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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 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

PIERIS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Nevada	**30-0784346**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
255 State Street 9th Floor	
Boston, MA	
United States	**02109**
(Address of principal executive offices)	**(Zip Code)**

857-246-8998

Registrant's telephone number, including area code

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

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

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

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

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

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

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

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

As of October 30, 2020, the registrant had 55,970,580 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 or Quarterly Reports on Form 10-Q, which may cause our or our industry's actual results, levels of activity, performance or achievements expressed or implied by these forward-looking statements to differ materially.

Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time and it is not possible for us to predict all risk factors, nor can we address the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause our actual results to differ materially from those contained in any forward-looking statements. Actual results could differ materially from our forward-looking statements due to a number of factors, including, without limitation, risks related to: the results of our research and development activities, including uncertainties relating to the discovery of potential drug candidates and the preclinical and ongoing or planned clinical testing of our drug candidates; the early stage of our drug candidates presently under development; our 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 U.S. Food and Drug Administration's, or FDA's, views as to the 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 Reports on Form 10-Q, for the fiscal quarters ended March 31, 2020 and June 30, 2020, filed with the SEC on May 11, 2020, and August 10, 2020, respectively, 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. $1.1699 based on information provided by Thomson Reuters as of September 30, 2020.

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements.

PIERIS PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(unaudited, in thousands)

	September 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 66,890	$ 62,260
Short term investments	15,750	41,894
Accounts receivable	2,944	6,787
Prepaid expenses and other current assets	3,074	4,072
Total current assets	88,658	115,013
Property and equipment, net	21,395	19,502
Operating lease right-of-use assets	3,678	3,436
Other non-current assets	1,993	3,146
Total assets	$ 115,724	$ 141,097
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,154	$ 5,803
Accrued expenses and other current liabilities	7,488	9,944
Deferred revenues, current portion	10,045	11,256
Total current liabilities	19,687	27,003
Deferred revenue, net of current portion	36,919	47,258
Operating lease liabilities	15,427	15,484
Total liabilities	72,033	89,745
Stockholders' equity:		
Preferred stock	—	—
Common stock	56	55
Additional paid-in capital	241,423	227,468
Accumulated other comprehensive loss	(782)	(1,995)
Accumulated deficit	(197,006)	(174,176)
Total stockholders' equity	43,691	51,352
Total liabilities and stockholders' equity	$ 115,724	$ 141,097

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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenue				
Customer revenue	$ 2,578	$ 3,589	$ 22,393	$ 15,538
Collaboration revenue	361	11,543	5,053	13,471
Total revenue	2,939	15,132	27,446	29,009
Operating expenses				
Research and development	11,822	13,211	35,913	40,880
General and administrative	4,116	4,835	13,043	13,956
Total operating expenses	15,938	18,046	48,956	54,836
Loss from operations	(12,999)	(2,914)	(21,510)	(25,827)
Other income (expense)				
Interest income	55	377	503	1,332
Other expense	(1,339)	(55)	(1,823)	(203)
Net loss	$ (14,283)	$ (2,592)	$ (22,830)	$ (24,698)
Other comprehensive income:				
Foreign currency translation	632	1,636	1,462	1,908
Unrealized (loss) gain on available-for-sale securities	(350)	374	(249)	377
Comprehensive loss	$ (14,001)	$ (582)	$ (21,617)	$ (22,413)
Net loss per share				
Basic and diluted	$ (0.26)	$ (0.05)	$ (0.42)	$ (0.50)
Weighted average number of common shares outstanding				
Basic and diluted	54,340	49,353	53,976	49,805

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 September 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 June 30, 2019	8	$ —	49,262	$ 49	$ 192,956	$ (2,707)	$ (170,813)	$ 19,485
Net loss	—	—	—	—	—	—	(2,592)	(2,592)
Foreign currency translation adjustment	—	—	—	—	—	1,636	—	1,636
Unrealized gains on investments	—	—	—	—	—	374	—	374
Stock based compensation expense	—	—	—	—	1,518	—	—	1,518
Issuance of common stock resulting from exercise of stock options	—	—	61	—	121	—	—	121
Issuance of common stock resulting from exercise of warrants	—	—	70	—	100	—	—	100
Balance as of September 30, 2019	8	$ —	49,393	$ 49	$ 194,695	$ (697)	$ (173,405)	$ 20,642
Balance as of June 30, 2020	14	$ —	52,399	$ 52	$ 230,407	$ (1,064)	$ (182,723)	$ 46,672
Net loss	—	—	—	—	—	—	(14,283)	(14,283)
Foreign currency translation adjustment	—	—	—	—	—	632	—	632
Unrealized loss on investments	—	—	—	—	—	(350)	—	(350)
Stock based compensation expense	—	—	—	—	1,396	—	—	1,396
Issuance of common stock pursuant to at the market offering program, net of $0.4 million in offering costs	—	—	3,571	4	9,620	—	—	9,624
Balance as of September 30, 2020	14	$ —	55,971	$ 56	$ 241,423	$ (782)	$ (197,006)	$ 43,691

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 Nine Months Ended September 30, 2019 and 2020

	Preferred shares		Common shares					
	No. of shares	Share capital	No. of shares	Share capital	Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total Stockholders' equity
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	—	—	—	—	—	—	(24,698)	(24,698)
Foreign currency translation adjustment	—	—	—	—	—	1,908	—	1,908
Unrealized gain on investments	—	—	—	—	—	377	—	377
Stock based compensation expense	—	—	—	—	4,260	—	—	4,260
Issuance of common stock resulting from exercise of stock options	—	—	111	—	218	—	—	218
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	—	—	73	—	105	—	—	105
Preferred stock conversion	5	—	(5,000)	(5)	5	—	—	—
Balance as of September 30, 2019	8	$ —	49,393	$ 49	$ 194,695	$ (697)	$ (173,405)	$ 20,642
Balance as of December 31, 2019	11	$ —	55,212	$ 55	$ 227,468	$ (1,995)	$ (174,176)	$ 51,352
Net loss	—	—	—	—	—	—	(22,830)	(22,830)
Foreign currency translation adjustment	—	—	—	—	—	1,462	—	1,462
Unrealized loss on investments	—	—	—	—	—	(249)	—	(249)
Stock based compensation expense	—	—	—	—	3,916	—	—	3,916
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
Issuance of common stock pursuant to at the market offering program, net of $0.4 million in offering costs	—	—	3,571	4	9,620	—	—	9,624
Preferred stock conversion (Series D)	3	—	(3,000)	(3)	3	—	—	—
Balance as of September 30, 2020	14	$ —	55,971	$ 56	$ 241,423	$ (782)	$ (197,006)	$ 43,691

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)

	Nine Months Ended September 30,	
	2020	**2019 [1]**
Operating activities:		
Net loss	$ (22,830)	$ (24,698)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	1,623	367
Right-of-use asset amortization	(103)	315
Stock-based compensation	3,916	4,260
Other non-cash transactions	(293)	90
Changes in operating assets and liabilities	(14,792)	(18,827)
Net cash used in operating activities	(32,479)	(38,493)
Investing activities:		
Purchases of property and equipment	(2,148)	(1,286)
Proceeds from maturity of investments	67,687	61,767
Purchases of investments	(41,178)	(48,762)
Net cash provided by investing activities	24,361	11,719
Financing activities:		
Proceeds from exercise of stock options	271	218
Proceeds from exercise of warrants	—	105
Proceeds from employee stock purchase plan	145	178
Issuance of common stock, net of issuance costs	9,624	—
Net cash provided by financing activities	10,040	501
Effect of exchange rate change on cash and cash equivalents	2,708	(2,526)
Net decrease in cash and cash equivalents	4,630	(28,799)
Cash and cash equivalents at beginning of period	62,260	74,867
Cash and cash equivalents at end of period	$ 66,890	$ 46,068
Supplemental cash flow disclosures:		
Net unrealized (loss)/gain on investments	$ (319)	$ 469
Property and equipment included in accounts payable	$ 370	$ 198

[1] 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-4Rα 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 September 30, 2020, the Company had cash, cash equivalents and investments of $82.6 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 nine months ended September 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 nine months ended September 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*, 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 nine months ended September 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 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 September 30, 2019			Nine Months Ended September 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	$ 14,498	$ (10,909)	$ 3,589	$ 26,966	$ (11,428)	$ 15,538
Collaboration revenue	634	10,909	11,543	2,043	11,428	13,471
Total Revenue	$ 15,132	$ —	$ 15,132	$ 29,009	$ —	$ 29,009

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. 2016-02, ASC 842, *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 (in thousands):

	Nine Months Ended September 30, 2019		
	Previously reported	ASC 842 Adjustment during the period	As adjusted
Operating activities:			
Net loss	$ (24,698)	$ —	$ (24,698)
Adjustments to reconcile net loss to net cash provided by operating activities:			
Depreciation	367	—	367
Right-of-use asset amortization	—	315	315
Stock-based compensation	4,260	—	4,260
Deferred rent expense	853	(853)	—
Other non-cash transactions	90	—	90
Changes in operating assets and liabilities	(19,365)	538	(18,827)
Net cash used in operating activities	$ (38,493)	$ —	$ (38,493)

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Seagen	$ 366	$ 576	$ 9,326	$ 2,005
AstraZeneca	2,182	2,903	7,227	12,811
Servier	391	11,653	10,893	14,193
Total Revenue	$ 2,939	$ 15,132	$ 27,446	$ 29,009

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	712	632
Seagen	764	450
Total potential milestone payments	$ 2,587	$ 2,042

Strategic Partnerships

Seagen

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

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

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

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

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

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

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

As a result, management concluded there weresix separate performance obligations at the inception of the Seagen Agreements: (i) three combined performance obligations, each comprised of a non-exclusive platform technology license, a co-exclusive

candidate research license, and research and development services for the first three approved Seagen antibody target programs, (ii) two performance obligations each comprised of a material right for an antibody target swap option for the first and the second approved Seagen antibody target for no additional consideration, and (iii) one performance obligation comprised of the participation on the various governance committees.

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

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

The amounts allocated to the performance obligations for the three research programs will be recognized on a proportional performance basis through the completion of each respective estimated research term of the individual research programs. The amounts allocated to the material right for the antibody target swap option will be recognized either at the time the material right expires or, if exercised, on a proportional performance basis over the estimated research term for that program. The amounts allocated to the participation on each of the committees will be recognized straight-line over the anticipated research term for all research programs. As of September 30, 2020, there was $20.2 million of aggregate transaction price allocated to remaining performance obligations.

In June 2020, Seagen and the Company entered into amendments to the Seagen Agreements, or together, the Amendment. The Amendment extended the deadline for Seagen 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 nine months ended September 30, 2020. The Company also recorded $5.0 million of milestone revenue due from Seagen 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 Seagen Agreements, the Company is eligible to receive other various research, development, commercial and sales milestones. There is uncertainty that the events to obtain the research and development milestones will be achieved given the nature of clinical development and the stage of the Company's technology. With the exception of the previously discussed achieved milestone, the Company has determined that all other research and development milestones will be constrained until it is deemed probable that a significant revenue reversal will not occur.

As of September 30, 2020, there were $3.4 million and $13.5 million of current and non-current deferred revenue, respectively, related to the Seagen Agreements.

AstraZeneca

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

In addition to the Company's lead inhaled drug candidate, 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 that the licenses granted for the AstraZeneca Collaboration Products should be combined with the research services for the AstraZeneca Collaboration Products, as the licenses are not capable of being distinct. A third party would not be able to provide the research and development services, due to the specific nature of the intellectual property and knowledge required to perform

the services, and AstraZeneca could not benefit from the licenses without the corresponding services. The Company also determined that each of the phase 1 services and the phase 2a services for the AstraZeneca Lead Product were distinct and that the participation on the various committees was also distinct, as all of the phase 1 services, phase 2a services and the committee services could be performed by an outside party. The Company determined that the commercial licenses for the AstraZeneca Collaboration Products granted at the inception of the arrangement should be combined with the development licenses for the AstraZeneca Collaboration Products as the company would not benefit from the commercial license without the ability to develop each product.

As a result, management concluded that there were16 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 September 30, 2020, there was $21.9 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 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 September 30, 2020, there were $0.9 million and $17.9 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 September 30, 2020, the remaining balance of the asset recognized from transaction costs to obtain the AstraZeneca contract was $ 0.7 million. Amortization during the three and nine months ended September 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 withone 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 thefour 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 forthree 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 were10 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 September 30, 2020, there was $11.2 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 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 September 30, 2020, there were $5.8 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 September 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 nine months ended September 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 September 30, 2020. Additions to deferred revenue were $1.6 million during the nine months ended September 30, 2020. Reductions to deferred revenue were $0.6 million and $14.3 million for the three and nine months, respectively, ended September 30, 2020.

4. Collaboration agreements

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 on 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 the second-line treatment of advanced or metastatic gastric cancer, 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.

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

5. Cash, cash equivalents and investments

As of September 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)
September 30, 2020				
Money market funds, included in cash equivalents	$ 54,910	$ 54,910	$ —	$ —
Investments - U.S. treasuries	8,999	8,999	—	—
Investments - Corporate bonds	6,751	—	6,751	—
Total	$ 70,660	$ 63,909	$ 6,751	$ —
December 31, 2019				
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	—
Total	$ 89,278	$ 52,684	$ 36,594	$ —

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 September 30, 2020.

Investments as of September 30, 2020 consisted of the following (in thousands):

	Contractual maturity (in days)	Amortized Cost	Unrealized gains	Unrealized losses	Fair Value
Investments					
U.S. treasuries	48-78	$ 9,215	$ —	$ (216)	$ 8,999
Corporate bonds	2-64	6,854	2	(105)	6,751
Total		$ 16,069	$ 2	$ (321)	$ 15,750

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

As of September 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.

