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

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**FORM 10-Q**

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- (Mark One)
- QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the quarterly period ended June 30, 2020  
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
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**PIERIS PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

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Nevada  
(State or other jurisdiction of  
incorporation or organization)  
255 State Street 9th Floor  
Boston, MA  
United States  
(Address of principal executive offices)

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

02109  
(Zip Code)

857-246-8998

Registrant's telephone number, including area code

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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 checked="" type="checkbox"/>
Non-accelerated filer	<input 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 August 3, 2020, the registrant had 52,398,600 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, 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 entitled “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, 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 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; our ability to successfully market and sell our drug candidates in the future as needed; the size and growth of the potential markets for any of our approved drug candidates, and the rate and degree of market acceptance of any of our approved drug candidates; competition in our industry; regulatory developments in the United States and foreign countries, including the timing for, and outcome of, the additional in-use and compatibility study for PRS-343 as requested by the FDA in July 2020, and the resolution of the partial clinical hold relating to that drug candidate; 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, 2019 filed with the Securities and Exchange Commission, or SEC, on March 13, 2020, as well as those in Part II, Item 1A (Risk Factors) of our Quarterly Report on Form 10-Q, for the fiscal quarter ended March 31, 2020, filed with the SEC on May 11, 2020, 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. \$1.1202 based on information provided by Thomson Reuters as of June 30, 2020.

## PART I - FINANCIAL INFORMATION

## Item 1. Financial Statements.

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

	June 30, 2020	December 31, 2019
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 44,302	\$ 62,260
Short term investments	32,912	41,894
Accounts receivable	10,712	6,787
Prepaid expenses and other current assets	4,102	4,072
<b>Total current assets</b>	<b>92,028</b>	<b>115,013</b>
Property and equipment, net	20,506	19,502
Operating lease right-of-use assets	3,274	3,436
Other non-current assets	1,975	3,146
<b>Total assets</b>	<b>\$ 117,783</b>	<b>\$ 141,097</b>
<b>Liabilities and stockholders' equity</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 4,406	\$ 5,803
Accrued expenses and other current liabilities	5,942	9,944
Deferred revenues, current portion	7,912	11,256
<b>Total current liabilities</b>	<b>18,260</b>	<b>27,003</b>
Deferred revenue, net of current portion	37,845	47,258
Operating lease liabilities	15,006	15,484
<b>Total liabilities</b>	<b>71,111</b>	<b>89,745</b>
<b>Stockholders' equity:</b>		
Preferred stock	—	—
Common stock	52	55
Additional paid-in capital	230,407	227,468
Accumulated other comprehensive loss	(1,064)	(1,995)
Accumulated deficit	(182,723)	(174,176)
<b>Total stockholders' equity</b>	<b>46,672</b>	<b>51,352</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 117,783</b>	<b>\$ 141,097</b>

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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
<b>Revenue</b>				
Customer revenue	\$ 10,930	\$ 4,723	\$ 19,815	\$ 11,949
Collaboration revenue	316	609	4,692	1,928
<b>Total revenue</b>	<b>11,246</b>	<b>5,332</b>	<b>24,507</b>	<b>13,877</b>
<b>Operating expenses</b>				
Research and development	11,333	13,373	24,091	27,669
General and administrative	4,568	4,189	8,927	9,121
<b>Total operating expenses</b>	<b>15,901</b>	<b>17,562</b>	<b>33,018</b>	<b>36,790</b>
<b>Loss from operations</b>	<b>(4,655)</b>	<b>(12,230)</b>	<b>(8,511)</b>	<b>(22,913)</b>
<b>Other (expense) income</b>				
Interest income	129	449	448	955
Other (expense) income, net	(424)	23	(484)	(148)
<b>Net loss</b>	<b>\$ (4,950)</b>	<b>\$ (11,758)</b>	<b>\$ (8,547)</b>	<b>\$ (22,106)</b>
<b>Other comprehensive income:</b>				
Foreign currency translation	178	(414)	830	272
Unrealized gain (loss) on available-for-sale securities	(15)	(237)	101	3
<b>Comprehensive loss</b>	<b>\$ (4,787)</b>	<b>\$ (12,409)</b>	<b>\$ (7,616)</b>	<b>\$ (21,831)</b>
<b>Net loss per share</b>				
Basic and diluted	\$ (0.09)	\$ (0.24)	\$ (0.16)	\$ (0.44)
<b>Weighted average number of common shares outstanding</b>				
Basic and diluted	52,371	49,204	53,792	50,034

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 June 30, 2019 and 2020**

	Preferred shares		Common shares		Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total Stockholders' equity
	No. of shares	Share capital	No. of shares	Share capital				
Balance as of March 31, 2019	8	\$ —	49,151	\$ 49	\$ 191,224	\$ (2,056)	\$ (159,055)	\$ 30,162
Change in Retained Earnings from adoption of ASC 606	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	(11,758)	(11,758)
Foreign currency translation adjustment	—	—	—	—	—	(414)	—	(414)
Unrealized gains/(losses) on investments	—	—	—	—	—	(237)	—	(237)
Stock based compensation expense	—	—	—	—	1,452	—	—	1,452
Issuance of common stock resulting from exercise of stock options	—	—	50	—	97	—	—	97
Issuance of common stock resulting from purchase of employee stock purchase plan shares	—	—	58	—	178	—	—	178
Issuance of common stock resulting from exercise of warrants	—	—	3	—	5	—	—	5
Balance as of June 30, 2019	8	\$ —	49,262	\$ 49	\$ 192,956	\$ (2,707)	\$ (170,813)	\$ 19,485
Balance as of March 31, 2020	11	\$ —	55,212	\$ 55	\$ 228,751	\$ (1,227)	\$ (177,773)	\$ 49,806
Net loss	—	—	—	—	—	—	(4,950)	(4,950)
Foreign currency translation adjustment	—	—	—	—	—	178	—	178
Unrealized gains/(losses) on investments	—	—	—	—	—	(15)	—	(15)
Stock based compensation expense	—	—	—	—	1,237	—	—	1,237
Issuance of common stock resulting from exercise of stock options	—	—	139	—	271	—	—	271
Issuance of common stock resulting from purchase of employee stock purchase plan shares	—	—	47	—	145	—	—	145
Preferred stock conversion (Series D)	3	—	(3,000)	(3)	3	—	—	—
Balance as of June 30, 2020	14	\$ —	52,399	\$ 52	\$ 230,407	\$ (1,064)	\$ (182,723)	\$ 46,672

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 Six Months Ended June 30, 2019 and 2020**

	Preferred shares		Common shares		Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total Stockholders' equity
	No. of shares	Share capital	No. of shares	Share capital				
Balance as of December 31, 2018	3	\$ —	54,151	\$ 54	\$ 189,929	\$ (2,982)	\$ (147,066)	\$ 39,935
Change in Retained Earnings from adoption of ASC 606	—	—	—	—	—	—	(1,641)	(1,641)
Net loss	—	—	—	—	—	—	(22,106)	(22,106)
Foreign currency translation adjustment	—	—	—	—	—	272	—	272
Unrealized loss on investments	—	—	—	—	—	3	—	3
Stock based compensation expense	—	—	—	—	2,742	—	—	2,742
Issuance of common stock resulting from exercise of stock options	—	—	50	—	97	—	—	97
Issuance of common stock resulting from purchase of employee stock purchase plan shares	—	—	58	—	178	—	—	178
Issuance of common stock resulting from exercise of warrants	—	—	3	—	5	—	—	5
Preferred stock conversion	5	—	(5,000)	(5)	5	—	—	—
Balance as of June 30, 2019	8	\$ —	49,262	\$ 49	\$ 192,956	\$ (2,707)	\$ (170,813)	\$ 19,485
Balance as of December 31, 2019	11	\$ —	55,212	\$ 55	\$ 227,468	\$ (1,995)	\$ (174,176)	\$ 51,352
Net loss	—	—	—	—	—	—	(8,547)	(8,547)
Foreign currency translation adjustment	—	—	—	—	—	830	—	830
Unrealized gain on investments	—	—	—	—	—	101	—	101
Stock based compensation expense	—	—	—	—	2,520	—	—	2,520
Issuance of common stock resulting from exercise of stock options	—	—	139	—	271	—	—	271
Issuance of common stock resulting from purchase of employee stock purchase plan shares	—	—	47	—	145	—	—	145
Preferred stock conversion (Series D)	3	—	(3,000)	(3)	3	—	—	—
Balance as of June 30, 2020	14	\$ —	52,399	\$ 52	\$ 230,407	\$ (1,064)	\$ (182,723)	\$ 46,672

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)

	Six Months Ended June 30,	
	2020	2019 <sup>(1)</sup>
<b>Operating activities:</b>		
Net loss	\$ (8,547)	\$ (22,106)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation	869	208
Right-of-use asset amortization	156	215
Stock-based compensation	2,520	2,742
Other non-cash transactions	343	(151)
Changes in operating assets and liabilities	(20,250)	(6,749)
Net cash used in operating activities	(24,909)	(25,841)
<b>Investing activities:</b>		
Purchases of property and equipment	(2,988)	(1,054)
Proceeds from maturity of investments	47,523	35,647
Purchases of investments	(38,525)	(26,997)
Net cash provided by investing activities	6,010	7,596
<b>Financing activities:</b>		
Proceeds from exercise of stock options	271	97
Proceeds from exercise of warrants	—	5
Proceeds from employee stock purchase plan	145	178
Net cash provided by financing activities	416	280
Effect of exchange rate change on cash and cash equivalents	525	(2,001)
Net decrease in cash and cash equivalents	(17,958)	(19,966)
Cash and cash equivalents at beginning of period	62,260	74,867
Cash and cash equivalents at end of period	\$ 44,302	\$ 54,901
<b>Supplemental cash flow disclosures:</b>		
Net unrealized gain on investments	\$ 31	\$ 93
Property and equipment included in accounts payable	\$ 329	\$ 31

<sup>(1)</sup> Restated to conform to ASC 842. See accompanying Note 2.

