UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

| | • | FORM 10-Q | | |
|---------|--|--|--|----|
| Mark | One) | | | |
| × | QUARTERLY REPORT PURSUANT | T TO SECTION 13 OR 15(d) OF THE SEC For the quarterly period ended June 30, 2019 OR | CURITIES EXCHANGE ACT OF 1934 | |
| | | TO SECTION 13 OR 15(d) OF THE SECTION 13 OR 15(d) OF THE SECTION 15 OF THE SECTION 1 | CURITIES EXCHANGE ACT OF 1934 - | |
| | PIERIS 1 | PHARMACEUTICA (Exact name of registrant as specified in its charter) | LS, INC. | |
| | Nevada (State or other jurisdiction of incorporation or organization) | | 30-0784346 (I.R.S. Employer Identification No.) | |
| | 255 State Street, 9th Floor Boston, MA United States (Address of principal executive offices) | 857-246-8998 Registrant's telephone number, including area code | 02109 (Zip Code) | |
| Sec | curities registered pursuant to Section 12(b) of the Act: | | | |
| | Title of Each Class | Trading Symbol | Name of Each Exchange on Which Registered | _ |
| | | PIRS I reports required to be filed by Section 13 or 15(d) of the S such reports), and (2) has been subject to such filing requirer | The Nasdaq Capital Market ecurities Exchange Act of 1934 during the preceding 12 mont ments for the past 90 days. Yes ⊠ No □ | hs |
| | | electronically every Interactive Data File required to be sub od that the registrant was required to submit such files). You | mitted pursuant to Rule 405 of Regulation S-T (§232.405 of t es \blacksquare No \square | hi |
| | | lerated filer, an accelerated filer, a non-accelerated filer, a su haller reporting company" and "emerging growth company" | maller reporting company or an emerging growth company. So in Rule 12b-2 of the Exchange Act. | зе |
| Large a | ccelerated filer | | Accelerated filer | |
| Non-ac | celerated filer | | Smaller reporting company | |
| | | | Emerging growth company | |
| | | 1 | | |
| - | | | | _ |

| 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 \Box No \blacksquare |
| As of August 5, 2019, the registrant had 49,392,706 shares of common stock outstanding. |
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Special Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, that involve risks and uncertainties, principally in the section 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," "ongoing," "could," "estimates," "expects," "intends," "may," "appears," "future," "likely," "plans," "potential," "projects," "predicts," "seek," "should," "target," "would" or "will" or the negative of these terms or other comparable terminology. Although we do not make forward-looking statements unless we believe we have a reasonable basis for doing so, we cannot guarantee their accuracy. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including the risks outlined under "Risk Factors" or elsewhere in our most recent Annual Report on Form 10-K, which may cause our or our industry's actual results, levels of activity, performance or achievements expressed or implied by these forward-looking statements to differ materially.

Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time and it is not possible for us to predict all risk factors, nor can we address the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause our actual results to differ materially from those contained in any forward-looking statements. Actual results could differ materially from our forward-looking statements due to a number of factors, including, without limitation, risks related to: the results of our research and development activities, including uncertainties relating to the discovery of potential drug candidates and the preclinical and ongoing or planned clinical testing of our drug candidates; the early stage of our drug candidates presently under development; our ability to obtain and, if obtained, maintain regulatory approval of our current drug candidates and any of our other future drug candidates; our need for substantial additional funds in order to continue our operations and the uncertainty of whether we will be able to obtain the funding we need; our future financial performance; our ability to retain or hire key scientific or management personnel; our ability to protect our intellectual property rights that are valuable to our business, including patent and other intellectual property rights; our dependence on third-party manufacturers, suppliers, research organizations, testing laboratories and other potential collaborators; the success of our collaborations with third parties; our ability to meet milestones; our ability to successfully market and sell our drug candidates in the future as needed; the size and growth of the potential markets for any of our approved drug candidates, and the rate and degree of market acceptance of any of our approved drug candidates; competition in our industry; regulatory developments in the United States and foreign countries; and the expected impact of new accounting standards.