6. Property and equipment, net

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

	September 30, 2020	December 31, 2019
Laboratory furniture and equipment	$ 10,447	$ 11,635
Office furniture and equipment	2,019	479
Computer equipment	373	245
Leasehold improvements	13,448	10,710
Property and equipment, cost	26,287	23,069
Accumulated depreciation	(4,892)	(3,567)
Property and equipment, net	$ 21,395	$ 19,502

7. Accrued Expenses

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

	September 30, 2020	December 31, 2019
Accrued accounts payable	$ 1,275	$ 4,251
Compensation expense	2,656	2,870
Research and development fees	1,833	1,048
Lease liabilities	934	733
Audit and tax fees	126	522
Other current liabilities	664	520
Total	$ 7,488	$ 9,944

8. Net Loss per Share

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

For the three months ended September 30, 2020 and 2019, and as calculated using the treasury stock method, approximately37.3 million and 21.7 million of weighted average shares, respectively, were excluded from the calculation of diluted weighted average shares outstanding as their effect was antidilutive.

9. Stockholders' Equity

The Company had 300,000,000 shares authorized and 55,970,580 and 55,212,437 shares of common stock issued and outstanding as of September 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 September 30, 2020. The Company had10,000,000 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 September 30, 2020 and December 31, 2019, respectively.
- Series B Convertible, 5,000 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively.
- Series C Convertible, 3,522 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively.
- Series D Convertible, 3,000 and zero shares issued and outstanding at September 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 were canceled and no additional awards will be made thereunder. All outstanding awards under the 2019 Plan will remain in effect and any awards forfeited from the outstanding awards will be allocated back into the 2020 Plan. There were approximately 1,579,678 shares remaining and available for grant under the 2019 Plan that terminated upon 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 of5,000 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 of9,014,960 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, or0.001 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. 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 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 of3,000 shares of Series D Preferred Stock. The Company designated3,000 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 into1,000 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 Sales Agreement

In August 2019, the Company entered into a sales 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, or the ATM Program, under a shelf registration statement on Form S-3. In the third quarter of 2020, the Company sold 3,571,428 shares at a price of $2.80 per share under the ATM Program. The transaction resulted in gross proceeds of $10.0 million, less a 3% contractual commission incurred for the sales agent, resulting in $9.7 million in net proceeds to the Company.

10. 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 off 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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating lease costs	$ 360	$ 419	$ 1,134	$ 1,060
Variable lease costs (1)	192	71	536	207
Total lease cost	$ 552	$ 490	$ 1,670	$ 1,267

(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 September 30, 2020
Weighted-average remaining lease term (years)	11.7
Weighted-average discount rate	10.5 %

Cash paid for amounts included in the measurement of the lease liabilities was $0.6 million and $1.5 million for the three and nine months ended September 30, 2020.

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

	Total
2020	$ 628
2021	2,513
2022	2,344
2023	2,309
2024	2,309
Thereafter	17,512
Total undiscounted lease payments	27,615
Less: present value adjustment	(11,254)
Present value of lease liabilities	$ 16,361

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 Reports on Form 10-Q for the quarter ended March 31, 2020 and June 30, 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-4Rα 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 Seagen (formerly known as Seattle Genetics, Inc.), both in IO. Our programs include:

- PRS-060/AZD1402, our lead respiratory program partnered with AstraZeneca, a drug candidate that antagonizes IL-4Rα, 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.

- 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 Seagen.

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 (≥ 35ppb). 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.

AstraZeneca submitted the first Clinical Trial Application for a global phase 2a study of PRS-060/AZD1402. Dependent on regulatory approval, site initiation and patient screening are expected to begin this year. The first patients will be dosed thereafter, which we anticipate will be in the first quarter of next year, triggering a milestone payment from AstraZeneca. The phase 2a study will be performed using a dry powder formulation and will evaluate the efficacy, safety, and pharmacokinetics of PRS-060/AZD1402 in moderate uncontrolled asthmatics over four weeks with FEV1 improvement as the primary endpoint, following a four-week dosing arm in moderate controlled asthmatics to establish the safety and pharmacokinetics of the dry powder formulation. The study of PRS-060/AZD1402, which is being developed for the treatment of moderate-to-severe asthma, is being sponsored, funded, and delivered by AstraZeneca. Upon completion of that study, Pieris will have the options to co-develop and, subsequently, co-commercialize PRS-060/AZD1402 in the United States.

- Our additional respiratory programs within and outside of the AstraZeneca alliance are in the discovery stage. AstraZeneca initiated the fourth program in the collaboration in the third quarter, taking full advantage of all available potential new project starts envisioned in the alliance. We retain co-development and co-commercialization rights to two out of the four programs beyond PRS-060/AZD1402. Outside of the AstraZeneca collaboration, Pieris continues to advance several proprietary respiratory programs, which are in the discovery stage.

- We presented additional detailed data from the phase 1 monotherapy study and atezolizumab combination study of PRS-343 in an oral presentation session at the European Society for Medical Oncology, or ESMO, Virtual Congress in September 2020. As of the July 2020 cutoff date, 74 patients had been enrolled in the monotherapy study, including 21 additional patients enrolled in the active dose cohorts (≥2.5 mg/kg) since the data were presented at the Society for Immunotherapy of Cancer 2019 Annual Meeting, and 41 patients had been enrolled in the atezolizumab combination therapy study. In the monotherapy study, out of 33 response-evaluable patients at the time of the data cutoff of July 27, 2020, according to RECIST 1.1, one patient with stage 4 rectal adenocarcinoma achieved a confirmed complete response at the 18 mg/kg Q2W dose (cohort 13b), three patients achieved a partial response at the 8 mg/kg Q2W dose (cohort 11b), and stable disease was observed in 13 patients as best response out of 33 evaluable patients across the predicted active dose ranges (cohorts 9-13b), translating to an ORR of 12% and a DCR of 52%. Additionally, a significant expansion of CD8+ T cells in the tumor microenvironment of responders and a substantial increase of peripheral soluble 4-1BB were observed in the active dose cohorts, suggesting 4-1BB-mediated target engagement. PRS-343 also showed an acceptable safety profile at all doses and schedules tested in each clinical study. In the atezolizumab combination trial, seven dose cohorts have been evaluated at a Q3W dosing schedule ranging from 0.05 mg/kg to 8 mg/kg in combination with a fixed 1200 mg dose of atezolizumab. In that trial, under RECIST 1.1, four patients achieved a confirmed partial response at active dose levels. The Company plans to advance PRS-343 into a phase 2 study for the second-line treatment of gastric cancer in combination with ramucirumab and paclitaxel.

  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 stability and compatibility study requested by the FDA. Treatment of currently-enrolled patients may continue, although no new patients can be enrolled until resolution of the partial hold. The Company has completed the in-use studies it deems necessary in connection with the partial clinical hold of the PRS-343 phase 1 studies. As part of the now-completed studies that supported a robust process for administration of PRS-343 in the clinical setting, we have optimized the level of an existing excipient to enhance the stability of PRS-343 under prescribed as well as stressed conditions that could occur in preparation of the drug candidate for patient administration in the real-world clinical setting.
  We recently provided these results to FDA in the form of a Type A meeting request to elicit the Agency's feedback on the adequacy of the stability data supporting the use of the existing excipient as a co-diluent for PRS-343 and the clinical proposal to initiate continued development of PRS-343. We believe that we have generated a robust dataset

which will allow FDA to lift the hold upon consideration of our forthcoming Complete Response Letter, which we expect to submit in December, pending a positive Type A meeting. As a result of this decision to formally engage FDA via a Type A meeting, we now expect to initiate the phase 2 study of PRS-343 in combination with ramucirumab and paclitaxel in the second line of treatment of HER2-positive gastric cancer next year.
In August 2020, we entered into a Clinical Trial Collaboration and Supply Agreement, or the Lilly Agreement, with Eli Lilly and Company, or 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.

- For our additional IO drug candidates, we are conducting activities relating to candidate identification, optimization and preclinical evaluation.

    - We anticipate filing an IND application for PRS-344, a 4-1BB/PD-L1 bispecific in 2021 and are currently completing CMC activities associated with the scale-up manufacture of the drug-product, while preparing for an IND submission to FDA. 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 intend to complete non-GLP preclinical work for PRS-352 this year before handing the program over to Servier, who would be fully responsible for further development. PRS-352 is a preclinical-stage program within the Servier alliance addressing undisclosed targets for immuno-oncology.
    - We achieved a key preclinical milestone for one of the programs in the Seagen collaboration, a bispecific tumor-targeted costimulatory agonist, triggering a $5 million milestone. We have handed the program over to Seagen, which is responsible for further advancement and funding of the asset. The program is one of up to three potential programs in the Seagen alliance, and we believe the achieved milestone further validates our approach and leadership in immuno-oncology bispecifics, complementing the encouraging clinical data seen with PRS-343.

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 nine months ended September 30, 2020, we reported a net loss of $14.3 million and $22.8 million, respectively. For the three and nine months ended September 30, 2019, we reported a net loss of $2.6 million and $24.7 million, respectively. As of September 30, 2020, we had an accumulated deficit of $197.0 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 nine months ended September 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 Seagen.

The revenues from AstraZeneca, Servier and Seagen 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 nine months ended September 30, 2020 and 2019

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenues	$ 2,939	$ 15,132	$ 27,446	$ 29,009
Research and development expenses	11,822	13,211	35,913	40,880
General and administrative expenses	4,116	4,835	13,043	13,956
Total operating expenses	15,938	18,046	48,956	54,836
Other (expense) income				
Interest income	55	377	503	1,332
Other (expense) income, net	(1,339)	(55)	(1,823)	(203)
Net loss	$ (14,283)	$ (2,592)	$ (22,830)	$ (24,698)

Revenues

The following table provides a comparison of revenues (in thousands):

	Three Months Ended September 30,		
	2020	2019	Increase/(Decrease)
Customer revenue	$ 2,578	$ 3,589	$ (1,011)
Collaboration revenue	361	11,543	(11,182)
Total Revenue	$ 2,939	$ 15,132	(12,193)

- The $1.0 million decrease in customer revenue in the three months ended September 30, 2020 compared to the three months ended September 30, 2019 relates to overall lower levels of activities with AstraZeneca, Seagen and Servier.

- The $11.2 million decrease in collaboration revenues in the three months ended September 30, 2020 compared to the three months ended September 30, 2019 relates to higher amounts of Servier revenue recorded upon the termination of the co-development of PRS-332 by Servier for strategic reasons in the prior year, as well as lower amounts of Servier cost-sharing revenue due to the timing of manufacturing costs incurred in the current year.

The following table provides a comparison of revenues (in thousands):

	Nine Months Ended September 30,		
	2020	2019	Increase/(Decrease)
Customer revenue	$ 22,393	$ 15,538	$ 6,855
Collaboration revenue	5,053	13,471	(8,418)
Total Revenue	$ 27,446	$ 29,009	(1,563)

- The $6.9 million increase in customer revenue for the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019 relates to higher Seagen 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 agreement with AstraZeneca.

- The $8.4 million decrease in collaboration revenues in the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019 relates to higher amounts of Servier revenue recorded upon the termination of the co-development of PRS-332 by Servier for strategic reasons in the prior year compared to revenue recorded upon the termination of a preclinical program by Servier for strategic reasons in the current year. In addition, lower amounts of cost-sharing revenue were recorded in the current year due to the timing of manufacturing costs incurred with respect to our collaboration agreement with Servier.

Research and Development Expenses

The following table provides a comparison of the research and development expenses (in thousands):

	Three Months Ended September 30,		
	2020	2019	Increase/(Decrease)
Respiratory	$ 2,359	$ 3,241	$ (882)
Immuno-oncology	3,473	4,102	(629)
Other R&D activities	5,990	5,868	122
Total	$ 11,822	$ 13,211	(1,389)

- The $0.9 million decrease in our respiratory programs is due to lower clinical costs and manufacturing costs with respect to activities for PRS-060 offset slightly by investment in other proprietary respiratory programs in the current year.

- The $0.6 million decrease in our immuno-oncology programs period-over-period is due primarily to lower investment across partnered and proprietary programs due to prioritization efforts which were partially offset by higher PRS-343 translational costs as we develop biomarker testing capabilities.

- The $0.1 million increase in other research and development activities expenses is mainly due to higher license fees 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. These increases were partially offset by lower overall travel costs related to COVID-19 restrictions.

The following table provides a comparison of the research and development expenses (in thousands):

	Nine Months Ended September 30,		
	2020	2019	Increase/(Decrease)
Respiratory	$ 7,784	$ 9,168	$ (1,384)
Immuno-oncology	9,494	13,950	(4,456)
Other R&D activities	18,635	17,762	873
Total	$ 35,913	$ 40,880	(4,967)

- The $1.4 million decrease for our respiratory programs period-over-period is due primarily to a decrease in manufacturing and clinical costs with respect to activities for PRS-060.

- The $4.5 million decrease in our immuno-oncology programs period-over-period is due primarily to lower manufacturing and preclinical costs for our PRS-344 program as the manufacturing costs were initiated and ramped up in the first half of 2019, lower preclinical costs on other Servier programs, and decreases in manufacturing costs across other proprietary immuno-oncology programs.

- The $0.9 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, and higher license fees. 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 and lower professional services.

General and Administrative Expenses

General and administrative expenses were $4.1 million for the three months ended September 30, 2020 and $4.8 million for the three months ended September 30, 2019. The period over period decrease is due to lower personnel expenses, including bonus and stock compensation, lower audit and professional services from Sarbanes-Oxley readiness procedures in the prior year, and lower overall travel costs related to COVID-19 restrictions. This was offset slightly by higher allocated IT and facility costs due to the move to a new R&D facility.

General and administrative expenses were $13.0 million for the nine months ended September 30, 2020 and $14.0 million for the nine months ended September 30, 2019. The period over period decrease 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 and higher allocated IT and facility costs due to the move to a new R&D facility.