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 $\alpha$  antagonist Anticalin protein to treat uncontrolled asthma and an immuno-oncology, or IO, bispecific targeting HER2 and 4-1BB.

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.

As of June 30, 2020, the Company had cash, cash equivalents and investments of \$77.2 million. The Company expects that its existing cash, cash equivalents and investments are sufficient to support operating expense and capital expenditure requirements for at least 12 months from the date of this filing.

**2. Summary of Significant Accounting Policies**

The Company's significant accounting policies are described in Note 2 - Summary of Significant Accounting Policies, within the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2019. There has been no material change to the significant accounting policies during the six months ended June 30, 2020, other than the Adoption of Financial Accounting Standards Board, or FASB, Accounting Standards Update, or ASU, No. 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606*, or ASU 2018-18, described in more detail below.

**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 and six months ended June 30, 2020 are not necessarily indicative of results that may be expected for the year ending December 31, 2020. 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, 2019, which was filed with the SEC on March 13, 2020.

**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 various accruals. 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 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 minimizes the exposure to concentration of credit risk. The Company has not experienced any credit losses in such accounts and does not believe it is exposed to any significant credit risk on these funds. Accounts receivable primarily consist of amounts due under strategic partnership and other license agreements with major multi-national pharmaceutical companies for which the Company does not obtain collateral.

### **Fair Value Measurement**

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

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

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

Financial instruments measured at fair value on a recurring basis include cash equivalents and investments (*Note 4*).

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. For the six months ended June 30, 2020, the Company added material assets related to the February 2020 move to a new research and development facility in Hallbergmoos, Germany. Because of this, the Company expanded its presentation of property and equipment to be more descriptive and updated the useful life for one asset category on a prospective basis only. The disclosures for property and equipment, net as of December 31, 2019 have been reclassified to confirm with the current period presentation. The estimated useful life of the different groups of property and equipment is as follows:

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

### Revenue Recognition

The Company 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 the Company's 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.

#### *Collaborative Arrangements*

The Company considers the nature and contractual terms of an arrangement and assess 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.

In November 2018, the FASB issued Accounting Standards Update, or ASU, 2018-18, which makes targeted improvements to generally accepted accounting principles for collaborative arrangements, including: clarification that certain transactions between collaborative arrangement participants should be accounted for as revenue under ASC 606, *Revenue from Contracts with Customers*, or ASC 606, when the collaborative arrangement participant is a customer in the context of a unit of account, adding unit-of-account guidance in ASC 808 to align with the guidance in ASC 606, and a requirement that in a transaction with a collaborative arrangement participant that is not directly related to sales to third parties, presenting the transaction together with revenue recognized under ASC 606 is precluded if the collaborative arrangement participant is not a customer. The guidance per ASU 2018-18 was adopted retrospectively to the date of initial application of ASC 606. The Company adopted ASU 2018-18 in the first quarter of 2020. The adoption of this standard did not have a material impact on the Company's condensed consolidated financial statements; however, revenue recognized under a collaborative arrangement involving a participant that is not a customer (Collaboration Revenue) is now presented separately from Customer Revenue. This change has been reflected in the condensed consolidated statement of operations and the 2019 amounts were adjusted to conform to ASC 808 as follows:

	Three Months Ended June 30, 2019			Six Months Ended June 30, 2019		
	As reported pre-adoption	ASC 808 Adoption Adjustment	As reported post-adoption	As reported pre-adoption	ASC 808 Adoption Adjustment	As reported post-adoption
Customer revenue	\$ 4,934	\$ (211)	\$ 4,723	\$ 12,468	\$ (519)	\$ 11,949
Collaboration revenue	398	211	609	1,409	519	1,928
<b>Total Revenue</b>	<b>\$ 5,332</b>	<b>\$ —</b>	<b>\$ 5,332</b>	<b>\$ 13,877</b>	<b>\$ —</b>	<b>\$ 13,877</b>

#### 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 the transaction price is variable and meets the criteria to be allocated entirely to a performance obligation or to a distinct good or service that forms part of a single performance obligation.

The Company allocates the transaction price based on the estimated standalone selling price of the underlying performance obligations or in the case of certain variable consideration to one or more performance obligations. The Company must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the

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

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

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

### *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.

### *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.

### **Leases**

Effective on December 31, 2019, the Company lost its emerging growth company, or EGC, status which accelerated the requirement of the adoption of FASB issued ASU No. 2016-02ASC, *Leases (Topic 842)*, or ASC 842. As a result, the Company adjusted its previously reported consolidated financial statements effective January 1, 2019 in the Company's 2019 Form 10-K, and amendments to previously filed Forms 10-Q were not required. Accordingly, the Company's prior period condensed consolidated financial statements and information, as presented herein, have been restated to conform to the new standard.

The following tables summarize the effects of adopting ASC 842 on our condensed consolidated financial statements for the six months ended June 30, 2020 (in thousands):

	Six Months Ended June 30, 2019		
	Previously reported	ASC 842 Adjustment during the period	As adjusted
<b>Operating activities:</b>			
Net loss	\$ (22,106)	\$ —	\$ (22,106)
Adjustments to reconcile net loss to net cash provided by operating activities:			
Depreciation	208	—	208
Right-of-use asset amortization	—	215	215
Stock-based compensation	2,742	—	2,742
Deferred rent expense	588	(588)	—
Other non-cash transactions	(151)	—	(151)
Changes in operating assets and liabilities	(7,122)	373	(6,749)
Net cash used in operating activities	\$ (25,841)	\$ —	\$ (25,841)

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 noncancelable lease periods and, when applicable, periods covered by an option to extend the lease if the Company is reasonably certain to exercise that option, as well as periods covered by an option to terminate the lease if the Company is reasonably certain not to exercise that option.

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

#### 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*, or ASU 2018-19, 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, or ASU 2019-11 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*, or ASU 2019-10, 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 is still evaluating the impact of the adoption of this standard.

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.

During the three and six months ended June 30, 2020 and 2019, respectively, the Company recognized revenue from the following strategic partnerships and other license agreements (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Seattle Genetics	\$ 8,512	\$ 504	\$ 8,960	\$ 1,429
AstraZeneca	2,334	3,888	5,045	9,908
Servier	400	940	10,502	2,540
<b>Total Revenue</b>	<b>\$ 11,246</b>	<b>\$ 5,332</b>	<b>\$ 24,507</b>	<b>\$ 13,877</b>

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	\$ 1,111	\$ 960
Servier	682	605
Seattle Genetics	764	450
<b>Total potential milestone payments</b>	<b>\$ 2,557</b>	<b>\$ 2,015</b>

#### Strategic Partnerships

##### Seattle Genetics

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

Under the terms of the Seattle Genetics Agreements, the companies will pursue multiple antibody-Anticalin fusion proteins during the research phase. The Seattle Genetics Agreements provide Seattle Genetics 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. Seattle Genetics will solely develop, fund and commercialize the other two programs. Seattle Genetics 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 Seattle Genetics Platform License grants Seattle Genetics a non-exclusive license to certain intellectual property related to the Anticalin platform technology.

Upon signing the Seattle Genetics Agreements, Seattle Genetics 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 Seattle Genetics 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 Seattle Genetics Agreements ends upon the expiration of all of Seattle Genetics' payment obligations under each such agreement. The Seattle Genetics Collaboration Agreement may be terminated by Seattle Genetics 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 Seattle Genetics' option. If any program is terminated by Seattle Genetics after a pre-defined pre-clinical stage, the Company will have full rights to continue such program. If any program is terminated by Seattle Genetics prior to such pre-defined pre-clinical stage, the Company will have the right to continue to develop such program, but will be obligated to offer a co-development option to Seattle Genetics for such program. The Seattle Genetics Collaboration Agreement may also be terminated by Seattle Genetics 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 Seattle Genetics 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 Seattle Genetics Agreements if the other party challenges the validity of any patents licensed under the Seattle Genetics Agreements, subject to certain exceptions. The Seattle Genetics Platform License will terminate upon termination of the Seattle Genetics Collaboration Agreement, whether in its entirety or on a product-by-product basis.

The Company determined that the Seattle Genetics Agreements should be combined and evaluated as a single arrangement under ASC 606 as they were executed on the same date. The arrangement with Seattle Genetics 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 Seattle Genetics 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 Seattle Genetics 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 Seattle Genetics 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 Seattle Genetics 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 straight-line over the anticipated research term for all research programs. As of June 30, 2020, there was \$19.8 million of aggregate transaction price allocated to remaining performance obligations.

In June 2020, Seattle Genetics and the Company entered into amendments to the Seattle Genetics Agreements, or together, the Amendment. The Amendment extended the deadline for Seattle Genetics to nominate a second and third antibody target. As a result of the Amendment, which completed the obligations under the research term for the first antibody target, the Company recorded \$4.2 million of previously deferred revenue for the three and six months ended June 30, 2020. The Company also recorded \$5.0 million of milestone revenue due from Seattle Genetics during the quarter ended June 30, 2020, as it was no longer deemed probable that a significant reversal of revenue would occur, and the remaining performance obligations on first antibody target were completed.

