreements.

2.2 A third party entering into the contract in accordance with section 566 BGB or by way of a tripartite contract shall not be bound by the obligations arising from section 2.1; it shall be entitled to the statutory rights without restriction. This shall not apply if the third party was aware or should have been aware of the parts of the contract that do not comply with the written form requirement before entering into the rental agreement, or if the parts of the contract that do not comply with the written form requirement only came into existence after entering into the rental agreement.

However, the third party shall in any case be entitled to the rights arising for the entering third party from Clause 2.1 against the other contracting party without restriction.

2.3 Ancillary agreements, amendments and additions to this contract that are not subject to the statutory written form requirement of section 126 BGB pursuant to sections 550, 578 (2) BGB must also be made in writing. This written form requirement can only be waived in writing. Such ancillary agreements, supplements and amendments must be expressly identified as such and signed by representatives of the party expressly authorized to do so. The written form requirement referred to in sentence 1 shall not be met by declarations made by e-mail or in electronic form. The parties unanimously declare that no ancillary agreements have been made.

2.4 Severability clause

Should any provision of this addendum be invalid or unenforceable, this shall not affect the validity of the remainder of this addendum. The parties are obliged to agree on a provision in place of the affected provision that comes as close as possible to what was intended in economic terms.

3. Continued validity of the remaining provisions of the rental agreement

Notwithstanding the provisions agreed within this addendum, the provisions of the rental agreement including its addendum no. 1 and addendum no. 2 and the respective annexes, to which reference is hereby made, shall otherwise remain in force.

4. Conclusion of the addendum, acceptance period

The first party to sign shall be bound by the contract offer to the other party within four weeks of receipt of the addendum signed by it. The acceptance period shall be deemed to have been met if the first signatory party receives the countersigned addendum no later than the last day of the aforementioned period.

For the Landlord:

Place, Date Grünwald, the *19.05.2020*

Signature: */s/ Peter Neumann*

Name: Peter G. Neumann

Position: Managing Director

For the Tenant:

Place, Date Hallbergmoos, the *15.05.2020*

Signature: */s/ Hitto Kaufmann*

Name: Dr. Hitto Kaufmann

Position: Managing Director

Exhibit 10.46

Addendum No. 4

to the Rental Agreement dated 16.10./24.10.2018 and Addendum no. 1 dated 21.05.2019 and Addendum no. 2 dated 12./13.02.2020 and Addendum no. 3 dated 15.05./19.05.2020

(re. space in the building Zeppelinstraße 3, 85399 Hallbergmoos)

between the

Hallbergmoos Grundvermögen GmbH
(registered in the Commercial Register of the Local Court of Munich under HRB 220581)
Nördliche Münchner Straße 28, 82031 Grünwald
represented by the person named in the signature line

- hereinafter referred to as the "**Landlord**" -

and

Pieris Pharmaceuticals GmbH
(registered in the Commercial Register of the Local Court of Munich under HRB 221043)
USTIdentNr: DE 813177203
Zeppelinstraße 3, 85399 Hallbergmoos
represented by the authorized signatory (sole power of attorney)
Dr. Shane Olwill
("Extract from the Commercial Register Annex 0")

- hereinafter referred to as "**Tenant**" -

- The Landlord and Tenant together are also referred to as the " **parties**".

Preamble:

The parties have entered an agreement for the building Zeppelinstraße 3, 85399 Hallbergmoos - hereinafter referred to as " **property**" - in accordance with the rental agreement dated 16.10./24.10.2018 including addendum no. 1 dated 21.05.2019, addendum no. 2 dated 12./13.02.2020 and addendum no. 3 dated 15.05./19.05.2020 - hereinafter referred to as the "**rental agreement**" - for office, laboratory, and technical space as well as parking spaces.

The parties to the rental agreement wish to terminate the rental agreement concluded between them by mutual agreement before the end of the contract term.

The parties agree as follows:

1. Termination of the rental agreement for the office and warehouse space on the 1st floor (MB 13 and 14)

1.1 The existing rental agreement between the parties will be terminated with regard to the office and laboratory space on the 1st floor (MB 13 and 14) with a size of approx. 1,324.09 sqm with effect from 31.12.2023 ("**end of contract term MB 13 and 14**").

1.2 Until the **end of the contract term MB 13 and 14**, i.e. until the end of 31.12.2023, the Tenant shall remain obliged to pay the contractually agreed rent and to bear the ancillary costs (with the exception of any ancillary costs incurred in connection with the conversion measures in the rented space on the first floor (MB 13 and 14) described in section 1.4 below and unless otherwise stipulated in the last sentence of section 1.3 below).

1.3 The Tenant is obliged to return the rented areas on the 1st floor (MB 13 and 14) to the Landlord swept clean by 18.12.2023. The Tenant must remedy any damage caused by the Tenant that goes beyond normal wear and tear and for which the Tenant is responsible, and which is recorded in the handover protocol (see following paragraph) within a reasonable period of time after the return at the Tenant's own expense. The parties agree that the broken window in MB 13 room 01.13.18 is not to be replaced by the Tenant. Office and laboratory furniture, situated within the rented areas according to section 1.1, which is exhaustively listed in **Annex 2.1**, shall all remain in the leased premises, insofar as these are the subject of the purchase agreement concluded between the parties in accordance with section 2 of this addendum (this expressly does not include: any IT-related equipment, such as in particular but not exclusively televisions, teleconferencing systems, cameras and loudspeaker systems). In accordance with the agreements in the rental contract, the fixtures, cables, and systems permanently installed in the rented space shall also remain in the rented property.

Otherwise, the rented areas on the 1st floor (MB 13 and 14) are to be handed over to the Landlord by the Tenant in a vacated condition, i.e. the Tenant is in particular not obliged to carry out maintenance, repair, replacement, cosmetic repairs and/or dismantling measures in relation to any structural alterations or installations or to submit proof in accordance with section 8.3.1 sentence 2 of the rental agreement.
The parties shall draw up and sign a handover protocol on the occasion of the handover to the Landlord in accordance with section 8.3.5 of the rental Agreement, in which all apparent defects and complaints shall be recorded. The Tenant is not obliged to rectify any defects and complaints not listed in the handover report. The duty to ensure public safety, risks and burdens are transferred to the Landlord upon handover of the rented space on 18.12.2023.

1.4 In this respect, the Landlord is entitled to carry out conversion measures in the aforementioned rental areas on the 1st floor (MB 13 and 14) for an intended subsequent letting, starting from 18.12.2023, at its own expense and risk. The Tenant must accept the associated effects on the other rental areas as being in accordance with the rental agreement. In this respect, the Tenant is neither entitled to reduce the rent nor to terminate the rental agreement prematurely.

1.5 For the premature termination of the rental agreement relating to the rental space on the first floor (MB 13 and 14), the Tenant shall pay the Landlord compensation in the amount of a lump sum of EUR 700,000.00 (net) (in words: seven hundred thousand euros) plus VAT at the statutory rate ("**Settlement Amount pursuant to section 1.5**") as compensation for the resulting loss of rent and any additional expenses for re-letting the rental space. This amount must be paid by the Tenant to the Landlord by 18.12.2023, but not before the expiry of 5 bank working days after receipt of a proper invoice by the Tenant. The receipt of the amount in the rental account is decisive for compliance with the aforementioned deadline.

2. Sale of laboratory and office furniture in the office and laboratory areas on the 1st floor (MB 13 and 14)

2.1 The Tenant sells the laboratory and office furniture currently located in the office and laboratory space on the 1st floor (MB 13 and 14), insofar as these are listed (exhaustively) in **Annex 2.1**, (hereinafter the "**Purchase Item 1**") to the Landlord (this expressly does not include: any IT-related equipment, such as in particular but not exclusively televisions, teleconferencing systems, cameras, and loudspeaker systems). The Tenant assures that only items that are owned by the Tenant and that the Tenant is entitled to sell the items are included in **Purchase Item 1** (KG 1). The purchase price to be paid by the Landlord for this is EUR 1.00 including statutory VAT (" **Purchase Price KG 1**") and is due for payment to the Landlord after proper invoicing.

2.2 The items listed in **Annex 2.1** are in used "as is" condition and the Tenant assumes no guarantees or warranties regarding their condition; the sale is made to the exclusion of any warranty. However, the Tenant assigns to the Landlord all warranty claims to which it may be entitled against third parties. Liability for the existence, assignability and enforceability of these claims is not associated with this. The Landlord accepts this assignment.

At the request of the Landlord in text form, the Tenant shall also provide the Landlord with information in text form about the contracts on which the warranty claims are based, including the contracting parties, the subject matter of the contract and the acceptance of the commissioned work performance or delivery of the goods, and shall provide the Landlord with the contractual documents required to enforce any warranty claims, insofar as they are available to the Tenant.

2.3 Transfer of ownership of the object of **Purchase Item 1**.

The Tenant transfers and assigns the ownership of **Purchase Item 1** to the Landlord subject to the condition precedent (i) payment of the **Purchase Price KG 1** and (ii) the expiry of 18.12.2023, and the Landlord hereby accepts this transfer and assignment

2.4 It is not intended to remove the **Purchase Item 1** from the rented property. With the return of the office and laboratory space on the 1st floor (MB 13 and 14) to the Landlord, the Landlord is in possession of the Purchase Item 1.

2.5 The parties shall cooperate in good faith for the purpose of transferring and transferring ownership of the Purchase Item 1 and, in particular,

shall make all declarations, issue all deeds and perform all other acts that may be necessary or expedient in connection with the sale and transfer of the Purchase Item 1 from the Tenant to the Landlord.

3. Cancellation of the rental agreement regarding all other rental spaces

3.1 The existing rental agreement between the parties is terminated with regard to all other rental areas, in particular the:

a) Technical areas in the basement with approx. 520.72 m²
b) Office and laboratory space on the ground floor (MB 11, 12, 13, 14, 16, 17, 18) with approx. 4,273.44 m²
c) Office and laboratory space on the 1st floor (MB 11, 12, 18) with approx. 2,114.34 m²
d) Office and storage space on the 2nd floor (MB 17) with approx. 579.04 m²
e) Office space on the 3rd floor (MB11) with approx. 474.14 m²
f) Office and laboratory space on the ground floor (MB 17a) with approx. 331.74 m²
g) Office and laboratory space on the 2nd floor (MB 11, 15, 16) (expansion area) approx. 2,070.27 m²
h) Car parking spaces 125 pieces

as well as any other option and extension areas including the rented parking spaces, i.e. in total, unless otherwise stated in sections 7 and 8, with effect from 31.12.2023 (" **end of the remaining contract term**").