Other Income (Expense)

Our other income (expense) was $(1.3) million for the three months ended September 30, 2020 and $0.3 million for the three months ended September 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 $(1.3) million for the nine months ended September 30, 2020 and $1.1 million for the nine months ended September 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 September 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 September 30, 2020, we had a total of $82.6 million in cash, cash equivalents and investments. We have incurred losses in every period since inception including the three months ended September 30, 2020 and 2019, respectively, and have a total accumulated deficit of $197.0 million as of September 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):

	Nine Months Ended September 30,	
	2020	2019
Net cash used in operating activities	$ (32,479)	$ (38,493)
Net cash provided by investing activities	24,361	11,719
Net cash provided by financing activities	10,040	501

Net cash used in operating activities for the nine months ended September 30, 2020 and 2019 was $32.5 million and $38.5 million, respectively. The change is primarily driven a $1.9 million decrease in the net loss in 2020 compared to the same period in 2019 and a decrease in accounts payable and accrued expenses due to higher accruals at year-end 2019 related to the new facility, offset by lower accounts receivable and prepaid expenses.

The change in net cash provided by investing activities for the nine months ended September 30, 2020 compared to the same period in 2019 is mainly attributable to lower net investments changes (lower purchases and increased maturities resulting in an overall decrease in investments) in the current year compared to 2019 along with an increase in purchases of property and equipment related to our move to a new R&D facility.

Financing activities for the nine months ended September 30, 2020 and 2019 were $10.0 million and $0.5 million, respectively. The change is primarily driven by proceeds from a strategic sale on our ATM Program to strenghten our shareholder base.

In August 2019, we entered into a sale agreement pursuant to which we 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, or the ATM Program, under a shelf registration statement on Form S-3 (File No. 333-226725). Through September 30, 2020, we sold $10.0 million of common shares under the ATM Program.

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 us 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 nine months ended September 30, 2020. These changes relate to revenue recognition and property and equipment and are described in "Note 2—Summary of Significant Accounting Policies".

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

- An opportunity for reduced disclosure obligations regarding executive compensation in its periodic and annual reports, including without limitation exemption from the requirement to provide a compensation discussion and analysis describing compensation practices and procedures.

- An opportunity for reduced financial statement disclosure in registration statements, which must include two years of audited financial statements rather than the three years of audited financial statements that are required for other public reporting companies.

- An opportunity for reduced audit and other compliance expenses as we are not subject to the requirement to obtain an auditor's report on internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act of 2002.

- An opportunity to 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 effective as of September 30, 2020.

Remediation of Material Weakness

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.

As previously disclosed, in connection with the preparation of our financial statements for the year ended December 31, 2019, we concluded that we had a material weakness in internal controls over our information technology general controls related to change and access management processes, and that as a result, internal controls related to substantially all underlying financial statement accounts and disclosures were 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. To remediate the material weaknesses identified, we performed the following actions during 2020:

- With respect to the material weakness in ITGC's, we have reevaluated our risk assessment and IT control environment within the finance department, developed an IT policy with a clear description on how the controls are designed to operate, and established more rigorous controls over system access, administration, and system changes.
- With respect to the material weakness in the revenue recognition controls, we have implemented improved policies and enhanced the rigor of our review documentation with regards to internal controls over our revenue recognition process.

As the enhanced policies, procedures and controls have functioned effectively for multiple quarters, we concluded that we have remediated the material weaknesses previously disclosed from 2019.

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

Except for changes in connection with our implementation of the remediation process described above, 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 September 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 and June 30, 2020, filed with the SEC on May 11, 2020 and August 11, 2020, respectively, 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.

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
10.1	Clinical Trial Collaboration and Supply Agreement, dated August 10, 2020, by and between Pieris Pharmaceuticals, Inc. and Eli Lilly and Company.	*			
31.1	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.	*			
31.2	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.	*			
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	**			
32.2	Certification of Principal Financial Officer and Principal Accounting Officer Pursuant to 18 U.S.C Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	**			
101.INS	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document)				
101.SCH	Inline XBRL Taxonomy Extension Schema Document	*			
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	*			
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	*			
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	*			
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	*			
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)	*			
*	Filed herewith.				
**	The certifications furnished in Exhibit 32.1 and Exhibit 32.2 hereto are deemed to accompany this Quarterly Report and will not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the registrant specifically incorporates it by reference.				
±	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.

November 4, 2020 By: /s/ Stephen S. Yoder
Stephen S. Yoder
Chief Executive Officer and President
(Principal Executive Officer)

November 4, 2020 By: /s/ Thomas Bures
Thomas Bures
Vice President, Finance and Treasurer
(Principal Financial Officer and Principal Accounting Officer)

CONFIDENTIAL Exhibit 10.1

CLINICAL TRIAL COLLABORATION AND SUPPLY AGREEMENT

(For Study PRS-343-PCS_09_20 and Lilly I4T-NS-I025)

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Confidential

CLINICAL TRIAL COLLABORATION AND SUPPLY AGREEMENT
(For Study PRS-343-PCS_09_20 and Lilly I4T-NS-I025)

This **CLINICAL TRIAL COLLABORATION AND SUPPLY AGREEMENT** (this "Agreement"), made as of August 10, 2020 (the "Effective Date"), is by and between Pieris Pharmaceuticals, Inc., having a place of business at 255 State Street, 9th floor, Boston, Massachusetts 02109 ("Sponsor"), and Eli Lilly and Company, having a place of business at Lilly Corporate Center, Indianapolis, Indiana 46285 ("Lilly"). Lilly and Sponsor are each referred to herein individually as "Party" and collectively as "Parties".

RECITALS

A. Lilly is developing the Lilly Compound (as defined below) for the treatment of certain tumor types.

B. Sponsor is developing the Sponsor Compound (as defined below) for the treatment of certain tumor types.

C. Sponsor desires to sponsor a clinical trial in which the Sponsor Compound and the Lilly Compound would be dosed concomitantly or sequentially.

D. Lilly and Sponsor, consistent with the terms of this Agreement, desire to collaborate as more fully described herein, including through Lilly providing the Lilly Compound to Sponsor for the Study (as defined below).

NOW, THEREFORE, in consideration of the premises and of the following mutual promises, covenants and conditions, the Parties, intending to be legally bound, mutually agree as follows:

ARTICLE 1.
DEFINITIONS.

For all purposes of this Agreement, the capitalized terms defined in this Article 1 and throughout this Agreement shall have the meanings herein specified.

"Adverse Event (AE)" means any untoward medical occurrence in a patient or clinical investigation subject administered with a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment.

"Affiliate" means, with respect to either Party, a firm, corporation or other entity which directly or indirectly owns or controls said Party, or is owned or controlled by said Party, or is under common ownership or control with said Party. The word "control" means (i) the direct or indirect ownership of fifty percent (50%) or more of the outstanding voting securities of a legal entity, or (ii) possession, directly or indirectly, of the power to direct the management or policies of a legal entity, whether through the ownership of voting securities, contract rights, voting rights, corporate governance or otherwise.

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"Agreement" means this agreement, as amended by the Parties from time to time, and as set forth in the preamble.

"Applicable Law" means those federal, state, local, national and regional laws applicable to the activities hereunder, including performance of clinical trials, medical treatment, the processing and protection of personal and medical data (such as those specified in the regulations issued under GDPR, CCPA or HIPAA), and the Manufacture, processing, distribution of the Compounds, as may be amended and in effect from time to time, including the United States Federal Food, Drug and Cosmetic Act (21 U.S.C. 301) and applicable federal, state and local laws and regulations, applicable cGMP and GCP and all other applicable laws and regulations, of any other applicable jurisdiction (each a "Regulatory Authority" and collectively, "Regulatory Authorities"), including export control and economic sanctions regulations which prohibit the shipment of United States-origin products and technology to certain restricted countries, entities and individuals; anti-bribery and anti-corruption laws pertaining to interactions with government agents, officials and representatives; laws and regulations governing payments to healthcare providers; and any United States or other country's or jurisdiction's successor or replacement statutes, laws, rules, regulations and directives relating to the foregoing.

"Business Day" means any day other than a Saturday, Sunday or any public holiday in the country where the applicable obligations are to be performed.

"CCPA" means the California Consumer Privacy Act of 2018, as amended from time to time.

"cGMP" means the current Good Manufacturing Practices officially published and interpreted by EMA, FDA and other applicable Regulatory Authorities that may be in effect from time to time and are applicable to the Manufacture of the Compounds.

"Clinical Data" means all data (including raw data) and results generated under the Study; excluding, however, Sample Testing Results (defined below), including, without limitation, all reports submitted by Study site(s) to Sponsor pursuant to the Study, provided however that the term "*Clinical Data*" shall not include medical records of Study subjects.

"CMC" means Chemistry Manufacturing and Controls.

"Compounds" means the Lilly Compound and the Sponsor Compound. A "Compound" means either the Lilly Compound or the Sponsor Compound, as applicable.

"Combination" means the use or method of using the Lilly Compound and the Sponsor Compound in concomitant or sequential administration.

"Confidential Information" means any information, Know-How or other proprietary information or materials furnished to one Party by the other Party pursuant to this Agreement, except to the extent that such information or materials: (a) was already known to the receiving Party, other than under an obligation of confidentiality, at the time of disclosure by the other Party, as demonstrated by competent evidence; (b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party; (c) became generally

of the public domain at the time of its disclosure to the receiving Party; (c) became generally

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available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement; (d) was disclosed to the receiving Party by a Third Party who had no obligation to the disclosing Party not to disclose such information to others; or (e) was subsequently developed by the receiving Party without use of the Confidential Information, as demonstrated by competent evidence.

"CTA" means an application to a Regulatory Authority for purposes of requesting the ability to start or continue the Study, including an IND.

"Delivery" shall have the meaning set forth in Section 8.2.1.

"Dispute" has the meaning set forth in Section 15.7.1.

"Effective Date" has the meaning set forth in the preamble.

"EMA" means the European Medicines Agency, or a successor Regulatory Authority thereto having similar responsibilities with respect to pharmaceutical products.

"FDA" means the United States Food and Drug Administration or any successor entity thereto.

"GCP" means the Good Clinical Practices officially published by EMA, FDA and the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) that may be in effect from time to time and are applicable to the testing of the Compounds in the Study.

"GDPR" means Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and any implementing directive or related legislation, rule, regulation, and regulatory guidance, as amended, extended, repealed and replaced, or re-enacted from time-to-time.

"Good Distribution Practices" or **"GDP"** has the meaning set forth in the Quality Agreement.

"Government Official" means: (i) any officer or employee of: (a) a government, or any department or agency thereof; (b) a government-owned or controlled company, institution, or other entity, including a government-owned hospital or university; or (c) a public international organization (such as the United Nations, the International Monetary Fund, the International Committee of the Red Cross, and the World Health Organization), or any department or agency thereof; (ii) any political party or party official or candidate for public or political party office; and (iii) any person acting in an official capacity on behalf of any of the foregoing.

"HIPAA" means United States Health Insurance Portability and Accountability Act of 1996, as amended from time to time.

"IND" means the Investigational New Drug Application filed or to be filed with the FDA as described in Title 21 of the U.S. Code of Federal Regulations, Part 312, and the equivalent

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application in the jurisdictions outside the United States, including an "Investigational Medicinal Product Dossier" filed or to be filed with the Regulatory Authorities in the European Union.

"Internal Compliance Codes" has the meaning set forth in Section 13.4.2.

"Inventions" means all inventions and discoveries which are made or conceived in the performance of the Study and/or which are made or conceived by a Party through use of the Clinical Data.

"Jointly Owned Invention" has the meaning set forth in Section 10.1.1.

"Joint Patent" means a patent that issues from a Joint Patent Application.

"Joint Patent Application" has the meaning set forth in Section 10.1.2.

"Know-How" means any proprietary invention, innovation, improvement, development, discovery, computer program, device, trade secret, method, know-how, process, technique or the like, including manufacturing, use, process, structural, operational and other data and information, whether or not written or otherwise fixed in any form or medium, regardless of the media on which contained and whether or not patentable or copyrightable, that is not generally known or otherwise in the public domain.

"Liability" has the meaning set forth in Section 14.2.1.

"Lilly" has the meaning set forth in the preamble.

"Lilly Class Compound" means any one or more VEGFR2 antagonist molecule, including an antibody such as an anti-VEGFR2 antibody or a small molecule inhibitor that is a specific and selective antagonist of VEGFR2.

"Lilly Compound" means ramucirumab, excluding, however, any biosimilar of ramucirumab other than a biosimilar owned or controlled by Lilly or its Affiliates.

"Manufacture," "Manufactured," or **"Manufacturing"** means all stages of the manufacture of a Compound, including planning, purchasing, manufacture, processing, compounding, storage, filling, packaging, waste disposal, labeling, leafleting, testing, quality assurance, sample retention, stability testing, release, dispatch and supply, as applicable.

"Manufacturing Site" means the facilities where a Compound is Manufactured by or on behalf of a Party, as such Manufacturing Site may change from time to time in accordance with Section 8.4 (Changes to Manufacturing).

"Non-Conformance" means, with respect to a given unit of Compound, (i) an event that deviates from an approved cGMP requirement with respect to the applicable Compound, such as a procedure, Specification, or operating parameter, or that requires an investigation to assess impact to the quality of the applicable Compound or (ii) that such Compound failed to meet the applicable representations and warranties set forth in Section 2.4. Classification of a Non-Conformance is detailed in the Quality Agreement.

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"Party" has the meaning set forth in the preamble.

"Party Specific Regulations" has the meaning set forth in Section 13.4.2.

"Pharmacovigilance Agreement" has the meaning set forth in Section 5.1.

"Project Manager(s)" has the meaning set forth in Section 3.8.

"Protocol" means the written documentation that describes the Study and sets forth specific activities to be performed as part of the Study conduct, a summary of which is attached hereto as Appendix A.

"Quality Agreement" means that certain Quality Agreement entered into between Sponsor and Lilly which governs the essential quality obligations of each party in the manufacture, testing and release of the Compounds, as the same may be amended from time to time.

"Regulatory Approvals" means any and all permissions (other than approvals that are required to Manufacture a Party's Compound in accordance with Applicable Law) required to be obtained from Regulatory Authorities and any other competent authority for the development, registration, importation and distribution of a Compound in the United States, Europe or other applicable jurisdictions for use in humans.

"Regulatory Authorities" has the meaning set forth in the definition of Applicable Law.

"Related Agreements" means the Pharmacovigilance Agreement and the Quality Agreement.

"Samples" means urine, blood or tissue samples from patients participating in the Study.