Under the Seattle Genetics 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.

As of June 30, 2020, there were \$1.4 million and \$15.2 million of current and non-current deferred revenue, respectively, related to the Seattle Genetics 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, PRS-060/AZD1402, or the AstraZeneca Lead Product, the Company and AstraZeneca will also collaborate to progress four additional novel Anticalin proteins against undisclosed targets for respiratory diseases, or the AstraZeneca Collaboration Products, and together with the AstraZeneca Lead Product, the AstraZeneca Products. 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 completion of 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 has the option to co-develop two of the four AstraZeneca Collaboration Products beginning at a pre-defined preclinical stage and would also have the option to co-commercialize these two programs in the United States, while AstraZeneca will be responsible for development and commercialization of the other programs worldwide.

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 dependent on 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 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.

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 June 30, 2020, there was \$23.2 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.

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.

As of June 30, 2020, there were \$1.1 million and \$17.2 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 June 30, 2020, the remaining balance of the asset recognized from transaction costs to obtain the AstraZeneca contract was \$0.6 million. Amortization during the three and six months ended June 30, 2020 was de minimis.

#### Servier

On January 4, 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.

Five committed programs were initially defined, which may 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. The collaboration may be expanded by up to three additional therapeutic programs. The Company had the option to co-develop and retain commercial rights in the United States for PRS-332, the initial lead program under the collaboration, or the Initial Lead, and has a similar option on up to three additional programs, or the Co-Development Collaboration Products, while Servier will be responsible for development and commercialization of the other programs worldwide, or the Servier Worldwide 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.

The Co-Development Collaboration Products may be jointly developed, according to a collaboration plan, through marketing approval from the U.S. Food and Drug Administration or the European Medicines Agency. Servier Worldwide Collaboration Products may be jointly developed, according to a collaboration plan, through specified preclinical activities, at which point Servier becomes responsible for further development of the Collaboration Product.

At inception, Servier was granted the following licenses: (i) development license for the Initial Lead, (ii) commercial license for the Initial Lead, (iii) individual research licenses for each of the four Collaboration Products, and (iv) individual non-exclusive platform technology licenses for the Initial Lead and for each of the four Collaboration Products. Upon achievement of certain development activities, specified by the collaboration for each Servier Agreement, Servier will be granted a development license and a commercial license. For the Initial Lead and the Co-Development Collaboration Products, the licenses granted are with respect to the entire world except for the United States. For Servier Worldwide Collaboration Products, the licenses granted are with respect to the entire world.

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.

For the Initial Lead and Co-Development Collaboration Products, the Company and Servier are responsible for an agreed upon percent of the shared costs required to develop the products through commercialization. In the event that the Company fails to exercise its option to co-develop the Co-Development Collaboration Products, Servier has the right to continue with the development and will be responsible for all costs required to develop the products through commercialization.

Under the Servier Agreements, the Company received an upfront, non-refundable payment of €30.0 million (approximately \$32.0 million). In addition, the Company is eligible to receive research, development, commercial and sales milestone payments as well as tiered royalties up to low double digits on the sales of commercialized products in the Servier territories. The Company achieved two preclinical milestones under the program, one in December 2018 for €0.5 million (approximately \$0.6 million) and another in February 2019 for €1.5 million (approximately \$1.7 million), both of which became billable on their respective achievement dates.

The initial research collaboration term, as it relates to the Initial Lead and Collaboration Products, shall continue for three years from the effective date of the Servier agreements and may be mutually extended for two one-year terms consecutively applied.

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 for convenience beginning 12 months after their effective date upon 180 days' notice. The Servier Agreements may also 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. The arrangement with Servier provides for the transfer of the following goods and services: (i) five non-exclusive platform technology licenses, a development license, a commercial license and research and development services for the Initial Lead, (ii) participation on each of the committees, (iii) four research licenses for Collaboration Products, and (iv) research and development services for the Collaboration Products. Additionally, as the development and commercial licenses on the four 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 goods and services were separate performance obligations. The Company determined that the licenses granted, at the inception of the Servier collaboration, should be combined with the research and development services to be provided for the Initial Lead and Collaboration Products, over the term of the Servier Agreements, as such 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 Servier could not benefit from the licenses without the corresponding services. The Company determined that the participation on the various committees was distinct as the services could be performed by an outside party.

As a result, management concluded that there were 10 performance obligations at the inception of the Servier Agreements. The following performance obligations are within the scope of ASC 808: (i) combined performance obligation comprised of a non-exclusive platform technology license, commercial license, development license and research and development services for the Initial Lead, (ii) two separate performance obligations each comprised of a combined non-exclusive platform technology license, research license and research and development services for each Co-Development Collaboration Product, (iii) one performance obligation comprised of participation in the various governance committees, and (iv) two combined performance obligations comprised of the development and commercial licenses granted for the Co-Development Collaboration Products (and corresponding discounts) upon the achievement of specified preclinical activities, resulting in material rights. Revenue recognized associated with these performance obligations are presented as Collaboration Revenue within the Statement of Operations. The following performance obligations are within the scope of ASC 606: (i) two separate performance obligations each comprised of a combined non-exclusive platform technology license, research license and research and development services for each Servier Worldwide Collaboration Product, and (ii) two combined performance obligations comprised of the development and commercial licenses granted for the Servier Worldwide Collaboration Products (and corresponding discounts) upon the achievement of specified preclinical activities, resulting in material rights. Revenue recognized associated with these performance obligations are presented as Customer Revenue within the Statement of Operations.

The Company allocated consideration to the performance obligations based on the relative proportion of their standalone selling prices. The Company developed its 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 its estimate of 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 estimate of standalone selling price for the material rights granted on the development and commercial licenses granted for the Collaboration Products by probability weighting multiple cash flow scenarios using the income approach.

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.

The amounts allocated to the performance obligation for the Initial Lead and the four performance obligations for the four research and development licenses for Collaboration Products will be recognized on a proportional performance basis as the activities are conducted over the life of the arrangement. The term of the performance at inception of the Servier Agreements for the Initial Lead and each of the Co-Development Collaboration Products may be through approval of certain regulatory bodies; a period which could be many years. The term of the performance for each of the other two Servier Worldwide Collaboration Products is through the initial research and collaboration term, plus potential extensions. The amounts 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 amounts allocated to the four performance obligations for the material rights to acquire development and commercial licenses for the Co-Development Collaboration Products are granted in the future will be recognized over time upon delivery of each of the licenses through marketing approval. The amounts allocated to the four performance obligations for the material rights to acquire development and commercial licenses for the Servier Developed Collaboration Products are granted in the future will be recognized upon delivery of each of the licenses. As of June 30, 2020, there was \$10.9 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 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. 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.

In September 2019, Servier notified the Company of its decision to discontinue co-development of PRS-332, a PD-1-LAG-3 bispecific that served as the initial development program under the Pieris-Servier alliance, for strategic reasons. The Company does not presently intend to continue development of PRS-332 but retains full rights to advance the development and commercialization of the product on a world-wide basis in the future.

In February 2020, the research term was extended for another 12 months. The Company has updated the transaction price for the extension for revenue recognition purposes and allocated it ratably over all unsatisfied performance obligations. In March 2020, Servier notified the Company of its decision to discontinue co-development of two earlier preclinical stage programs for strategic reasons based upon an extensive portfolio review. The notification required a 60-day period to complete remaining obligations on the programs, however the Company determined that the material rights to acquire development and commercial licenses for one Co-Development Collaboration Product and for one Servier Developed Collaboration Products lapsed in March 2020 and recognized as revenue \$7.1 million of previously deferred revenue associated with these material rights during the three-month period ended March 31, 2020. The parties continue to advance the development of two preclinical programs: PRS-344, a 4-1BB/PD-L1 bispecific designed as a co-development program, and PRS-352, which addresses undisclosed targets and for which Servier has worldwide rights.

As of June 30, 2020, there were \$5.5 million and \$5.4 million of current and non-current deferred revenue, respectively, related to the Servier Agreements.

The Company incurred costs to obtain the contract with Servier. Upon adoption of ASC 606, the Company capitalized \$0.5 million of third-party service fees in accordance with ASC 340. As of June 30, 2020, the remaining balance of the asset recognized from costs to obtain the Servier contract was \$0.1 million. Amortization during the three and six months ended June 30, 2020 was de minimis and \$0.1 million, respectively.

#### **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 June 30, 2020. Additions to deferred revenue were \$1.6 million during the six months ended June 30, 2020. Reductions to deferred revenue were \$3.7 million and \$13.8 million for the three and six months, respectively, ended June 30, 2020.



#### 4. Cash, cash equivalents and investments

As of June 30, 2020 and December 31, 2019, cash, cash equivalents and investments comprised of funds in depository, money market accounts, U.S. 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 (in thousands):

	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
<b>June 30, 2020</b>				
Money market funds, included in cash equivalents	\$ 25,502	\$ 25,502	\$ —	\$ —
Investments - U.S. treasuries	11,993	11,993	—	—
Investments - Asset-backed securities	1,569	—	1,569	—
Investments - Corporate bonds	19,350	—	19,350	—
<b>Total</b>	<b>\$ 58,414</b>	<b>\$ 37,495</b>	<b>\$ 20,919</b>	<b>\$ —</b>
<b>December 31, 2019</b>				
Money market funds, included in cash equivalents	\$ 47,384	\$ 47,384	\$ —	\$ —
Investments - U.S. treasuries	5,300	5,300	—	—
Investments - Asset-backed securities	7,950	—	7,950	—
Investments - Corporate bonds	28,644	—	28,644	—
<b>Total</b>	<b>\$ 89,278</b>	<b>\$ 52,684</b>	<b>\$ 36,594</b>	<b>\$ —</b>

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 June 30, 2020.