3.2 The Tenant remains obliged to pay the contractually agreed rent and ancillary costs until the **end of the remaining lease term**, i.e. until 31.12.2023.

3.3 The Tenant is obliged to return to the Landlord the rented areas specified in section 3.1 of this addendum swept clean by 31.12.2023, unless otherwise stipulated in sections 7 and 8 (i.e. a right of use extending beyond 31.12.2023 and existing from 01.01.2024 with regard to the temporary rented areas and the temporary storage areas). The Tenant must remedy any damage caused by the Tenant which goes beyond normal wear and tear and for which the Tenant is responsible, and which is recorded in the handover protocol (see following paragraph) within a reasonable period of time after the return at its own expense. The laboratory furniture and other fixtures and fittings located in the rented space in section 3.1, which are listed (exhaustively) in **Annex 4.1**, shall remain in the rented premises insofar as they are the subject of the purchase agreement concluded between the parties in accordance with section 4 of this addendum (this expressly does not include: any IT-related equipment, such as in particular but not exclusively televisions, teleconferencing systems, cameras and loudspeaker systems). In accordance with the agreements in the rental contract, the fixtures, cables, and systems permanently installed in the rented space also remain in the rented property. In all other respects, the rented space must be returned to the Landlord by the Tenant in a vacated condition, i.e. the Tenant is in particular not obliged to carry out maintenance, repair, replacement, cosmetic repair and/or dismantling measures in relation to any structural alterations or installations or to submit proof in accordance with section 8.3.1 sentence 2 of the rental agreement.

The parties shall draw up and sign a handover protocol on the occasion of the handover to the Tenant in accordance with section 8.3.5 of the Rental Agreement, in which all apparent defects and complaints shall be recorded. The Tenant shall not be required to rectify any defects and complaints not listed in the handover protocol.

3.4 For the premature termination of the rental agreement in relation to the rental space specified in section 3.1 of this addendum, the Tenant shall pay the Landlord compensation in the amount of a lump sum of EUR 9,000,000.00 (net) (in words: nine million euros) plus VAT at the statutory rate ("**Settlement Amount pursuant to section 3.4**") as compensation for the resulting loss of rent and any additional expenses for re-letting the rental space. This amount must be paid by the Tenant to the Landlord by 18.12.2023 at the latest, but not before the expiry of 5 bank working days after receipt of a proper invoice by the Tenant. The receipt of the amount in the rental account shall be decisive for compliance with the aforementioned deadline.

4. Sale of the laboratory furniture in the laboratory areas as well as the furnishing and technical equipment of the rental space (canteen area) on the 3rd floor (MB 11) and basement (technical areas) in accordance with section 3.1

4.1 The Tenant sells the technical equipment currently installed by him in the building, such as e.g. demineralized water system, the tea kitchens, the laboratory furniture located in the laboratory areas pursuant to section 3.1 of this addendum, the storage building for technical gases located next to the exit to the underground car park, including the technical equipment located therein (such as, for example the emergency power generator) as well as the refrigeration units, cold storage cells, kitchen furniture and refrigeration units currently stored in the basement in the preparation kitchen and the furnishings and technical equipment (in particular catering equipment, refrigeration, counters, convection ovens) of the rental space (canteen space) on the 3rd floor (MB 11), insofar as these systems, facilities, furniture and other items are listed (conclusively) in **Annex 4.1** (hereinafter referred to as "**Purchase Item 2**") to the Landlord (this expressly does not include: any IT-related equipment, such as in particular but not exclusively televisions, teleconferencing systems, cameras and loudspeaker systems). The Tenant assures that the **Purchase Item 2** (KG 2) only includes items that are the property of the Tenant and that the Tenant is entitled to sell the items. The purchase price to be paid by the Landlord for this is EUR 1.00 including statutory VAT ("**Purchase Price KG 2**") and is due for payment to the Tenant after proper invoicing.

4.2 The items listed in **Annex 4.1** are in used "as is" condition and the Tenant does not assume any guarantees or warranties regarding their condition; the sale is made to the exclusion of any warranty. However, the Tenant assigns to the Landlord all warranty claims to which it may be entitled against third parties. Liability for the existence, assignability and enforceability of these claims is not associated with this. The Landlord accepts this assignment.

At the request of the Landlord in text form, the Tenant shall also provide the Landlord with information in text form about the contracts on which the warranty claims are based, including the contracting parties, the subject matter of the contract and the acceptance of the commissioned work performance or delivery of the goods, and shall provide the Landlord with the contractual documents required to enforce any warranty claims, insofar as they are available to the Tenant.

4.3 Transfer of ownership of the Purchase Item 2

The Tenant transfers and assigns the ownership of **Purchase Item 2** to the Landlord subject to the condition precedent (i) payment of the **purchase price KG 2** and (ii) expiry of 31.12.2023 and the Landlord hereby accepts this transfer and assignment.

4.4 As it is not intended to remove the **Purchase Item 2** from the rented property, the Tenant shall convey possession of the **Purchase Item 2** to the Landlord for the transfer of ownership of the Purchase Item 2 by means of a constitutive possession (§§ 929, 930 BGB).

4.5 The parties shall cooperate in good faith for the purpose of transferring and transferring ownership of the **Purchase Item** 2 and, in particular, shall make all declarations, issue all deeds, and perform all other acts that may be necessary or expedient in connection with the sale and transfer of the **Purchase Item 2** from the Tenant to the Landlord.

5. Right of withdrawal of the Landlord

5.1 If the Tenant is more than 5 working days in arrears with the payment of a settlement amount in accordance with Clause 1.5 or 3.4 of this addendum or if the settlement amounts have to be repaid (also pro rata) by the Landlord to the Tenant or a third party (e.g. due to the exercise of a right of avoidance by an insolvency administrator), the Landlord shall be entitled to withdraw from this addendum in compliance with Clause 5.3 of this addendum.

5.2 The Landlord must notify the Tenant of the withdrawal in writing within two weeks of becoming aware of the reason for withdrawal.

5.3 Insofar as the conditions for the Landlords right of withdrawal pursuant to Clause 5.1 are met, the Landlord shall be entitled to declare his withdraw from this addendum limited to the rental spaces according to section 1 and 2 or section 3 and 4. It is at the discretion of the Landlord to terminate the entire addendum by means of a withdrawal and thus continue the rental agreement as a whole or to restrict the continuation of the rental agreement to the rental areas specified in section 1 or section 3 at the applicable conditions of the rental agreement by means of a partial withdrawal. At the Landlord's request, the Tenant shall be obliged to determine the effects of the withdrawal on the Tenancy Agreement within the framework of an addendum that complies with the written form requirement pursuant to sections 578, 550, 126 BGB.

6. Repayment of the rental deposit

6.1 The Landlord shall within 10 working days of receipt of the settlement amounts in accordance with sections 1.5 and 3.4 of this Agreement,

(i.) return to the Tenant the original copies of the rental deposit provided to him by the Tenant, i.e. (a) the bank guarantee of Deutsche Bank dated December 7, 2018, in the amount of EUR 691,756.62 (section 6.1.1 of the Rental Agreement) and (b) the Debt Assumption Agreement of the parent company Pieris Pharmaceuticals Inc. dated October 24/26, 2018 (section 6.1.2 of the Rental Agreement) provided by the Tenant,

(ii.) provide the Tenant with a declaration that the aforementioned Debt Assumption Agreement is terminated with immediate effect, i.e. the parent company Pieris Pharmaceuticals Inc. is released from liability under the aforementioned Debt Assumption Agreement with immediate effect and the Landlord cannot assert any claims against the parent company Pieris Pharmaceuticals Inc. under the aforementioned Debt Assumption Agreement, and

(iii.) make any other declarations and take any other actions required to return the aforementioned rental deposits on expiry of the aforementioned period, and

(iv.) return to the Tenant any additional security deposits provided.

6.2 In the event that the Landlord exercises a right of withdrawal in accordance with Clause 5 of this addendum, the Landlord shall not be obliged to return or surrender the security deposit in accordance with this Clause 6; instead, the provisions of the Rental Agreement shall apply.

7. Temporary rental space

7.1 The parties agree that the Tenant shall not initially return the rental space MB 11 on the ground floor with an area of approx. 768.03 sqm, the server rooms (01.12.07 and 00.18.07) and ELT room (01.12.16) in MB 12, 15 underground parking spaces (no. 345-354 + 388-392) and the two outdoor parking spaces already used by the Tenant ("**Temporary Rental Space**") - in deviation from the provisions in section 3 - to the Landlord but may continue to use them exclusively from 01.01.2024 until 30.06.2024 ("**end of the temporary rental**") rent-free (subject to the flat-rate ancillary costs pursuant to section 7.2) within the scope of the rental purpose (section 3.1 of the rental agreement). During this period, the Tenant is entitled to terminate the use with a notice period of 2 weeks in text form (e-mail) and to return the **Temporary Rental Space** to the Landlord in accordance with the provisions of section 3.3 above.

7.2 The Tenant is obliged to pay the Landlord a monthly lump sum of EUR 2,265.00 plus statutory VAT (currently 19%) for ancillary costs attributable to the **Temporary Rental Space** for the period up to the end of the temporary rental, making a total of EUR 2,695.35. The Tenant shall not bear any further costs for the period up to the end of the temporary letting. In particular, the Tenant is not obliged to carry out any maintenance, repair, replacement, or cosmetic repair measures for the period up to the end of the temporary letting. However, any damage caused by the Tenant that goes beyond normal wear and tear and for which the Tenant is responsible must be rectified by the Tenant.

7.3 At the **End of the Temporary Rental** , the temporary rental space must be returned to the Landlord by the Tenant in accordance with the provisions of section 3.3 above.

8. Temporary storage space

8.1 The Parties agree that the Tenant shall not initially return the previous leased areas, i.e. the leased areas under section 3.1 a) to f) inclusive above, insofar as these are marked in color in the site plan in **Annex 8.1** (together "**Temporary Storage Area**") - in deviation from the provisions in section 3 - to the Landlord but may continue to use them from 01.01.2024 (at the longest) until 30.06. 2024 ("**End of Temporary Storage**") without additional costs, i.e. in particular rent-free and without the obligation to pay operating and ancillary costs, in order to temporarily store the furnishings and equipment already located there, which are not part of the sale pursuant to section 4 of this addendum, until their sale, at the latest until the end of the period of use of the Temporary Storage Space, to show them to prospective buyers and to sell them to third parties. During this period, the Tenant is entitled to terminate the use with a notice period of 2 weeks in text form (e-mail) and to return the Temporary Storage Area (with the exception of the sublet space pursuant to section 8.6) to the Landlord in accordance with the provisions of section 3.3 above.