"Sample Testing" means the analyses to be performed by either Party using the applicable Samples, as described in the Sample Testing Schedule.

"Sample Testing Results" means those results arising from the Sample Testing which are to be shared between Lilly and Sponsor, as set forth in the Sample Testing Schedule.

"Sample Testing Schedule" means the schedule attached hereto as Appendix B.

"Specifications" means, with respect to a given Compound, the set of requirements for such Compound as set forth in the Quality Agreement.

"Sponsor" has the meaning set forth in the preamble.

"Sponsor Class Compound" means any one or more bi- or multi- specific molecule that agonizes CD137 (4-1BB).

"Sponsor Compound" means cinrebafusp alfa (PRS-343), a bivalent, bispecific fusion protein targeting CD137 (4-1BB) and HER2 excluding, however, any biosimilar of PRS-343 other than a biosimilar owned or controlled by Sponsor or its Affiliates.

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"**Study**" means the Phase 2 study of the Sponsor Compound and the Lilly Compound, together with chemotherapy, a summary of which is attached hereto as Appendix A.

"**Study Completion**" has the meaning set forth in Section 3.5.

"**Territory**" means anywhere in the world.

"**Third Party**" means any person or entity other than Sponsor, Lilly or their respective Affiliates.

ARTICLE 2.
GENERAL PRINCIPLES.

Section 2.1. Contribution of Parties. Each Party shall contribute to the Study such resources as are reasonably necessary to fulfill its obligations set forth in this Agreement.

Section 2.2. Standard of Performance. Each Party agrees to (i) act in good faith in performing its obligations under this Agreement and each Related Agreement, (ii) commit to perform its obligations under this Agreement and each Related Agreement carefully and accurately, to the best of its respective ability, with qualified staff and on the basis of sound scientific and engineering principles and in compliance with Applicable Laws, and (iii) shall notify the other Party as promptly as possible in the event of any Manufacturing delay that is likely to adversely affect supply of its Compound as contemplated by this Agreement. As part of this standard of performance, the Parties agree that the current coronavirus pandemic may result in unexpected delays that would not be considered a breach of this Section 2.2 by such Party.

Section 2.3. Non-Exclusive Relationship. Each Party acknowledges and agrees that this arrangement is not an exclusive arrangement on its part and that each Party may enter similar arrangements with other parties including parties that may compete with the other Party.

Section 2.4. Manufacturing Representations and Warranties.

2.4.1 Lilly agrees to Manufacture and supply the Lilly Compound for purposes of the Study as set forth in Article 8, and Lilly hereby represents and warrants to Sponsor that, at the time of Delivery of the Lilly Compound, such Lilly Compound shall have been Manufactured and supplied in compliance with the Specifications for the Lilly Compound and in compliance with Applicable Law, including cGMP and health, safety and environmental protections, as more particularly set forth in the Quality Agreement. Sponsor agrees to Manufacture and supply the Sponsor Compound for purposes of the Study as set forth in Article 8, and Sponsor hereby represents and warrants to Lilly that, at the time of use of the Sponsor Compound, such Sponsor Compound shall have been Manufactured and supplied in compliance with the Specifications for the Sponsor Compound and in compliance with Applicable Law, including cGMP and health, safety and environmental protections, as more particularly set forth in the Quality Agreement.

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2.4.2 Lilly hereby represents and warrants to Sponsor that, at the time of Delivery of the Lilly Compound, such Lilly Compound shall be free from any Non-Conformance.

2.4.3 Sponsor hereby represents and warrants to Lilly that, at the time of use of the Sponsor Compound, such Sponsor Compound shall be free from any Non-Conformance.

2.4.4 Without limiting the foregoing, each Party is responsible for obtaining Regulatory Approvals (including facility licenses) that are required to Manufacture its Compound in accordance with Applicable Law (provided that for clarity, Sponsor shall be responsible for obtaining Regulatory Approvals for the Study as set forth in Section 3.3).

Section 2.5. Subcontractors. Each Party shall have the right to subcontract any portion of its obligations hereunder: (i) to its own Affiliates, without the other Party's written consent; or (ii) to third parties, provided that the other Party's Project Manager has approved (in a written document, but such approval not to be unreasonably withheld, conditioned or delayed) the use of such third parties in the performance of such activities, and provided further that no consent shall be necessary for either Party's delegation to or use of contract research organizations or other third parties that (A) are already conducting clinical trials of such Party's Compound and are set forth in the Protocol as performing such Study activities, or (B) are already conducting Sample Testing for such Party. In any event, each Party shall remain fully liable for the performance of its subcontractors. Notwithstanding the foregoing, the Parties agree to Sponsor's use of the subcontractors identified in Appendix B. Each Party shall ensure that each of its subcontractors performs its obligations pursuant to the terms of this Agreement, including the Appendices attached hereto. Each Party shall use reasonable efforts to obtain and maintain copies of documents relating to the obligations performed by such subcontractors that are held by or under the control of such subcontractors and that are required to be provided to the other Party under this Agreement.

Section 2.6. No Additional Obligations to Supply. This Agreement does not create any obligation on the part of Lilly to provide the Lilly Compound for any activities other than in connection with the Study, nor does it create any obligation on the part of Sponsor to provide the Sponsor Compound for any activities other than the Study.

Section 2.7. Other Studies. Nothing in this Agreement shall (i) prohibit either Party from performing clinical studies other than the Study relating to its own Compound, either individually or in combination with any other compound(s) or product(s), in any therapeutic area, or (ii) create an exclusive relationship between the Parties with respect to any Compound.

ARTICLE 3.
CONDUCT OF THE STUDY.

Section 3.1. Sponsor of Study. Sponsor shall act as the sponsor of the Study and shall hold each IND/CTA and/or equivalent in each jurisdictions relating to the Study; provided, however, that in no event shall Sponsor file a separate IND/CTA and/or equivalent in other

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jurisdictions in relation to the Study unless required by Regulatory Authorities to do so. If a Regulatory Authority requests a separate IND/CTA and/or equivalent in other jurisdictions for the Study, the Parties will meet and mutually agree on an approach to address such requirement.

Section 3.2. Performance. Sponsor shall ensure that the Study is performed in accordance with this Agreement, the Protocol and Applicable Law, including GCP.

Section 3.3. Compliance and Regulatory Discussions; Right of Reference.

3.3.1 Sponsor shall ensure that all directions from any Regulatory Authority and/or ethics committee with jurisdiction over the Study are followed. Further, Sponsor shall ensure that all required Regulatory Approvals from any Regulatory Authority and/or ethics committee with jurisdiction over the Study are obtained prior to initiating performance of the Study. Sponsor shall participate in and lead all discussions with any Regulatory Authority regarding the Study, provided, however, that Lilly shall have the right (but no obligation) to participate in any discussions with a Regulatory Authority to the extent such discussions include substantive or material regarding matters related to the Lilly Compound. For such discussions, Sponsor shall consider in good faith any advance comments from Lilly regarding the planned content of such discussions. For the sake of clarity, any discussions related to safety or efficacy of the Lilly Compound shall be considered substantive and material.

3.3.2 Sponsor will promptly provide Lilly with a copy of any written reports (or excerpts thereof) from Regulatory Authorities to the extent related to the Lilly Compound within a reasonable time after receipt thereof and shall provide Lilly with draft copies of any responses to a Regulatory Authority (or excerpts thereof) to the extent related to the Lilly Compound within a reasonable time prior to submission to such Regulatory Authority. Sponsor shall reasonably consider Lilly's comments to such draft response, with any disputes being escalated through the Project Managers (as defined in Section 3.8).

3.3.3 Each Party grants to the other Party a non-exclusive, non-transferable (except in connection with a permitted assignment, sublicense or subcontract, including those contemplated under Section 3.12) "right of reference" (as defined in US FDA 21 CFR 314.3(b)), or similar "right of reference" as defined in applicable regulations in the relevant part of the Territory, with respect to Clinical Data and results related to Compounds, solely as necessary for the other Party to prepare, submit and maintain regulatory submissions related to the other Party's Compound and Regulatory Approvals.

3.3.4 Notwithstanding anything to the contrary in this Agreement, neither Party shall have any right to access the other Party's CMC data with respect to its Compound. If necessary to support conduct of the Study, Lilly will authorize FDA and other applicable Regulatory Authorities to cross-reference the appropriate Lilly Compound U.S. and EU Regulatory Approvals (if the Lilly Compound is commercial material) or the appropriate INDs or CTAs (if the Lilly Compound is

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clinical trial material) to provide data access to Sponsor and/or the appropriate Regulatory Authority. If the cross-references to such Regulatory Approvals and the equivalency statements are not deemed sufficient by a Regulatory Authority in a country approved by Lilly as part of the Study, Lilly, shall discuss in good faith the filing of the complete CMC components of the Common Technical Document for each Lilly Compound (the "CMC Data") with such Regulatory Authority, with a letter of authorization for Sponsor to cross-reference the CMC Data for the review of the CTA; however, Sponsor shall have no right to directly access the CMC Data. Sponsor shall reimburse Lilly for reasonable and direct costs for preparing the CMC Data for filing with such Regulatory Authority(ies) and related filing costs. In addition to the foregoing, Lilly shall provide any additional materials mutually agreed to by the Parties to Sponsor on a schedule agreed to by the Parties, and shall provide such other documents and information as may be requested by a Regulatory Authority to such Regulatory Authority following such request by the Regulatory Authority, to the extent such documents and information are reasonably available to Lilly. Lilly hereby agrees that it shall review Section D of the European Clinical Trials Database (EudraCT) Application Form Worksheets completed by Sponsor with respect to the Lilly Compound for purposes of the CTA and, no later than [***] business days, provide any corrections or additions required for accuracy and completeness of such worksheets.

3.3.5 For avoidance of doubt, Sponsor shall not be responsible for complying with any laws or regulations that solely relate to the commercialization of the Lilly Compound.

Section 3.4. Reports and Documentation. Sponsor shall maintain reports and all related documentation (paper or electronic) in good scientific manner, consistent with industry norms and in compliance with Applicable Law. Each Party shall provide to the other any Study information and documentation (excluding information and documentation relating to the Sample Testing other than the Sample Testing Results themselves) reasonably requested by such other Party to enable it to (i) comply with any of its legal and regulatory obligations, or any request by any Regulatory Authority, in each case, to the extent related to the Study or such Party's Compound, (ii) conduct the Sample Testing, (iii) satisfy any contractual obligation to a subcontractor engaged pursuant to Section 2.4 hereof, and (iv) in the case of Lilly, determine whether the Study has been performed by Sponsor in accordance with this Agreement.

Section 3.5. Access to Clinical Data. Subject to Applicable Law, Sponsor shall obtain the consent of Study participants to share Clinical Data with Lilly, including for secondary purposes that are reasonably identified to Pieris in a manner that allows for their inclusion in the consent, in accordance with the terms of this Agreement. To the extent permitted under Applicable Law, Sponsor shall provide to Lilly copies of Clinical Data, in a summary, electronic form or other mutually agreeable alternate form, (a) at major decision points during the Study to track study progress, (b) at an appropriate time to support publications, (c) as needed to support interpretation of Clinical Data including efficacy analyses as mutually agreed by the Project Managers, or (d) as otherwise agreed upon by the Project Managers. Subject to Applicable Law, Sponsor shall provide to Lilly a complete copy of the Clinical Data in the manner and format prepared by the Sponsor no later than [***] days following Study Completion. "Study Completion" shall be deemed to

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occur following final lock of the Study database and when analysis for meeting Study endpoints has been completed or as otherwise agreed by the Project Managers. Subject to Applicable Law and to the extent applicable, Sponsor shall ensure that all patient authorizations and consents required under HIPAA, GDPR or any other similar Applicable Law in connection with the Study permit such sharing of Clinical Data with Lilly.

Section 3.6. Sample Use and Ownership. Notwithstanding anything to the contrary in this Section 3.6, Sponsor shall retain all Samples and conduct all Sample Testing. Each Party shall use the Samples only for the Sample Testing and in compliance with the applicable informed consent forms and each Party shall be responsible for conducting the Sample Testing related to its own Compound. [***] Sponsor shall obtain the consent of Study participants to share Sample Testing Results with Lilly in accordance with the terms of this Agreement, to the extent applicable. Sponsor shall provide to Lilly the Sample Testing Results for the Sample Testing conducted by or on behalf of Sponsor, in electronic form or other mutually agreeable alternate form, as may be permissible under Applicable Law, and on the timelines specified in the Sample Testing Schedule or other mutually agreed timelines. Each Party hereby grants each of the other Parties hereto a [***] to use the Sample Testing Results for the sole purposes of [***]. Sponsor shall be responsible for the conduct of all Sample Testing and Lilly shall provide reasonable access and support to Sponsor in the conduct of the Lilly Compound-specific Sample Testing as indicated on Appendix B. Responsibilities shall include, but are not limited to, data generation and payment to conduct the assay. The Parties agree to provide sufficient quantities of their Compounds for interference testing in bioanalytical or proprietary assays in order to confirm, as applicable, that their Compound does not interfere with the other Party's assay performance. Initial experiments may be performed to determine impact to assay performance and will follow a validated protocol and/or standard operating procedure. [***]

Section 3.7. Ownership of Clinical Data. All Clinical Data generated under this Agreement, [***]. It is understood and acknowledged by the Parties that positive Clinical Data could be used to obtain label changes for the Compounds. Lilly covenants not to disclose any unpublished Clinical Data [***], and Sponsor covenants not to disclose any unpublished Clinical Data [***].

Section 3.8. Roles of Project Managers. Each Party shall designate a Project Manager who shall be responsible for implementing and coordinating activities and facilitating the exchange of scientific information between the Parties with respect to the Study. The Project Managers shall meet as soon as practicable after the Effective Date and then no less than twice yearly, and more often as reasonably considered necessary at the request of either Party, to provide an update on Study progress. Prior to any such meeting, the Sponsor Project Manager shall provide an update in writing to the Lilly Project Manager, which update shall contain information about overall Study progress, recruitment status, and other information relevant to the conduct of the Study. Sponsor Project Manager shall supplement the update as necessary to reflect any material information discussed at such meetings. Sponsor Project Manager shall schedule reviews of Clinical Data in alignment with Appendix C (Data Sharing Table). In the event that an issue arises and the Project Managers cannot or do not, after good faith efforts, reach agreement on such issue, the issue shall be elevated to the Senior Vice President, Head of Clinical Development, for Sponsor, and the Vice President of Oncology Late Phase Development for Lilly.