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, 2018 filed with the Securities and Exchange Commission, or SEC, on March 18, 2019, 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 " ϵ " 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. \$1.1368 based on Thomson Reuters as of June 30, 2019.

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements.

PIERIS PHARMACEUTICALS, INC. CONDENSED CONSOLIDATED BALANCE SHEETS

(unaudited)

(in thousands, except share and per share data)

| | June 30 | D | ecember 31, |
|---|---------------|----|-------------|
| | 2019 | | 2018 |
| Assets | | | |
| Current assets: | | | |
| Cash and cash equivalents | \$ 54,901 | \$ | 74,867 |
| Short term investments | 44,782 | | 53,240 |
| Accounts receivable | 7,174 | | 2,701 |
| Prepaid expenses and other current assets | 4,605 | | 4,574 |
| Total current assets | 111,462 | | 135,382 |
| Property and equipment, net | 7,888 | | 5,049 |
| Other non-current assets | 11,490 | | 910 |
| Total assets | \$ 130,840 | \$ | 141,341 |
| Liabilities and stockholders' equity | | | |
| Current liabilities: | | | |
| Accounts payable | \$ 4,031 | \$ | 3,350 |
| Accrued expenses and other current liabilities | 8,491 | | 9,114 |
| Deferred revenues, current portion | 28,406 | | 35,612 |
| Total current liabilities | 40,928 | | 48,076 |
| Deferred revenue, net of current portion | 58,110 | | 53,303 |
| Other long-term liabilities | 12,317 | | 27 |
| Total liabilities | 111,355 | | 101,406 |
| Stockholders' equity: | | | |
| Preferred stock, \$0.001 par value per share, 10,000,000 shares authorized at June 30, 2019 and December 31, 2018, respectively | | | |
| Series A Convertible, 2,907 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively | _ | | _ |
| Series B Convertible, 5,000 shares issued and outstanding at June 30, 2019. No shares issued and outstanding at December 31, 2018. | _ | | _ |
| Common stock, \$0.001 par value per share, 300,000,000 shares authorized and 49,261,517 and 54,151,219 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively | 49 | | 54 |
| Additional paid-in capital | 192,956 | | 189,929 |
| Accumulated other comprehensive loss | (2,707) | | (2,982) |
| Accumulated deficit | (170,813) | | (147,066) |
| Total stockholders' equity | 19,485 | | 39,935 |
| Total liabilities and stockholders' equity | \$ 130,840 | \$ | 141,341 |

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

PIERIS PHARMACEUTICALS, INC.

${\bf CONDENSED\ CONSOLIDATED\ STATEMENTS\ OF\ OPERATIONS\ AND\ COMPREHENSIVE\ LOSS}$

(unaudited)

(in thousands, except per share data)

| | 7 | Three Months | s End | led June 30 | Six Months | Ende | d June 30 |
|---|----|--------------|-------|-------------|----------------|------|-----------|
| | | 2019 | | 2018 | 2019 | | 2018 |
| Revenue | \$ | 5,332 | \$ | 11,691 | \$ 13,877 | \$ | 15,843 |
| Operating expenses | | | | | | | |
| Research and development | | 13,373 | | 9,155 | 27,669 | | 17,091 |
| General and administrative | | 4,189 | | 4,779 | 9,121 | | 9,131 |
| Total operating expenses | | 17,562 | | 13,934 | 36,790 | | 26,222 |
| Loss from operations | | (12,230) | | (2,243) | (22,913) | | (10,379) |
| Interest income | | 449 | | 662 | 955 | | 987 |
| Other income (expense), net | | 23 | | 1,230 | (148) | | 327 |
| Loss before income taxes | | (11,758) | | (351) | (22,106) | | (9,065) |
| Income tax benefit | | _ | | (148) | | | (148) |
| Net loss | \$ | (11,758) | \$ | (203) | \$ (22,106) | \$ | (8,917) |
| | | | | | | | |
| Other comprehensive income (loss): | | | | | | | |
| Foreign currency translation | | (414) | | 1,266 | 272 | | 519 |
| Unrealized (loss) gain on available-for-sale securities | | (237) | | 2,133 | 3 | | 1,602 |
| Comprehensive (loss) income | \$ | (12,409) | \$ | 3,196 | \$ (21,831) | \$ | (6,796) |
| Net loss per share | | | | | | | |
| Basic and diluted | \$ | (0.24) | \$ | | \$ (0.44) | \$ | (0.17) |
| Weighted average number of common shares outstanding | | | | | | | |
| Basic and diluted | | 49,204 | _ | 53,983 | 50,034 | | 52,025 |