Investments at June 30, 2020 consisted of the following (in thousands):

	Contractual maturity (in days)	Amortized Cost	Unrealized gains	Unrealized losses	Fair Value
<b>Investments</b>					
U.S. treasuries	44-170	\$ 11,944	\$ 49	\$ —	\$ 11,993
Asset-backed securities	77	1,567	3	(1)	1,569
Corporate bonds	22-132	19,370	20	(40)	19,350
<b>Total</b>		<b>\$ 32,881</b>	<b>\$ 72</b>	<b>\$ (41)</b>	<b>\$ 32,912</b>

The Company recorded de minimis and \$0.2 million in realized gains from the maturity of available-for-sale securities during the three and six months, respectively, ended June 30, 2020. The Company recorded realized gains of \$0.1 million from the maturity of available-for-sale securities for both the three and six months ended June 30, 2019.

As of June 30, 2020, 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.

#### 5. Property and equipment, net

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

	June 30, 2020	December 31, 2019
Laboratory furniture and equipment	\$ 9,485	\$ 11,635
Office furniture and equipment	1,939	479
Computer equipment	354	245
Leasehold improvements	12,889	10,710
Property and equipment, cost	24,667	23,069
Accumulated depreciation	(4,161)	(3,567)
<b>Property and equipment, net</b>	<b>\$ 20,506</b>	<b>\$ 19,502</b>

#### 6. Accrued Expenses

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

	June 30, 2020	December 31, 2019
Accrued accounts payable	\$ 1,276	\$ 4,251
Compensation expense	2,189	2,870
Research and development fees	1,177	1,048
Lease liabilities	881	733
Audit and tax fees	69	522
Other current liabilities	350	520
<b>Total</b>	<b>\$ 5,944</b>	<b>\$ 9,944</b>

#### 7. Net Loss per Share

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

For the three months ended June 30, 2020 and 2019, and as calculated using the treasury stock method, approximately 37.3 million and 21.6 million of weighted average shares, respectively, were excluded from the calculation of diluted weighted average shares outstanding as their effect was antidilutive.

#### 8. Stockholders' Equity

The Company had 300,000,000 shares authorized and 52,399,152 and 55,212,437 issued and outstanding as of June 30, 2020 and December 31, 2019, respectively, with a par value of \$0.001 per share.

The Company had 10,000,000 shares authorized and 14,429 shares of preferred stock issued and outstanding as of June 30, 2020. The Company had 10,000,000 shares authorized and 11,429 shares of preferred stock issued and outstanding as of December 31, 2019. Preferred stock has a par value of \$0.001 per share, and consists of the following:

- Series A Convertible, 2,907 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively.
- Series B Convertible, 5,000 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively.
- Series C Convertible, 3,522 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively.
- Series D Convertible, 3,000 and zero shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively.

#### 2020 Employee, Director and Consultant Equity Incentive Plan

At the Annual Shareholder Meeting, held on June 23, 2020, the shareholders 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 will be 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 approval of the 2020 Plan.

#### **Series B Preferred Stock Conversion**

On January 30, 2019, the Company and certain entities affiliated with Biotechnology Value Fund, L.P., or BVF, entered into an exchange agreement pursuant to which BVF agreed to exchange an aggregate of 5,000,000 shares of the Company's common stock owned by BVF for an aggregate of 5,000 shares of Series B Preferred Stock. On January 31, 2019, the Company designated 5,000 shares of its authorized and unissued preferred stock as Series B Preferred Stock and filed a Certificate of Designation of Series B Convertible Preferred Stock of Pieris Pharmaceuticals, Inc., or the Series B Certificate of Designation, with the Nevada Secretary of State.

#### **2019 Private Placement**

In November 2019, the Company entered into a securities purchase agreement for a private placement, or the Purchase Agreement, with a select group of institutional investors, including lead investor BVF as well as existing and new investors, or Investors. At the time of entering into the Purchase Agreement, BVF was a more than 5% stockholder of the Company, holding shares of common stock, Series A Preferred Stock, Series B Preferred Stock and warrants to purchase shares of common stock.

The private placement consisted of 9,014,960 units, at a price of \$3.55 per unit for gross proceeds of approximately \$32.0 million, and net proceeds to the Company of approximately \$31.0 million. Each unit consists of (i) one share of the Company's common stock, or Common Shares, or 0.001 shares of non-voting Series C convertible preferred stock, or Series C Preferred Shares, and together with the Common Shares, or Shares, and (ii) one immediately-exercisable warrant to purchase one share of the Company's common stock with an exercise price of \$7.10, or Exercise Price.

If (i) the initial public disclosure of the Phase 2a Study of PRS-060/AZD1402 that includes the "p" value achieved for the primary endpoint of such study reveals top-line data on the primary efficacy endpoint in the Phase 2a Study with a "p" value below 0.05 (i.e.,  $p < 0.05$ ) in at least one dose level; and (ii) the 10-day volume weighted average stock price commencing on the trading day immediately after the initial public disclosure is at least three percent more than the Exercise Price, ((i) and (ii), collectively, the "Performance Condition"), then the warrants will be exercisable for a period of 60 days from the date of the initial data disclosure and may only be exercised for cash. Otherwise, the warrants will be exercisable for a period of five years from the date of issuance, or Exercise Date. If the Performance Condition has not been met and the last reported sale price of the Company's common stock immediately prior to the Expiration Date was greater than the Exercise Price, then the warrants shall be automatically deemed exercised on a cashless basis on the Expiration Date.

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

The terms of the Series C Preferred Shares, specifically voting rights, rights of conversion, beneficial ownership limitations, entitlement to dividends and distributions upon liquidation or dissolution, are identical to the Series B Preferred Shares.

#### **Series D Preferred Stock Conversion**

On March 31, 2020, the Company and certain entities affiliated with Biotechnology Value Fund, L.P., or BVF entered into an exchange agreement pursuant to which, on April 1, 2020, BVF exchanged an aggregate of 3,000,000 shares of the Company's common stock owned by BVF for an aggregate of 3,000 shares of Series D Preferred Stock. The Company designated 3,000 shares of its authorized and unissued preferred stock as Series D Preferred Stock and filed a Certificate of Designation of Series D Convertible Preferred Stock of Pieris Pharmaceuticals, Inc., or the Series D Certificate of Designation, with the Nevada Secretary of State.

Each share of Series D Preferred Stock is convertible into 1,000 shares of Common Stock (subject to adjustment as provided in the Series D Certificate of Designation) at any time at the option of the holder, provided that the holder is prohibited from converting the Series D Preferred Stock into shares of Common Stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 9.99% of the total number of shares of Common Stock then issued and outstanding. The holder may reset the Beneficial Ownership Limitation to a higher or lower number (not to exceed 19.99% of the total number of Common Shares issued and outstanding immediately after giving effect to a conversion) upon providing written notice to the Company. Any such notice providing for an increase to the Beneficial Ownership Limitation will be effective 61 days after delivery to the Company. In the event of the Company's liquidation, dissolution, or winding up, subject to the rights of holders of Senior Securities (defined below), holders of Series D Preferred Stock are entitled to receive a payment equal to \$0.001 per share of Series D Preferred Stock before any proceeds are distributed to the holders of Common Stock and Junior Securities (defined below) and pari passu with any distributions to the holders of the Series A Preferred Stock, Series B Preferred Stock and Series C Preferred Stock, plus an additional amount equal to any dividends declared but unpaid on such shares. However, if the assets of the Company are insufficient to comply with the preceding sentence, then all remaining assets of the Company shall be distributed ratably to holders of the shares of the Series D Preferred Stock and Parity Securities (defined below). Shares of Series D Preferred Stock generally have no voting rights, except as required by law and except that the consent of holders of a majority of the then outstanding Series D Preferred Stock is required to amend the terms of the Series D Certificate of Designation. Holders of Series D Preferred Stock are entitled to receive any dividends payable to holders of Common Stock, and rank:

- senior to all of the Common Stock;
- senior to any class or series of capital stock of the Company created after the designation of the Series D Preferred Stock specifically ranking by its terms junior to the Series D Preferred Stock (the "Junior Securities");
- on parity with all shares of Series A Preferred Stock, Series B Preferred Stock, Series C Preferred Stock and any class or series of capital stock of the Company created after the designation of the Series D Preferred Stock specifically ranking by its terms on parity with the Series D Preferred Stock (the "Parity Securities"); and
- junior to any class or series of capital stock of the Company created after the designation of the Series D Preferred Stock specifically ranking by its terms senior to the Series D Preferred Stock (the "Senior Securities"),

in each case, as to distributions of assets upon the Company's liquidation, dissolution or winding up whether voluntarily or involuntarily and/or the right to receive dividends.

#### **Open Market Sale Agreement**

In August 2019, the Company entered into a sale agreement pursuant to which the Company may offer and sell shares of its common stock, from time to time, up to an aggregate gross sales proceeds of \$50.0 million through an "at the market offering" program under a shelf registration statement on Form S-3. To date, the Company has not sold any shares under this agreement.