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Section 3.9. Supply Chain Representative. Each Party shall appoint a supply chain representative to hold telephone discussions at a mutually agreed-upon frequency to review the quantities of Sponsor Compound and Lilly Compound needed for the Study (in accordance with Article 8 and Appendix D) and any other supply chain issues that may arise during the Study.

Section 3.10. Study Report. Sponsor shall provide Lilly with (i) an electronic draft of each study report for Lilly to provide comments to Sponsor within [***] days of receipt of such draft final study report and (ii) the final version of the study report promptly following Study Completion. Sponsor shall consider in good faith any comments provided by Lilly on the draft of the final study report and shall not include any statements relating to the Lilly Compound which have not been approved by Lilly.

Section 3.11. Future Business Opportunities. Notwithstanding anything in this Agreement to the contrary, each Party acknowledges and agrees that the other Party may have present or future business activities or opportunities, including business activities or opportunities with Third Parties, involving Sponsor Class Compounds, in the case of Lilly, or Lilly Class Compounds, in the case of Sponsor, or other similar products, programs, technologies or processes. Accordingly, each Party acknowledges and agrees that nothing in this Agreement shall be construed as a representation or inference that the other Party will not develop for itself, or enter into business relationships with other Third Parties regarding, any products, programs, studies (including combination studies), technologies or processes that are similar to or that may compete with the Combination or any other product, program, technology or process, including Sponsor Class Compound or Lilly Class Compound, provided that the Clinical Data, Sample Testing Results, Jointly Owned Inventions, and Confidential Information are used or disclosed in connection therewith consistent with and not in violation of Section 3.3, Section 3.5, Section 3.6, Section 3.7, Section 9.1 or Article 10 of this Agreement.

Section 3.12. Partnership, Licensing, Assignment, and Transfer; Party Owned Materials. Nothing in this Agreement shall prohibit or restrict a Party from licensing, partnering, assigning, co-developing, or otherwise transferring in whole or in part to an Affiliate or Third Party its interest in its Compound and the related Clinical Data, Confidential Information, Sample Testing Results or Jointly Owned Inventions (along with this Agreement in the case of a transfer or assignment), including freedom to use such information; provided, however, that in the case of any such license, partnership, assignment, co-development or transfer in whole or in part, the licensee, partner, assignee or transferee shall agree in writing to be bound by the terms of this Agreement.

ARTICLE 4.
PROTOCOL AND RELATED DOCUMENTS.

Section 4.1. Protocol. A summary of the initial Protocol, entitled "A Phase 2, Multi-Center, Open-Label Study of Cinrebafusp alpha (PRS-343) in Combination with Ramucirumab and Paclitaxel in Patients with HER2-Positive Gastric or GEJ Adenocarcinoma", has been agreed to by the Parties as of the Effective Date, and is attached as Appendix A. Sponsor shall have the final decision regarding the contents of the Protocol; provided, however, that any material changes to the Protocol (other than relating solely to the Sponsor Compound), and any changes (whether or not material) relating to the Lilly Compound, shall require Lilly's prior written consent, which

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shall not be unreasonably withheld, conditioned or delayed. Any such proposed changes will be sent in writing to Lilly's Project Manager. Lilly will provide such consent, or a written explanation for why such consent is being withheld, within [***] Business Days of receiving a copy of Sponsor's requested changes; provided that if Lilly fails to provide such written explanation within such [***] Business Day period, then Lilly shall be deemed to have consented to such change or changes.

Section 4.2. Patient Informed Consent. Sponsor shall prepare the patient informed consent form for the Study (which shall include any required consent for the Sample Testing) in consultation with Lilly regarding any safety language related to the Lilly Compound (it being understood and agreed that the portion of the informed consent form relating to the safety of the Lilly Compound will be provided to Sponsor by Lilly). Any changes to such form that relate to the Sample Testing or the Lilly Compound shall be subject to Lilly's review and prior written consent. Any such proposed changes will be sent in writing to Lilly's Project Manager. Lilly will provide such consent, or a written explanation for why such consent is being withheld, within [***] Business Days of receiving a copy of Sponsor's requested changes; provided that if Lilly fails to provide such written explanation within such [***] Business Day period, then Lilly shall be deemed to have consented to such change or changes.

Section 4.3. Sunshine Reporting. Sponsor will be responsible for reporting payments and other transfers of value made to health care professionals (e.g. investigators, steering committee members, data monitoring committee members, consultants, etc.) in connection with its role as Sponsor of the Study in accordance with reporting requirements, if any, under Applicable Law (including the Physician Payment Sunshine Act and state gift laws, and the European Federation of Pharmaceutical Industries and Associations Disclosure Code) and Sponsor policies. Lilly shall provide all information required for such reporting regarding the value of the Lilly Compound provided for use in the Study. Such information shall be provided to the point of contact within Sponsor's clinical supplies group who is identified to Lilly in writing upon the execution of the Agreement and thereafter promptly following any change to such point of contact. Lilly shall provide the necessary information regarding the value of the Lilly Compound within [***] business days following the execution of this Agreement. In the event that, at any time during the term of this Agreement, the value of the Lilly Compound provided under this Agreement changes, Lilly shall notify Sponsor of such revised value, and the effective date of such revised value, within [***] business days following such change in value.

ARTICLE 5.
ADVERSE EVENT REPORTING.

Section 5.1. Pharmacovigilance. Sponsor will be solely responsible for compliance with Applicable Law pertaining to safety reporting for the Study and related activities. The Parties (or their respective Affiliates) will execute a pharmacovigilance agreement (the "Pharmacovigilance Agreement") prior to the initiation of clinical activities under the Study, but in any event, within [***] days following the Effective Date of this Agreement to ensure the exchange of relevant safety data within appropriate timeframes and in appropriate format to enable the Parties to fulfill local and international regulatory reporting obligations and to facilitate appropriate safety reviews. The Pharmacovigilance Agreement will include safety data exchange procedures governing the coordination of collection, investigation, reporting, and exchange of

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information concerning any adverse experiences, pregnancy reports, and any other safety information arising from or related to the use of the Lilly Compound and Sponsor Compound in the Study, consistent with Applicable Law. Such guidelines and procedures shall be in accordance with, and enable the Parties and their Affiliates to fulfill, local and international regulatory reporting obligations to Regulatory Authorities.

Section 5.2. Prevailing Terms. In the event of any inconsistency between the terms of this Agreement and the Pharmacovigilance Agreement, the terms of this Agreement shall prevail and govern except to the extent such inconsistent term relates directly to the pharmacovigilance responsibilities of the Parties (including the exchange of safety data), in which case the terms of the Pharmacovigilance Agreement shall prevail and govern.

ARTICLE 6.
TERM AND TERMINATION.

Section 6.1. Term. The term of this Agreement shall commence on the Effective Date and shall continue in full force and effect until completion of all of the obligations of the Parties hereunder (excluding obligations that survive termination) or until terminated by either Party pursuant to this Article 6.

Section 6.2. Lilly Termination for Unsafe Use. In the event that Lilly reasonably and in good faith believes that the Lilly Compound is being used in the Study in an unsafe manner and notifies Sponsor in writing of the grounds for such belief, the Sponsor shall have the reasonable opportunity to review and consider the Sponsor's notification and grounds and shall promptly respond to Lilly in writing with the actions Sponsor proposes to take or, if Sponsor disagrees with Lilly's belief, providing such a response promptly to Lilly, including the basis for such disagreement. In the event that Lilly continues—reasonably and in good faith—to believe that that the Lilly Compound is being used in the Study in an unsafe manner and Sponsor thereafter fails to promptly incorporate (subject to approval by applicable Regulatory Authorities or Institutional Review Boards) changes into the Protocol reasonably requested by Lilly to address such issue or to otherwise in good faith address such issue, Lilly may terminate this Agreement and the supply of the Lilly Compound effective upon written notice to Sponsor.

Section 6.3. Termination for Material Breach. Either Party may terminate this Agreement if the other Party commits a material breach of this Agreement, and such material breach continues for [***] days after receipt of written notice thereof from the non-breaching Party; provided that if such material breach cannot reasonably be cured within [***] days, the breaching Party shall be given a reasonable period of time to cure such breach.

Section 6.4. Termination for Patient Safety. If either Party determines in good faith, based on a review of the Clinical Data or other Study-related Know-How or other information, that the Study may unreasonably affect patient safety, such Party shall promptly notify the other Party of such determination. The Party receiving such notice may propose modifications to the Study to address the safety issue identified by the other Party and, if the notifying Party agrees, shall act to immediately implement such modifications; provided, however, that if the notifying Party, in its sole discretion, believes that there is imminent danger to patients, such Party need not wait for the other Party to propose modifications and may instead terminate this Agreement

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immediately upon written notice to such other Party. Furthermore, if the notifying Party, in its sole discretion, believes that any modifications proposed by the other Party will not resolve the patient safety issue, such Party may terminate this Agreement effective upon written notice to such other Party. Notwithstanding the foregoing, to the extent that a Party in good faith disputes a notice of termination provided under this Section, then the SVP, Head of Clinical Development of Sponsor and the Vice President of Oncology Late Phase Development for Lilly shall within [***] Business Days have a discussion in good faith prior to termination.

Section 6.5. Termination for Regulatory Action. Either Party may terminate this Agreement [***] days following written notice to the other Party in the event that any Regulatory Authority takes any action, or raises any objection, that precludes the terminating Party from supplying its Compound for purposes of the Study. Additionally, either Party shall have the right to terminate this Agreement [***] days following written notice to the other Party in the event that it determines in its sole discretion to discontinue development of its Compound, for medical, scientific, legal or other reasons.

Section 6.6. Return of Lilly Compound. In the event that this Agreement is terminated, Sponsor shall, at Lilly's sole discretion, promptly either return or destroy all unused Lilly Compound in its possession and control or in the possession and control of Sponsor's subcontractors or Affiliates, pursuant to Lilly's instructions. If Lilly requests that Sponsor destroy the unused Lilly Compound, Sponsor shall provide written certification of such destruction.

Section 6.7. Immediate Termination for Breach. Either Party shall be entitled to terminate this Agreement immediately upon written notice to the other Party, if such other Party fails to perform any of its material obligations under Section 13.3 or materially breaches any representation or warranty contained in Section 13.1. Such termination shall not be exercisable by a Party without giving notice and [***] days to cure with respect to subcontractors that have been evaluated and cleared by such Party. Subject to Section 6.11, the non-terminating Party shall have no claim against the terminating Party for compensation for any loss of whatever nature by virtue of the termination of this Agreement in accordance with this Section 6.7.

Section 6.8. Survival. The provisions of this Section 6.8, Section 3.6 (other than the first sentence thereof), Section 3.7, Section 3.10, Section 6.6, Section 6.7 (other than the first sentence thereof), Section 6.9, Section 6.10, Section 6.11, Section 12.2, Section 12.3, Section 12.4, Section 12.5, Section 14.2 (Indemnification), Section 14.4 (Limitation of Liability), and Article 1 (Definitions), Article 5 (Adverse Event Reporting), Article 7 (Costs of the Study), Article 9 (Confidentiality), Article 10 (Intellectual Property), Article 11 (Reprints and Rights of Cross-Reference), Article 12 (Press Releases and Publications), Section 15.6 (No Additional Obligations), Section 15.7 (Dispute Resolution and Jurisdiction), Section 15.8 (Notices), Section 15.9 (Relationship of the Parties) and Section 15.12 (Construction) shall survive the expiration or termination of this Agreement.

Section 6.9. No Prejudice to Claims. Termination of this Agreement shall be without prejudice to any claim or right of action of either Party against the other Party for any prior breach of this Agreement.

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Section 6.10. Return of Confidential Information. Upon termination of this Agreement, each Party and its Affiliates shall promptly return to the other Party or destroy any Confidential Information of the other Party (other than Clinical Data, Sample Testing Results and Inventions) furnished to the receiving Party by the other Party, except that the receiving Party shall have the right to retain one copy for record-keeping purposes.

Section 6.11. Reimbursements. Provided the Parties do not otherwise dispute the circumstances of termination, in the event of termination due to Section 6.2 (only to the extent Lilly Compound supplied under this Agreement continues to be used by Sponsor following Lilly's notice of its unsafe use), Section 6.3 (only in the case of termination by Lilly for Sponsor's material breach) or Section 6.7 above, Lilly shall be entitled to reimbursement by Sponsor for the Direct Manufacturing Costs and Indirect Manufacturing Costs (as defined herein) incurred by Lilly for the Lilly Compound Delivered for the Study.

ARTICLE 7.
COSTS OF THE STUDY.

The Parties agree that (i) Lilly shall provide the Lilly Compound for use in the Study, as described in Article 8 below, [***]; and (ii) Sponsor shall bear all other costs associated with the conduct of the Study, including that Sponsor shall provide the Sponsor Compound for use in the Study, [***].

ARTICLE 8.SUPPLY AND USE OF THE COMPOUNDS.

Section 8.1. Supply of the Compounds. Lilly will supply, or cause to be supplied, the quantities of its respective Compound as set forth on Appendix D on the approximate timelines set forth in Appendix D, in each case, for use in the Study. In the event that Sponsor determines that the quantities of Compounds set forth on Appendix D are not sufficient to complete the Study (due, for example, to the addition of Study sites or countries), Sponsor shall so notify Lilly, and the Parties shall discuss in good faith regarding additional quantities of Compounds to be provided and the schedule on which such additional quantities may be provided. Each Party shall also provide to the other Party a contact person for the supply of its Compound under this Agreement as set forth in Section 3.8. Notwithstanding the foregoing, or anything to the contrary herein, in the event that either Party is not supplying its Compound in accordance with the terms of this Agreement, or is allocating under Section 8.9, then the other Party shall have no obligation to supply its Compound, or may allocate proportionally. Notwithstanding anything to the contrary herein, Lilly shall only be obligated to supply the Lilly Compound for use in the countries set forth in Appendix D and may decline to provide the Lilly Compound, for any reason or no reason, to any countries not otherwise agreed to in advance between the parties or set forth in Appendix D.