8.2 The Tenant is aware that the Landlord may store or park furniture in the temporary storage areas (with the exception of the sublet area in accordance with section 8.6). The Landlord will take the Tenant's particular needs into consideration and will not move the Tenant's stored items. Furthermore, the Landlord shall consult with the Tenant in advance of any storage of its own in order to rule out any risk to the Tenant's furniture and not to hinder the removal of the Tenant's furniture. In particular, the Landlord shall notify the Tenant in advance if third parties commissioned by the Landlord enter the temporary storage areas (with the exception of the sublet area pursuant to section 8.6) in connection with the storage of the Landlord's furniture. Considering the legitimate interests of the Tenant, however, the Tenant shall permit the storage of the Landlord's furniture in the temporary storage areas (with the exception of the sublet area pursuant to section 8.6). Until the end of the temporary storage, the Landlord is not entitled to use the temporary storage area for purposes other than those specified in this section 8.2.

8.3 The Landlord may also terminate the use of the temporary storage areas - with the exception of the sublet areas within the meaning of section 8.6 below - prior to the expiry of the period agreed in section 8.1 with a notice period of 4 weeks in text form (e-mail), but no earlier than April 1, 2024.

After the end of the temporary storage period (in the event of termination) after expiry of the notice period, the Tenant shall be obliged to vacate and surrender the temporary storage space in accordance with the provisions of section 3.3 above.

If the Tenant defaults on vacating the temporary storage space and the Landlord has unsuccessfully set a grace period of 10 working days in writing, all items still in the temporary storage space shall become the property of the Landlord, provided that the Landlord has informed the Tenant in writing of the legal consequences associated with the default when setting the grace period.

8.4 The use of the temporary storage area is at the risk of the Tenant. The Landlord and its vicarious agents shall only be liable for any damage to the Tenants items stored there (i) for intent and gross negligence and/or (ii) - irrespective of fault - insofar as damage is covered by an insurance policy of the Landlord or one of its vicarious agents. However, the parties clarify that the Landlord and its vicarious agents are only entitled to enter the temporary storage areas until the end of the temporary storage in accordance with the provisions of section 8.2 or section 9.1 above of the rental agreement; in particular, the Landlord is not entitled to convert, modernize or use the temporary storage areas until the end of the temporary storage (with the exception of the storage of furniture permitted under section 8.2 above). The parties also clarify that the Tenant is not obliged to carry out any maintenance, repair, replacement, or cosmetic repair measures until the end of the temporary storage.

8.5 The temporary storage areas are used by the Tenant to sell the furniture and equipment specified in section 8.1 to third parties.

8.6 The Tenant has sublet one of the rental spaces and future temporary storage spaces (1st floor MB 18), including the furniture and other items located there (together the "Sublet Furniture", listed **in Annex 8.6**) to Nanogami GmbH ("**Subtenant**") on the basis of a sublease agreement. This sublease agreement ends automatically upon termination of the main lease agreement without the need for notice of termination. By way of a genuine contract in favor of third parties, the Tenant permits the Subtenant to use the rental space currently covered by the subtenancy agreement on the 1st floor of MB 18 (hereinafter also referred to as the "**Sublet Areas**") and sublet furnishings until it moves into the areas specified in section 1.1. of this addendum, but at the latest until 31.05.2024. The Subtenant shall not be obliged to pay compensation to the Tenant for the use of the sublet areas upon termination of the subtenancy agreement on 31.12.2023, i.e. from 01.01.2024 but at the latest until 31.05.2024. However, the Tenant is entitled to demand a monthly rent of EUR 1,000 plus VAT at the statutory rate per month from the Subtenant for the part of the sublet furnishings that is not sold to the Landlord in accordance with section 4 of this addendum from January 1, 2024. Unless the sub-furniture is part of the purchase agreement under section 4 of this addendum, the Tenant expressly remains the owner of the sub-furniture, i.e. ownership of it is expressly not transferred to the Landlord or the sub-Tenant. The Tenant shall not hand over the sublet furnishings to third parties until the Subtenant has ceased to use the rental area MB 18 on the first floor; however, the Tenant shall in any case be entitled to hand over the sublet furnishings to third parties from 31.05.2024 at the latest. The Landlord consents to the use of the sublet space by the Subtenant in accordance with this Clause. 8.6 hereby expressly.
Should the Landlord wish to settle operating and ancillary costs relating to the sublet space from 01.01.2024, he must conclude a direct agreement with the Subtenant in this regard and settle directly with the Subtenant. The Tenant is not liable for ensuring that any operating and ancillary costs relating to the sublet space are paid to the Landlord, utility companies or other third parties from 01.01.2024.

Should the Subtenant - for whatever reason - use the sublet space for longer than 31.05.2024, the Tenant is entitled, but not obliged, to leave the sublet furniture in the sublet space for as long as the Subtenant uses the sublet space.

After the Subtenant has finished using the sublet space, the Tenant is in any case entitled to use the sublet space for a further 4 weeks without additional costs, i.e. in particular rent-free and without the obligation to pay operating and ancillary costs, in order to temporarily store the sublet furniture until it is sold, at the latest until the end of these 4 weeks (or until the end of the period of use of the temporary storage space - whichever is later), to show it to prospective buyers and to sell it to third parties. The parties clarify that Clause 8.3 paragraph 2 and Clause 8.4 of this addendum apply accordingly and that the provisions of this Clause 8.6 constitute special provisions for the sublet areas and therefore take precedence over the provisions in Clause 8.1.

9. General provisions

9.1 The parties are aware that the rental agreement to which this addendum refers requires the statutory written form pursuant to section 126 BGB due to its term of more than one year in accordance with sections 550, 578 (2) BGB. The parties wish to comply with the written form requirement.

a) They therefore mutually undertake, at the request of either party at any time, all actions and make all declarations necessary to comply with the statutory written form requirements.

b) They further will not terminate this rental agreement prematurely on the grounds of non-compliance with the statutory written form.

c) The rights and obligations under lit. a) and lit. b) apply not only to this addendum, but also to the original rental agreement and to all further addenda/amendments and supplementary agreements.

9.2 A third party entering into the contract in accordance with section 566 BGB or by way of a tripartite contract shall not be bound by the obligations arising from section 9.1; it shall be entitled to the statutory rights without restriction. This shall not apply if the third party was aware or should have been aware of the parts of the contract that do not comply with the written form requirement before entering into the rental agreement, or if the parts of the contract that do not comply with the written form requirement only came into existence after entering into the rental agreement.

However, the third party shall in any case be entitled to the rights arising for the entering third party from Clause 9.1 against the other contracting party without restriction.

9.3 Ancillary agreements, amendments and additions to this contract that are not subject to the statutory written form requirement of section 126 BGB pursuant to sections 550, 578 (2) BGB must also be made in writing. This written form requirement can only be waived in writing. Such ancillary agreements, supplements and amendments must be expressly identified as such and signed by representatives of the party expressly authorized to do so. The written form requirement referred to in sentence 1 shall not be met by declarations made by e-mail or in electronic form. The parties unanimously declare that no ancillary agreements have been made.

9.4 Severability clause

Should any provision of this addendum be invalid or unenforceable, this shall not affect the validity of the remainder of this addendum. The parties are obliged to agree on a provision in place of the affected provision that comes as close as possible to what was intended in economic terms.

10. Continued validity of the remaining provisions of the rental agreement

Notwithstanding the provisions agreed within this addendum, the provisions of the rental agreement including its addendum no. 1, addendum no. 2 and addendum no. 3 and the respective annexes, to which reference is hereby made, shall otherwise remain in force.

11. Conclusion of the addendum, acceptance period

The first party to sign shall be bound by the contract offer to the other party within three weeks of receipt of the addendum signed by it. The acceptance period shall be deemed to have been met if the first signatory party receives the countersigned addendum no later than the last day of the aforementioned period.

12. Attachments

The following annexes are part of this addendum:

Annex 0: Extract from the commercial register Pieris dated 11.12.2023

Annex 2.1 List of office and laboratory furniture on the 1st floor (MB 13 and 14) to be sold to the Landlord (Purchase Item 1)

Annex 4.1 List of equipment, fixtures and fittings, furniture, and other items to be sold to the Landlord (Purchase Item 2)

Annex 8.1 Temporary storage areas

Annex 8.6 Listing of the objects rented to the Subtenant (Sublet Furnishings)

For the Landlord:

Place, Date Grünwald, the 15.12.2023

Signature: /s/ Peter G. Neumann

Name: Peter G. Neumann

Position: Managing Director (with sole power of representation)

For the Tenant:

Place, Date Hallbergmoos, the 15.12.2023

Signature: /s/ Shane Olwill

Name: Dr. Shane Olwill

Position: Authorized signatory (sole power of attorney)

Annex 0

1. **Number of previous entries:**

10

2. **a) Company:**

Pieris Pharmaceuticals GmbH

b) Registered office, branch office, domestic business address, authorized recipient, branch offices:

Freising
Business address: Zeppelinstraße 3, 85399 Hallbergmoos

c) **Object of the company:**

Biotechnological research and development and distribution of applications of this research, in particular in the field of Anticalin proteins, a class of biomolecules obtained by protein design with potential applications in medicine, bioanalytics, food technology and bioscientific research, as well as participation in other companies with the same or similar corporate purpose in Germany and abroad, establishment of such companies and acquisition of all or individual assets, regardless of whether tangible or intangible, or parts of such companies. The company will not engage in any transactions that require government approval.

3. Basic or share capital:
100.000,00 EUR

3. **a) General representation regulations:**

If only one managing director has been appointed, he shall represent the company alone. If several managing directors have been appointed, the company shall be represented by two managing directors or by one managing director together with an authorized signatory.

b) Management board, management body, managing directors, personally liable partners, managing directors, authorized representatives and specific authorization to represent:

Authorized to act as sole representative; with the authority to enter into legal transactions on behalf of the company in its own name or as representative of a third party:

Managing Director: Yoder, Stephen S., Pittsburgh, Pennsylvania / United States, *17.12.1975

5. Power of attorney:
Sole authorized signatory with the authority to enter into legal transactions on behalf of the company in his own name or as a representative of a third party:

Dr. Olwill, Shane, Freising

6. a) Legal form, commencement, statutes or company agreement:

Company with limited liability
Company agreement dated 26.08.2015

b) Other legal relationships:
Created through a change in the legal form of Pieris AG with its registered office in Freising (Munich Local Court HRB 133223).

