

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 10-Q

(Mark One)

- QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended March 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
(State or other jurisdiction of
incorporation or organization)
225 Franklin Street, 26th Floor
Boston, MA
United States
(Address of principal executive offices)

30-0784346
(I.R.S. Employer
Identification No.)

02110
(Zip Code)

857-246-8998

Registrant's telephone number, including area code

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

| Title of Each Class | Trading Symbol | Name of Each Exchange on which Registered |
|---|----------------|---|
| Common Stock, \$0.001 par value per share | PIRS | The Nasdaq Capital Market |

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 of this chapter) 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 | <input type="checkbox"/> | Accelerated filer | <input type="checkbox"/> |
| Non-accelerated filer | <input checked="" type="checkbox"/> | Smaller reporting company | <input checked="" type="checkbox"/> |
| | | Emerging growth company | <input type="checkbox"/> |

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

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

As of May 8, 2023, the registrant had 82,019,103 shares of common stock outstanding.

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Special Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q 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 section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” All statements other than statements of historical fact contained in this Quarterly Report on Form 10-Q, including statements regarding future events, our future financial performance, expectations for growth and revenues, 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 terminology including “anticipates,” “believes,” “can,” “continue,” “look forward,” “ongoing,” “could,” “estimates,” “expects,” “intends,” “may,” “appears,” “suggests,” “future,” “likely,” “plans,” “potential,” “possibly,” “projects,” “predicts,” “seek,” “should,” “target,” “would” or “will” or the negative of these terms or other comparable terminology. Although we do not make forward-looking statements unless we believe we have a reasonable basis for doing so, we cannot guarantee their accuracy. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including the risks outlined under “Risk Factors” or elsewhere in our most recent Annual Report on Form 10-K or Quarterly Reports on Form 10-Q, which may cause our or our industry’s actual results, levels of activity, performance or achievements expressed or implied by these forward-looking statements to differ materially.

Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time, and it is not possible for us to predict all risk factors, nor can we address the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause our actual results to differ materially from those contained in any forward-looking statements. Actual results could differ materially from our forward-looking statements due to a number of factors, including, without limitation, risks related to: the results of our research and development activities, including uncertainties relating to the discovery of potential drug candidates and the preclinical and ongoing or planned clinical testing of our drug candidates; the early stage of our drug candidates presently under development; our continued progress in the areas of co-stimulatory bispecifics and inhaled therapeutics; our ability to obtain and, if obtained, maintain regulatory approval of our current drug candidates and any of our other future drug candidates; our need for substantial additional funds in order to continue our operations and the uncertainty of whether we will be able to obtain the funding we need; our future financial performance; our ability to retain or hire key scientific or management personnel; our ability to protect our intellectual property rights that are valuable to our business, including patent and other intellectual property rights; our dependence on third-party manufacturers, suppliers, research organizations, testing laboratories and other potential collaborators; the success of our collaborations with third parties; our ability to meet milestones; the receipt of royalty and milestone payments provided for in our collaboration agreements; our ability to successfully market and sell our drug candidates in the future as needed; the size and growth of the potential markets for any of our product candidates for which we may obtain regulatory approval, and the rate and degree of market acceptance of any 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; AstraZeneca’s ability to advance the phase 2 study for elarekibep (PRS-060/AZD1402); our ability to continue to advance the phase 1 study for PRS-220; our ability to continue to advance PRS-400; our and Servier’s ability to advance the phase 1 study for PRS-344/S095012; Seagen’s ability to continue to advance SGN-BB228 (also known as PRS-346); Boston Pharmaceuticals ability to continue to advance PRS-342/BOS-342; our other partners’ ability to continue to advance programs out-licensed to them; the expected impact of new accounting standards; and the length and severity of the pandemic relating to SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2), or coronavirus, which causes coronavirus disease 2019, or COVID-19, which could have an impact on our research, development, supply chain and clinical trials.

You should not place undue reliance on any forward-looking statement(s), each of which applies only as of the date of this Quarterly Report on Form 10-Q. Before you invest in our securities, you should be aware that the occurrence of the events described in Part I, Item 1A (Risk Factors) of our Annual Report on Form 10-K for the fiscal year ended December 31, 2022 filed with the Securities and Exchange Commission, or SEC, on March 31, 2023, 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 Quarterly Report on Form 10-Q to conform our statements to actual results or changed expectations.

Currency Presentation and Currency Translation

Unless otherwise indicated, all references to “dollars,” “\$,” “U.S. \$” or “U.S. dollars” are to the lawful currency of the United States. All references in this Quarterly Report on Form 10-Q 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 income/loss.

Where in this Quarterly Report on Form 10-Q 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. \$1.08838 based on information provided by Xignite as of March 31, 2023.

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements.

PIERIS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited, in thousands)

| | <u>March 31,</u> | <u>December 31,</u> |
|---|------------------|---------------------|
| | <u>2023</u> | <u>2022</u> |
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 39,742 | \$ 38,635 |
| Short term investments | 8,637 | 20,534 |
| Accounts receivable | 1,055 | 5,810 |
| Prepaid expenses and other current assets | 11,071 | 8,445 |
| Total current assets | <u>60,505</u> | <u>73,424</u> |
| Property and equipment, net | 16,706 | 16,992 |
| Operating lease right-of-use assets | 3,796 | 3,705 |
| Other non-current assets | 1,251 | 1,369 |
| Total assets | <u>\$ 82,258</u> | <u>\$ 95,490</u> |
| Liabilities and stockholders' equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 5,833 | \$ 4,154 |
| Accrued expenses and other current liabilities | 10,354 | 11,605 |
| Deferred revenues, current portion | 26,688 | 20,824 |
| Total current liabilities | <u>42,875</u> | <u>36,583</u> |
| Deferred revenue, net of current portion | 11,727 | 18,734 |
| Operating lease liabilities | 12,198 | 12,244 |
| Total liabilities | <u>66,800</u> | <u>67,561</u> |
| Stockholders' equity: | | |
| Preferred stock | — | — |
| Common stock | 74 | 74 |
| Additional paid-in capital | 319,414 | 318,530 |
| Accumulated other comprehensive loss | (426) | (254) |
| Accumulated deficit | (303,604) | (290,421) |
| Total stockholders' equity | <u>15,458</u> | <u>27,929</u> |
| Total liabilities and stockholders' equity | <u>\$ 82,258</u> | <u>\$ 95,490</u> |

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

PIERIS PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(unaudited)

(in thousands, except per share data)

| | Three Months Ended March 31, | |
|---|------------------------------|-------------------|
| | 2023 | 2022 |
| Revenue | | |
| Customer revenue | \$ 2,010 | \$ 11,180 |
| Collaboration revenue | (74) | (192) |
| Total revenue | 1,936 | 10,988 |
| Operating expenses | | |
| Research and development | 13,424 | 14,066 |
| General and administrative | 4,023 | 4,379 |
| Total operating expenses | 17,447 | 18,445 |
| Loss from operations | (15,511) | (7,457) |
| Other income (expense) | | |
| Interest income | 357 | (3) |
| Grant income | 2,028 | 2,130 |
| Other income | (57) | 229 |
| Net loss | <u>\$ (13,183)</u> | <u>\$ (5,101)</u> |
| Other comprehensive income (loss): | | |
| Foreign currency translation | (242) | 143 |
| Unrealized gain (loss) on available-for-sale securities | 70 | (19) |
| Comprehensive loss | <u>\$ (13,355)</u> | <u>\$ (4,977)</u> |
| Net loss per share | | |
| Basic and diluted | <u>\$ (0.18)</u> | <u>\$ (0.07)</u> |
| Weighted average number of common shares outstanding | | |
| Basic and diluted | <u>74,519</u> | <u>73,711</u> |

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

PIERIS PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

(unaudited, in thousands)

For the Three Months Ended March 31, 2022 and 2023

| | Preferred shares | | Common shares | | ATM proceeds receivable | 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 December 31, 2021 | 16 | \$ — | 72,222 | \$ 72 | \$ — | \$ 306,998 | \$ 829 | \$ (257,144) | \$ 50,755 |
| Net loss | — | — | — | — | — | — | — | (5,101) | (5,101) |
| Foreign currency translation adjustment | — | — | — | — | — | — | 143 | — | 143 |
| Unrealized loss on investments | — | — | — | — | — | — | (19) | — | (19) |
| Stock based compensation expense | — | — | — | — | — | 1,178 | — | — | 1,178 |
| Issuance of common stock resulting from exercise of stock options | — | — | 43 | — | — | 85 | — | — | 85 |
| Issuance of common stock pursuant to ATM offering program, net of \$0.3 million in offering costs | — | — | 1,833 | 2 | — | 6,407 | — | — | 6,409 |
| Balance at March 31, 2022 | 16 | \$ — | 74,098 | \$ 74 | \$ — | \$ 314,668 | \$ 953 | \$ (262,245) | \$ 53,450 |
| Balance as of December 31, 2022 | 16 | \$ — | 74,519 | \$ 74 | \$ — | \$ 318,530 | \$ (254) | \$ (290,421) | \$ 27,929 |
| Net loss | — | — | — | — | — | — | — | (13,183) | (13,183) |
| Foreign currency translation adjustment | — | — | — | — | — | — | (242) | — | (242) |
| Unrealized loss on investments | — | — | — | — | — | — | 70 | — | 70 |
| Stock based compensation expense | — | — | — | — | — | 884 | — | — | 884 |
| Balance at March 31, 2023 | 16 | \$ — | 74,519 | \$ 74 | \$ — | \$ 319,414 | \$ (426) | \$ (303,604) | \$ 15,458 |