#### **9. Leases**

The Company currently leases office space in Boston, Massachusetts. In August 2015, the Company entered into a sublease to lease approximately 3,950 square feet. The sublease expires on February 27, 2022 or such earlier date pursuant to the termination provisions of the sublease.

The Company also leased approximately 19,000 square feet of office and laboratory space in Freising, Germany under four agreements, the Freising Leases, including three leases for space on three floors of the same building and a letter agreement for additional conference room space within the building. The Freising Leases expired on March 31, 2020.

In October 2018, Pieris GmbH entered into a new lease for office and laboratory space located in Hallbergmoos, Germany, or the Hallbergmoos Lease. Pieris GmbH moved its operations, formerly conducted in Freising, Germany, to the Hallbergmoos facility in February 2020.

Under the Hallbergmoos Lease, Pieris GmbH will rent approximately 105,000 square feet, of which approximately 98,400 square feet were delivered by the lessor in February 2020 and approximately 5,100 square feet were delivered by the lessor in

May 2020. 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.

The Hallbergmoos Lease provides for an initial rental term of 12.5 years which commenced in February 2020 when the leased property was delivered to Pieris GmbH. Pieris GmbH also has 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, which amount shall be adjusted starting on the second anniversary of the commencement date by an amount equal to the German consumer price index. 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.

The Hallbergmoos Lease included \$11.5 million of tenant improvements allowance for normal tenant improvements, for which construction began in March 2019. The date of the construction coincided with the lease commencement date for accounting purposes under ASC 840, which did not change with the adoption of ASC 842. 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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Operating lease costs	\$ 347	\$ 423	\$ 751	\$ 646
Variable lease costs (1)	156	69	344	137
Total lease cost	<u>\$ 503</u>	<u>\$ 492</u>	<u>\$ 1,095</u>	<u>\$ 783</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 June 30, 2020:

	As of June 30, 2020
Weighted-average remaining lease term (years)	11.9
Weighted-average discount rate	10.5 %

Cash paid for amounts included in the measurement of the lease liabilities was \$0.6 million and \$0.9 million for the three and six months ended June 30, 2020.

As of June 30, 2020, the maturities of the Company's operating lease liabilities and future minimum lease payments were as follows (in thousands):

	Total
2020	\$ 1,206
2021	2,415
2022	2,246
2023	2,211
2024	2,211
Thereafter	16,768
Total undiscounted lease payments	27,057
Less: present value adjustment	(11,172)
Present value of lease liabilities	<u>\$ 15,885</u>

#### **10. Subsequent Event**

On August 10, 2020, the Company entered into a Clinical Trial Collaboration and Supply Agreement, or the Lilly Agreement, with Eli Lilly and Company, or Lilly, pursuant to which the Company and Lilly will collaborate in a Phase 2 Clinical Study, or the Study, to determine the safety and efficacy of the Company's PRS-343 in combination with the standard of care regimen for advanced or metastatic gastric cancer in the second line, ramucirumab (Cyramza®) and paclitaxel, for the second-line treatment of HER2+ gastric cancer.

Under the terms of the non-exclusive Lilly Agreement, the Company will sponsor the Study and Lilly will supply the Company with ramucirumab as well as provide input on certain clinical and regulatory aspects of the Study in exchange for jointly owning clinical data and inventions relating to the combination regimen that may arise from the Study. Any material changes to the protocol for the Study, and any changes relating to ramucirumab, will require Lilly's prior written consent, which shall not be unreasonably withheld, conditioned or delayed.

The Lilly Agreement will expire upon completion of the parties' contractual obligations. The Lilly Agreement may also be terminated (a) by either party for an uncured material breach by the other party upon 60 days' notice, subject to a reasonable extension if such material breach requires more than 60 days to cure; (b) by either party in the event that the Study unreasonably affects patient safety, provided that the terminating party promptly notifies the other party and the other party is given the opportunity to propose modifications to the Study to address the safety issues; (c) by either party, following 15 days' written notice, if regulatory action is taken preventing the terminating party from providing its compound or if the terminating party decides to discontinue development of its compound; (d) by either party, immediately upon written notice to the other party for breach by the other party of its material obligations under certain sections of the Lilly Agreement, or breach of certain of the other party's representations and warranties; and (e) by Lilly in the event of certain safety concerns related to the use of ramucirumab in the Study.

## 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, 2019, 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, 2019, filed with the SEC on March 13, 2020. 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, 2019 and the Quarterly Report on Form 10-Q for the quarter ended March 31, 2020.*

*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. Our clinical pipeline includes an inhaled IL-4R $\alpha$  antagonist Anticalin protein to treat uncontrolled asthma, and an immuno-oncology (IO) bispecific targeting HER2 and 4-1BB. Proprietary to us, Anticalin proteins are a novel class of therapeutics validated in the clinic and through partnerships with leading pharmaceutical companies. Our core Anticalin technology and platform were developed in Germany and we have collaborations with major multi-national pharmaceutical companies. In particular, we have an alliance with AstraZeneca to treat respiratory diseases and partnerships with Servier and Seattle Genetics, both in IO. Our programs include:

- PRS-060/AZD1402, our lead respiratory program partnered with AstraZeneca, a drug candidate that antagonizes IL-4R $\alpha$ , thereby inhibiting 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. We are sponsoring the phase 1 studies of PRS-060/AZD1402 with AstraZeneca, and AstraZeneca is funding the costs. AstraZeneca will conduct and fund the phase 2a study of the drug candidate, after which we will have separate options to co-develop and co-commercialize PRS-060/AZD1402 in the United States.
- Additional respiratory drug candidates beyond PRS-060/AZD1402, both within and outside of the AstraZeneca alliance. In addition to PRS-060/AZD1402, the alliance includes four respiratory programs, the targets and disease areas of which are undisclosed. We retain co-development and co-commercialization rights to two out of the four programs beyond PRS-060/AZD1402. Our portfolio also includes several respiratory programs outside of the AstraZeneca collaboration.
- PRS-343, our lead IO program, is a fusion protein comprising a HER2-targeting antibody genetically linked to 4-1BB-targeting Anticalin proteins. PRS-343 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 bispecific T-cell co-stimulatory agonist to enter clinical development.
- Additional IO drug candidates beyond PRS-343 that are multispecific Anticalin-based fusion proteins designed to engage immunomodulatory targets, comprising a variety of multifunctional biotherapeutics, including PRS-344, a bispecific antibody-Anticalin fusion protein comprising an PD-L1-targeting antibody genetically fused to Anticalin proteins specific for 4-1BB. PRS-344 is being developed as part of our IO collaboration with Servier. Other IO drug candidates are being developed as part of our collaboration with Servier and Seattle Genetics.

Our programs are in varying stages:

- PRS-060/AZD1402 was tested in a nebulized formulation in 54 healthy volunteers at nominal dose levels ranging from 0.25 mg to 400 mg in a phase 1 SAD study. Data from that study were presented at the American Thoracic Society International Conference in May 2019 showing that PRS-060/AZD1402 was well tolerated when given as a single inhaled or intravenous doses to healthy volunteers and there was systemic target engagement (as measured by pSTAT6 inhibition). We presented interim data from the PRS-060/AZD1402 phase 1 MAD study at the European Respiratory Society International Congress in October 2019 and reported that PRS-060/AZD1402 was safe and 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 ( $\geq 35$ ppb). In that study, during the treatment period, 30 patients were randomized to receive delivered doses of PRS-060/AZD1402 ranging from 2 mg to 60 mg (5 mg to 150 mg administered through a nebulizer (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. Statistically significant and pronounced inhibition of FeNO relative to placebo was observed at all doses. When comparing the 20 mg PRS-060/AZD1402 powered cohort (n=12) to placebo, the primary statistical analysis using the emax model demonstrated a 36% relative reduction in FeNO (p-value <0.0001). Systemic target engagement was dose-dependent and closely aligned with systemic exposure of the drug, consistent with results of the phase 1 SAD study. No systemic target engagement and minimal systemic exposure was observed at the 2 mg dose, suggesting that local target engagement by the drug may be sufficient to reduce airway inflammation, as evidenced by FeNO reduction at that 2 mg dose level. Following these reported results we and AstraZeneca are preparing to move PRS-060/AZD1402 into a phase 2a study in the fourth quarter of 2020.
- Our additional respiratory programs within and outside of the AstraZeneca alliance are in the discovery stage. Within the AstraZeneca alliance, beyond PRS-060/AZD1402, Pieris continues to advance three discovery programs and Pieris expects AstraZeneca will initiate the fourth and final discovery program in the collaboration later this year. Outside of the AstraZeneca collaboration, Pieris continues to advance several proprietary respiratory programs, which are in the discovery stage.
- Based on the totality of the data in the phase 1 dose-escalation monotherapy study of PRS-343, a 4-1BB/HER2 bispecific for HER2-positive solid tumors, we plan to initiate a phase 2 single-arm study of PRS-343 in combination with ramucirumab and paclitaxel in second-line gastric cancer in the second half of this year. At the active dose levels for which we presented interim data last year in cohorts 9 (2.5 mg/kg Q3W) through 11b (8 m/kg Q2W), a partial response was observed in three patients and stable disease was observed in 11 patients as best response out of 21 evaluable patients, translating to an ORR of 14% and a DCR of 67%. All three objective responses in these cohorts were observed in cohort 11b, in which disease stabilization was also observed in three patients out of seven evaluable patients, translating to an ORR of 43% and a DCR of 86%. Additional clinical benefit, including complete response, was also observed in the higher dose cohorts, which are still open for enrollment. Pieris plans to present detailed data from both the monotherapy study and atezolizumab combination study in an oral presentation session at the European Society for Medical Oncology (ESMO) Virtual Congress in September 2020.