7. a) Date of last entry:
09.10.2023

Annex 2.1 List of office and laboratory furniture on the 1st floor (MB 13 and 14) to be sold to the Landlord (Purchase Item 1)

Annex 4.1 List of equipment, fixtures and fittings, furniture, and other items to be sold to the Landlord (Purchase Item 2)

Annex 8.1 Temporary storage areas

Annex 8.6 Listing of the objects rented to the Subtenant
(Sublet Furnishings)

EXHIBIT 10.62

Pieris Pharmaceuticals, Inc.

225 Franklin Street, Floor 26

Boston, MA 02110

+1-857-250-0363

www.pieris.com

December 11, 2023

NOTICE OF EXTENSION NO.1 TO CONSULTING AGREEMENT

The Consulting Agreement ("Agreement"), entered into between Pieris Pharmaceuticals, Inc. and Pieris Pharmaceuticals GmbH (collectively, "Pieris") and Ahmed Mousa located at 755 Boylston Street, Apt. 702, Boston, MA 02116 (hereinafter the "Advisor"), with an effective date of September 11, 2023, expires on December 11, 2023. Pursuant to Section 10 of the Agreement, this letter extension ("Extension No. 1") hereby confirms both Parties' agreement to extend the Term of the Agreement by an additional three (3) months. This Extension No. 1 shall form an integral part of the Agreement. The provisions of the Agreement that are not amended or deleted by this Extension No. 1 remain unchanged and in full force and effect. All capitalized terms used herein and not specifically defined will have the meanings ascribed to such terms in the Agreement.

This Extension No. 1 is executed, effective as of the date at the top of this letter, by the Parties' duly authorized representatives.

Pieris	Advisor
By: /s/ Tom Bures	By: /s/ Ahmed Mousa
Name: Tom Bures	Name: Ahmed Mousa
Title: Chief Financial Officer	Title: _____

Exhibit 10.65

Employment Agreement

between

1. **Pieris AG**, Lise-Meitner-Str. 30, 85354 Freising, Germany, represented by the Executive Board

- the "**Employer**" -,

and

2. **Dr. Shane Olwill,** [***]

- the "**Employee**" -,

- each individually the "**Party**" and jointly the "**Parties**" -

§ 1
Employment and Duties

1. Employer hereby employs the Employee as Senior Director R & D. The Employee shall be bound to all instructions of his manager.

2. Employer is entitled to assign other reasonable duties and responsibilities to the Employee that correspond to his training and his skills and that may result in a change in title or position in Employers's organization.

3. Employee shall perform his duties well and faithfully in the interests of Employer and will comply with all applicable statutes, regulations, ethical and industrial codes and Employers' policies as well as all directions lawfully and properly given by Employer.

§ 2
Hours of Work

1. The position is full-time. The normal working hours are 40 hours per week, but the Employee will be required to work such additional hours as are required to perform his duties (including on Saturdays, Sundays and public holidays).

2. Specific working hours may be determined from time to time by Employee's managers.

3. The overall annual payments according to § 5 cover payment for all hours worked and the overall performance.

4. Overtime or time off in lieu will not be available and Employee's salary covers all aspects of his employment.

§ 3
Effective Date, Term

1. The employment with Employer shall commence on June 15th, 2011 (the "**Start Date**") and shall be concluded for an indefinite period.

2. The employment will include an initial trial period of 6 months, commencing on the Start Date (the " **Trial Period**"). During or at the end of this Trial Period or any extension of the Trial Period required by Employer, either the Employee or Employer may terminate the employment by two weeks' notice in writing to the end of each calendar month (the "**Trial Period Notice**") without reason and without indemnification.

3. For the avoidance of doubt, Employer or the Employee does not have the right to terminate the employment prior to the Start Date.

4. Following the Trial Period, if any, the employment can be terminated by either party giving to the other in writing with a notice period of three months to the end of each calendar month.

5. The right of extraordinary termination (*außerordentliche Kündigung*) remains unaffected.

6. Any notice of termination must be made in writing.

7. The normal retirement age of employees of Employer is 65. By reaching this age the employment will end automatically without any notice of termination.

8. Employer may suspend Employee from the employment after notice of termination on full salary until the end of the notice period. Any remaining holidays will be taken into consideration.

§ 4
Place of Work

Place of work shall be the business seat of Employer, currently Freising.

§ 5
Annual Salary

1. The initial annual base salary is EUR 100.000,- (in words: Euro one-hundred thousand) (less any deductions required by law) payable in arrears in 12 equal monthly instalments at the end of each calendar month. The annual base salary will be reviewed annually during the employment. Employer is under no obligation to increase Employee's salary following an annual base salary review.

2. In addition to the remuneration provided for under § 5 (1), dependent upon the achievement of certain targets to be agreed on between the Parties, Employee shall receive an annual bonus payment of EUR 10.000,- (in words: Euro ten thousand) gross (the "Annual Bonus"). The Annual Bonus will be paid promptly after Employee's annual review and will be paid pro rata temporis if the employment has not existed the entire year, depending on the achievement of the agreed targets, whereby the determination of the fulfilment of the agreed targets is within the sole discretion of the Company.

3. In addition to the remuneration provided for under § 5 (1)-(2), Employee shall receive for his contractual employment an annual car allowance of EUR 5.000,- (in words: Euro five thousand) gross, payable in twelve (12) equal monthly installments at the time of his monthly salary.

4. The Company shall incur (either directly or by reimbursing the Employee upon submission of the respective receipts) the relocation costs incurred by the Employee due to the relocation from his current domicile to a domicile near Freising (collectively, the "Relocation Costs"). The Relocation Costs shall be limited to a maximum of EUR 7.500,- (in words: Euro seven thousand five hundred). This claim is excluded if the Employee does not plead for it within 12 (twelve) months after signing this Agreement.

5. The Employee shall be eligible to participate in the option pool of the Company, the terms and conditions of which will be set upon the discretion of the Company.

6. Any excess payments have to be repaid. The Employee waives his right according to § 818 Abs. 3 BGB *(Verzicht auf die Geltendmachung des Entreicherungseinwand*).

7. Employee shall not be entitled to any additional salary in respect of any overtime worked.

§ 6
EXPENSES

Employer will reimburse any travelling, hotel, entertainment and other out-of-pocket expenses properly and reasonably incurred by Employee in connection with the discharge of his duties of employment and in accordance with Employers's instructions and general guidelines and procedures. Any abuse of the expenses policy may be treated as a major breach of the terms of employment.

§ 7
HOLIDAYS

1. Employee is entitled to 28 working days holiday (in addition to statutory holidays). Holidays are to be taken at such time or times as may be approved by Employee's manager who should be given at least two weeks' advance notice of the intention to take holiday but who will not unreasonably withhold his or her approval. Holiday entitlement may not be carried forward to a future calendar year unless with the consent of the manager but such carry over may not exceed 5 days and the holiday carried over must be used by 31st March in that future calendar year. If Employee starts or leaves Employer during a calendar year, holiday entitlement in respect of that calendar year will be calculated on a pro rata basis. On the termination of the employment, Employee will be entitled to pay in lieu of outstanding holiday entitlement (if any) but must repay any holiday pay received for holiday taken in excess of his actual entitlement.

2. During the Trial Period holidays can not be taken.

§ 8
PERIODS OF ABSENCE, SICKNESS

1. Employee shall advise Employer without delay and in any event no later than 10.00 a.m. if possible on the first day of absence, of any absence from work and the foreseeable duration of such absence. If Employee cannot work due to sickness or injury of less than 3 days, Employee shall, on return to work, complete a self-certification sickness absence form.

2. In the event of any inability to work due to sickness or injury of 3 days or more, Employee shall submit to Employer a certificate from a registered medical practitioner within 3 working days from the first day of absence from work. This certificate must state the reason for the absence and shall also state the anticipated duration of the inability to work.

3. Subject to compliance with 8.1 or 8.2 Employee shall receive his basic salary, less normal deductions, for the time period as set forth in the law of continued remuneration (*Entgeltfortzahlungsgesetz*). The Employee shall transfer any rights against third parties which caused the sickness to Employer. This transfer is limited to the amount Employer has to pay. The Employee has to give any information about the rights to Employer.

§ 9
TRANSFER OF RIGHTS AND PLEDGE OF THE SALARY

1. No payments based on this Agreement shall be transferred or pledged without prior written consent of the Employer.

2. If legally permitted, all rights of retention (*Zurückbehaltungsrecht*), rights to refuse (*Leistungsverweigerungsrecht*) and rights of compensation (*Aufrechnung*) shall be excluded.

§ 10
CONFIDENTIALITY

1. Unless it is already in the public domain, Employee will keep secret and shall use his best endeavours to prevent the publication or disclosure of and will not at any time (whether during the employment or thereafter) use for his own or another's advantage, or reveal to any person, firm, company or organisation any trade secrets, or other confidential information of Employer. This information may include, for example, lists and details of employees, customers, distributors, wholesalers, clinical investigators, prescribers of products or others whom Employer are in the habit of dealing with, product details, business methods, market information (including details of adverse events and product complaints), terms of business, technical data, drawings, diagrams, plans, any matter or product in the research or testing stage, clinical trials, information on Employers's marketing or other computer databases, sales and marketing strategy, pricing and discount policy, contracts with customers, distributors, wholesalers or clinical investigators, dealings with prescribers, salary and benefits of employees of Employer, actual and potential contracts or assets of Employer and any other commercial information, which Employee knows or oughts reasonably to have known to be confidential. Confidential information may also include information which has been made available to Employer by a third party and which Employer is obliged to keep confidential.

2. The restrictions contained in clause 10.1 shall not apply to any disclosure or use authorized by the management or required by any applicable law.

3. Any breach of this obligation may lead to an extraordinary termination of this Agreement with immediate effect.

§ 11
EMPLOYER DOCUMENTS AND PROPERTY

1. All property, including emails, books, papers, materials, documents and photocopies or electronic versions, which relate to the business of Employer is and shall remain the property of Employer. Employee must return this property at Employers's first request or in any event upon suspension from work or termination of the employment.

2. Business records of any kind, including private notes concerning Employers' affairs and activities, shall be carefully kept and shall be used only for business purposes. Copies or extracts of drawings, notes, calculations, statistics and the like as well as any other business documents are only permitted for business purposes.