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

PIERIS PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited, in thousands)

| | Three Months Ended March 31, | |
|--|------------------------------|------------|
| | 2023 | 2022 |
| Operating activities: | | |
| Net loss | \$ (13,183) | \$ (5,101) |
| Adjustments to reconcile net loss to net cash (used in) operating activities: | | |
| Depreciation and amortization | 605 | 845 |
| Right-of-use asset (accretion) amortization | (34) | (5) |
| Stock-based compensation | 884 | 1,178 |
| Realized investment gains | 53 | — |
| Other non-cash transactions | 72 | 91 |
| Changes in operating assets and liabilities | 607 | (19,651) |
| Net cash provided by (used in) operating activities | (10,996) | (22,643) |
| Investing activities: | | |
| Purchases of property and equipment | (48) | (389) |
| Proceeds from maturity of investments | 13,495 | — |
| Purchases of investments | (1,544) | (16,559) |
| Net cash (used in) investing activities | 11,903 | (16,948) |
| Financing activities: | | |
| Proceeds from exercise of stock options | — | 85 |
| Proceeds from issuance of common stock resulting from ATM sales, net of \$0.3 million in transaction costs | — | 6,473 |
| Net cash provided by financing activities | — | 6,558 |
| Effect of exchange rate change on cash and cash equivalents | 200 | (994) |
| Net decrease in cash and cash equivalents | 1,107 | (34,027) |
| Cash and cash equivalents at beginning of period | 38,635 | 117,764 |
| Cash and cash equivalents at end of period | \$ 39,742 | \$ 83,737 |
| Supplemental cash flow disclosures: | | |
| Net unrealized gain on investments | \$ 70 | \$ (19) |
| Property and equipment included in accounts payable | \$ 16 | \$ 298 |

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

PIERIS PHARMACEUTICALS, INC.
NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

1. Corporate Information

Pieris Pharmaceuticals, Inc. was founded in May 2013, and acquired 100% interest in Pieris Pharmaceuticals GmbH (formerly Pieris AG, a German company that was founded in 2001) in December 2014. Pieris Pharmaceuticals, Inc. and its wholly-owned subsidiaries, hereinafter collectively Pieris, or the Company, is a clinical-stage biopharmaceutical company that discovers and develops Anticalin®-based drugs to target validated disease pathways in unique and transformative ways. Pieris' corporate headquarters is located in Boston, Massachusetts and its research facility is located in Hallbergmoos, Germany.

Pieris' clinical pipeline includes an inhaled IL-4R α antagonist Anticalin protein to treat moderate-to-severe asthma, which is being advanced by AstraZeneca, an inhaled Anticalin protein targeting connective tissue growth factor to treat idiopathic pulmonary fibrosis and an immuno-oncology, or IO, bispecific targeting 4-1BB and PD-L1, which is being advanced in partnership with Servier, and an IO bispecific targeting 4-1BB and CD228, which is being advanced by Seagen.

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

The Company is subject to risks common to companies in the biotechnology industry, including but not limited to, the need for additional capital, risks of failure of preclinical studies and clinical trials, the need to obtain marketing approval and reimbursement for any drug product candidate that it may identify and develop, the need to successfully commercialize and gain market acceptance of its product candidates, dependence on key personnel, protection of proprietary technology, compliance with government regulations, development of technological innovations by competitors, reliance on third-party manufacturers and the ability to transition from pilot-scale production to large-scale manufacturing of products.

The future success of the Company is dependent on its ability to identify and develop its product candidates, expand its corporate infrastructure and ultimately upon its ability to attain profitable operations. The Company has devoted substantially all of its financial resources and efforts to research and development and general and administrative expenses to support such research and development. The Company has several research and development programs underway in varying stages of development, and it expects that these programs will continue to require increasing amounts of cash for development, conducting clinical trials, and testing and manufacturing of product material. Cash necessary to fund operations will increase significantly over the next several years as the Company continues to conduct these activities necessary to pursue governmental regulatory approval of clinical-stage programs and other product candidates.

Going Concern Uncertainties

As of March 31, 2023, cash, cash equivalents, and investments were \$48.4 million. For the three months ended March 31, 2023 and 2022, the Company's net loss was \$13.2 million and \$5.1 million respectively. The Company has incurred net losses since inception and had an accumulated deficit of \$303.6 million as of March 31, 2023. Net losses and negative cash flows from operations 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 at least the next several years.

The Company would need to raise additional capital over the next year to continue its current level of research and development activities across all of its active programs, as well as to maintain the general and administrative functions to support such activities. Without access to additional capital or management making decisions to reduce spending, these conditions raise substantial doubt about the ability of the Company to continue as a going concern.

The Company plans to raise additional capital to fulfill its operating and capital requirements through public or private equity financings, utilization of its current "at the market offering" program, or ATM Program, strategic collaborations, licensing arrangements, government grants and/or the achievement of milestones under its collaborative agreements. The funding requirements of the Company's operating plans, however, are based on estimates that are subject to risks and uncertainties and *may* change as a result of many factors currently unknown. Although management continues to pursue these funding plans, there is *no* assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all. Until such time that the Company can generate substantial product revenues, if ever, the Company expects to finance its cash needs through a combination of equity offerings, debt financings, strategic partnerships, licensing arrangements and government grants. The terms of any future financing *may* adversely affect the holdings or the rights of the Company's existing stockholders.

If the Company is unable to obtain additional funding on acceptable terms when needed, the Company will defer or limit a substantial portion of its research, development and clinical projects, reduce discretionary expenditures and other fixed or variable personnel costs to alleviate the substantial doubt as to the Company's ability to continue as a going concern. The Company's budget and operating plan for 2023, approved by the Board, does not include such discretionary costs, and management is prepared to gate future investments on PRS-220 and PRS-400, including certain Phase 2-readiness activities for PRS-220 and IND-enabling activities for PRS-400, in the interest of achieving its top priority, namely, obtaining data from the elarekibep Phase 2a study in asthma. On the basis of the Company's approved budget and actions within management's control, the Company believes that its currently available funds will be sufficient to fund the Company's remaining limited operations through at least the next 12 months from the issuance of this Quarterly Report on Form 10-Q. The Company's belief with respect to its ability to fund operations is based on estimates that are subject to risks and uncertainties.

2. Summary of Significant Accounting Policies

The Company's significant accounting policies are described in Note 2—Summary of Significant Accounting Policies, in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022. There have been no material additions to the significant accounting policies for the three months ended March 31, 2023.

Unaudited Interim Financial Information

The accompanying unaudited condensed consolidated financial statements included herein have been prepared by the Company in accordance with accounting principles generally accepted in the United States, or U.S. GAAP, for interim financial information and pursuant to the rules and regulations of the SEC. Accordingly, certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to such rules and regulations. In the opinion of management, all adjustments, consisting of normal recurring adjustments, and disclosures considered necessary for a fair presentation of interim period results have been included. Interim results for the three months ended March 31, 2023 are not necessarily indicative of results that may be expected for the year ending December 31, 2023. For further information, refer to the financial statements and footnotes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022, which was filed with the SEC on March 31, 2023.

Basis of Presentation and Use of Estimates

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

The preparation of the financial statements in accordance with U.S. GAAP requires management to make estimates, judgments and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and the related disclosures at the date of the financial statements and during the reporting period. Significant estimates are used for, but are not limited to, revenue recognition; deferred tax assets, deferred tax liabilities and valuation allowances; determination of the incremental borrowing rate to calculate right-of-use assets and lease liabilities; beneficial conversion features; fair value of stock options, preferred stock, and warrants; and 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.

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 Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, 320, *Investments—Debt and Equity Securities*. The Company classifies investments available to fund current operations as current assets on its balance sheets.

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

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

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 minimize 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*, 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 (see 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.

Property and Equipment

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

| <u>Asset Classification</u> | <u>Estimated useful life (in years)</u> |
|------------------------------------|---|
| 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 |

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.

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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.

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

In accordance with ASU No. 2016-2, Leases (Topic 842), or ASC 842, and for each of the Company's leases, the following is recognized: (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.

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 noncancellable 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.

Recent Accounting Pronouncements Not Yet Adopted

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

Subsequently, in November 2018, the FASB issued ASU No. 2018-19, *Codification Improvements to Topic 326, Financial Instruments-Credit Losses*, which clarifies codification and corrects unintended application of the guidance. In November 2019, the FASB issued ASU No. 2019-11, *Codification Improvements to Topic 326, Financial Instruments-Credit Losses*, which clarifies or addresses specific issues about certain aspects of ASU 2016-13. In November 2019 the FASB also issued ASU No. 2019-10, *Financial Instruments-Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842): Effective Dates*, which delays the effective date of ASU 2016-13 by three years for certain smaller reporting companies such as the Company. The guidance in ASU 2016-13 is effective for the Company for financial statements issued for fiscal years beginning after December 15, 2022 and interim periods within those fiscal years, with early adoption permitted. The Company adopted the standard as of January 1, 2023 and concluded the effect to the unaudited condensed consolidated financial statements was immaterial.