In July 2020, we announced that our phase 1 studies of PRS-343 have been placed on partial clinical hold by the U.S. Food and Drug Administration (FDA) while we conduct an additional in-use and compatibility study requested by the Agency. The partial hold was initially communicated by FDA in a teleconference and the Company has since received written correspondence from the Agency confirming the partial hold. Treatment of currently-enrolled patients may continue, although no new patients can be enrolled until resolution of the partial hold. Separately, the Company has received a written response from the Agency to a Type C meeting request in which they agreed with the proposal to waive further toxicology testing of PRS-343 and provided input related to the design of the planned phase 2 proof of concept study of PRS-343 in combination with ramucirumab and paclitaxel. Based on this response and pending successful completion of the requested in-use and compatibility study, we continue to believe it can initiate this clinical study later this year.

On August 10, 2020, we entered into a Clinical Trial Collaboration and Supply Agreement (the "Lilly Agreement") with Eli Lilly and Company ("Lilly"), pursuant to which we and Lilly will collaborate in a Phase 2 Clinical Study to determine the safety and efficacy of our PRS-343 in combination with the standard of care regimen for advanced or metastatic gastric cancer in the second line, ramucirumab (Cyramza®) and paclitaxel, for the second-line treatment of HER2+ gastric cancer. Under the terms of the non-exclusive Lilly Agreement, we will sponsor the Study and Lilly will supply us with ramucirumab as well as provide input on certain clinical and regulatory aspects of the Study in exchange for jointly owning clinical data and inventions relating to the combination regimen that may arise from the



Study. Any material changes to the protocol for the Study, and any changes relating to ramucirumab, will require Lilly's prior written consent, which shall not be unreasonably withheld, conditioned or delayed.

- For our additional IO drug candidates, we are conducting activities relating to candidate identification, optimization and preclinical evaluation.
  - In March 2020, Servier notified us of its decision to discontinue co-development of two earlier preclinical stage programs for strategic reasons based upon an extensive portfolio review and focus exclusively on the two later-stage programs in the collaboration, PRS-344 and PRS-352.
  - We anticipate filing an IND application for PRS-344, a 4-1BB/PD-L1 bispecific, in 2021. We hold exclusive commercialization rights for PRS-344 in the United States and will receive royalties on ex-U.S. sales from Servier for this program.
  - We are also focused on completing the non-GLP preclinical work for PRS-352, a preclinical-stage program within the Servier alliance addressing undisclosed targets, and expects to hand it over this year to Servier.
  - We achieved a key preclinical milestone for one of the programs in the Seattle Genetics collaboration, a bispecific tumor-targeted costimulatory agonist, triggering a \$5 million milestone. The program is one of up to three potential programs in the Seattle Genetics alliance, and the achieved milestone further validates our approach and leadership in immuno-oncology bispecifics, complementing the encouraging clinical data seen with PRS-343. We have handed the program over to Seattle Genetics, who is responsible for further advancement and funding of the asset.

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 and six months ended June 30, 2020, we reported a net loss of \$5.0 million and \$8.5 million, respectively. For the three and six months ended June 30, 2019, we reported a net loss of \$11.8 million and \$22.1 million, respectively. As of June 30, 2020, we had an accumulated deficit of \$182.7 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 and six months ended June 30, 2020 and 2019 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 AstraZeneca, Servier and Seattle Genetics.

The revenues from AstraZeneca, Servier and Seattle Genetics 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, PRS-060/AZD1402 and our other respiratory programs, our IO programs, currently comprised of PRS-343 as well as multiple additional proprietary and partnered programs, including PRS-344. These programs consume a large proportion of our current, as well as projected, resources.

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

- internal recurring costs, such as 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 and six months ended June 30, 2020 and 2019

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenues	\$ 11,246	\$ 5,332	\$ 24,507	\$ 13,877
Research and development expenses	11,333	13,373	24,091	27,669
General and administrative expenses	4,568	4,189	8,927	9,121
Total operating expenses	15,901	17,562	33,018	36,790
Other (expense) income				
Interest income	129	449	448	955
Other (expense) income, net	(424)	23	(484)	(148)
Net loss	\$ (4,950)	\$ (11,758)	\$ (8,547)	\$ (22,106)

#### Revenues

The following table provides a comparison of revenues for the three months ended June 30, 2020 and 2019 (in thousands):

	Three Months Ended June 30,		Increase/(Decrease)
	2020	2019	
Customer revenue	\$ 10,930	\$ 4,723	\$ 6,207
Collaboration revenue	316	609	(293)
Total Revenue	\$ 11,246	\$ 5,332	5,914

- The \$6.2 million increase in customer revenue in the three months ended June 30, 2020 compared to the three months ended June 30, 2019 relates to higher Seattle Genetics revenue recorded upon the execution of a contractual amendment (approximately \$3.5 million) in the current period as well as the achievement of a \$5.0 million milestone

on the first collaboration program. This increase was partially offset by lower levels of activities with respect to our collaboration agreements with AstraZeneca.

- The \$0.3 million decrease in collaboration revenues in the three months ended June 30, 2020 compared to the three months ended June 30, 2019 relates to lower amounts of cost-sharing revenue due to the timing of manufacturing costs incurred with respect to our collaboration agreement with Servier.

The following table provides a comparison of revenues for the six months ended June 30, 2020 and 2019 (in thousands):

	Six Months Ended June 30,		Increase/(Decrease)
	2020	2019	
Customer revenue	\$ 19,815	\$ 11,949	\$ 7,866
Collaboration revenue	4,692	1,928	2,764
Total Revenue	\$ 24,507	\$ 13,877	10,630

- The \$7.9 million increase in customer revenue in the six months ended June 30, 2020 compared to the six months ended June 30, 2019 relates to higher Seattle Genetics revenue recorded upon the execution of a contractual amendment (approximately \$3.5 million) in the current period, as well as the achievement of a \$5.0 million milestone on that first program. This increase was partially offset by lower levels of activities with respect to our collaboration agreements with AstraZeneca.
- The \$2.8 million increase in collaboration revenues in the six months ended June 30, 2020 compared to the six months ended June 30, 2019 relates to higher amounts of revenue upon the termination of a preclinical program by Servier for strategic reasons.

#### Research and Development Expenses

The following table provides a comparison of the research and development expenses for the three months ended June 30, 2020 and 2019 (in thousands):

	Three Months Ended June 30,		Increase/(Decrease)
	2020	2019	
Respiratory	\$ 2,697	\$ 2,694	\$ 3
Immuno-oncology	2,585	4,074	(1,489)
Other R&D activities	6,051	6,605	(554)
Total	\$ 11,333	\$ 13,373	(2,040)

- Research and development in our respiratory programs remained flat period-over-period due to offsetting increases in clinical costs and decreases in manufacturing costs with respect to activities for PRS-060.
- The \$1.5 million decrease in our immuno-oncology programs period-over-period is due primarily to lower manufacturing and preclinical costs for our PRS-344 program on a period-over-period basis as the manufacturing costs were initiated and ramped up in the first half of 2019.
- The \$0.6 million decrease in other research and development activities expenses is mainly due to lower clinical costs on non-core programs (including Anemia), lower recruiting costs and lower overall travel costs related to COVID-19 restrictions. These decreases were partially offset by higher personnel costs and higher allocated IT and facility costs due to the move to a new R&D facility in Hallbergmoos, Germany in the first quarter of 2020.

The following table provides a comparison of the research and development expenses for the six months ended June 30, 2020 and 2019 (in thousands):

	Six Months Ended June 30,		Increase/(Decrease)
	2020	2019	
Respiratory	\$ 5,425	\$ 5,927	\$ (502)
Immuno-oncology	6,021	9,848	(3,827)
Other R&D activities	12,645	11,894	751
Total	\$ 24,091	\$ 27,669	(3,578)

- The \$0.5 million decrease for our respiratory programs period-over-period is due primarily to decreases in manufacturing costs with respect to activities for PRS-060 as well as lower activities for other proprietary respiratory programs.
- The \$3.8 million decrease in our immuno-oncology programs period-over-period is due primarily to lower manufacturing and preclinical costs for our PRS-344 program as the manufacturing costs were initiated and ramped up in the first half of 2019.
- The \$0.8 million increase in other research and development activities expenses is mainly due to higher personnel expenses, including bonus and stock compensation, higher allocated IT and facility costs due to the move to a new R&D facility in Hallbergmoos, Germany in the first quarter of 2020. These increases were slightly offset by lower clinical and preclinical costs related to non-core programs and lower overall travel costs related to COVID-19 restrictions.

#### *General and Administrative Expenses*

General and administrative expenses were \$4.6 million for the three months ended June 30, 2020 and \$4.2 million for the three months ended June 30, 2019. The period over period increase is due to higher legal and audit, as well as allocated IT and facility costs due to the move to a new R&D facility, offset slightly by lower personnel costs, lower professional services and lower overall travel costs related to COVID-19 restrictions.