Section 8.2. Provision of Compounds.

8.2.1 Lilly will deliver the Lilly Compound DAP (Incoterms 2020) to Sponsor's, or its designee's, location as mutually agreed ("Delivery" with respect to such Lilly Compound). Title and risk of loss for the Lilly Compound shall transfer from Lilly to Sponsor at Delivery. All costs associated with the subsequent transportation, warehousing and distribution of Lilly Compound shall be borne by

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Sponsor. Sponsor will, or will cause its designee to: (i) take delivery of the Lilly Compound supplied hereunder; (ii) perform the acceptance procedures allocated to it under the Quality Agreement; and (iii) subsequently label and pack, as appropriate (in accordance with Section 8.4) and promptly ship the Lilly Compound to the Study sites, in compliance with cGMP, GCP and other Applicable Law and the Quality Agreement.

8.2.2 Sponsor is solely responsible, at its own cost, for supplying (including all Manufacturing, acceptance and release testing) the Sponsor Compound for the Study, and the subsequent handling, storage, transportation, warehousing and distribution of the Sponsor Compound supplied hereunder. Sponsor shall ensure that all such activities are conducted in compliance with cGMP, GCP GDP and other Applicable Law and the Quality Agreement.

Section 8.3. Labeling and Packaging; Use, Handling and Storage.

8.3.1 The Parties' obligations with respect to the labeling and packaging of the Compounds are as set forth in the Quality Agreement. Notwithstanding the foregoing or anything to the contrary contained herein, Lilly shall provide Lilly Compound to Sponsor in the form set forth on Appendix D, and, unless otherwise agreed to by the parties in writing, Sponsor shall be responsible for any applicable labeling, packaging and leafleting such Lilly Compound in accordance with the terms and conditions of the Quality Agreement and otherwise in accordance with Applicable Law, including cGMP, GCP, GDP, and health, safety and environmental protections.

8.3.2 Sponsor shall (i) use the Lilly Compound solely for purposes of performing the Study; (ii) not use the Lilly Compound in any manner inconsistent with this Agreement or for any commercial purpose; and (iii) use, store, transport, handle and dispose of the Lilly Compound in compliance with the Specifications, Applicable Law and the Quality Agreement. Sponsor shall not reverse engineer, reverse compile, disassemble or otherwise attempt to derive the composition or underlying information, structure or ideas of the Lilly Compound, and in particular shall not analyze the Lilly Compound by physical, chemical or biochemical means except as necessary to perform its obligations under the Quality Agreement.

Section 8.4. Changes to Manufacturing. Each Party may make changes from time to time to its Compound or the Manufacturing Site; provided that such changes shall be in accordance with the Quality Agreement and proper notice is provided to the other party of such changes as set forth in the Quality Agreement.

Section 8.5. Product Testing; Noncompliance.

8.5.1 After Manufacturer's Release. After manufacturer's release of the Lilly Compound and concurrently with Delivery of the Compound to Sponsor, Lilly shall provide Sponsor with such certificates and documentation as are described in the Quality Agreement. Sponsor shall, within the time defined in the Quality

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Agreement, perform (i) with respect to the Lilly Compound, the acceptance procedures allocated to it under the Quality Agreement, and (ii) with respect to the Sponsor Compound, the testing and release procedures allocated to it under the Quality Agreement. Sponsor shall take all steps necessary to determine that the Sponsor Compound is suitable for release before making such Sponsor Compound available for human use, and Lilly shall provide reasonable cooperation or assistance as reasonably requested by Sponsor in connection with such determination with respect to the Lilly Compound. After Delivery by Lilly of the Lilly Compound, Sponsor shall be responsible for storage and maintenance of the Lilly Compound, which storage and maintenance shall be in compliance with the Specifications for the Lilly Compound, the Quality Agreement and Applicable Law, and shall be responsible for any failure of the Lilly Compound to meet the Specifications to the extent caused by shipping, storage or handling conditions after Delivery to Sponsor hereunder.

8.5.2 Non-Conformance.

(a) In the event that either Party becomes aware that any Compound may have a Non-Conformance, despite testing and quality assurance activities (including any activities conducted by the Parties under Section 8.5.1), such Party shall immediately notify the other Party in accordance with the procedures of the Quality Agreement. The Parties shall investigate any Non-Conformance in accordance with Section 8.7 (Investigations) and any discrepancy between them shall be resolved in accordance with Section 8.6 (Resolution of Discrepancies).

(b) In the event that any proposed or actual shipment of the Lilly Compound (or portion thereof) shall be agreed to have a Non-Conformance at the time of Delivery to Sponsor, then unless otherwise agreed to by the Parties, Lilly shall replace such Lilly Compound as is found to have a Non-Conformance (with respect to the Lilly Compound that has not yet been administered in the course of performing the Study). Unless otherwise agreed to by the Parties in writing, the sole and exclusive remedies of Sponsor with respect to any Lilly Compound that is found to have a Non-Conformance at the time of Delivery shall be (i) replacement of such Lilly Compound as set forth in this Section 8.5.2(b), (ii) indemnification under Section 14.2 (to the extent applicable) and (iii) termination of this Agreement pursuant to Section 6.3 (to the extent applicable, but subject to the applicable cure periods set forth therein). In the event that Lilly Compound is lost or damaged after Delivery, Lilly shall provide additional Lilly Compound to Sponsor, if available for the Study, provided that Sponsor shall reimburse Lilly for the Direct Manufacturing Costs and Indirect Manufacturing Costs of such replaced Lilly Compound to the extent that the loss or damage is due to the negligence of Sponsor or any of its vendors, subcontractors or Affiliates, and provided further that Lilly shall have no obligation to provide replacement Lilly Compound for any Lilly Compound supplied hereunder other than such Lilly Compound as has been agreed or determined to have a Non-Conformance at the time of Delivery to Sponsor (so long as such Non-Conformance was discovered within a reasonable time period). "Direct Manufacturing Costs" shall be calculated consistent with Generally

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Accepted Accounting Principles ("GAAP") and include manufacturing fees, raw materials, direct labor, freight and duty, and factory overhead costs that can be directly attributed to the Compound, including but not limited to equipment maintenance and repair, supplies, ongoing stability program costs, other plan services, indirect labor and depreciation on direct capital assets. "Indirect Manufacturing Costs" shall be calculated consistent with GAAP and include allocations of indirect factory overhead and site support costs, including but not limited to utilities, quality, planning, engineering, maintenance, safety, site science and technology, and depreciation on indirect capital assets, procurement, warehousing, and corporate services. Allocations shall be based on each compound's utilization relative to a manufacturing site's total activity.

(c) Sponsor shall be responsible for, and Lilly shall have no obligations or liability with respect to, any Sponsor Compound supplied hereunder that is found to have a Non-Conformance. Sponsor shall replace any Sponsor Compound as is found to have a Non-Conformance (with respect to Sponsor Compound that has not yet been administered in the course of performing the Study). Unless otherwise agreed to by the Parties in writing, the sole and exclusive remedies of Lilly with respect to any Sponsor Compound that is found to have a Non-Conformance shall be (i) replacement of such Sponsor Compound as set forth in this Section 8.5.2(c), (ii) indemnification under Section 14.2 (to the extent applicable) and (iii) termination of this Agreement pursuant to Section 6.3 (to the extent applicable, but subject to the applicable cure periods set forth therein).

Section 8.6. Resolution of Discrepancies. Disagreements regarding any determination of Non-Conformance by Sponsor shall be resolved in accordance with the provisions of the Quality Agreement.

Section 8.7. Investigations. The process for investigations of any Non-Conformance shall be handled in accordance with the Quality Agreement.

Section 8.8. Shortage; Allocation. In the event that a Party's Compound is in short supply as a result of a manufacturing disruption, manufacturing difficulties or other similar event such that a Party reasonably believes in good faith that it will not be able to fulfill its supply obligations hereunder with respect to its Compound, such Party will provide prompt written notice to the other Party thereof (including the shipments of Compound hereunder expected to be impacted and the quantity of its Compound that such Party reasonably determines it will be able to supply) and the Parties will promptly discuss such situation (including how the quantity of Compound that such Party is able to supply hereunder will be allocated within the Study). In such event, the Party experiencing such shortage shall (i) use its commercially reasonable efforts to remedy the situation giving rise to such shortage and to take action to minimize the impact of the shortage on the Study, and (ii) allocate to the other Party an amount of Compound as is fair and equitable in such Party's sole discretion.

Section 8.9. Manufacturing Records. Each Party shall maintain complete and accurate records in all material respects pertaining to its Manufacture of its Compound supplied hereunder, and, upon the reasonable prior request of the other Party, will make such records available to

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review by such other Party in accordance with the Quality Agreement solely for the purpose of confirming such Party's compliance with this Agreement with respect to its Manufacturing obligations hereunder.

Section 8.10. Quality. Quality matters related to the Manufacture of the Compounds shall be governed by the terms of the Quality Agreement in addition to the relevant quality provisions of this Agreement.

Section 8.11. Audits and Inspections. The Parties' audit and inspection rights under this Agreement shall be governed by the terms of the Quality and Pharmacovigilance Agreements.

Section 8.12. VAT. It is understood and agreed between the Parties that any payments made under this Agreement are exclusive of any value added or similar tax ("VAT"), which shall be added thereon as applicable. Where VAT is properly charged by the supplying Party and added to a payment made under this Agreement, the Party making the payment will pay the amount of VAT only on receipt of a valid tax invoice from the supplying Party issued in accordance with the laws and regulations of the country in which the VAT is chargeable.

ARTICLE 9.
CONFIDENTIALITY.

Section 9.1. Treatment of Confidential Information. Sponsor and Lilly agree to hold in confidence any Confidential Information of the other Party, and neither Party shall use Confidential Information of the other Party except for the performance of the Study and for permitted uses otherwise stated in this Agreement. Neither Party shall, without the prior written permission of the other Party, disclose any Confidential Information of the other Party to any Third Party except to the extent disclosure (i) is required by Applicable Law; (ii) is pursuant to the terms of this Agreement; or (iii) is necessary for the conduct of the Study, and in each case ((i) through (iii)) provided that the disclosing Party shall provide reasonable advance notice to the other Party before making such disclosure. For the avoidance of doubt, Sponsor may, without Lilly's consent, disclose Confidential Information to clinical trial sites and clinical trial investigators performing the Study, the data safety monitoring and advisory board relating to the Study, and Regulatory Authorities working with Sponsor on the Study, in each case to the extent necessary for the performance of the Study, in compliance with Applicable Law, and provided that such persons (other than governmental entities) are bound by an obligation of confidentiality at least as stringent as the obligations contained herein. Either party may, without the other party's consent, disclose, to the extent requested, relevant and applicable, Confidential Information to any national, federal, state, local or foreign governmental, regulatory or administrative authority, agency, department or arbitral body of any country having responsibility for the imposition of any tax in connection with an audit or examination of any tax return.

Section 9.2. Jointly Owned Confidential Information. [***]

9.2.1 Sponsor shall have the right to (i) use jointly owned Confidential Information [***]; and

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9.2.2 Lilly shall have the right to (i) use jointly owned Confidential Information [***].

Section 9.3. Disclosure of Confidential Information. Subject to Section 3.6, Lilly may use and disclose to Third Parties any Lilly solely owned Confidential Information for any purpose without obligation or accounting to Sponsor. Subject to Section 3.6, Sponsor may use and disclose to Third Parties any Sponsor solely owned Confidential Information for any purpose without obligation or accounting to Lilly.

Section 9.4. Confidential Information with PHI. Confidential Information containing personal identifiable data shall be handled in accordance with all applicable data protection and privacy laws, rules and regulations applicable to such Party, including the EU General Data Protection Regulation and HIPAA, to the extent and as applicable.

ARTICLE 10.
INTELLECTUAL PROPERTY.

Section 10.1. Joint Ownership and Prosecution.

10.1.1 Subject to Section 10.2 and Section 10.3, all rights to all Inventions relating to or covering the [***] (each a "Jointly Owned Invention") shall belong jointly to Sponsor and Lilly. For those countries where a specific license is required for a joint owner of a Jointly Owned Invention to exploit such Jointly Owned Invention in such countries, (i) [***]. For clarity, the terms of this Agreement do not provide Sponsor or Lilly with any rights, title or interest or any license to the other Party's background intellectual property except as necessary to conduct the Study and as expressly set forth in this Agreement. Each Party shall have the right to freely exploit each Jointly Owned Invention, both within and outside the scope of the Study, without accounting to or any other obligation to the other Party, and each Party may grant licenses (with a right to sublicense) to Third Parties under such Party's interest in each Jointly Owned Invention.

10.1.2 As needed following the Effective Date, patent representatives of each of the Parties shall meet (in person or by telephone) to discuss the patenting strategy for any Jointly Owned Inventions that may arise. In particular, the Parties shall discuss which Party will file a patent application (including any provisional, substitution, divisional, continuation, continuation in part, reissue, renewal, reexamination, extension, supplementary protection certificate and the like) in respect of any Jointly Owned Invention (each, a "Joint Patent Application") [***]. In any event, the Parties shall consult and reasonably cooperate with one another in the preparation, filing, prosecution (including prosecution strategy) and maintenance of such patent application and shall equally share the expenses associated with the Joint Patent Applications. In the event that one Party (the "Filing Party") wishes to file a patent application for a Jointly Owned Invention and the other Party (the "Non-filing Party") does not want to file any patent application for such Jointly Owned Invention or does not want to file in a particular country, the Non-filing Party shall execute such documents and perform such acts at the Filing

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Party's expense as may be reasonably necessary to effect an assignment of such Jointly Owned Invention to the Filing Party (in such country or all countries, as applicable) in a timely manner to allow the Filing Party to prosecute such patent application. Likewise, if a Party (the "Opting-out Party") wishes to discontinue the prosecution and maintenance of a Joint Patent Application, the other Party, at its sole option (the "Continuing Party"), may continue such prosecution and maintenance. In such event, the Opting-out Party shall execute such documents and perform such acts at the Continuing Party's expense as may be reasonably necessary to effect an assignment of such Joint Patent Application to the Continuing Party (in such country or all countries, as applicable) in a timely manner to allow the Continuing Party to prosecute and maintain such patent application. [***].