The Company has considered other recent accounting pronouncements and concluded that they are either not applicable to the business or that the effect is not expected to be material to the unaudited condensed 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 and revenue from collaboration agreements, which include upfront payments for licenses or options to obtain licenses, payments for research and development services and milestone payments.

The Company recognized revenue from the following strategic partnerships and other license agreements (in thousands):

| | Three Months Ended March 31, | |
|----------------------|------------------------------|------------------|
| | 2023 | 2022 |
| Seagen | \$ 1,423 | \$ 312 |
| AstraZeneca | 434 | 4,753 |
| Servier | (74) | 4,734 |
| Genentech | 153 | 1,189 |
| Total Revenue | \$ 1,936 | \$ 10,988 |

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

| | Research, Development, Regulatory & Commercial Milestones | Sales Milestones |
|---|--|-------------------------|
| AstraZeneca | \$ 504 | \$ 3,750 |
| Servier | 20 | — |
| Seagen | 759 | 450 |
| Boston Pharmaceuticals | 88 | 265 |
| Genentech | 626 | 450 |
| Total potential milestone payments | \$ 1,997 | \$ 4,915 |

The above table is reflective of changes after certain subsequent events under the AstraZeneca and Genentech collaborations as discussed below.

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 up to approximately \$1.4 billion in 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 is responsible for discovery and preclinical development of two initial programs. The Company is responsible for research activities following target nomination through the late-stage research go decision. The parties will then collaborate on drug candidate characterization until the development go decision. After the development go decision, Genentech will be responsible for pursuing the preclinical and clinical development of each program, and thereafter, the commercialization efforts. Each party is 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 the Company 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 are initially identified and committed in the Genentech Agreement. To reach a total of up to four research programs, the Company has granted Genentech options to nominate two additional 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. The Company has 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.

The arrangement with Genentech provides for the transfer of the following goods or services: (i) exclusive research and commercial license for the collaboration programs, (ii) a non-exclusive platform improvement license, (iii) research and development services, (iv) participation in a governance committee, and (v) replacement target options on the first two programs upon a screening failure which were assessed as material rights.

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

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As a result, management concluded there were five separate performance obligations at the inception of the Genentech Agreement: (i) two combined performance obligations, each comprised of an exclusive research and commercial license, a non-exclusive platform improvement license, and research and development services for the first two Genentech programs, (ii) two performance obligations each comprised of a material right for a target swap option for the first two Genentech programs, and (iii) one performance obligation comprised of participation on the governance committee.

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

The transaction price at inception is comprised of fixed consideration of \$20.0 million in upfront fees and was allocated to each of the performance obligations based on the relative proportion of their standalone selling prices. The amounts allocated to the performance obligations for the two research programs will be recognized on a proportional performance basis through the completion of each respective estimated research term of the individual research programs. The amounts allocated to the material right for the target options will be recognized either at the time the material right expires or, if exercised, on a proportional performance basis over the estimated research term for that program along with any remaining deferred revenue associated with the replacement target. The amounts allocated to the participation on the committee will be recognized on a straight-line basis over the anticipated research term for all research programs. As of March 31, 2023, there was \$12.6 million of aggregate transaction price allocated to remaining performance obligations.

Under the Genentech Agreement, 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 determined that all other research and development milestones will be constrained until it is deemed probable that a significant revenue reversal will not occur.

In April 2023, Genentech and the Company decided to discontinue a discovery-stage program in ophthalmology for scientific reasons. Pursuant to this decision, the material right performance obligation related to the target swap for this program also expired. The Company assessed these events as non-recognized subsequent events and will appropriately recognize revenue related to them in the second quarter. The companies continue to advance the respiratory program.

As of March 31, 2023, there were \$10.1 million and \$2.5 million of current and non-current deferred revenue, respectively, related to the Genentech Agreement.

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/BOS-342, a 4-1BB/GPC3 preclinical immuno-oncology Mabcalin™ (antibody-Anticalin fusion) protein.

Under the term of the BP Agreement, Boston Pharmaceuticals exclusively licensed worldwide right to PRS-342/BOS-342. The Company received an upfront payment of \$10.0 million and is 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/BOS-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 will also contribute up to \$4.0 million toward manufacturing activities

The amounts allocated to the performance obligations did not meet the criteria to be recognized over time on a proportional performance basis and thus will be recognized at a point in time. The Company determined that the performance obligation will be fully satisfied when all of the deliverables in the combined performance obligation are transferred to Boston Pharmaceuticals as that is the point at which Boston Pharmaceuticals can fully use and benefit from the license to PRS-342/BOS-342. In the fourth quarter of 2021, the Company transferred all deliverables to Boston Pharmaceuticals related to the one performance obligation under the collaboration. Therefore, the Company recognized the full transaction price, or \$5.7 million, as revenue in 2021 and there are no remaining obligations.

Seagen

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

Under the terms of the Seagen Agreements, the companies will pursue multiple antibody-Anticalin fusion proteins during the research phase. The Seagen Agreements provide Seagen 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. Seagen will solely develop, fund and commercialize the other two programs. Seagen may also decide to select additional candidates from the initial research phase for further development in return for the payment to the Company of additional fees, milestone payments and royalties.

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

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

The term of each of the Seagen Agreements ends upon the expiration of all of Seagen's payment obligations under each such agreement. The Seagen Collaboration Agreement may be terminated by Seagen 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 Seagen's option. If any program is terminated by Seagen after a predefined preclinical stage, the Company will have full rights to continue such program. If any program is terminated by Seagen prior to such predefined preclinical stage, the Company will have the right to continue to develop such program, but will be obligated to offer a co-development option to Seagen for such program. The Seagen Collaboration Agreement may also be terminated by Seagen or the Company for an uncured material breach by the other party upon 90 days' notice, subject to extension for an additional 90 days if the material breach relates to diligence obligations and subject, in all cases, to dispute resolution procedures. The Seagen 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 Seagen Agreements if the other party challenges the validity of any patents licensed under the Seagen Agreements, subject to certain exceptions. The Seagen Platform License will terminate upon termination of the Seagen Collaboration Agreement, whether in its entirety or on a product-by-product basis.

The Company determined that the Seagen Agreements should be combined and evaluated as a single arrangement under ASC 606 as they were executed on the same date. The arrangement with Seagen provides for the transfer of the following goods or services: (i) three candidate research licenses that each consist of a non-exclusive platform technology license, a co-exclusive candidate research license, and research and development services, (ii) research, development and manufacturing services associated with each candidate research license, (iii) participation on various governance committees, and (iv) two antibody target swap options which were assessed as material rights.

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

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

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

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

The amounts allocated to the performance obligations for the three research programs will be recognized on a proportional performance basis through the completion of each respective estimated research term of the individual research programs. The amounts allocated to the material right for the antibody target swap option will be recognized either at the time the material right expires or, if exercised, on a proportional performance basis over the estimated research term for that program. The amounts allocated to the participation on each of the committees will be recognized on a straight-line basis over the anticipated research term for all research programs. As of March 31, 2023, there was \$14.0 million of aggregate transaction price allocated to remaining performance obligations.

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On March 24, 2021, the Company announced that Seagen made a strategic equity investment in Pieris, and that the companies had entered into a combination study agreement, or the Combination Study Agreement, to evaluate the safety and efficacy of combining Pieris' cinrebafusp alfa with Seagen's tucatinib, a small-molecule tyrosine kinase HER2 inhibitor, for the treatment of gastric cancer patients expressing lower HER2 levels. Enrollment into the phase 2 study was ceased in August 2022 as part of a strategic pipeline prioritization, and the Combination Study Agreement was terminated. The companies have also entered into an Amended and Restated License and Collaboration Agreement, or the Second Seagen Amendment, in which their existing IO collaboration agreement has been amended relating to joint development and commercial rights for the second program in the alliance. In connection with the agreements described above, the Company and Seagen also entered into a subscription agreement, or the Seagen Subscription Agreement.

Under the Second Seagen Amendment, Pieris' option to co-develop and co-commercialize the second of three programs in the collaboration has been converted to a co-promotion option of one of the three programs in the United States, with Seagen 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 Seagen Subscription Agreement, the Company agreed to issue to Seagen, and Seagen 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. The Seagen Subscription Agreement includes a provision to the effect that Seagen may ask the Company to file a registration statement to register the resale of the shares issued to Seagen, 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 Seagen 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.

The Company has concluded that the Combination Study Agreement is within the scope of ASC 808, which defines collaborative arrangements and addresses the presentation of the transactions between the two parties in the income statement and related disclosures. However, ASC 808 does not provide guidance on the recognition of consideration exchanged or accounting for the obligations that may arise between the parties. The Company has concluded that ASC 730, *Research and Development*, should be applied by analogy. There is no financial statement impact for the Combination Study Agreement as the value of the drug supply received from Seagen is offset against the drug supply cost.