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, except per share data) For the Three Months Ended June 30

| | Series A preferi | | Series B o | convertib ed shares | | Comm | on Sl | nares | Additional | A | ccumulated other | | Total | |
|---|---------------------|------------------|------------------|------------------------|---|---------------|-------|-----------------|--------------------|----|---------------------|---------------------|-------------------------|--|
| | No. of shares | Share capital | No. of shares | Shar capit | | No. of shares | | Share apital | paid-in capital | co | mprehensive loss | Accumulated deficit | Stockholders' equity | |
| Balance as of March 31, 2018 | 2,907 | \$ _ | _ | | _ | 53,974 | \$ | 54 | \$ 185,638 | \$ | (5,974) | \$ (129,026) | \$ 50,692 | |
| Net loss | _ | _ | _ | | _ | _ | | _ | _ | | _ | (203) | (203) | |
| Foreign currency translation adjustment | _ | _ | _ | | _ | _ | | _ | _ | | 1,266 | _ | 1,266 | |
| Unrealized gains/(losses) on investments | _ | _ | _ | | _ | _ | | _ | _ | | 2,134 | _ | 2,134 | |
| Stock based compensation expense | _ | _ | _ | | _ | _ | | _ | 1,360 | | _ | _ | 1,360 | |
| Issuance of common stock resulting from exercise of stock options | _ | _ | _ | | _ | 6 | | _ | 13 | | _ | _ | 13 | |
| Issuance of common stock resulting from exercise of warrants | | _ | _ | | _ | 28 | | _ | 55 | | _ | _ | 55 | |
| Balance as of June 30, 2018 | 2,907 | \$ _ | _ | \$ | _ | 54,008 | \$ | 54 | \$ 187,066 | \$ | (2,574) | \$ (129,229) | \$ 55,317 | |
| | | | | | | | | | | | | | | |
| Balance as of March 31, 2019 | 2,907 | \$ _ | 5,000 | | _ | 49,151 | \$ | 49 | \$ 191,224 | \$ | (2,056) | \$ (159,055) | \$ 30,162 | |
| Net loss | _ | _ | _ | | _ | _ | | _ | _ | | _ | (11,758) | (11,758) | |
| Foreign currency translation adjustment | _ | _ | _ | | _ | _ | | _ | _ | | (414) | _ | (414) | |
| Unrealized gains/(losses) on investments | _ | _ | _ | | _ | _ | | _ | _ | | (237) | _ | (237) | |
| Stock based compensation expense | _ | _ | _ | | _ | _ | | _ | 1,452 | | _ | _ | 1,452 | |
| Issuance of common stock resulting from exercise of stock options | _ | _ | _ | | _ | 50 | | _ | 97 | | _ | _ | 97 | |
| Issuance of common stock from employee stock purchase plan | _ | _ | _ | | _ | 58 | | | 178 | | _ | _ | 178 | |
| Issuance of common stock resulting from exercise of warrants | | _ | _ | | _ | 3 | | _ | 5 | | _ | _ | 5 | |
| Balance as of June 30, 2019 | 2,907 | \$ _ | 5,000 | \$ | _ | 49,262 | \$ | 49 | \$ 192,956 | \$ | (2,707) | \$ (170,813) | \$ 19,485 | |

PIERIS PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

(unaudited)

(in thousands, except per share data)