3. After notice of termination of the employment has been given – irrespective whether the notice is given by Employer or Employee – Employee shall, without delay and without specific request on behalf of Employer, return all working material and other items belonging to Employer, in particular all business documents and copies thereof. Employee shall have no right of retention and no damages claim relating thereto.

§ 12
Intellectual Property

1. In this Agreement, the intellectual property rights means copyrights, patents, utility models, trade marks, service marks, design rights (whether registered or unregistered), database rights, know how, trade or business names and other similar rights or obligations whether registerable or not in any country ("**Intellectual Property Rights**").

2. All Intellectual Property Rights arising in the course of or as a consequence of the employment or other work undertaken by Employee for Employer under this Employment Agreement shall belong to Employer.

3. Employee shall forthwith communicate to Employer any designs, discoveries or inventions or other matters potentially the subject of such Intellectual Property Rights, and shall at the request of Employer deliver to it all documents, drawings, models, samples, prototypes and the like prepared by or for Employer and which relate to such rights.

4. Employee hereby assigns to Employer by way of future assignment all copyrights or other Intellectual Property Rights arising under clause 13.2 (and waive any equivalent moral rights) immediately on their coming into existence. Further, to the extent that full legal title to any Intellectual Property Rights so arising shall fail automatically to belong to Employer by virtue of the provisions of clause 13.2 Employee shall hold such right on trust for Employer absolutely, and shall (notwithstanding the prior termination of this Employment Agreement for any reason) forthwith at the Employers' request execute any document or do anything required by Employer at Employers' expense to vest in it (or as it shall direct) the full legal title to such Intellectual Property Rights and to enable it (or its nominee) to enjoy the benefit of such right.

§ 13
Additional Activities/Prohibition of Competition

1. Employee shall on principle be obliged to dedicate his entire working capacity to the tasks and duties under this Employment Agreement. During the term of this employment relationship, any side-line activities (*Nebentätigkeiten*) which Employee takes up against payment or which impair the employment hereunder shall not be admissible except with the prior written approval of Employer. Employee shall be obliged to notify the Employer of any side-line engagement before its beginning. The Employer shall not refuse its approval without cause.

2. Employee has to report to the management about all side-line activities at the beginning of each following month.

3. During the term of the employment relationship, Employee shall be prohibited from working, whether directly or indirectly, whether on a self-employed basis or as employee, for any competing enterprise or from taking up any self-employed activities capable of competing with the Employer.

4. During the term of the employment relationship, Employee shall refrain from any direct or indirect financial interest in any enterprises competing with the Employer.

§ 14
Data Protection

1. Employee shall be obliged to create backups of the data on his computer at the end of each week.

2. Employee must not delete any data or make any copies without the prior written consent of Employer.

§ 15
Expiration Date

All claims of the Employee arising out of the employment and such claims which are related to the employment shall lapse if they are not asserted against the Employer in writing within three months after the assertion of the claim. The claim shall lapse if it is not asserted before the courts within 3 months after receipt of the rejection. Claims of the Employee which accrue during the legal dispute as to termination and which are dependent upon its outcome, are to be asserted in writing within 3 months after a final and legally binding conclusion of the legal dispute, or such shall lapse.

§ 16
Miscellaneous

1. Amendments to this Employment Agreement shall only be valid if made in writing and duly signed by both parties hereto. This shall also apply to this clause.

2. This contract represents the entire agreement and understanding of the parties. Other verbal or written agreements have not been made. This contract supersedes all prior written or verbal agreements (including but not limited to any letters of offer of employment) and employment contracts between the parties.

3. Employee represents and warrants to Employer that he will not by reason of entering into this Employment Agreement, performing any duties under the Employment Agreement, be in breach of any terms of employment with a third party whether expressed or implied or of any other obligation binding on him.

4. In case single provisions of this Employment Agreement are or prove to be invalid or not enforceable or in case this Employment Agreement should contain gaps, the binding force and effectiveness of the other provisions of this Employment Agreement shall remain unaffected. The invalid or unenforceable provision shall be replaced by such provision(s) which the Parties would have foreseeably agreed upon had they had knowledge of the invalidity, unenforceability or the gap as of the time of the signing of this Employment Agreement. Should a provision be or prove to be invalid for the stipulated extent and scope of the respective obligation contained therein, the scope and extent of such obligation shall be adjusted to match the legally admissible extent and scope of obligation.

5. To the extent legally permissible, the exclusive venue for all disputes arising from this Employment Agreement shall be the registered seat of Employer.

6. This Employment Agreement shall be governed by the laws of the Federal Republic of Germany.

§ 17
Copy of contract

Employee confirms by his own signature that he has received a written copy of this Employment Agreement.

Freising, _09.05.2011	[***]
/s/ Stephen Yoder	/s/ Shane Olwill
Employer	Employee

Exhibit 10.66

Amendment to the Employment Agreement

between

1. Pieris AG, Lise-Meitner-Str. 30, 85354 Freising, Germany, represented by the Executive Board
- **the** "Employer"-,

and

2. **Dr. Shane Olwill, [***]**

- **the** "Employee" -,
- each individually the **"Party"** and jointly the **"Parties"** -

The parties agree as follows:

§5

Annual Salary

§ 5 of the current employment agreement read as follows:

"1. ,,The initial annual base salary is EUR 100.000,- (in words: Euro one-hundred thousand) (less any deductions required by law) payable in arrears in 12 equal monthly installments at the end of each calendar month. The annual base sal ary will be reviewed annually during the employment. Employer is under no obligation to increase Employee's salary following an annual base salary review."

§ 5 of the employment agreement read as follows from September, 1, 2011:

"1. ,,The initial annual base salary is EUR 110.000,- (in words: Euro one-hundred

-ten-thousand) (less any deductions required by Jaw) payable in arrears in 12 equal monthly instalments at the end of each calendar month. The annual base salary will be reviewed annually during the employment. Employer is un der no obligation to increase Employee's salary following an annual base salary review.

The other wording of the contract remains unaffected.

Freising, October 14, 2011 [***], October 17, 2013

Place Date Place Date

/s/ Stephen Yoder /s/ Shane Olwill
Employer Employee

Amendment to the Employment Agreement

between

1. Pieris AG, Lise-Meitner-Str. 30, 85354 Freising, Germany, represented by the Executive Board

- the "Employer" **-,**

and

2. Dr. Shane Olwill, **[***]**

- the "Employee" **-,**

- each individually the "**Party**" and jointly the "**Parties**" -

The parties agree as follows:

§ 5
Annual Salary

§ 5 of the current employment agreement read as follows:

"1. „The initial annual base salary is EUR 110.000,- (in words: Euro one-hundred -ten-thousand) (less any deductions required by law) payable in arrears in 12 equal monthly instalments at the end of each calendar month. The annual base salary will be reviewed annually during the employment. Employer is under no obligation to increase Employee's salary following an annual base salary review.

§ 5 of the employment agreement read as follows from January 1st, 2012:

"1. „The initial annual base salary is EUR 114.400,- (in words: Euro one-hundred -fourteen-thousand-four-hundred) (less any deductions required by law) payable in arrears in 12 equal monthly instalments at the end of each calendar month. The annual base salary will be reviewed annually during the employment. Employer is under no obligation to increase Employee's salary following an annual base salary review.

The other wording of the contract remains unaffected.

Freising, 16. Feb 2012 [***], 16/2/12
Place Date Place Date

/s/ Stephen Yoder /s/ Shane Olwill
Employer **Employee**

Amendment to the Employment Agreement

between

3. Pieris AG, Lise-Meitner-Str. 30, 85354 Freising, Germany, represented by the Executive Board

- the "Employer" **-,**

and

4. Dr. Shane Olwill, [***]

- the "Employee" **-,**

- each individually the "**Party**" and jointly the "**Parties**" -

The parties agree as follows:

§ 5
Annual Salary

§ 5 of the current employment agreement read as follows:

"1. „*The initial annual base salary is EUR 114.400,- (in words: Euro one-hundred -fourteen-thousand-four-hundred) (less any deductions required by law) payable in arrears in 12 equal monthly instalments at the end of each calendar month. The annual base salary will be reviewed annually during the employment. Employer is under no obligation to increase Employee's salary following an annual base salary review.*

§ 5 of the employment agreement read as follows from January 1st, 2013:

"*1.* „*The initial annual base salary is EUR 116.688,00,- (in words: Euro one-hundred -sixteen-thousand-six-hundred-eighty-eight) (less any deductions required by law) payable in arrears in 12 equal monthly instalments at the end of each calendar month. The annual base salary will be reviewed annually during the employment. Employer is under no obligation to increase Employee's salary following an annual base salary review.*

The other wording of the contract remains unaffected.

Freising, 26.02.13	[***], 06/03/13
Place Date	Place Date
/s/ Stephen Yoder	/s/ Shane Olwill
Employer	Employee