Under the Seagen Agreements, the Company is eligible to receive other 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. With the exception of the previously discussed achieved milestone, the Company has determined that all other research and development milestones will be constrained until it is deemed probable that a significant revenue reversal will not occur.

In
January 2023, the Company achieved a milestone for the
first program in the Seagen 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.

As of March 31, 2023, there were \$11.9 million and \$1.5 million of current and non-current deferred revenue, respectively, related to the Seagen Agreements.

AstraZeneca

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

In addition to the Company's lead inhaled drug candidate, elarekibep (formerly known as PRS-060/AZD1402), or the AstraZeneca Lead Product, the Company and AstraZeneca agreed to collaborate, under the original terms of the AstraZeneca Collaboration Agreement, to progress four additional novel Anticalin proteins against undisclosed targets for respiratory diseases, or the AstraZeneca Collaboration Products, and together with the AstraZeneca Lead Product, the AstraZeneca Products. The Company is responsible for advancing the AstraZeneca Lead Product through its phase 1 study, with the associated costs funded by AstraZeneca. The parties will collaborate thereafter to conduct a phase 2a study in asthma patients, with AstraZeneca continuing to fund development costs. After the availability of topline data from a phase 2a study, Pieris has the option to co-develop the AstraZeneca Lead Product and also has a separate option to co-commercialize the AstraZeneca Lead Product in the United States. For the AstraZeneca Collaboration Products, the Company will be responsible for the initial discovery of the novel Anticalin proteins, after which AstraZeneca will take the lead on continued development of the AstraZeneca Collaboration Products. The Company retained the option to co-develop two of the four AstraZeneca Collaboration Products beginning at a predefined preclinical stage and would also have the option to co-commercialize these two programs in the United States, while AstraZeneca will be responsible for development and commercialization of the other programs worldwide.

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

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

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

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

The Company determined that the AstraZeneca Agreements should be combined and evaluated as a single arrangement under ASC 606 as they were executed on the same date. The arrangement with AstraZeneca, including the impact of any modifications, provides for the transfer of the following goods and services: (i) five non-exclusive platform technology licenses, (ii) research and development license for the AstraZeneca Lead Product, (iii) commercial license for the AstraZeneca Lead Product, (iv) development and manufacturing services for the AstraZeneca Lead Product (or the phase 1 services), (v) technology transfer services for the AstraZeneca Lead Product, (vi) research services related to the AstraZeneca Lead Product, (vii) participation on each of the committees, (viii) four research licenses for the AstraZeneca Collaboration Products, (ix) four commercial licenses for the AstraZeneca Collaboration Products, (x) research services for the AstraZeneca Collaboration Products and (xi) certain phase 2a services for the AstraZeneca Lead Product. Additionally, as the development licenses on the four AstraZeneca Collaboration Products may be granted at a discount in the future, the Company determined such discounts should be assessed as material rights at inception.

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

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

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

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

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

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

The amounts allocated to the license performance obligation for the AstraZeneca Lead Product and the four performance obligations for the four research licenses for AstraZeneca Collaboration Products will be recognized on a proportional performance basis as the activities are conducted over the life of the arrangement. The amounts allocated to the performance obligation for phase 1 services, technology transfer services for the AstraZeneca Lead Product will be recognized on a proportional performance basis over the estimated term of development through phase 2a study. The amounts allocated to the performance obligation for phase 2a services for the AstraZeneca Lead Product will be recognized on a proportionate performance basis over an estimated term of 12 months. The amounts allocated to the performance obligation for participation on each of the committees will be recognized on a straight-line basis over the expected term of development of the AstraZeneca Lead Product and the AstraZeneca Collaboration Products. The term of performance is approximately five years. The amounts allocated to the four performance obligations for the material rights to acquire a development license and the four performance obligations for commercial licenses for the AstraZeneca Collaboration Products will be recognized upon exercise of the specific material right and delivery of each of the development licenses. As of March 31, 2023, there was \$8.0 million of aggregate transaction price allocated to remaining performance obligations.

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

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

On March 29, 2021, the Company and AstraZeneca entered into (1) Amendment No. 1 to the Non-exclusive Anticalin Platform License Agreement dated May 2, 2017, and (2) Amendment No. 2 to the License and Collaboration Agreement dated May 2, 2017, as previously amended by Amendment No. 1 dated September 14, 2020, collectively, the Amended Collaboration Agreement. Under the Amended Collaboration Agreement, the parties agreed to restructure certain commercial economics for the elarekibep program by increasing potential sales milestones and reducing potential sales royalties, while fundamentally maintaining the overall value split between AstraZeneca and the Company.

In connection with the Amended Collaboration Agreement, the Company and AstraZeneca entered into a subscription agreement, or the AstraZeneca Subscription Agreement, pursuant to which the Company agreed to issue to AstraZeneca, and AstraZeneca agreed to acquire from the Company, 3,584,230 shares of the Company's common stock for a total purchase price of \$10.0 million, or \$2.79 per share, in a private placement transaction pursuant to Section 4(a)(2) of the Securities Act. The AstraZeneca Subscription Agreement closed on April 1, 2021 and included a requirement that the Company file a registration statement to register the resale of the shares issued to AstraZeneca within 60 calendar days of the issuance of the shares. The Company assessed the payment under ASC 606 and concluded that the fair value of the shares on a per share basis was \$2.60 per share as of the transaction date. This resulted in a premium paid for the shares of \$0.7 million, which was added to the deferred revenue balance and will be recognized over time in line with our revenue recognition pattern for all remaining performance obligations.

In January 2022, the Company and AstraZeneca jointly discontinued one discovery-stage program, as they were not able to validate an exploratory target. Approximately \$4.7 million of revenue was recorded related to a material right performance obligation that ceased with the discontinuation of this program.

In August 2022, the Company and AstraZeneca entered into another amendment of the License and Collaboration Agreement dated May 2, 2017, and extended the research term for two discovery-stage programs through December 2023. As a result of this amendment, the Company and AstraZeneca jointly agreed to discontinue a second discovery-stage program. Approximately \$5.0 million of revenue was recorded pursuant to a performance obligation related to transfer of a license that ceased with the discontinuation of this program. Furthermore, in April 2023, one of the two remaining programs was discontinued. The Company assessed this as a non-recognized subsequent event and will appropriately recognize revenue related to it in the second quarter. Pieris retains co-development and U.S. co-commercialization options for the one remaining program.

As of March 31, 2023, there were \$4.0 million and \$3.5 million of current and non-current deferred revenue, respectively, related to the AstraZeneca Agreements.

The Company incurred \$1.6 million of third-party success fees to obtain the contract with AstraZeneca. Upon adoption of ASC 606, the Company capitalized \$1.1 million in accordance with ASC 340. As of March 31, 2023, the remaining balance of the asset recognized from transaction costs to obtain the AstraZeneca contract was \$0.3 million. Amortization during the three months ended March 31, 2023 and 2022 was de minimis and \$0.2 million, respectively.

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.

Each party is responsible for an agreed upon percentage of shared costs, as set forth in the budget for the collaboration plan, and as further discussed below.

Since inception, three of the five initially committed programs have been discontinued, including the initial lead. The Company does not presently intend to continue development of the three discontinued programs but retains full rights to advance the development and commercialization of those products on a world-wide basis in the future. The parties continue to advance the development of two programs. The Company is co-developing PRS-344/S095012, a 4-1BB/PD-L1 bispecific Mabcalin protein, and retains commercial rights in the United States. PRS-344/S095012, may be jointly developed, according to a collaboration plan, through marketing approval from the FDA or the European Medicines Agency. Servier has worldwide rights to PRS-352/S095025, a preclinical bispecific Mabcalin protein comprising an PD-L1-targeting antibody genetically fused to Anticalin proteins specific for OX40, and is responsible for further development of the Collaboration Product.

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

Under the Servier Agreements, the Company received an upfront, non-refundable payment of €30.0 million (approximately \$32.0 million). Additionally, the Company has achieved three developmental milestones under PRS-344/S095012 totaling €3.3 million (approximately \$3.7 million) all of which became billable on their respective achievement dates.

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

As the Company and Servier are considered to be active participants in the Servier Agreements and are exposed to significant risks and rewards, certain units of account within the Servier Agreements are within the scope of ASC 808.

Upon signing the Servier Agreements, management evaluated all of the promised goods or services within the contract and determined which goods and services were separate performance obligations. Of the initial 10 performance obligations identified at the inception of the Servier Agreements, only three are still ongoing as of March 31, 2023. The following performance obligations are the remaining active performance obligations that are within the scope of ASC 808:

- one performance obligation comprised of a combined non-exclusive platform technology license, research license and research and development services for PRS-344/S095012,
- one performance obligation comprised of participation in the various governance committees, and
- one performance obligation comprised of the development and commercial licenses granted for PRS-344/S095012 (and corresponding discounts) upon the achievement of specified preclinical activities, resulting in a material right.

Revenue recognized associated with these performance obligations are presented as Collaboration Revenue within the Statement of Operations.