10.1.3 Except as expressly provided in Section 10.1.1 and in furtherance and not in limitation of Section 9.1, each Party agrees to make no patent application based on the other Party's Confidential Information, and to give no assistance to any Third Party for such application, without the other Party's prior written authorization.

10.1.4 Sponsor shall have the first right to initiate legal action to enforce all Joint Patents against infringement, and to protect all Jointly Owned Inventions from misappropriation, by any Third Party [***], or to defend any declaratory judgment action relating thereto, at its sole expense (subject to Section 10.1.5). In the event that Sponsor fails to initiate or defend such action within [***] days after being first notified of such infringement or misappropriation, Lilly shall have the right to do so at its sole expense (subject to Section 10.1.5). Similarly, Lilly shall have the first right to initiate legal action to enforce all Joint Patents against infringement and to protect all Jointly Owned Inventions from misappropriation, by any Third Party [***], or to defend any declaratory judgment action relating thereto, at its sole expense (subject to Section 10.1.5). In the event that Lilly fails to initiate or defend such action within [***] days after being first notified of such infringement, Sponsor shall have the right to do so at its sole expense (subject to Section 10.1.5). In the event that legal action to enforce [***], the Parties shall work together to coordinate such action and shall share the costs and expenses of such litigation equally. For clarity, if the alleged infringer is selling or intending to sell only one of either a Sponsor Class Compound or a Lilly Class Compound, then the Parties obligation to share the costs and expenses of such litigation shall not apply.

10.1.5 If one Party brings any prosecution or enforcement action or proceeding against a Third Party [***]. Any damages or other monetary awards recovered shall be shared by the Parties in proportion based on their relative contributions to the total costs and expenses of the litigation. A settlement or consent judgment or other voluntary final disposition of a suit under this Section 10.1.5 may not be entered into without the consent of the Party not bringing the suit, which shall not be unreasonable withheld, conditioned or delayed.

Section 10.2. Inventions Owned by Sponsor. Notwithstanding Section 10.1, the Parties agree that all rights to Inventions relating solely to the Sponsor Compound are the exclusive

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property of Sponsor. Sponsor shall be entitled to file in its own name relevant patent applications and to own resultant patent rights for any such Invention. For the avoidance of doubt, any Invention generically encompassing the Sponsor Compound (and not any Lilly proprietary compound including the Lilly Compound) within its scope, even where the Sponsor Compound is not disclosed per se, is the exclusive property of Sponsor.

Section 10.3. Inventions Owned by Lilly. Notwithstanding Section 10.1, the Parties agree that all rights to Inventions relating solely to the Lilly Compound are the exclusive property of Lilly. Lilly shall be entitled to file in its own name relevant patent applications and to own resultant patent rights for any such Invention. For the avoidance of doubt, any Invention generically encompassing the Lilly Compound (and not any Sponsor proprietary compound including the Sponsor Compound) within its scope, even where the Lilly Compound is not disclosed per se, is the exclusive property of Lilly.

Section 10.4. Mutual Freedom to Operate for Combination Inventions.

10.4.1 Sponsor hereby grants to Lilly a non-exclusive, worldwide, royalty-free, fully paid-up license, transferable and sublicensable, [***].

10.4.2 Lilly hereby grants to Sponsor a non-exclusive, worldwide, royalty-free, fully paid-up license, transferable and sublicensable, [***].

10.4.3 For clarity, the terms of this Section 10.4 do not provide Lilly or Sponsor with any rights, title or interest or any license to the other Party's background intellectual property which does not claim the Combination (i.e., intellectual property owned or licensed by either Party which does not constitute an Invention and does not claim the Combination) except as necessary to conduct the Study.

ARTICLE 11.
REPRINTS AND RIGHTS OF CROSS-REFERENCE.

Consistent with applicable copyright and other laws, each Party may use, refer to, and disseminate reprints of scientific, medical and other published articles and materials from journals, conferences and/or symposia relating to the Study which disclose the name of a Party, provided such use does not constitute an endorsement of any commercial product or service by the other Party.

ARTICLE 12.
PRESS RELEASES AND PUBLICATIONS.

Section 12.1. Public Announcements. Unless otherwise required by Applicable Law, neither Party shall make any public announcement concerning this Agreement without the prior written consent of the other Party. Notwithstanding the foregoing, Lilly acknowledges that information related to the Agreement may be material information with respect to Sponsor and require disclosure under applicable SEC rules or other Applicable Law. Such required disclosures shall not be considered a breach of this Section 12.1. To the extent a Party desires to make a public announcement in relation to this Agreement or the Study (including any press release, earnings

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call release, or investor presentation that contain data updates regarding the study), such Party shall provide the other Party with a draft thereof at least [***] Business Days prior to the date on which such Party intends to make the public announcement; the other Party shall review the draft within such time period and provide any comments, which the Party seeking to make the disclosure shall review in good faith. Lilly acknowledges the Sponsor of the Study's interest in providing periodic updates regarding Study and shall not unreasonably withhold, condition or delay consent for public announcements requested by Sponsor. In addition, Lilly agrees that Sponsor may provide enrollment updates regarding the study without prior consent. In addition, the parties hereby agree to work together in good faith to approve a press release that may be published following the execution of this Agreement.

Section 12.2. Registration of Clinical Trial. To the extent required by Applicable Law or as reasonably requested by Lilly, Sponsor will register the Study with the Clinical Trials Registry located at www.clinicaltrials.gov. Sponsor is committed to timely publication of the results following Study Completion, after taking appropriate action to secure intellectual property rights (if any) arising from the Study. The publication of the results of the Study will be in accordance with the Protocol. Lilly agrees not to publish any results of the Study prior to the timely publication of such Study results by Sponsor; the Parties agree that publication within [***] of Study Completion is timely publication.

Section 12.3. Publication. Subject to Section 12.2, each Party shall use commercially reasonable efforts to publish or present scientific papers dealing with the Study in accordance with accepted scientific practice. Each Party may issue a press release related to any scientific presentation or publication regarding the Study in a form mutually agreed to by the Parties.

Section 12.4. Review of Materials. The Parties agree that prior to submission of the results of the Study for publication or presentation or any other dissemination of results including oral dissemination, the publishing Party shall invite the other to comment on the content of the material to be published or presented according to the following procedure:

12.4.1 At least [***] days prior to submission for publication of any paper, letter, abstract, poster, talk or any other presentation or publication, the publishing Party shall provide to the other Party the initial draft of the proposed publication or presentation in an electronic version. During the [***] day period, the publishing Party and the other Party shall work together in good faith in order to allow for all actions to be taken to preserve rights for patent protection. At least [***] days prior to submission for presentation of any abstract, poster, talk or any other presentation and at least [***] days prior to submission of any paper, letter, or publication, the publishing Party shall provide to the other Party the full draft of the proposed presentation or publication for review and comment.

12.4.2 The publishing Party shall give reasonable consideration to any request by the other Party made within the periods mentioned in this Section 12.4 to modify the publication and the Parties shall work in good faith and in a timely manner to resolve any issue regarding the content for publication.

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12.4.3 The publishing Party shall remove all Confidential Information of the other Party before finalizing the publication.

Section 12.5. Acknowledgments. Each Party agrees to identify and acknowledge the other Party's support in any press release and any other publication or presentation of the results of the Study.

ARTICLE 13.
GENERAL REPRESENTATIONS AND WARRANTIES; DISCLAIMERS.

Section 13.1. General Representations. Each of Sponsor and Lilly represents and warrants to the other that:

13.1.1 it is a corporation duly organized, validly existing, and in good standing under the laws of its jurisdiction of formation;

13.1.2 it has full corporate power and authority to execute, deliver, and perform this Agreement, and has taken all corporate action required by law and its organizational documents to authorize the execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement;

13.1.3 this Agreement constitutes a valid and binding agreement enforceable against it in accordance with its terms;

13.1.4 all consents, approvals and authorizations from all governmental authorities or other Third Parties required to be obtained by such Party in connection with this Agreement have been obtained; and

13.1.5 the execution and delivery of this Agreement and all other instruments and documents required to be executed pursuant to this Agreement, and the consummation of the transactions contemplated hereby do not and will not (i) conflict with or result in a breach of any provision of its organizational documents, (ii) result in a breach of any agreement to which it is a party; or (iii) violate any law.

Section 13.2. No Guaranteed Results. Neither Party undertakes that the Study shall lead to any particular result and both Parties agree and understand that the success of the Study is not guaranteed. Neither Party accepts any responsibility for any use of the Clinical Data by the other Party nor for advice or information given in connection therewith.

Section 13.3. Anti-Corruption.

13.3.1 In performing their respective obligations hereunder, the Parties acknowledge that the corporate policies of Sponsor and Lilly and their respective Affiliates require that each Party's business be conducted within the letter and spirit of Applicable Law. By signing this Agreement, each Party agrees to conduct the business contemplated herein in a manner which is consistent with Applicable Law, including the U.S. Foreign Corrupt Practices Act of 1977 (as amended, the "FCPA") and any laws enacted to implement the Organization of Economic Cooperation and

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Development Convention on Combating Bribery of Foreign Officials in International Business Transactions and good business ethics, and its ethics and other corporate policies, and to abide by the spirit of the other Party's applicable ethics and compliance guidelines which may be provided by such other Party from time to time.

Specifically, each Party agrees that it and its Affiliates, and its and its Affiliates' directors, employees, officers, and anyone acting on its behalf, in connection with the performance of this Agreement, have not made, offered, given, promised to give, authorized, ratified, offered to make or taken any action in furtherance of, and will not, directly or indirectly, make, offer, promise to give, authorize, ratify or offer to make, or take any action in furtherance of, any payment or transfer of anything of value to any person or to any Government Official to do or omit to do an act in violation of a lawful or otherwise required duty or for the purpose of securing any improper advantage or inducing the person or Government Official to improperly influence the act or decision of any organization, including any government or government instrumentality, to assist Lilly or Sponsor in obtaining or retaining business.

13.3.2 Each Party shall not contact, or otherwise knowingly meet with, any Government Official for the purpose of discussing activities arising out of or in connection with this Agreement, without the prior written approval of the other Party, except where such meeting is consistent with the purpose and terms of this Agreement and in compliance with Applicable Law.

13.3.3 Each Party represents that: (i) it has no impediment to enter into the transaction contemplated in this Agreement; (ii) it is not excluded, debarred, suspended, proposed for suspension or debarment, or otherwise ineligible for government programs; and (iii) no individual involved in the Study has been debarred under Subsection (a) or (b) of Section 306 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 335a) and no Person on any of the FDA clinical investigator enforcement lists (including, but not limited to, the (1) Disqualified/Totally Restricted List, (2) Restricted List and (3) Adequate Assurances List) is involved in the Study or any other activity with respect to a Compound;

13.3.4 Each Party represents and warrants that except as disclosed to the other in writing prior to the commencement of this Agreement: (i) it does not have any interest which directly or indirectly conflicts with its proper and ethical performance of this Agreement; (ii) it shall maintain arm's length relations with all Third Parties with which it deals for or on behalf of the other in performance of this Agreement; and (iii) it has provided complete and accurate information to the other Party in the course of negotiating this Agreement, including disclosure of any officers, employees, owners or persons directly or indirectly retained by such Party, if any, in relation to the performance of this Agreement who are Government Officials or relatives of Government Officials. Each Party shall make all further disclosures as necessary to the other Party to ensure the information provided remains complete and accurate throughout the term of this Agreement. Subject to

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the foregoing, each Party agrees that it shall not hire or retain any Government Official to assist in its performance of this Agreement, with the sole exception of conduct of or participation in clinical trials under this Agreement, provided that such hiring or retention shall be subject to the completion by the hiring or retaining Party of a satisfactory anti-corruption and bribery (e.g., FCPA) due diligence review of such Government Official. Each Party further covenants that any future information and documentation submitted to the other Party as part of further due diligence or a certification shall be complete and accurate.

13.3.5 Each Party shall have the right during the term of this Agreement, and for a period of [***] following termination of this Agreement, to conduct an investigation and audit of the other Party's activities, books and records, to the extent they relate to that other Party's performance under this Agreement, to verify compliance with the terms of this Section 13.3. Such other Party shall cooperate fully with such investigation or audit, the scope, method, nature and duration of which shall be at the sole reasonable discretion of the Party requesting such audit.

13.3.6 Each Party shall ensure that all transactions under the Agreement are properly and accurately recorded in all material respects on its books and records and that each document upon which entries in such books and records are based is complete and accurate in all material respects. Each Party further represents, warrants and covenants that all books, records, invoices and other documents relating to payments and expenses under this Agreement are and shall be complete and accurate and reflect in reasonable detail the character and amount of transactions and expenditures. Each Party must maintain a system of internal accounting controls reasonably designed to ensure that no off-the-books or similar funds or accounts will be maintained or used in connection with this Agreement.

13.3.7 Each Party agrees that in the event that the other Party believes in good faith that there has been a possible violation of any provision of Section 13.3, such other Party may make full disclosure of such belief and related information needed to support such belief at any time and for any reason to any competent government bodies and its agencies, and to whoever such Party determines in good faith has a legitimate need to know.

13.3.8 Each Party agrees to ensure that all employees performing its obligations under this Agreement are provided ethics and compliance training in accordance with such Party's corporate policies and procedures.

Section 13.4. Compliance.

13.4.1 Compliance with Party Specific Regulations. The Parties agree to cooperate with each other as may reasonably be required to ensure that each is able to fully meet its obligations with respect to the Party Specific Regulations applicable to it. Neither Party shall be obligated to pursue any course of conduct that would result in such Party being in material breach of any Party Specific Regulation

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applicable to it. All Party Specific Regulations are binding only in accordance with their terms and only upon the Party to which they relate.