Ergänzungsvereinbarung zum Arbeitsvertrag	**Amendment Agreement to the Employment Agreement**
zwischen	**between**
5. Pieris AG, **Lise-Meitner-Straße 30, 85354 Freising, vertreten durch den Vorstand, dieser vertreten durch den Vorsitzenden des Vorstands Stephen Yoder**	**1.** Pieris AG, **Lise-Meitner-Straße 30, 85354 Freising, represented by the management, this one represented by the CEO Stephen Yoder**
- nachfolgend „Arbeitgeber“ **-,**	**- hereinafter** „Employer“ **-,**
2. Dr. Shane Olwill**,**	**3.** Dr. Shane Olwill**,**
[***]	**[***]**
- nachfolgend „Arbeitnehmer“ **-,**	- hereinafter „**Employee**“ -,
- Arbeitgeber und Arbeitnehmer zusammen nachfolgend auch die „Parteien“**, jeder gesondert auch die** „Partei“ –	**- Employer and Employee hereinafter collectively also the** “Parties”**, each individually also a** “Party” **-**
Präambel	Preamble
Zwischen den Parteien besteht aufgrund des am 09.05.2011 geschlossenen Arbeitsvertrages (nachfolgend der „Arbeitsvertrag“**) ein Arbeitsverhältnis. Zur Bewältigung von konjunkturellen Schwankungen und getragen von dem Ziel, Entlassungen zu vermeiden, ist beabsichtigt, im Betrieb des Arbeitgebers mit Wirkung ab dem 15. August 2013 Kurzarbeit einzuführen. Diesbezüglich vereinbaren die Parteien in Ergänzung des Arbeitsvertrages was folgt:**	**The Employee is employed by the Employer on the basis of the employment agreement concluded on 09.05.2011 (hereinafter the** “Employment Agreement”**). In order to properly deal with economic fluctuations in demand and for the purpose of avoiding dismissals, it is intended to introduce reduced working hours (*Kurzarbeit*) in the company of the Employer effective August 15, 2013. In this regard, Parties agree to amend the Employment Agreement as follows:**
§ 1 **Einführung von Kurzarbeit**	**Sec. 1** **Introduction of reduced working hours**
1. Der Arbeitgeber kann Kurzarbeit anordnen, wenn und solange ein erheblicher Arbeitsausfall im Betrieb des Arbeitgebers vorliegt, der auf wirtschaftlichen Gründen oder einem unabwendbaren Ereignis beruht, und der Arbeitsausfall der Arbeitsverwaltung angezeigt ist (§§ 95 ff. SGB III) und die persönlichen Voraussetzungen im Hinblick auf den Arbeitnehmer nach § 98 SGB III erfüllt sind.	1. The Employer is entitled to introduce reduced working hours if and as long as a significant lack of work exists in the company of the Employer, which is based on economic reasons or an inevitable event, and the loss of work has been notified to the labour administration (Sec. 95 et. eqq. of Social Code III) and the personal requirements regarding the Employee according to Sec. 98 Social code III are being met.
2. Von der Kurzarbeit betroffen sind der gesamte Betrieb und sämtliche Mitarbeiter des Arbeitgebers.	2. The entire business unit as well as all employees of the Employer are affected by the reduced working hours.
3. Die Kurzarbeit kann längstens für die Dauer dieser Vereinbarung angeordnet werden.	3. The reduced working hours may only be ordered for no longer than the term of this Agreement.
4. Für die Dauer von gewährtem Erholungsurlaub im Sinne des Arbeitsvertrages ist der Arbeitnehmer von der Anordnung von Kurzarbeit ausgenommen.	4. No reduced working hours shall be ordered in the instance and the term of agreed vacation of the Employee in the sense of the Employment Agreement.
§ 2 **Kürzung von Arbeitszeit und Vergütung**	**Sec. 2** **Reduction of working time and compensation**
Bei Anordnung von Kurzarbeit ist der Arbeitnehmer damit einverstanden, dass sich seine Arbeitszeit entsprechend des Arbeitsausfalls verkürzt und für die Dauer der Arbeitszeitverkürzung die Arbeitsvergütung im Verhältnis der ausgefallenen Arbeitszeit reduziert wird.	**Upon instruction of reduced working hours, the Employee agrees that his working time will be reduced according to the loss of work and that his remuneration will be reduced for the duration of the reduction of working time at the ratio of the omitted working time.**
§ 3 **Verteilung der Arbeitszeit**	**Sec. 3** **Allocation of working time**
Die mit der Kurzarbeit verbundene Verringerung der Arbeitszeit erfolgt innerhalb einer Arbeitswoche (Montag bis Freitag) zu gleichen Teilen und verkürzt die Dauer der wöchentlichen Arbeitszeit entsprechend. Bei dringenden betrieblichen Erfordernissen und/oder im Einvernehmen beider Parteien ist auch eine andere Verteilung der gekürzten Arbeitszeit auf die Wochentage möglich.	**The reduction of working time related to the reduced working hours shall take place in every working week (Monday to Friday) in equal parts and shall reduce the duration of the weekly working time accordingly. In the instance of urgent operational requirements and/or upon agreement of both Parties, a different allocation of the reduced working time as to the weekly days is possible.**
§ 4 **Ankündigungsfrist**	**Sec. 4** **Notice period**
Der Arbeitgeber hat bei der Anordnung von Kurzarbeit gegenüber dem Arbeitnehmer eine Ankündigungsfrist von 3 Wochen einzuhalten. Er hat dem Arbeitnehmer mitzuteilen, auf wie viele Stunden die derzeitige wöchentliche Arbeitszeit des Arbeitnehmers gesenkt wird.	**The Employer shall meet a notice period of three weeks vis-à-vis the Employee when ordering reduced working hours. He shall inform the Employee by how many hours the current weekly working time of the Employee will be reduced.**
§ 5 **Verzicht auf betriebsbedingte Kündigung**	**Sec. 5** **Waiver to termination for operational reasons**
Der Arbeitgeber verzichtet im Zeitraum, für den gegenüber dem Arbeitnehmer Kurzarbeit angeordnet ist, auf die ordentliche betriebsbedingte Kündigung des Arbeitsverhältnisses.	**For the time in which reduced working hours are ordered, the Employer waives its right to terminate the employment in compliance of the applicable notice period due to operational reasons (*aus betriebsbedingten Gründen*).**
§ 6 **Laufzeit**	**Sec. 6** **Term**
Diese Vereinbarung ist bis zum 14. August 2014 befristet und endet mit Ablauf dieses Tages, ohne dass es einer Kündigung bedarf.	**This Agreement is entered into until August 14, 2014, and shall automatically end upon expiry of this day without need to further notice.**
§ 7 **Schlussbestimmungen**	**Sec. 7** **Final provisions**

1. Die Parteien sind sich darüber einig, dass die übrigen Bestimmungen des Arbeitsvertrages uneingeschränkt fortgelten, sofern sie nicht durch diese Ergänzungsvereinbarung ausdrücklich abgeändert wurden.	1. Parties agree that the other provisions of the Employment Agreement shall continue to be in full force and affect as long they are not explicitly amended by this Amendment Agreement.
2. Falls einzelne Bestimmungen dieses Vertrages unwirksam oder undurchführbar sein oder werden sollten oder dieser Vertrag Lücken enthält, wird dadurch die Wirksamkeit der übrigen Bestimmungen dieses Vertrages nicht berührt. Anstelle der unwirksamen oder undurchführbaren Bestimmungen vereinbaren die Parteien eine solche wirksame Bestimmung, wie die Parteien sie voraussichtlich vereinbart hätten, wenn ihnen bei Abschluss dieses Vertrages die Unwirksamkeit, Undurchführbarkeit oder das Fehlen der betreffenden Bestimmungen bewusst gewesen wäre. Sollte eine Bestimmung wegen des darin vereinbarten Leistungsumfangs unwirksam sein oder werden, ist der in der Bestimmung vereinbarte Leistungsumfang dem rechtlich zulässigen Maß anzupassen.	2. Should single provisions of this Agreement be or become invalid or non-executable or should it contain gaps, the validity of the remaining provisions shall not be affected. The Parties shall be obliged to agree on an arrangement instead of the invalid or non-executable provision which comes as close as possible to the original provision in its legal and economic effect, taking into account the mutual interests of both Parties by the time of the execution of this Agreement. Should a provision be or become invalid due to its scope of services, the scope of services agreed in the provision shall be adjusted to the legally permissible scope of services.
3. Für den Fall der Abweichung der deutschen Fassung dieses Vertrages von der englischen, gilt die deutsche Fassung.	3. In the instance of a discrepancy between the German version of this Agreement and the English one, the German one shall apply.

_____, der July 15, 2013__	_____, the July 15, 2013
_____**[***]**_____	_____**[***]**_____
Arbeitgeber	**Employer**
_____, der July 18, 2013	**_____, the _July 18, 2013**
_____/s/ Shane Olwill_____	**_____/s/ Shane Olwill_____**
Arbeitnehmer	**Employee**

Amendment to the Employment Agreement

between

1. Pieris AG, Lise-Meitner-Str. 30, 85354 Freising, Germany, represented by the Executive Board

   - **the** "Employer" -,

and

2. Dr. Shane Olwill, [***]

   - **the** "Employee" -,

- each individually the **"Party"** and jointly the **"Parties"**

The parties agree as follows:

§1

Employment and Duties

§1 of the current employment agreement read as follows:

"1. Employer hereby employs the Employee as Senior Director R & D. The Em- ployee shall be bound to all instructions of his manager.

§ 1 of the employment agreement read as follows from November 11th, 2011:

"1. Employer hereby promotes the Employee to VP Development.

The other wording of the contract remains unaffected.

Freising, 7 November, 2013 [***], 7 November 2013

Place Date Place Date

/s/ Stephen Yoder /s/ Shane Olwill
Employer Employee

Amendment to the Employment Agreement

between

6. Pieris AG, Lise-Meitner-Str. 30, 85354 Freising, Germany, represented by the Executive Board

- the "Employer" **-,**

and

7. Dr. Shane Olwill, [***]

- the "Employee" **-,**

- each individually the "**Party**" and jointly the "**Parties**" -

The parties agree as follows:

§ 5
Annual Salary

§ 5 of the current employment agreement read as follows:

"1. „The initial annual base salary is EUR 116.688,00,- (in words: Euro one-hundred -sixteen-thousand-six-hundred-eighty-eight) (less any deductions required by law) payable in arrears in 12 equal monthly instalments at the end of each calendar month. The annual base salary will be reviewed annually during the employment. Employer is under no obligation to increase Employee's salary following an annual base salary review.

§ 5 of the employment agreement read as follows from January 1st, 2014:

"1. „The initial annual base salary is EUR 124.856,16,- (in words: Euro one-hundred -Twenty-four thousand-eight-hundred-six fifty) (less any deductions required by law) payable in arrears in 12 equal monthly instalments at the end of each calendar month. The annual base salary will be reviewed annually during the employment. Employer is under no obligation to increase Employee's salary following an annual base salary review.

The other wording of the contract remains unaffected.

Freising, Febr. 14, 2014	[***], Feb 21, 2014
Place Date	Place Date
/s/ Stephen Yoder	/s/ Shane Olwill
Employer	Employee

Amendment to the Employment Agreement

Between

1. Pieris AG, Lise-Meitner-Str. 30, 85354 Freising, Germany, represented by the Executive Board

- **the** "Employer" -,

and

2. Dr. Shane Olwill, [***]

- **the** "Employee" -,

- each individually the **"Party"** and jointly the **"Parties"** -

The parties agree as follows:

§5

Annual Salary

§ 5 of the current employment agreement read as follows:

"1. ,,The initial annual base salary is EUR 124.856,16,- (in words: Euro one hundred -Twenty-four thousand-eight-hundred-six fifty) (less any deductions required by law) payable in arrears in 12 equal monthly instalments at the end of each calendar month. The annual base salary will be reviewed annually during the employment. Employer is under no obligation to increase Employ ee's salary following an annual base salary review.

§ 5 of the employment agreement read as follows from January 1st, 2015:

"1. ,,The initial annual base salary is EUR 137.342,- (in words: Euro one-hundred

-Thirty-seven-thousand-three-hundred-fourty-two) (less any deductions re quired by law) payable in arrears in 12 equal monthly instalments at the end of each calendar month. The annual base salary will be reviewed annually during the employment. Employer is under no obligation to increase Employee's sal ary following an annual base salary review.