The following performance obligation is within the scope of ASC 606: the development and commercial licenses granted for PRS-352/S095012 (and corresponding discounts) upon the achievement of specified preclinical activities, resulting in a material right. Revenue recognized associated with this performance obligation is presented as Customer Revenue within the Statement of Operations. The final revenue amount related to this performance obligation was recognized during the three months ended March 31, 2022 and thus the performance obligation is now considered complete.

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

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The amounts allocated to the performance obligation for the research and development licenses for PRS-344/S095012 are being recognized on a proportional performance basis as the activities are conducted over the life of the arrangement. The term of the performance for PRS-344/S095012 is through approval of certain regulatory bodies; a period which could be many years. The amount allocated to the performance obligation for participation on each of the committees will be recognized on a straight-line basis over the anticipated performance period over the entirety of the arrangement with Servier. The amount allocated to the one remaining performance obligation for the material right to acquire development and commercial licenses for PRS-344/S095012 is granted in the future is being recognized over time upon delivery of the license through marketing approval. As of March 31, 2023, there was \$4.9 million of aggregate transaction price allocated to remaining performance obligations under the Servier Agreements.

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

Under the Servier Agreements, the Company is eligible to receive various research, development, commercial and sales milestones as well as tiered royalties up to low double digits on the sales of commercialized products in the Servier territories. 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 research and development milestones will be constrained until it is deemed probable that a significant revenue reversal will not occur.

In the first quarter of 2022, the Company satisfied the performance obligation related to the material right for PRS-352/S095025, 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 PRS-352/S095025 based upon a strategic portfolio review.

As of March 31, 2023, there were \$0.7 million and \$4.2 million of current and non-current deferred revenue, respectively, related to the Servier Agreements.

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 three months ended March 31, 2023. Reductions to deferred revenue were \$1.7 million and \$10.6 million for the three months ended March 31, 2023 and 2022, respectively.

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, and it is being developed as a local treatment for idiopathic pulmonary fibrosis and other forms of fibrotic lung diseases. In June 2021, the Company was selected to receive a €14.2 million (approximately \$17.0 million as of June 2021) 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 June 2023 (with submissions for reimbursements allowed through August 2023), though this period may be extended. The timing of reimbursements follows the expected development timeline of this program. Qualifying costs incurred may exceed the annual grant funding thresholds. If the Company receives any proceeds from the sale of or licensing income from PRS-220, the funds available for reimbursement will be reduced proportionally if they are obtained prior to June 2023, if the reimbursement period is not extended. The Company is required to communicate the amount of such proceeds to the Bavarian Ministry of Economic Affairs, Regional Development and Energy in each case with the request to draw down the funds.

5. Cash, cash equivalents and investments

As of March 31, 2023 and 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 March 31, 2023 and December 31, 2022.

| | Total | Quoted prices in active markets (Level 1) | Significant other observable inputs (Level 2) | Significant unobservable inputs (Level 3) |
|--|-----------|--|--|---|
| March 31, 2023 | | | | |
| Money market funds, included in cash equivalents | \$ 27,009 | \$ 27,009 | \$ — | \$ — |
| Investments - US treasuries | 2,377 | 2,377 | — | — |
| Investments - Corporate bonds | 6,260 | — | 6,260 | — |
| Total | \$ 35,646 | \$ 29,386 | \$ 6,260 | \$ — |

| | 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 March 31, 2023.

Investments at March 31, 2023 consisted of the following (in thousands):

| | Contractual maturity (in days) | Amortized Cost | Unrealized gains | Unrealized losses | Fair Value |
|--------------------|--|----------------|---------------------|----------------------|------------|
| Investments | | | | | |
| US treasuries | 20-111 | \$ 2,377 | \$ — | \$ — | \$ 2,377 |
| Corporate bonds | 4-138 | 6,263 | — | (3) | 6,260 |
| Total | | \$ 8,640 | \$ — | \$ (3) | \$ 8,637 |

The Company recorded realized losses from the maturity of available-for-sale securities of (\$0.1) million during the three months ended March 31, 2023 and recorded no realized gains or losses from the maturity of available-for-sale securities during the three months ended March 31, 2022.

As of March 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. Property and equipment, net

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

| | March 31, 2023 | December 31, 2022 |
|------------------------------------|-------------------------|-------------------------|
| Laboratory furniture and equipment | \$ 12,204 | \$ 11,970 |
| Office furniture and equipment | 1,767 | 1,861 |
| Computer equipment | 354 | 364 |
| Leasehold improvements | 12,355 | 12,444 |
| Property and equipment, cost | <u>26,680</u> | <u>26,639</u> |
| Accumulated depreciation | (9,974) | (9,647) |
| Property and equipment, net | <u><u>\$ 16,706</u></u> | <u><u>\$ 16,992</u></u> |

7. Accrued Expenses

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

| | March 31, 2023 | December 31, 2022 |
|---------------------------------------|-------------------------|-------------------------|
| Research and development fees | \$ 5,082 | \$ 5,758 |
| Compensation expense | 1,677 | 3,015 |
| Accrued license obligations | 278 | 245 |
| Accrued accounts payable | 1,837 | 1,245 |
| Lease liabilities | 890 | 859 |
| Other current liabilities | 590 | 483 |
| Collaboration cost-sharing obligation | — | — |
| Total | <u><u>\$ 10,354</u></u> | <u><u>\$ 11,605</u></u> |

8. 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.

As of March 31, 2023 and 2022, and as calculated using the treasury stock method, approximately 40.9 million and 39.4 million of weighted average shares, respectively, were excluded from the calculation of diluted weighted average shares outstanding as their effect was antidilutive.

9. Stockholders' Equity

The Company had 300,000,000 shares authorized and 74,519,103 shares of common stock issued and outstanding as of March 31, 2023 and December 31, 2022 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 March 31, 2023 and December 31, 2022. Preferred stock has a par value of \$0.001 per share, and consists of the following:

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

2020 Employee, Director and Consultant Equity Incentive Plan

At the 2020 Annual Meeting of Stockholders, the Company's stockholders approved the 2020 Employee, Director and Consultant Equity Incentive Plan, or the 2020 Plan. The 2020 Plan permits 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. There were approximately 1,579,678 shares remaining and available for grant under the 2019 Plan that terminated upon original approval of the 2020 Plan.

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. At the 2022 Annual Meeting of Stockholders held on June 22, 2022, the Company's stockholders approved a second amendment to the 2020 Plan to add 3,000,000 shares of common stock for issuance under the 2020 Plan.

Open Market Sales Agreements

In August 2021, the Company established an at-the-market, or ATM, Program, under a sales agreement with Jefferies LLC, pursuant to which 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 \$50.0 million. The ATM Program is offered under a shelf registration statement on Form S-3 that was filed with and declared effective by the SEC in August 2021. 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.

For the three months ended March 31, 2023, the Company did not sell any shares under the ATM program.

10. Leases

In August 2015, the Company entered into a sublease to lease approximately 3,950 square feet of office space in Boston, Massachusetts. The Company did not extend the sublease, which expired on December 31, 2022..

In October 2018, Pieris GmbH entered into a new lease for office and laboratory space located in Hallbergmoos, Germany, or the Hallbergmoos Lease. Under the Hallbergmoos Lease, which commenced in February 2020 and provides an initial rental term of 12.5 years, Pieris GmbH rents approximately 105,000 square feet. An additional approximately 22,300 square feet is expected to be delivered by the lessor by October 2024. Pieris GmbH has a first right of refusal to lease an additional approximate 13,400 square feet, and an option to extend the Hallbergmoos Lease for two additional 60-month periods. The Company is not reasonably certain to exercise the option to extend the lease expiration beyond its current expiration date. Pieris GmbH may sublease space within the leased property with lessor's consent, which may not be unreasonably withheld.

Monthly base rent for the initial 105,000 square feet of the leased property, including parking spaces, will total approximately \$0.2 million per month. In addition to the base rent, Pieris GmbH is also responsible for certain administrative and operational costs in accordance with the Hallbergmoos Lease. Pieris GmbH provided a security deposit of \$0.8 million as required by the Hallbergmoos Lease. The Company will serve as a guarantor for the Hallbergmoos Lease.

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The Hallbergmoos Lease included \$11.5 million of tenant improvements allowance for normal tenant improvements, for which construction began in March 2019. The Company capitalized the leasehold incentives which are included in Property and equipment, net on the Condensed Consolidated Balance Sheet and are amortized on a straight-line basis over the shorter of the useful life or the remaining lease term. The lease incentive allowance was also factored in as a reduction to the right-of-use asset upon the adoption of ASC 842.

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

| | Three Months Ended March 31, | |
|--------------------------|------------------------------|---------------|
| | 2023 | 2022 |
| Operating lease costs | \$ 288 | \$ 349 |
| Variable lease costs (1) | 186 | 159 |
| Total lease cost | <u>\$ 474</u> | <u>\$ 508</u> |

(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.