For the Six Months Ended June 30

| | Series A preferr | | Series B o | convertibled shares | le | Comm | on Sł | nares | Additional | 1 | Accumulated other | | | Total |
|---|---------------------|-----------------|---------------|---------------------|----|---------------|-------|----------------|--------------------|----|----------------------|---------------------|----|-----------------------|
| | No. of shares | Share apital | No. of shares | Shar capit | | No. of shares | | hare apital | paid-in capital | C | omprehensive loss | Accumulated deficit | st | ockholders' equity |
| Balance as of December 31, 2017 | 4,963 | \$ _ | _ | | _ | 45,017 | \$ | 45 | \$136,484 | \$ | (4,695) | \$ (120,312) | \$ | 11,522 |
| Net loss | _ | _ | _ | | _ | _ | | _ | _ | | _ | (8,917) | | (8,917) |
| Foreign currency translation adjustment | _ | _ | _ | | _ | _ | | _ | _ | | 519 | _ | | 519 |
| Unrealized gains/(losses) on investments | _ | _ | _ | | _ | _ | | _ | _ | | 1,602 | _ | | 1,602 |
| Stock based compensation expense | _ | _ | _ | | _ | _ | | _ | 2,364 | | _ | _ | | 2,364 |
| Issuance of common stock resulting from exercise of stock options | _ | _ | _ | | _ | 519 | | 1 | 838 | | _ | _ | | 839 |
| Issuance of common stock resulting from exercise of warrants | _ | _ | _ | | _ | 91 | | _ | 181 | | _ | _ | | 181 |
| Issuance of common stock net \$3,374 in offering costs | _ | _ | _ | | _ | 6,325 | | 6 | 47,201 | | _ | _ | | 47,207 |
| Preferred stock conversion | (2,056) | _ | _ | | _ | 2,056 | | 2 | (2) | | _ | _ | | _ |
| Balance as of June 30, 2018 | 2,907 | \$ _ | _ | \$ | _ | 54,008 | \$ | 54 | \$187,066 | \$ | (2,574) | \$ (129,229) | \$ | 55,317 |
| | | | | | | | | | | | | | | |
| Balance as of December 31, 2018 | 2,907 | \$ _ | _ | | _ | 54,151 | \$ | 54 | \$189,929 | \$ | (2,982) | \$ (147,066) | \$ | 39,935 |
| Change in Retained Earnings from adoption of ASC 606 | _ | _ | _ | | _ | _ | | _ | _ | | _ | (1,641) | | (1,641) |
| Net loss | _ | _ | _ | | _ | _ | | _ | _ | | _ | (22,106) | | (22,106) |
| Foreign currency translation adjustment | _ | _ | _ | | _ | _ | | _ | _ | | 272 | _ | | 272 |
| Unrealized gains/(losses) on investments, net of \$0.1 million of tax | _ | _ | _ | | _ | _ | | _ | _ | | 3 | _ | | 3 |
| Stock based compensation expense | _ | _ | _ | | _ | _ | | _ | 2,742 | | _ | _ | | 2,742 |
| Issuance of common stock resulting from exercise of stock options | _ | _ | _ | | _ | 50 | | _ | 97 | | _ | _ | | 97 |
| Issuance of common stock from employee stock purchase plan | _ | _ | _ | | _ | 58 | | _ | 178 | | _ | _ | | 178 |
| Issuance of common stock resulting from exercise of warrants | _ | _ | _ | | _ | 3 | | _ | 5 | | _ | _ | | 5 |
| Preferred stock conversion | | _ | 5,000 | | _ | (5,000) | | (5) | 5 | | _ | _ | | _ |
| Balance as of June 30, 2019 | 2,907 | \$ | 5,000 | \$ | _ | 49,262 | \$ | 49 | \$192,956 | \$ | (2,707) | \$ (170,813) | \$ | 19,485 |