The other wording of the contract remains unaffected.

Freising, Feb 3, 2015	[***], Feb. 13, 2015
Place Date	Place Date
/s/ Stephen Yoder	/s/ Shane Olwill
Employer	Employee

Amendment to the Employment Agreement

between

8. Pieris AG, Lise-Meitner-Str. 30, 85354 Freising, Germany, represented by the Executive Board

- the "Employer" **-,**

and

9. Dr. Shane Olwill, [***]

- the "Employee" **-,**

- each individually the "**Party**" and jointly the "**Parties**" -

The parties agree as follows:

&5
Annual Salary

2. In addition to the remuneration provided for under § 5 (1), dependent upon the achievement of certain targets to be agreed on between the Parties, Employee shall receive an annual bonus payment of EUR 10.000,- (in words: Euro ten thousand) gross (the "Annual Bonus"). The Annual Bonus will be paid promptly after Employee's annual review and will be paid pro rata temporis if the employment has not existed the entire year, depending on the achievement of the agreed targets, whereby the determination of the fulfilment of the agreed targets is within the sole discretion of the Company.

§ 5.2 of the employment agreement read as follows from January 1st, 2015:

2. In addition to the remuneration provided for under § 5 (1), dependent upon the achievement of certain targets to be agreed on between the Parties, Employee shall receive an annual bonus payment of 20% of the annual base salary gross (the "Annual Bonus"). The Annual Bonus will be paid promptly after Employee's annual review and will be paid pro rata temporis if the employment has not existed the entire year, depending on the achievement of the agreed targets, whereby the determination of the fulfilment of the agreed targets is within the sole discretion of the Company.

The other wording of the contract remains unaffected.

Freising, Feb 17, 2015	[***], Feb. 24, 2015
Place Date	Place Date
/s/ Stephen Yoder	/s/ Shane Olwill
Employer	Employee

Amendment to the Employment Agreement

between

3. Pieris Pharmaceuticals GmbH, Lise-Meitner-Str. 30, 85354 Freising, Germany, represented by the Managing Director Stephen S. Yoder

- the "Employer" **-,**

and

4. Dr. Shane Olwill, [***]

- the "Employee" **-,**

- each individually the "**Party**" and jointly the "**Parties**"

The parties agree as follows:

§ 5
Annual Salary

§ 5 of the current employment agreement read as follows:

"*1.* „*The initial annual base salary is EUR 137.342,- (in words: Euro one-hundred –Thirty-seven-thousand-three-hundred-fourty-two) (less any deductions required by law) payable in arrears in 12 equal monthly instalments at the end of each calendar month. The annual base salary will be reviewed annually during the employment. Employer is under no obligation to increase Employee's salary following an annual base salary review.*"

§ 5 of the employment agreement read as follows from January 1st, 2016:

"*1.* „*The initial annual base salary is EUR 162.064,- (in words: Euro one-hundred –sixty-two-thousand-sixty-four) (less any deductions required by law) payable in arrears in 12 equal monthly installments at the end of each calendar month. The annual base salary will be reviewed annually during the employment. Employer is under no obligation to increase Employee's salary following an annual base salary review.* "

The other wording of the contract remains unaffected.

Freising, Feb 24, 2016	[***], Feb. 24, 2016
Place Date	Place Date
/s/ Stephen Yoder	/s/ Shane Olwill
Employer	Employee

Amendment to the Employment Agreement

between

5. Pieris AG, Lise-Meitner-Str. 30, 85354 Freising, Germany, represented by the Executive Board

- the “Employer“ **-,**

and

6. Dr. Shane Olwill, [***]

- the “Employee“ **-,**

- each individually the “**Party**“ and jointly the “**Parties**“ -

The parties agree as follows:

§5

Effective Date, Term

1. “The initial annual base salary is EUR 162.064, - (in words: Euro one-hundred -sixty two-thousand-sixty-four) (less any deductions required by law) payable in arrears in 12 equal monthly installments at the end of each calendar month. The annual base salary will be reviewed annually during the employment. Employer is under no obligation to increase Employee's salary following an annual base salary review.”

§ 5.1 of the employment agreement read as follows from January 1st, 2017:

§5

Effective Date, Term

1. "The initial annual base salary is EUR 184.752,91, - (in words: Euro one-hundred - eighty-four-thousand-seven-hundred-fifty-two-ninety-one) (less any deductions required by law) payable in arrears in 12 equal monthly installments at the end of each calendar month. The annual base salary will be reviewed annually during the employment. Employer is under no obligation to increase Employee's salary following an annual base salary review. "

The other wording of the contract remains unaffected.

Freising, Feb 24, 2017	[***], Feb. 24, 2017
Place Date	Place Date
/s/ Stephen Yoder	/s/ Shane Olwill
Employer	Employee

Amendment to the Employment Agreement

Between

Pieris Pharmaceuticals GmbH

Zeppelinstraße 3

85399 Hallbergmoos

represented by Stephen S. Yoder and Hitto Kaufmann

- the „Employer" -

and

Shane Olwill

[***]

- the „Employee" -

The parties agree as follows:

§1 Employment and Duties

§1.1 of the contract of May 9th, 2011 in connection with the amendment from November 7th, 2013 the current version reads as follows:

"1. Employer hereby employs the Employee as VP, Head of Translational Science.“

§1.1 will be given the following version from August 1st, 2021:

"1. Employer hereby promotes the Employee to SVP, Chief Development Officer. “

§ 5 Annual Salary

§5.2 of the contract of May 9th, 2011 in connection with the salary letter of February 2020 the current version reads as follows:

"1. The Employee is entitled to an annual bonus in the maximum amount of 30% of his respective yearly gross base salary. “

§3.1 will be given the following version from August 1st, 2021:

"1. The Employee is entitled to an annual bonus in the maximum amount of 40% of his respective yearly gross base salary. “

The other wording of the contract remains unaffected.

Hallbergmoos, September 29, 2021	[***], September 30, 2021
Place, Date	Place, Date
[***]	/s/ Shane Olwill
Employer	Employee

Exhibit 10.67

Shane Olwill

Pieris Pharmaceuticals GmbH

Hallbergmoos, February 22nd, 2024

Your Compensation Package

Dear Shane,

Since you are a key contributor to Pieris Pharmaceuticals, Inc. and/or its subsidiaries ("Pieris" or the "Company") moving forward, we would like to confirm our prior communication about your enhanced compensation package in exchange for your continued service.

Your compensation package consists of the following elements, based on the conditions outlined below:

	Monthly	April 2024 (or earlier) (if 100% achievement)	Qualifying Termination or Resignation (calculated for termination notice on or before June 30, 2024)
1. Base salary	25.337 EUR		
2. Target bonus (40%)		121.620 EUR	
3. Severance payment			445.300 EUR

Please find below the detailed explanations to the above listed components:

1. **2024 Bonus:** The Compensation and Management Development Committee has approved your 2023 bonus in an amount of 121.620 EUR in consideration of the full achievement of the newly established corporate goals (the "2023 restated corporate goals") as approved by the Committee on August 30, 2023.

2. **Severance:** The severance payment listed above has been calculated based on the same determinants as those utilized by Pieris in the Company's July 2023 reduction in force "Severance Payment," and inclusive of a bonus based on your annual bonus target (i.e. 40% of your gross base salary). Provided you sign a separation agreement with Pieris, or their successor or assigns, in a form substantially similar to Pieris' standard separation agreement, which includes a release of claims and confidentiality provisions, then you will be entitled to this Severance Payment at the end of your employment as a result of Pieris, or their successor or assigns, terminating your employment.

   If you provide a notice of resignation or are terminated for cause, however, you shall be ineligible to receive the Severance Payment. Notwithstanding anything to the contrary, if you provide a resignation notice to Pieris, or their successor or assigns, between July 1, 2024 through July 15, 2024, you will be provided a retention payment in the same amount as the Severance Payment you would have received had Pieris, or their successor or assigns, terminated your employment in accordance with this paragraph. Such payment will be made as of the effective date of your resignation.

Any payments made pursuant to this letter shall be subject to applicable employment-related withholding. This letter shall be binding upon Pieris and their respective successors and assigns, including any corporation with which, or into which, the Company may be merged or which may succeed to the Company's assets or business, provided, however, that your obligations are personal and shall not be assigned by you. This letter shall not be amended or modified without your written consent.

Kind regards,

/s/ Stephen Yoder

Stephen Yoder
President & CEO

Exhibit 21.1

Subsidiaries

Entity	Jurisdiction of Organization
Pieris Pharmaceuticals GmbH	Germany
Pieris Australia Pty Limited	Australia
Pieris Pharmaceuticals Securities Corporation	Massachusetts

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statements (Form S-3 Nos. 333-212439 and 333-235350),
(2) Registration Statement (Form S-8 No. 333-204487) pertaining to the Pieris Pharmaceuticals, Inc. 2014 Employee, Director and Consultant Equity Incentive Plan,
(3) Registration Statement (Form S-8 No. 333-209308) pertaining to the Pieris Pharmaceuticals, Inc. 2014 Employee, Director and Consultant Equity Incentive Plan and Inducement Stock Option Award for Louis Matis, M.D.,
(4) Registration Statement (Form S-8 No. 333-213771) pertaining to the Pieris Pharmaceuticals, Inc. 2016 Employee, Director and Consultant Equity Incentive Plan,
(5) Registration Statement (Post-Effective Amendment to Form S-1 on Form S-3 No. 333-202123),
(6) Registration Statement (Form S-8 No. 333-221497) pertaining to Inducement Stock Option Awards for Claude Knopf, Allan Reine, M.D, and Ingmar Bruns, M.D., Ph.D.,
(7) Registration Statement (Form S-8 No. 333-226733) pertaining to the Pieris Pharmaceuticals, Inc. 2018 Employee, Director and Consultant Equity Incentive Plan,
(8) Registration Statement (Form S-8 No. 333-226735) pertaining to the Pieris Pharmaceuticals, Inc. 2018 Employee Stock Purchase Plan,
(9) Registration Statement (Form S-8 No. 333-233194) pertaining to the Pieris Pharmaceuticals, Inc. 2019 Employee, Director and Consultant Equity Incentive Plan,
(10) Registration Statement (Form S-8 No. 333-234625) pertaining to the Non-Qualified Stock Option Agreement, dated August 30, 2019,
(11) Registration Statement (Form S-8 No. 333-243735) pertaining to the Pieris Pharmaceuticals, Inc. 2020 Employee, Director and Consultant Equity Incentive Plan,
(12) Registration Statements (Form S-3 No. 333-256218 and 333-258497),
(13) Registration Statement (Form S-8 No. 333-258502) pertaining to the Pieris Pharmaceuticals, Inc. 2020 Employee, Director and Consultant Equity Incentive Plan, as amended and the Inducement Stock Option Award for Tim Demuth, M.D., Ph.D.,
(14) Registration Statement (Form S-8 No. 333-266539) pertaining to the Pieris Pharmaceuticals, Inc. 2020 Employee, Director and Consultant Equity Incentive Plan, as amended, and
(15) Registration Statement (Form S-8 No. 333-273893) pertaining to the Pieris Pharmaceuticals, Inc. 2020 Employee, Director and Consultant Equity Incentive Plan, as amended, and the Pieris Pharmaceuticals, Inc. 2023 Employee Stock Purchase Plan;

of our report dated March 29, 2024, with respect to the consolidated financial statements of Pieris Pharmaceuticals, Inc. included in this Annual Report (Form 10-K) of Pieris Pharmaceuticals, Inc. for the year ended December 31, 2023.