The following table summarizes the weighted-average remaining lease term and discount rate:

| | As of March 31, 2023 |
|---|-------------------------|
| Weighted-average remaining lease term (years) | 9.3 |
| Weighted-average discount rate | 10.5% |

Cash paid for amounts included in the measurement of the lease liabilities were \$0.5 million and \$0.6 million, respectively, for the three months ended March 31, 2023 and 2022.

As of March 31, 2023, the maturities of the Company's operating lease liabilities and future minimum lease payments were as follows (in thousands):

| | Total |
|------------------------------------|------------------|
| 2023 | \$ 1,611 |
| 2024 | 2,148 |
| 2025 | 2,148 |
| 2026 | 2,148 |
| 2027 | 2,148 |
| Thereafter | 9,846 |
| Total undiscounted lease payments | 20,049 |
| Less: present value adjustment | (6,963) |
| Present value of lease liabilities | <u>\$ 13,086</u> |

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The interim financial statements and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2022, and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed with the SEC on March 31, 2023. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, including but not limited to those set forth under the caption "Risk Factors" in the Annual Report on Form 10-K for the fiscal year ended December 31, 2022.

As used in this Quarterly Report on Form 10-Q, 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 subsidiaries.

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

Overview

We are a clinical-stage biotechnology company that discovers and develops Anticalin-based drugs to target validated disease pathways in unique and transformative ways. Proprietary to us, Anticalin proteins are a novel class of therapeutics validated in the clinic and through partnerships with leading pharmaceutical companies. In particular, we have alliances with AstraZeneca and Genentech to treat respiratory diseases and with Servier, Seagen, and Boston Pharmaceuticals in IO. Our discovery and development programs are in varying stages and include:

- *Elarekibep*, our lead respiratory program partnered with AstraZeneca for the treatment of asthma, is a drug candidate that antagonizes IL-4R α , 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.
 - Elarekibep was tested in a nebulized formulation and in two IV arms for pharmacokinetic, or PK, assessment in 54 healthy volunteers at nominal dose levels ranging from 0.25 mg to 400 mg in a phase 1 single-ascending dose, or SAD, study. Data from that study were presented at the American Thoracic Society International Conference in May 2019 showing that elarekibep was well-tolerated when given as single inhaled or intravenous doses to healthy volunteers and there was systemic target engagement (as measured by pSTAT6 inhibition) following inhalation. Elarekibep was also tested in a phase 1 multiple-ascending dose, or MAD, study in 30 patients that were randomized to receive delivered doses via nebulizer ranging from 2 mg to 60 mg (5 mg to 150 mg nominal dose) twice daily for nine consecutive days and one final dose on the 10th day, and 12 patients were randomized to receive placebo at the same intervals. We presented interim data from the elarekibep phase 1 MAD study at the European Respiratory Society International Congress in October 2019 and reported that elarekibep was well-tolerated at all doses, led to a statistically significant reduction in FeNO, a validated biomarker for eosinophilic airway inflammation, and showed dose-dependent systemic target engagement in patients with mild asthma and elevated levels of FeNO (≥ 35 ppb).
 - The phase 2a asthma study is ongoing at multiple sites globally. This phase 2a study is a two-part, multi-center, placebo-controlled clinical study of elarekibep that will evaluate elarekibep at up to three dose levels using a dry powder formulation administered twice daily. In part 1a (1 mg and 3 mg dose safety) of the study, 31 asthma patients, controlled on standard of care (medium dose inhaled corticosteroids, or ICS, with long-acting beta agonists, or LABA), received elarekibep twice daily over four weeks to establish the safety profile and pharmacokinetics of the dry powder formulation of elarekibep. A safety review following completion of part 1a included an evaluation, compared to placebo, of the incidence of adverse events, changes in laboratory markers (immuno-biomarkers, clinical chemistry, and hematology), and forced expiratory volume in one second, or FEV1. Following the safety review, AstraZeneca began enrollment of part 2a (1 mg and 3 mg dose efficacy) of the study to evaluate efficacy, safety, and pharmacokinetics of elarekibep administered twice daily to asthma patients, uncontrolled on medium dose ICS with LABA, that have a blood eosinophil count of ≥ 150 cells/ μ L and FeNO ≥ 25 ppb in the 1 mg and 3 mg arms and a placebo arm. Following a four-week run-in period, patients will be dosed and monitored over four weeks. FEV1 improvement at four weeks compared to placebo will be the primary endpoint in this portion of the study. Also following the safety review, AstraZeneca initiated part 1b of the study to evaluate the safety of the 10 mg dose in asthma patients controlled on standard of care who will receive elarekibep twice daily over four weeks, and part 1b has now completed enrollment. As with part 1a the safety review of part 1b included an evaluation, compared to placebo, of the incidence of adverse events, changes in laboratory markers (immuno-biomarkers, clinical chemistry, and hematology), and forced expiratory volume in one second, or FEV1. Evaluation of the data indicated that the 10 mg dose met the safety and tolerability criteria that would enable evaluation of a dose of up to 10 mg in future clinical trials. AstraZeneca conducted a reforecast of the study, which has taken into account the global challenges of recruiting for respiratory clinical trials caused by the continued impact of the COVID-19 pandemic, and has broadened enrollment criteria in part 2 (previously referenced as part 2a) of the study to facilitate recruitment of the study. AstraZeneca is focusing part 2 on the 3 mg cohort for the efficacy readout and is no longer enrolling for the 1 mg cohort. AstraZeneca no longer plans to enroll the 10 mg cohort for the efficacy readout (previously referenced as part 2b). AstraZeneca has additionally added several new countries and a significant number of additional clinical trial sites to further facilitate recruitment of the study.

Topline results from part 2 of this study are expected to be reported by the middle of 2024.

- Upon receipt of the topline data and notice from AstraZeneca, including a product development plan and budget, we will have 30 days to opt into co-development of the program with AstraZeneca at one of two levels, neither of which includes an option exercise fee. If we do not choose to participate in co-development, we would still be entitled to sales royalties from single-digit up to the mid-teens, plus the potential for more than \$1 billion in sales milestones. At the first opt-in level, we would be responsible for 25% of the cost-share through regulatory approval with a predetermined cost cap. At this level, for the lifetime of this product, we would receive sales royalties from single-digit up to the high teens, plus the potential for multi-billion dollar sales milestones. The second opt-in level would be at a 50% cost share without a cost cap which, instead of sales royalties and milestones, would result in a gross margin share in the mid-twenty percent range for the lifetime of the product. We also have a separate option to co-commercialize elarekibep with AstraZeneca in the United States independent of the co-development opt-in decision.

- In the second quarter of 2023, one discovery-stage program was jointly discontinued to focus resources on the one remaining and most advanced discovery-stage program included in the AstraZeneca alliance beyond elarekibep. The target and disease area remain undisclosed and Pieris retains co-development and U.S. co-commercialization options for the remaining discovery-stage program.
- Our lead fully proprietary respiratory asset, *PRS-220*, an orally inhaled Anticalin protein targeting connective tissue growth factor, or CTGF, is 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. Clinical data from a phase 2 study with pamrevlumab conducted by Fibrogen indicated that inhibition of CTGF reduced the decline in lung function in patients, thus demonstrating clinical proof of concept for this target.
 - 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 presented initial preclinical data for PRS-220 at the European Respiratory Society International Congress 2021 demonstrating a more potent and durable target engagement profile compared to the clinical-stage, systemically delivered anti-CTGF antibody benchmark. Additionally, the targeting of CTGF locally in the lung showed increased attenuation of fibrotic lung remodeling *in vivo* compared to the systemically delivered antibody. This outcome correlates with superior lung tissue exposure of PRS-220 compared to that of the systemically administered antibody in head-to-head studies, where intratracheally administered PRS-220 efficiently penetrates the fibrotic, interstitial lung tissue of mice. In May 2023, preclinical data will be presented at the ATS 2023 International Conference, including data demonstrating that inhaled PRS-220 significantly reduced collagen deposition in a silica-induced lung fibrosis mouse model.
 - We are conducting a phase 1 study of PRS-220 in healthy volunteers in Australia. The study is 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. We expect to report the outcome of the study in the second half of 2023.
- 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 2023, the ophthalmology program was discontinued jointly for scientific reasons and the companies continue to advance the respiratory program.
- *PRS-400* is a fully proprietary Anticalin protein targeting Jagged-1 and is being developed as a local treatment for muco-obstructive lung diseases. Jagged-1 is one of five cell surface ligands interacting with Notch receptors. It has been demonstrated that Jagged-1/Notch signaling drives secretory cell trans-differentiation in the airways and that blocking Jagged-1/Notch signaling reduces secretory cell number, mucin expression and mucus plugging *in vivo*. In August 2022, we presented preclinical data at the European Respiratory Society International Congress 2022 indicating that candidate molecules inhibit Jagged-1-induced Notch 2 signaling in a dose-dependent manner and also demonstrate that PRS-400 reduces mucin expression *ex vivo*. Additionally, PRS-400 was found *in vivo* to reduce mucin gene expression and goblet cells in mice with IL-13-induced airway inflammation. These findings suggest that PRS-400 represents a promising opportunity to address muco-obstructive respiratory diseases locally with an attractive therapeutic index.
 - In May 2023, preclinical data will be presented at the ATS 2023 International Conference demonstrating that PRS-400 reduced inflammation-driven goblet cell metaplasia and mucus hypersecretion in a therapeutic disease model.
- *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 was presented at the American Association of Cancer research annual meeting. These data provided encouraging evidence of clinical activity for this program and we are considering a range of transaction to facilitate the continuation of cinrebafusp alfa, including an immuno-oncology focused spinout to traditional partnering transactions.
- *PRS-344/S095012* is a bispecific Mabcalin compound comprising a PD-L1-targeting antibody genetically linked to 4-1BB-targeting Anticalin proteins. PRS-344/S095012 is being developed as part of our IO collaboration with Servier.
 - The first patient in phase 1/2 study of PRS-344/S095012 was dosed in November 2021 and the study is being conducted in multiple countries, including the United States.
 - The first-in-human phase 1/2 multicenter open-label dose escalation study is designed to determine the safety and preliminary activity of PRS-344/S095012 in patients with advanced and/or metastatic solid tumors. We plan to present the escalation data at a medical meeting in 2023.