General and administrative expenses were \$8.9 million for the six months ended June 30, 2020 and \$9.1 million for the six months ended June 30, 2019. The period over period fluctuation is due to lower personnel expenses, including bonus and stock compensation, lower professional services, and lower overall travel costs related to COVID-19 restrictions. These were slightly offset by higher legal costs, higher insurance premiums and higher investor relation costs.

#### *Other Income (Expense)*

Our other income (expense) was \$(0.3) million for the three months ended June 30, 2020 and \$0.5 million for the three months ended June 30, 2019. This was due to the impact of lower interest income (both lower invested amounts and lower interest rates in the current quarter) and a weakening U.S. dollar against the euro in the current quarter versus the prior year quarter.

Our other income (expense) was de minimis for the six months ended June 30, 2020 and \$0.8 million for the three months ended June 30, 2019. This was due to the impact of lower interest income (both lower invested amounts and lower interest rates in the current quarter) and a weakening U.S. dollar against the euro in the current year versus the prior year.

#### **Liquidity and Capital Resources**

Through June 30, 2020, 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 June 30, 2020, we had a total of \$77.2 million in cash, cash equivalents and investments. We have incurred losses in every period since inception including the three months ended June 30, 2020 and 2019, respectively, and have a total accumulated deficit of \$182.7 million as of June 30, 2020.

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):

	Six Months Ended June 30,	
	2020	2019
Net cash used in operating activities	\$ (24,909)	\$ (25,841)
Net cash provided by investing activities	6,010	7,596
Net cash provided by financing activities	416	280

Net cash used in operating activities for the six months ended June 30, 2020 and 2019 was \$24.9 million and \$25.8 million, respectively. The change is primarily driven by lower accounts payable, accrued expenses and deferred revenue mainly driven by revenue recognized for the discontinued Servier programs and the satisfaction of a performance obligation under the Seattle Genetics agreements during the six months ended June 30, 2020, offset by a \$13.6 million decrease in the net loss in 2020 compared to 2019.

The change in net cash provided by investing activities for the six months ended June 30, 2020 compared to the same period in 2019 is mainly attributable to lower overall investment balance in the current year compared to 2019 and an increase in purchases of property and equipment related to our move to a new R&D facility.

Financing activities for the six months ended June 30, 2020 and 2019 were \$0.4 million and \$0.3 million, respectively, due to higher proceeds from exercises of options and warrants along with proceeds from our employee stock purchase plan.

In August 2019, we entered into a sale agreement pursuant to which the Company may offer and sell shares of its common stock, from time to time, up to an aggregate gross sales proceeds of \$50.0 million through an "at the market offering" program under a shelf registration statement on Form S-3 (File No. 333-226725). To date, the Company has not sold any shares under this agreement.

In November 2019, we entered into a securities purchase agreement for a private placement with a select group of institutional investors. The private placement, referred to as the PIPE, consisted of 9,014,960 units, at a price of \$3.55 per unit, for gross proceeds of approximately \$32.0 million, and net proceeds to the Company of approximately \$31.0 million, after deducting placement agent fees and estimated offering expenses payable by us. Each unit consists of (i) one share of our common stock or 0.001 shares of non-voting Series C convertible preferred stock, and (ii) one immediately-exercisable warrant to purchase one share of our common stock with an exercise price of \$7.10.

We expect that our existing cash, cash equivalents and investments will enable us to fund our operational and capital expenditure requirements for at least twelve months from the issuance date of these financial statements. 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.

Due to the often-volatile nature of the financial markets, equity and debt financing(s) may be difficult to obtain. In addition, any unfavorable development or delay in the progress of our core clinical-stage programs including PRS-343 and PRS-060/AZD1402 could have a material adverse impact on our ability to raise additional capital.

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

#### **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, 2019 for a discussion of our critical accounting policies and estimates. There have been two material changes to the critical accounting policies during the six months ended June 30, 2020. These changes relate to revenue recognition and property and equipment and are described in "Note 2—Summary of Significant Accounting Policies" and "Note 5—Property and Equipment, net", respectively.

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. generally accepted accounting principles. 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 been significant changes to our revenue recognition, multiple-element and milestone accounting policies discussed in the Annual Report on Form 10-K for the fiscal year ended on December 31, 2019. Please refer to "Note 2—Summary of Significant Accounting Policies" for the updated revenue recognition policy that encompasses the changes to the historical revenue recognition, multiple-element and milestone accounting policies.

#### **Recently Issued Accounting Pronouncements**

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

#### **Smaller Reporting Company Status**

Currently, we qualify as a smaller reporting company.

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

- An opportunity for reduced disclosure obligations regarding executive compensation in 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 no longer 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 utilize the non-accelerated filer time-line requirements beginning with our annual report for the year ending December 31, 2020 and quarterly filings thereafter.

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 not effective as of June 30, 2020 as a result of the previously reported material weakness discussed below.

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

In connection with the preparation of our financial statements for the year ended December 31, 2019, we identified a material weakness in internal controls over our information technology general controls, or ITGC, related to change and access management process, and as a result, internal controls related to substantially all underlying financial statement accounts and disclosures are ineffective. We also identified deficiencies in internal controls over our quarterly revenue recognition procedures in that they were not operating effectively for a sufficient period of time in 2019 and certain controls related to the implementation of ASU No. 2014-09 "Revenue from Contracts with Customers" (Topic 606), or ASC 606, which, taken together, led us to determine that we had a material weakness in the revenue recognition process.

These material weaknesses created a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements may not be prevented or detected on a timely basis. No material financial statement misstatements were identified in relation to these material weaknesses in our internal control over financial reporting.

Management has implemented remediation plans to address the control deficiencies that led to these material weaknesses and continues to evaluate and take actions to improve our internal control over financial reporting. Our remediation plan with respect to our controls over ITGC includes reevaluation of our risk assessment and IT control environment within the finance department, developing an IT policy with a clear description on how the controls are designed to operate, and establishing or enhancing controls over system access, administration, and system changes. Our remediation plan with respect to our controls over our revenue recognition process includes, beginning with the first quarter of 2020, performing and retaining sufficient documentation of our operating controls. Our remediation plan with respect to ASC 606 implementation will involve instances of control execution with respect to any new and existing collaboration agreements and the allocation of up-front consideration to the identified performance obligations. All remediation plans are currently ongoing and progressing as planned.

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

**Changes in Internal Control over Financial Reporting**

There have been no changes in 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 June 30, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting other than the remediation efforts described above.



## 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, 2019, filed with the SEC on March 13, 2020, and to Item 1A of the Company's Quarterly Report on Form 10-Q, for the fiscal quarter ended March 31, 2020, filed with the SEC on May 11, 2020, 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. Those risk factors are further updated by the revised risk factor set forth below.

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

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

We initiated phase 1 studies for PRS-060/AZD1402 and PRS-343 in 2017 and initiated a phase 1 study of PRS-343 in combination with atezolizumab in 2018. We may experience delays in pursuing our current or future clinical trials, and any planned clinical trials may not begin on time, may require redesign, may not enroll sufficient healthy volunteers or patients in a timely manner, and may not be completed on schedule, if at all.

Additionally, clinical trials may be delayed, suspended or prematurely terminated because costs are greater than we anticipate or for a variety of reasons, such as:

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

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

Further, we may also encounter delays if a clinical trial is suspended or terminated by us, by any IRB or ethics committee, by a Data Safety Monitoring Board, or DSMB, or by the FDA or EMA, or other regulatory authority. A suspension or termination may be due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements, inspection of the clinical trial operations or trial site by the FDA, EMA or other regulatory authorities, exposing participants to health risks caused by unforeseen safety issues or adverse side effects, development of previously unseen safety issues, failure to demonstrate a benefit from using a drug candidate, or changes in governmental regulations or administrative actions. In July 2020, we announced that our phase 1 studies of PRS-343 have been placed on partial clinical hold by the FDA while we conduct an additional in-use and compatibility study requested by the FDA. Currently-enrolled patients may continue to receive treatment, although no new patients can be enrolled until resolution of this partial hold. We cannot predict the outcome of this additional study nor how long it will take to complete, or whether the outcome of the study will require additional work beyond that which we currently anticipate will be required before the partial clinical hold can be lifted. Therefore, we cannot predict with any certainty the schedule for commencement or completion of any currently ongoing, planned or future clinical trials.

Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of marketing approval for our product candidates.

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

**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.**

Exhibit Number	Exhibit Description	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File / Registration Number
<a href="#">10.1</a>	Pieris Pharmaceuticals, Inc. 2020 Employee, Director and Consultant Equity Incentive Plan.	Form 8-K (Exhibit 10.1)	June 29, 2020	001-37471
<a href="#">10.2</a>	Amendment No. 1 to the February 8, 2018 License and Collaboration Agreement by and among Pieris Pharmaceuticals, Inc. and Pieris Pharmaceuticals GmbH and Seattle Genetics, Inc. * ±			

Exhibit Number	Exhibit Description	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File / Registration Number
<a href="#">10.3</a>	Amendment No. 1 to the February 8, 2018 Platform Agreement by and among Pieris Pharmaceuticals, Inc. and Pieris Pharmaceuticals GmbH and Seattle Genetics, Inc.	* ±		
<a href="#">31.1</a>	Certification of Principal Executive Officer Pursuant to Rules 12a-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.	*		
<a href="#">31.2</a>	Certification of Principal Financial Officer and Principal Accounting Officer Pursuant to Rules 12a-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.	*		
<a href="#">32.1</a>	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.	**		
<a href="#">32.2</a>	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.			
±	Confidential treatment received as to portions of the exhibit. Confidential materials omitted and filed separately with the SEC.			