/s/ Ernst & Young LLP

Boston, Massachusetts
March 29, 2024

Exhibit 31.1

CERTIFICATIONS UNDER SECTION 302

I, Stephen S. Yoder, certify that:

1. I have reviewed this annual report on Form 10-K of Pieris Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 29, 2024

/s/ Stephen S. Yoder
Stephen S. Yoder
Title: Chief Executive Officer and President (principal executive officer)

Exhibit 31.2

CERTIFICATIONS UNDER SECTION 302

I, Thomas Bures, certify that:

1. I have reviewed this annual report on Form 10-K of Pieris Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 29, 2024

/s/ Thomas Bures
Thomas Bures
Title: Senior VP, Chief Financial Officer and Treasurer (principal financial officer)

Exhibit 32.1

CERTIFICATIONS UNDER SECTION 906

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), the undersigned officer of Pieris Pharmaceuticals, Inc., a Nevada corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The Annual Report for the year ended December 31, 2023 (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 29, 2024

/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, 2023 (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 29, 2024

/s/ Thomas Bures
Thomas Bures
Title: Senior VP, Chief Financial Officer and Treasurer
(principal financial officer)

Exhibit 97

PIERIS PHARMACEUTICALS, INC.
CLAWBACK POLICY

I. Introduction

The Board of Directors (the "**Board**") of Pieris Pharmaceuticals, Inc., a Nevada corporation (the " **Company**") believes that it is in the best interests of the Company and its shareholders to create and maintain a culture that emphasizes integrity and accountability and that reinforces the Company's pay-for-performance compensation philosophy. The Board has therefore adopted this policy which provides for the recoupment of certain executive compensation in the event of an accounting restatement resulting from material noncompliance with financial reporting requirements under the federal securities laws (the "**Policy**"). This Policy is designed to comply with Section 10D of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**") and final rules and amendments adopted by the Securities and Exchange Commission (the " **SEC**") to implement the aforementioned legislation.

II. Administration

This Policy shall be administered by the Board or, if so designated by the Board, the Compensation Committee of the Board, in which case references herein to the Board shall be deemed references to the Compensation Committee. Any determinations made by the Board shall be final and binding on all affected individuals.

III. Covered Executives

This Policy applies to the Company's current and former executive officers, as determined by the Board in accordance with the requirements of Section 10D of the Exchange Act and any applicable rules or standards adopted by the SEC and any national securities exchange on which the Company's securities are listed, and such other employees who may from time to time be deemed subject to the Policy by the Board ("**Covered Executives**").

IV. Incentive-Based Compensation

For purposes of this Policy, incentive-based compensation (" **Incentive-Based Compensation**") includes any compensation that is granted, earned, or vested based wholly or in part upon the attainment of any financial reporting measures that are determined and presented in accordance with the accounting principles ("**GAAP Measures**") used in preparing the Company's financial statements and any measures derived wholly or in part from such measures, as well as non-GAAP Measures, stock price, and total shareholder return (collectively, "**Financial Reporting Measures**"); however, it does not include: (i) base salaries; (ii) discretionary cash bonuses; (iii) awards (either cash or equity) that are solely based upon subjective, strategic or operational standards or standards unrelated to Financial Reporting Measures, and (iv) equity awards that vest solely on completion of a specified employment period or without any performance condition. Incentive-Based Compensation is considered received in the fiscal period during which the applicable reporting measure is attained, even if the payment or grant of such award occurs after the end of that period. If an award is subject to both time-based and performance-based vesting conditions, the award is considered received upon satisfaction of the performance-based conditions, even if such an award continues to be subject to the time-based vesting conditions.

For the purposes of this Policy, Incentive-Based Compensation may include, among other things, any of the following:

- Annual bonuses and other short- and long-term cash incentives.
- Stock options.
- Stock appreciation rights.
- Restricted stock or restricted stock units.
- Performance shares or performance units.

For purposes of this Policy, Financial Reporting Measures may include, among other things, any of the following:

- Company stock price.
- Total shareholder return.
- Revenues.
- Net income.
- Earnings before interest, taxes, depreciation, and amortization (EBITDA).
- Funds from operations.
- Liquidity measures such as working capital or operating cash flow.
- Return measures such as return on invested capital or return on assets.
- Earnings measures such as earnings per share.

V. Recoupment; Accounting Restatement

In the event the Company is required to prepare an accounting restatement of its financial statements due to the Company's material noncompliance with any financial reporting requirement under U.S. securities laws, including any required accounting restatement to correct an error in previously issued financial statements that (i) is material to the previously issued financial statements or (ii) is not material to previously issued financial statements, but that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period, the Board will require reimbursement or forfeiture of any excess Incentive-Based Compensation received by any Covered Executive during the three completed fiscal years immediately preceding the date on which the Company is required to prepare the accounting restatement (the "**Look-Back Period**"). For the purposes of this Policy, the date on which the Company is required to prepare an accounting restatement is the earlier of (i) the date the Board concludes or reasonably should have concluded that the Company is required to prepare a restatement to correct a material error, and (ii) the date a court, regulator, or other legally authorized body directs the Company to restate its previously issued financial statements to correct a material error. The Company's obligation to recover erroneously awarded compensation is not dependent on if or when the restated financial statements are filed.

Recovery of the Incentive-Based Compensation is only required when the excess award is received by a Covered Executive (i) after the beginning of their service as a Covered Executive, (ii) who served as an executive officer at any time during the performance period for that Incentive-Based Compensation, (iii) while the Company has a class of securities listed on a national securities exchange or a national securities association, and (iv) during the Look-Back Period immediately preceding the date on which the Company is required to prepare an accounting restatement.

VI. Excess Incentive Compensation: Amount Subject to Recovery

The amount of Incentive-Based Compensation subject to recovery is the amount the Covered Executive received in excess of the amount of Incentive-Based Compensation that would have been paid to the Covered Executive had it been based on the restated financial statements, as determined by the Board. The amount subject to recovery will be calculated on a pre-tax basis.

For Incentive-Based Compensation received as cash awards, the erroneously awarded compensation is the difference between the amount of the cash award that was received (whether payable in a lump sum or over time) and the amount that should have been received applying the

restated Financial Reporting Measure. For cash awards paid from bonus pools, the erroneously awarded Incentive-Based Compensation is the pro rata portion of any deficiency that results from the aggregate bonus pool that is reduced based on applying the restated Financial Reporting Measure.

For Incentive-Based Compensation received as equity awards that are still held at the time of recovery, the amount subject to recovery is the number of shares or other equity awards received or vested in excess of the number that should have been received or vested applying the restated Financial Reporting Measure. If the equity award has been exercised, but the underlying shares have not been sold, the erroneously awarded compensation is the number of shares underlying the award.

In instances where the Company is not able to determine the amount of erroneously awarded Incentive-Based Compensation directly from the information in the accounting restatement, the amount will be based on the Company's reasonable estimate of the effect of the accounting restatement on the applicable measure. In such instances, the Company will maintain documentation of the determination of that reasonable estimate.

VII. Method of Recoupment

The Board will determine, in its sole discretion, subject to applicable law, the method for recouping Incentive-Based Compensation hereunder, which may include, without limitation:

- requiring reimbursement of cash Incentive-Based Compensation previously paid;
- seeking recovery of any gain realized on the vesting, exercise, settlement, sale, transfer, or other disposition of any equity-based awards;
- offsetting the recouped amount from any compensation otherwise owed by the Company to the Covered Executive;
- cancelling outstanding vested or unvested equity awards; and/or
- taking any other remedial and recovery action permitted by law, as determined by the Board.

VIII. No Indemnification; Successors

The Company shall not indemnify any Covered Executives against the loss of any incorrectly awarded Incentive-Based Compensation. This Policy shall be binding and enforceable against all Covered Executives and their beneficiaries, heirs, executors, administrators or other legal representatives.

IX. Exception to Enforcement

The Board shall recover any excess Incentive-Based Compensation in accordance with this Policy unless such recovery would be impracticable, as determined by the Board in accordance with Rule 10D-1 of the Exchange Act and any applicable rules or standards adopted by the SEC and the listing standards of any national securities exchange on which the Company's securities are listed.

X. Interpretation

The Board is authorized to interpret and construe this Policy and to make all determinations necessary, appropriate, or advisable for the administration of this Policy. It is intended that this Policy be interpreted in a manner that is consistent with the requirements of Section 10D of the Exchange Act and any applicable rules or standards adopted by the SEC and any national securities exchange on which the Company's securities are listed.

XI. Effective Date

This Policy shall be effective as of October 2, 2023 (the " **Effective Date**") and shall apply to Incentive-Based Compensation that is received by a Covered Executive on or after that date, as determined by the Board in accordance with applicable rules or standards adopted by the SEC and the listing standards of any national securities exchange on which the Company's securities are listed.

XII. Amendment; Termination

The Board may amend this Policy from time to time in its discretion and shall amend this Policy as it deems necessary to comply with any rules or standards adopted by the SEC and the listing standards of any national securities exchange on which the Company's securities are listed. The Board may terminate this Policy at any time.

XIII. Other Recoupment Rights

Any right of recoupment under this Policy is in addition to, and not in lieu of, any other remedies or rights of recoupment that may be available to the Company pursuant to the terms of any similar policy in any employment agreement, equity award agreement, or similar agreement and any other legal remedies available to the Company.