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- Pieris and Servier presented preclinical data and the phase 1/2 study design at the American Association for Cancer Research, or AACR, medical meeting in April 2022.
- Our IO portfolio also includes additional drug candidates beyond PRS-344/S095012 that are multi-specific Anticalin-based fusion proteins designed to engage immunomodulatory targets, comprising a variety of multifunctional biotherapeutics. Other IO drug candidates are being developed as part of our collaborations with Servier, Seagen, and Boston Pharmaceuticals.
 - We have already handed one of the programs in the Seagen collaboration, SGN-BB228 (also referenced as PRS-346), a CD228 x 4-1BB bispecific antibody-Anticalin compound, over to Seagen, which is responsible for further advancement and funding of the asset. In January 2023, the first patient was dosed in a Seagen-sponsored phase 1 study of SGN-BB228, upon which we achieved a \$5.0 million milestone. Seagen presented preclinical data for this program at the Society for Immunotherapy of Cancer 37th Annual Meeting in November 2022. The program is one of three programs in the Seagen 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. 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 Seagen. We retain a co-promotion option for one program in the Seagen collaboration in the United States.
 - PRS-342/BOS-342 is a GPC3 x 4-1BB bispecific Mabcalin compound that we have exclusively licensed to Boston Pharmaceuticals. Boston Pharmaceuticals continues to advance PRS-342/BOS-342 towards the clinic, with phase 1 expected to begin in the coming months.

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 three months ended March 31, 2023 and 2022, we reported net losses of \$13.2 million and \$5.1 million, respectively. As of March 31, 2023, we had an accumulated deficit of \$303.6 million. We expect to continue incurring substantial losses for the next several years as we continue to develop our clinical and preclinical drug candidates and programs. Our operating expenses are comprised of research and development expenses and general and administrative expenses.

We have not generated any revenues from product sales to date and we do not expect to generate revenues from product sales for the foreseeable future. Our revenues for the three months ended March 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 Pieris Pharmaceuticals GmbH). Remeasurement gains and losses are recorded in the statement of operations line item "Other income (expense), net." All assets and liabilities denominated in euros are translated into U.S. dollars at the exchange rate on the balance sheet date. Revenues and expenses are translated at the weighted average rate during the period. Equity transactions are translated using historical exchange rates. All adjustments resulting from translating foreign currency financial statements into U.S. dollars are included in accumulated other comprehensive loss.

Key Financial Terms and Metrics

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

Revenues

We have not generated any revenues from product sales to date and we do not expect to generate revenues from product sales for the foreseeable future. Our revenues for the last two years have been primarily from the license and collaboration agreements with our partners.

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

Research and Development Expenses

The process of researching and developing drugs for human use is lengthy, unpredictable and subject to many risks. We expect to continue incurring substantial expenses for the next several years as we continue to develop our clinical and preclinical drug candidates and programs. We are unable, with any certainty, to estimate either the costs or the timelines in which those expenses will be incurred. Our current development plans focus on the following programs: our lead respiratory program, elarekibep, our proprietary respiratory programs, PRS-220 and PRS-400, and our partnered IO programs, including PRS-344/S095012. These programs consume a large proportion of our current, as well as projected, resources.

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

- internal recurring costs, such as personnel-related costs (salaries, employee benefits, equity compensation and other costs), materials and supplies, facilities and maintenance costs attributable to research and development functions; and
- fees paid to external parties who provide us with contract services, such as preclinical testing, manufacturing and related testing and clinical trial activities.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, employee benefits, equity compensation and other personnel-related costs associated with executive, administrative and other support staff. Other significant general and administrative expenses include the costs associated with professional fees for accounting, auditing, insurance costs, consulting and legal services along with facility and maintenance costs attributable to general and administrative functions.

Results of Operations**Comparison of the three months ended March 31, 2023 and 2022**

The following table sets forth our revenues and operating expenses (in thousands):

| | Three Months Ended March 31, | |
|-------------------------------------|-------------------------------------|-------------|
| | 2023 | 2022 |
| Revenues | \$ 1,936 | \$ 10,988 |
| Research and development expenses | 13,424 | 14,066 |
| General and administrative expenses | 4,023 | 4,379 |
| Total operating expenses | 17,447 | 18,445 |
| Other (expense) income | | |
| Interest income | 357 | (3) |
| Grant income | 2,028 | 2,130 |
| Other income | (57) | 229 |
| Net loss | \$ (13,183) | \$ (5,101) |

Revenues

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

| | Three Months Ended March 31, | | Increase/(Decrease) |
|-----------------------|-------------------------------------|------------------|----------------------------|
| | 2023 | 2022 | |
| Customer revenue | \$ 2,010 | \$ 11,180 | \$ (9,170) |
| Collaboration revenue | (74) | (192) | 118 |
| Total Revenue | \$ 1,936 | \$ 10,988 | (9,052) |

- The \$9.2 million decrease in customer revenue in the three months ended March 31, 2023 compared to the three months ended March 31, 2022 is driven by revenue recognized for the discontinuation of a program under the AstraZeneca collaboration and higher revenue recognized under both the Servier (due to achievement of a developmental milestone for PRS-352/S095025) and Genentech collaboration in the prior period.
- The \$0.1 million increase in collaboration revenues in the three months ended March 31, 2023 compared to the three months ended March 31, 2022 reflects changes in the estimated progress for PRS-344/S095012 under the Servier collaboration in 2022 that led to higher revenue offsets in that period.

Research and Development Expenses

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

| | Three Months Ended March 31, | | Increase/(Decrease) |
|----------------------|-------------------------------------|------------------|----------------------------|
| | 2023 | 2022 | |
| Respiratory | \$ 4,146 | \$ 2,278 | \$ 1,868 |
| Immuno-oncology | 2,508 | 4,424 | (1,916) |
| Other R&D activities | 6,770 | 7,364 | (594) |
| Total | \$ 13,424 | \$ 14,066 | (642) |

- The \$1.9 million increase in our respiratory programs for the three months ended March 31, 2023 compared to the three months ended March 31, 2022 is due to higher overall program costs for PRS-220 and higher pre-clinical costs for discovery-stage programs, both partnered and proprietary, partially offset by lower pre-clinical costs for proprietary discovery stage programs.
- The \$1.9 million decrease in our IO programs for the three months ended March 31, 2023 compared to the three months ended March 31, 2022 is due primarily to a decrease in clinical costs for cinrebafusp alfa and lower license fees, offset slightly by higher pre-clinical costs for a partnered discovery-stage program and higher professional services and consulting.
- The \$0.6 million decrease in other research and development activities expenses for the three months ended March 31, 2023 compared to the three months ended March 31, 2022 is due primarily to lower personnel costs due to lower headcount and lower software costs.

General and Administrative Expenses

General and administrative expenses were \$4.0 million for the three months ended March 31, 2023 and \$4.4 million for the three months ended March 31, 2022. The slight period-over-period decrease was driven primarily by lower professional services and consulting costs as well as lower insurance costs.

[Table of Contents](#)*Other Income (Expense)*

Our other income (expense) was \$2.3 million for the three months ended March 31, 2023 and \$2.4 million for the three months ended March 31, 2022. This period over period decrease was primarily due to slightly lower grant income recorded for PRS-220 and foreign exchange losses in the current period, partially offset by higher interest income on investments in the current period.

Liquidity and Capital Resources

We are subject to risks common to companies in the biotechnology industry, including but not limited to, the need for additional capital, risks of failure of preclinical studies and clinical trials, the need to obtain marketing approval and reimbursement for any drug product candidate that we may identify and develop, the need to successfully commercialize and gain market acceptance of our product candidates, dependence on key personnel, protection of proprietary technology, compliance with government regulations, development of technological innovations by competitors, reliance on third-party manufacturers and the ability to transition from pilot-scale production to large-scale manufacturing of products.

Through March 31, 2023, we have funded our operations primarily through private and public sales of equity, payments received under our license and collaboration agreements (including research and development services costs, upfront and milestone payments), government grants and loans.

As of March 31, 2023, we had a total of \$48.4 million in cash, cash equivalents and investments. We have incurred losses in every period since inception, including the three months ended March 31, 2023 and 2022, and have a total accumulated deficit of \$303.6 million as of March 31, 2023.