**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.**

August 10, 2020

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

August 10, 2020

By: /s/ Thomas Bures  
Thomas Bures  
Vice President, Finance and Treasurer  
*(Principal Financial Officer and Principal Accounting Officer)*

**AMENDMENT NO. 1 TO THE FEBRUARY 8, 2018 LICENSE AND COLLABORATION  
BY AND AMONG**

**PIERIS PHARMACEUTICALS, INC. AND PIERIS PHARMACEUTICALS GMBH**

**AND**

**SEATTLE GENETICS, INC.**

This amendment to the license and collaboration agreement (the “**Amendment No. 1**”) is entered into as of June 2, 2020 (the “**Amendment No. 1 Effective Date**”) by and among Pieris Pharmaceuticals, Inc., a Nevada corporation located at 255 State Street, 9th floor, Boston, MA 02109 and Pieris Pharmaceuticals GmbH, a company organized and existing under the laws of Germany located at Zeppelinstrasse 3, 85399, Hallbergmoos, Germany (collectively and together with their Affiliates, “**PIRS**”), and Seattle Genetics, Inc., a Delaware corporation located at 21823 30th Drive SE, Bothell, WA 98021 (together with its Affiliates, “**SGEN**”). SGEN and PIRS are individually referred to herein as a “**Party**” and collectively, as the “**Parties**”.

**RECITALS**

**WHEREAS**, on February 8, 2018, the Parties entered into the License and Collaboration Agreement (the “**Collaboration Agreement**”) to grant to each other licenses to certain patents and know-how in order to research, develop, manufacture, and commercialize certain novel products in accordance with the Collaboration Agreement; and

**WHEREAS**, the Parties wish to amend the Collaboration Agreement by this Amendment No. 1 in order to extend the timeframe by which SGEN shall nominate the second and third SGEN Antibody Targets in exchange for the consideration set forth herein.

**NOW, THEREFORE**, in consideration of the promises and mutual covenants herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

**1. Research and Development**

1.1 Second and Third SGEN Antibody Targets. The Parties hereby agree to extend the deadline designated under Section 4.1.1.3 of the Collaboration Agreement for SGEN to nominate the second and third SGEN Antibody Targets, such that SGEN shall now nominate the second SGEN Antibody Target and third SGEN Antibody Target by [\*\*\*]. For avoidance of doubt, SGEN shall continue to be obligated to nominate the [\*\*\*] but shall not be obligated to nominate the [\*\*\*].

1.2 Go/No-Go DP. Notwithstanding anything to the contrary in the Collaboration Agreement, the Parties agree that the [\*\*\*] as specified in Section 7.4 of the Collaboration Agreement for the Research Candidate targeting [\*\*\*] and [\*\*\*] is deemed achieved as of [\*\*\*] such that (a) such Research Candidate shall become a Collaboration Product effective upon payment of the Go/No-Go Decision Fee and (b) SGEN shall pay the Go/No-Go Decision Fee

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[\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

within [\*\*\*] days of receipt of the applicable invoice from PIRS on or after [\*\*\*]. The Parties further agree that this Amendment No. 1 serves as the written notice required for notification of the [\*\*\*] under Section 1.114 (i) of the Collaboration Agreement. For clarity, all provisions of the Collaboration Agreement relating to Collaboration Products (including but not limited to Section 4.4.2.3, relating to SGEN's sole discretion to issue (or not issue) an Option Notice for the [\*\*\*] Collaboration Product to reach the CoDev Decision Point) shall continue to apply.

1.3 Press Release. In the event PIRS decides to issue a press release pursuant to Section 13.4.2(b), or the last sentence of Section 13.4.2, of the Collaboration Agreement, the Parties agree to commence drafting by no later than [\*\*\*], with the goal of finalizing a mutually approved press release no later than [\*\*\*].

## **2. Miscellaneous**


2.1 Capitalized Terms. Unless defined in this Amendment No. 1, capitalized terms shall have the same meaning as that attributed to them in the Collaboration Agreement.

2.2 Written Amendment. The Parties acknowledge that this is an amendment to the Collaboration Agreement reduced to writing and signed by the respective authorized officers of the Parties as set forth in Section 17.12 of the Collaboration Agreement.


2.3 Effectiveness. The Amendment No. 1 shall enter into force as of its Amendment No. 1 Effective Date.

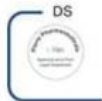
2.4 Entire Agreement. As of the Amendment No. 1 Effective Date, this Amendment No. 1 shall form an integral part of the Collaboration Agreement. Except as explicitly and specifically modified and amended herein, all of the terms, provisions, requirements and specifications contained in the Collaboration Agreement remain in full force and effect.

IN WITNESS WHEREOF, the Parties have caused this Amendment No. 1 to be executed by their duly authorized representatives.

DocuSigned by:  
  
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\_\_\_\_\_  
Stephen S. Yoder  
President & CEO  
Pieris Pharmaceuticals, Inc.

DocuSigned by:  
  
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Clay B. Siegall, Ph.D.  
President & CEO  
Seattle Genetics, Inc.

DocuSigned by:  
  
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Stephen S. Yoder  
Managing Director  
Pieris Pharmaceuticals GmbH







**AMENDMENT NO. 1 TO THE FEBRUARY 8, 2018 PLATFORM AGREEMENT BY  
AND AMONG**

**PIERIS PHARMACEUTICALS, INC. AND PIERIS PHARMACEUTICALS GMBH**

**AND**

**SEATTLE GENETICS, INC.**

This amendment to the Non-Exclusive Anticalin® Platform Technology License Agreement (the “**Amendment No. 1**”) is entered into as of June 2, 2020 (the “**Amendment No. 1 Effective Date**”) by and among Pieris Pharmaceuticals, Inc., a Nevada corporation located at 255 State Street, 9th floor, Boston, MA 02109 and Pieris Pharmaceuticals GmbH, a company organized and existing under the laws of Germany located at Zeppelinstrasse 3, 85399, Hallbergmoos, Germany (collectively and together with their Affiliates, “**PIRS**”), and Seattle Genetics, Inc., a Delaware corporation located at 21823 30th Drive SE, Bothell, WA 98021 (together with its Affiliates, “**SGEN**”). SGEN and PIRS are individually referred to herein as a “**Party**” and collectively, as the “**Parties**”.

**RECITALS**

**WHEREAS**, on February 8, 2018, the Parties entered into the Non-Exclusive Anticalin® Platform Technology License Agreement (the “**Platform Agreement**”) to grant SGEN a non-exclusive license to certain intellectual property related to Pieris’ Platform Technology in order to research, develop, manufacture, and commercialize Licensed Products in Licensed Fields and Licensed Territories; and

**WHEREAS**, the Parties wish to amend the Platform Agreement by this Amendment No. 1 in order to amend the time in which SGEN shall pay PIRS the milestone payment related to the initiation of a GLP Tox Study of the [\*\*\*] Licensed Product.

**NOW, THEREFORE**, in consideration of the promises and mutual covenants herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

**1. Milestone Payments**

1.1 Initiation of GLP Tox Study Milestone Payment. Notwithstanding anything to the contrary in the Platform Agreement, the Parties hereby agree that the initiation of the GLP Tox Study, as specified in Section 3.3 of the Platform Agreement, for the [\*\*\*] Licensed Product will be deemed achieved on [\*\*\*], such that SGEN will pay the milestone payment to PIRS for initiation of the GLP Tox Study for the [\*\*\*] Licensed Product within [\*\*\*] days after receiving the applicable invoice from PIRS on or after [\*\*\*]. For clarity, the [\*\*\*] Licensed Product includes the [\*\*\*] targeting Anticalin Protein and the [\*\*\*] as defined in the February 8, 2020 License and Collaboration Agreement between the Parties.

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[\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

## **2. Miscellaneous**

2.1 Capitalized Terms. Unless defined in this Amendment No. 1, capitalized terms shall have the same meaning as that attributed to them in the Platform Agreement.

2.2 Written Amendment. The Parties acknowledge that this is an amendment to the Platform Agreement reduced to writing and signed by the respective authorized officers of the Parties as set forth in Section 10.11 of the Platform Agreement.

2.3 Effectiveness. The Amendment No. 1 shall enter into force as of its Amendment No. 1 Effective Date.

2.4 Entire Agreement. As of the Amendment No. 1 Effective Date, this Amendment No. 1 shall form an integral part of the Platform Agreement. Except as explicitly and specifically modified and amended herein, all of the terms, provisions, requirements and specifications contained in the Platform Agreement remain in full force and effect.

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IN WITNESS WHEREOF, the Parties have caused this Amendment No. 1 to be executed by their duly authorized representatives.

DocuSigned by:  
  
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Stephen S. Yoder  
President & CEO  
Pieris Pharmaceuticals, Inc.

DocuSigned by:  
  
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Clay B. Siegall, Ph.D.  
President & CEO  
Seattle Genetics, Inc.

DocuSigned by:  
  
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Stephen S. Yoder  
Managing Director  
Pieris Pharmaceuticals GmbH





**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: August 10, 2020

/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: August 10, 2020

/s/ Thomas Bures

Thomas Bures

Title: Vice President, Finance and Treasurer (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 June 30, 2020 (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: August 10, 2020

/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 June 30, 2020 (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: August 10, 2020

/s/ Thomas Bures

Thomas Bures

Title: Vice President, Finance and Treasurer  
(principal financial officer and principal accounting officer)