13.4.2 Compliance with Internal Compliance Codes. All Internal Compliance Codes shall apply only to the Party to which they relate. The Parties agree to cooperate with each other to ensure that each Party is able to comply with the substance of its respective Internal Compliance Codes and, to the extent practicable, to operate in a manner consistent with its usual Compliance related processes. "Internal Compliance Codes" shall mean a Party's internal policies and procedures intended to ensure that a Party complies with Applicable Laws, Party Specific Regulations, and such Party's internal ethical, medical and similar standard. "Party Specific Regulations" shall mean all judgments, decrees, orders or similar decisions issued by any Governmental Authority specific to a Party, and all consent decrees, corporate integrity agreements, or other agreements or undertakings of any kind by a Party with any Governmental Authority, in each case as the same may be in effect from time to time and applicable to a Party's activities contemplated by this Agreements.

Section 13.5. NO OTHER REPRESENTATIONS AND WARRANTIES. EXCEPT AS EXPRESSLY PROVIDED HEREIN, LILLY MAKES NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, WITH RESPECT TO THE LILLY COMPOUND, AND SPONSOR MAKES NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, WITH RESPECT TO THE SPONSOR COMPOUND.

ARTICLE 14.
INSURANCE; INDEMNIFICATION; LIMITATION OF LIABILITY.

Section 14.1. Insurance. Each Party warrants that it maintains a policy or program of insurance or self-insurance at levels sufficient to support the indemnification obligations assumed herein with carriers rated A-VII or better with A. M. Best or like rating agencies. Upon request, a Party shall provide evidence of such insurance. At a minimum each party will procure and maintain or at its option, satisfy, in whole or in part through its self- insurance program:

14.1.1 Workers' Compensation accordance with applicable statutory requirements and will provide a waiver of subrogation in favor of the other party;

14.1.2 Employer's Liability with a limit of liability in an amount of not less than [***];

14.1.3 Commercial General Liability for premises/ongoing operations in an amount not less than [***];

Section 14.2. Indemnification.

14.2.1 Indemnification by Sponsor. Sponsor agrees to defend, indemnify and hold harmless Lilly, its Affiliates, and its and their employees, directors

and hold harmless Lilly, its Affiliates, and its and their employees, directors,

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subcontractors and agents from and against any loss, damage, reasonable costs and expenses (including reasonable attorneys' fees and expenses) incurred in connection with any claim, proceeding, or investigation by a Third Party arising out of this Agreement or the Study (a "Liability"), except to the extent that such Liability (A) was directly caused by (i) negligence or willful misconduct on the part of Lilly (or any of its Affiliates, or its and their employees, directors, subcontractors or agents); (ii) a breach on the part of Lilly of any of its representations and warranties or any other covenants or obligations of Lilly under this Agreement; or (iii) a breach of Applicable Law by Lilly; or (B) is determined to be attributable to the Lilly Compound.

14.2.2 Indemnification by Lilly. Lilly agrees to defend, indemnify and hold harmless Sponsor, its Affiliates, and its and their employees, directors, subcontractors and agents from and against any Liability except to the extent that such Liability (A) was directly caused by (i) negligence or willful misconduct on the part of Sponsor (or any of its Affiliates, or its and their employees, directors, subcontractors or agents); (ii) a breach on the part of Sponsor of any of its representations and warranties or any other covenants or obligations of Sponsor under this Agreement; or (iii) a breach of Applicable Law by Sponsor; or (B) is determined to be attributable to the Sponsor Compound.

14.2.3 Procedure. The obligations of Lilly and Sponsor under this Section 14.2 are conditioned upon the delivery of written notice to Lilly or Sponsor, as the case might be, of any potential Liability within a reasonable time after a Party becomes aware of such potential Liability. A Party will have the right to assume the defense of any suit or claim related to the Liability (using counsel reasonably satisfactory to the other Party) if it has assumed responsibility for the suit or claim in writing. The other Party may participate in (but not control) the defense thereof at its sole cost and expense. The Party controlling such defense (the "Defending Party") shall keep the other Party (the "Other Party") advised of the status of such action, suit, proceeding or claim and the defense thereof and shall consider recommendations made by the Other Party with respect thereto. The Defending Party shall not agree to any settlement of such action, suit, proceeding or claim without the prior written consent of the Other Party, which shall not be unreasonably withheld. The Defending Party shall not agree to any settlement of such action, suit, proceeding or claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Other Party from all liability with respect thereto or that imposes any liability or obligation on the Other Party without the prior written consent of the Other Party.

Section 14.3. Study Subjects. Sponsor shall not offer compensation on behalf of Lilly to any Study subject or bind Lilly to any indemnification obligations in favor of any Study subject. Likewise, Lilly shall not offer compensation on behalf of Sponsor to any Study subject or bind Sponsor to any indemnification obligations in favor of any Study subject.

Section 14.4. LIMITATION OF LIABILITY. OTHER THAN WITH RESPECT TO DAMAGES ARISING OUT OF OR RELATED TO A PARTY'S BREACH OF ITS

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OBLIGATIONS UNDER THIS AGREEMENT TO USE, DISCLOSE, LICENSE, ASSIGN OR OTHERWISE TRANSFER SAMPLE TESTING RESULTS, CLINICAL DATA, CONFIDENTIAL INFORMATION AND JOINTLY-OWNED INVENTIONS ONLY FOR THE PERMITTED USE, IN NO EVENT SHALL EITHER PARTY (OR ANY OF ITS AFFILIATES OR SUBCONTRACTORS) BE LIABLE TO THE OTHER PARTY FOR, NOR SHALL ANY INDEMNIFIED PARTY HAVE THE RIGHT TO RECOVER, ANY SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES (INCLUDING LOST PROFITS OR DAMAGES FOR LOST OPPORTUNITIES), WHETHER IN CONTRACT, WARRANTY, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE, ARISING OUT OF (x) THE MANUFACTURE OR USE OF ANY COMPOUND SUPPLIED HEREUNDER OR (y) ANY BREACH OF OR FAILURE TO PERFORM ANY OF THE PROVISIONS OF THIS AGREEMENT OR ANY REPRESENTATION, WARRANTY OR COVENANT CONTAINED IN OR MADE PURSUANT TO THIS AGREEMENT, EXCEPT THAT SUCH LIMITATION SHALL NOT APPLY TO DAMAGES PAID OR PAYABLE TO A THIRD PARTY BY AN INDEMNIFIED PARTY FOR WHICH THE INDEMNIFIED PARTY IS ENTITLED TO INDEMNIFICATION HEREUNDER.

ARTICLE 15.
MISCELLANEOUS

Section 15.1. Use of Name. Except as expressly provided herein, neither Party shall have any right, express or implied, to use in any manner the name or other designation of the other Party or any other trade name, trademark or logo of the other Party for any purpose in connection with the performance of this Agreement.

Section 15.2. Force Majeure. If in the performance of this Agreement, one of the Parties is prevented, hindered or delayed by reason of any cause beyond such Party's reasonable control (e.g., war, riots, fire, strike, governmental laws), such Party shall be excused from performance to the extent that it is necessarily prevented, hindered or delayed ("Force Majeure"). The non-performing Party will notify the other Party of such Force Majeure within [***] days after such occurrence by giving written notice to the other Party stating the nature of the event, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance will be of no greater scope and no longer duration than is necessary and the non-performing Party will use commercially reasonable efforts to remedy its inability to perform.

Section 15.3. Entire Agreement; Modification. The Parties agree to the full and complete performance of the mutual covenants contained in this Agreement. This Agreement, together with the Related Agreements, constitutes the sole, full and complete agreement by and between the Parties with respect to the subject matter of this Agreement, and all prior agreements, understandings, promises and representations, whether written or oral, with respect thereto are superseded by this Agreement. No amendments, changes, additions, deletions or modifications to or of this Agreement shall be valid unless reduced to writing and signed by the Parties hereto. In the event of a conflict between this Agreement, the Pharmacovigilance Agreement or the exhibits and appendices attached hereto, the Pharmacovigilance Agreement shall control with respect to pharmacovigilance matters. For avoidance of doubt, the Quality Agreement shall control in the event of a conflict between this Agreement and the Quality Agreement with respect to quality matters.

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Section 15.4. Assignment and Sub-Contracting. Neither Party shall assign or transfer this Agreement without the prior written consent (which shall not be unreasonably withheld, conditioned or delayed) of the other Party; provided, however, that either Party may assign all or any part of this Agreement to one or more of its Affiliates without the other Party's consent, and any and all rights and obligations of either Party may be exercised or performed by its Affiliates, provided that such Affiliates agree to be bound by this Agreement and such Party shall be jointly and severally liable for such Affiliate's compliance with the terms of this Agreement and Related Agreements.

Section 15.5. Invalid Provision. If any provision of this Agreement is held to be illegal, invalid or unenforceable, the remaining provisions shall remain in full force and effect and will not be affected by the illegal, invalid or unenforceable provision. In lieu of the illegal, invalid or unenforceable provision, the Parties shall negotiate in good faith to agree upon a reasonable provision that is legal, valid and enforceable to carry out as nearly as practicable the original intention of the entire Agreement.

Section 15.6. No Additional Obligations. Sponsor and Lilly have no obligation to renew this Agreement or apply this Agreement to any clinical trial other than the Study. Neither Party is under any obligation to enter into another type of agreement at this time or in the future.

Section 15.7. Dispute Resolution and Jurisdiction.

15.7.1 The Parties shall attempt in good faith to settle all disputes arising out of or in connection with this Agreement in an amicable manner through the Project Managers. Any claim, dispute or controversy arising out of or relating to this Agreement, including the breach, termination or validity hereof or thereof (each, a "Dispute"), shall be governed by and construed in accordance with the substantive laws of the State of New York, without giving effect to its choice of law principles.

15.7.2 Nothing contained in this Agreement shall deny either Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction in the context of a bona fide emergency or prospective irreparable harm, and such an action may be filed or maintained notwithstanding any ongoing discussions between the Parties.

Section 15.8. Notices. All notices or other communications that are required or permitted hereunder shall be in writing and delivered personally, sent by facsimile or email, as applicable, (and promptly confirmed by personal delivery or overnight courier), or sent by internationally recognized overnight courier addressed as follows:

If to Lilly, to: Eli Lilly & Company
Lilly Corporate Center
893S. Delaware
Indianapolis, IN, USA 46285
Attention: VP of Oncology Late Phase Development
Facsimile No: (317) 277-3652

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With a copy to: Eli Lilly & Company
Lilly Corporate Center
893S. Delaware
Indianapolis, IN, USA 46285
Attention: General Counsel
Facsimile No: (317) 433-3000

If to Sponsor, to: Pieris Pharmaceuticals, Inc.
255 State Street, 9th floor
Boston, MA 02109
Attention: SVP, Head of Clinical Development
[***]

With a copy to: Pieris Pharmaceuticals, Inc.
255 State Street, 9th floor
Boston, MA 02109
Attention: General Counsel
[***]

Section 15.9. Relationship of the Parties. The relationship between the Parties is and shall be that of independent contractors, and does not and shall not constitute a partnership, joint venture, agency or fiduciary relationship. Neither Party shall have the authority to make any statements, representations or commitments of any kind, or take any actions, which are binding on the other Party, except with the prior written consent of the other Party to do so. All persons employed by a Party will be the employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such Party.

Section 15.10. Counterparts and Due Execution. This Agreement, any amendment and Related Agreements may be executed in two (2) or more counterparts (including by way of facsimile or electronic transmission), each of which shall be deemed an original, but all of which together shall constitute one and the same instrument, notwithstanding any electronic transmission, storage and printing of copies of this Agreement from computers or printers. When executed by the Parties, this Agreement shall constitute an original instrument, notwithstanding any electronic transmission, storage and printing of copies of this Agreement from computers or printers. For clarity, facsimile signatures and signatures transmitted via PDF shall be treated as original signatures.

Section 15.11. Condition Precedent. This Agreement will enter into force as of the Effective Date, but will remain conditional upon the parties negotiating and delivering the Related Agreements, signed by all required authorized quality officers and representatives of both parties.

Section 15.12. Construction. Except where the context otherwise requires, wherever used, the singular will include the plural, the plural the singular, the use of any gender will be applicable to all genders, and the word "or" is used in the inclusive sense (and/or). Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar

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days. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term "including" as used herein shall be deemed to be followed by the phrase "without limitation" or like expression. The term "will" as used herein means shall. References to "Article," "Section" or "Appendix" are references to the numbered sections of this Agreement and the appendices attached to this Agreement, unless expressly stated otherwise. Except where the context otherwise requires, references to this "Agreement" shall include the appendices attached to this Agreement. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction will be applied against either Party hereto.

[Remainder of page intentionally left blank.]

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IN WITNESS WHEREOF, the respective representatives of the Parties have executed this Agreement as of the Effective Date.

"SPONSOR"

PIERIS PHARMACEUTICALS, INC.

By: /s/ Stephen Yoder_____

Name: Stephen Yoder_____

Title: President & CEO_____

"LILLY"

ELI LILLY AND COMPANY

By: /s/ Maura Dickler_____
Maura Dickler
Vice President Oncology Late Phase Development

ELI LILLY AND COMPANY

By: /s/ Michael Franklin_____
Michael Franklin
Senior Advisor Commercial Product Delivery

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Appendix A

[***, 23 pages]

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Appendix B

[***, 1 page]

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Appendix C

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Appendix D

[***, 3 pages]

[***] = 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.

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Exhibit 31.1

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: November 4, 2020

/s/ Stephen S. Yoder

Stephen S. Yoder
Title: Chief Executive Officer and President (principal executive officer)

Exhibit 31.2

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: November 4, 2020

/s/ Thomas Bures

Thomas Bures

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

Exhibit 32.1

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 September 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: November 4, 2020

/s/ Stephen S. Yoder

Stephen S. Yoder

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

Exhibit 32.2

CERTIFICATIONS UNDER SECTION 906

Pursuant to 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 September 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: November 4, 2020

/s/ Thomas Bures

Thomas Bures

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