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

The following table provides a summary of operating, investing and financing cash flows (in thousands):

| | Three Months Ended March 31, | |
|---|------------------------------|-------------|
| | 2023 | 2022 |
| Net cash provided by (used in) operating activities | \$ (10,996) | \$ (22,643) |
| Net cash (used in) investing activities | 11,903 | (16,948) |
| Net cash provided by financing activities | — | 6,558 |

Net cash used in operating activities for the three months ended March 31, 2023 was \$11.0 million compared to net cash used in operating activities of \$22.6 million for the three months ended March 31, 2022.

Cash used by operations in the current period is impacted by lower deferred revenue, lower accrued expenses and higher prepaid expenses, offset partially by higher accounts payable. This compares to the impact of lower deferred revenue, primarily driven by higher revenue recognized for AstraZeneca and Servier, lower accounts payable and accrued expenses and higher prepaid expenses, offset partially by lower accounts receivables in the prior period.

Cash provided by investing activities for the three months ended March 31, 2023 was \$11.9 million as compared to cash used in investing activities of \$16.9 million for the same period in 2022. The change in net cash used 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).

There was no cash provided by or used in financing activities for the three months ended March 31, 2023 as compared to \$6.6 million for the same period in 2022. The prior period included sales under the ATM program.

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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 three months ended March 31, 2023, we did not sell any shares under the ATM program.

Our future success is dependent on our ability to identify and develop our product candidates, expand our corporate infrastructure and, ultimately, upon our ability to attain profitable operations. We have 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 have several research and development programs underway in varying stages of development, and we expect that these programs will continue to require increasing amounts of cash for development, conducting clinical trials and testing and manufacturing of product material. Cash necessary to fund operations will increase significantly over the next several years as we continue to conduct these activities necessary to pursue governmental regulatory approval of clinical-stage programs and other product candidates.

Any requirements for additional capital will depend on many factors, including the following:

- the scope, rate of progress, results and cost of our clinical studies, preclinical testing and other related activities;
- the cost of manufacturing clinical supplies, and establishing commercial supplies, of our drug candidates and any products that we may develop;
- the number and characteristics of drug candidates that we pursue;
- the cost, timing and outcomes of regulatory approvals;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the timing, receipt and amount of sales, profit sharing or royalties, if any, from our potential products;
- the cost of preparing, filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the extent to which we acquire or invest in businesses, products or technologies, although we currently have no commitments or agreements relating to any of these types of transactions; and
- the effects of the COVID-19 pandemic and the cost and timing of actions taken to contain it.

In addition, any unfavorable development or delay in the progress of our core clinical-stage programs, including elarekibep, could have a material adverse impact on our ability to raise additional capital. We would need to raise additional capital over the next year to continue our current level of research and development activities across all of our active programs, as well as to maintain the general and administrative functions to support such activities. Without access to additional capital or management making decisions to reduce spending, these conditions raise substantial doubt about our ability to continue as a going concern.

We plan 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. The funding requirements of our operating plans, however, are based on estimates that are subject to risks and uncertainties and may change as a result of many factors currently unknown. Although management continues to pursue these funding plans, 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. Until such time that we can generate substantial product revenues, if ever, we expect to finance our cash needs through a combination of equity offerings, debt financings, strategic partnerships, licensing arrangements and government grants. The terms of any future financing may adversely affect the holdings or the rights of our existing stockholders.

If we are unable to obtain additional funding on acceptable terms when needed, we will defer or limit a substantial portion of our research, development and clinical projects, reduce discretionary expenditures and other fixed or variable personnel costs to alleviate the substantial doubt as to our ability to continue as a going concern. Our budget and operating plan for 2023, approved by the Board, does not include such discretionary costs, and management is prepared to gate future investments on PRS-220 and PRS-400, including certain Phase 2-readiness activities for PRS-220 and IND-enabling activities for PRS-400, in the interest of achieving our top priority, namely, obtaining data from the elarekibep Phase 2a study in asthma. On the basis of our approved budget and actions within management's control, 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 Quarterly Report on Form 10-Q. Our belief with respect to our ability to fund operations is based on estimates that are subject to risks and uncertainties.

Off-Balance Sheet Arrangements

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

Critical Accounting Policies and Estimates

Refer to Part II, Item 7, “Critical Accounting Policies and Estimates” of our Annual Report on Form 10-K for the fiscal year ended on December 31, 2022 for a discussion of our critical accounting policies and estimates.

This discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with U.S. GAAP. We believe that several accounting policies are important to understanding our historical and future performance. We refer to these policies as critical because these specific areas generally require us to make judgments and estimates about matters that are uncertain at the time we make the estimate, and different estimates—which also would have been reasonable—could have been used. On an ongoing basis, we evaluate our estimates and judgments, including those described in greater detail below. We base our estimates on historical experience and other market-specific or other relevant assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe that our most critical accounting policies are those relating to revenue recognition, contingencies, research and development expense and income taxes, and there have not been significant changes to our accounting policies discussed in the Annual Report on Form 10-K for the fiscal year ended on December 31, 2022.

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 for, 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 its periodic and annual reports, including without limitation 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, 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.
- 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.
- An opportunity to continue utilizing the non-accelerated filer time-line requirements, which became applicable to us at the time of filing of our annual report for the year ending December 31, 2022.

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 3. 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 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, have evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms, and such information is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Our principal executive officer and principal financial officer have concluded that, based on such evaluation, our disclosure controls and procedures were effective as of March 31, 2023.

Changes in Internal Control over Financial Reporting

There have been no changes in our 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 quarter ended March 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings.

As of the date of this Quarterly Report on Form 10-Q, we are not party to and our property is not subject to any material pending legal proceedings. However, from time to time, we may become involved in legal proceedings or subject to claims that arise in the ordinary course of our business activities. Regardless of the outcome, such legal proceedings or claims could have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors.

Please refer to the complete Item 1A of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed with the SEC on March 31, 2023 for risks and uncertainties facing the Company that may have a material adverse effect on the Company's business prospects, financial condition and results of operations. There have been no material changes in the risk factors described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

| <u>Exhibit Number</u> | <u>Exhibit Description</u> | <u>Incorporated by Reference herein from Form or Schedule</u> | <u>Filing Date</u> | <u>SEC File / Registration Number</u> |
|-----------------------|---|---|--------------------|---------------------------------------|
| 31.1 | Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. | * | | |

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| Exhibit Number | Exhibit Description | Incorporated by Reference herein from Form or Schedule | Filing Date | SEC File / Registration Number |
|----------------------|--|---|-------------|--------------------------------------|
| 31.2 | Certification of Principal Financial Officer and Principal Accounting Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. | * | | |
| 32.1 | Certification of Principal Executive Officer Pursuant to 18 U.S.C Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. | ** | | |
| 32.2 | Certification of Principal Financial Officer and Principal Accounting Officer Pursuant to 18 U.S.C Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. | ** | | |
| 101.INS | Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL 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 (formatted as inline XBRL and contained in Exhibit 101) | * | | |
| * | Filed herewith. | | | |
| ** | The certifications furnished in Exhibit 32.1 and Exhibit 32.2 hereto are deemed to accompany this Quarterly Report and will not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the registrant specifically incorporates it by reference. | | | |
| # | Indicates a management contract or compensatory plan. | | | |
| + | 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. | | | |

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Quarterly Report on Form 10-Q to be signed on its behalf by the undersigned thereunto duly authorized.

PIERIS PHARMACEUTICALS, INC.

May 10, 2023

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

May 10, 2023

By: /s/ Thomas Bures
Thomas Bures
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

**CERTIFICATIONS UNDER
SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002**

I, Stephen S. Yoder, certify that:

1. I have reviewed this quarterly report on Form 10-Q 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: May 10, 2023

/s/ Stephen S. Yoder

Stephen S. Yoder

Title: Chief Executive Officer and President (principal executive officer)

**CERTIFICATIONS UNDER
SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002**

I, Thomas Bures, certify that:

1. I have reviewed this quarterly report on Form 10-Q 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: May 10, 2023

/s/ Thomas Bures

Thomas Bures

Title: Chief Financial Officer (principal financial officer and principal accounting officer)

CERTIFICATIONS UNDER SECTION 906

Pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Pieris Pharmaceuticals, Inc. (the “Company”) hereby certifies, to his knowledge, that:

(i) the accompanying Quarterly Report on Form 10-Q of the Company for the fiscal quarter ended March 31, 2023 (the “Report”) fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 10, 2023

/s/ Stephen S. Yoder

Stephen S. Yoder

Title: Chief Executive Officer and President
(principal executive officer)

CERTIFICATIONS UNDER SECTION 906

Pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Pieris Pharmaceuticals, Inc. (the “Company”) hereby certifies, to his knowledge, that:

(i) the accompanying Quarterly Report on Form 10-Q of the Company for the fiscal quarter ended March 31, 2023 (the “Report”) fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 10, 2023

/s/ Thomas Bures

Thomas Bures

Title: Chief Financial Officer
(principal financial officer and principal accounting officer)