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

PIERIS PHARMACEUTICALS, INC. CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited, in thousands)

| | | Six Months E | nded J | June 30 |
|---|----|--------------|--------|----------|
| | | 2019 | | 2018 |
| Operating activities: | | _ | | |
| Net loss | \$ | (22,106) | \$ | (8,917) |
| Adjustments to reconcile net loss to net cash provided by operating activities: | | | | |
| Depreciation | | 208 | | 275 |
| Stock-based compensation | | 2,742 | | 2,355 |
| Deferred rent expense | | 588 | | _ |
| Other | | (151) | | 54 |
| Changes in operating assets and liabilities | | (7,122) | | 28,584 |
| Net cash (used in) provided by operating activities | | (25,841) | | 22,351 |
| Investing activities: | | | | |
| Purchases of property and equipment | | (1,054) | | (808) |
| Proceeds from maturity of investments | | 35,647 | | 10,974 |
| Purchases of investments | | (26,997) | | (67,222) |
| Net cash provided by (used in) investing activities | ' | 7,596 | | (57,056) |
| Financing activities: | | | | |
| Proceeds from exercise of stock options | | 97 | | 839 |
| Proceeds from exercise of warrants | | 5 | | 182 |
| Proceeds from employee stock purchase plan | | 178 | | _ |
| Issuance of common stock, net of issuance costs | | _ | | 47,207 |
| Net cash provided by financing activities | ' | 280 | | 48,228 |
| Effect of exchange rate change on cash and cash equivalents | | (2,001) | | (825) |
| Net (decrease) increase in cash and cash equivalents | | (19,966) | | 12,698 |
| Cash and cash equivalents at beginning of period | | 74,867 | | 37,878 |
| Cash and cash equivalents at end of period | \$ | 54,901 | \$ | 50,576 |
| Supplemental cash flow disclosures: | | | | |
| Net unrealized gain on investments | \$ | 93 | \$ | 1,667 |
| Property and equipment included in accounts payable | \$ | 31 | \$ | 202 |

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

PIERIS PHARMACEUTICALS, INC. NOTES TO 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 which 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 Freising-Weihenstephan, Germany.

Pieris's clinical pipeline includes an inhaled IL-4Rα antagonist Anticalin protein to treat uncontrolled asthma, an immuno-oncology, or IO, bispecific targeting HER2 and 4-1BB, and a half-life-optimized hepcidin-antagonizing Anticalin protein to treat anemia.

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

As of June 30, 2019, the Company had cash, cash equivalents and investments of \$99.7 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, 2018. There has been no material change to the significant accounting policies during thesix months ended June 30, 2019 other than the adoption of Financial

Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 606, Revenue from Contracts with Customers, or ASC 606, 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 adjustment, and disclosures considered necessary for a fair presentation of interim period results have been included. Interim results for the three and six months ended June 30, 2019 are not necessarily indicative of results that may be expected for the year ending December 31, 2019. 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, 2018, which was filed with the SEC on March 18, 2019.

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; fair value of stock options 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 ASC 320, *Investments—Debt and Equity Securities*. The Company classifies investments available to fund current operations as current assets on its balance sheets. Investments are classified as non-current assets on the balance sheets if (i) the Company has the intent and ability to hold the investments for a period of at least one year and (ii) the contractual maturity date of the investments is greater than one year.

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. Realized gains of \$0.1 million were recognized for the three and six months ended June 30, 2019. Realized gains of approximately \$0.1 million and realized losses \$0.1 million were recognized for the three and six months ended June 30, 2018.

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. As of June 30, 2019, 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.

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. These amounts, at times, may exceed federally insured limits. The Company has not experienced any credit losses in such accounts and does not believe it is exposed to any significant credit risk on these funds. Accounts receivable primarily consist of amounts due under strategic partnership and other license agreements with major multi-national pharmaceutical companies for which the Company does not obtain collateral.

Fair Value Measurement

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

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

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

Financial instruments measured at fair value on a recurring basis include cash equivalents and investments (Vote 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.

Revenue Recognition

Pieris has entered into several licensing agreements with collaboration partners for the development of Anticalin therapeutics against a variety of targets. The terms of these agreements provide for the transfer of multiple goods or services which may include: (i) licenses, or options to obtain licenses, to Pieris'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.

Effective January 1, 2019, the Company adopted ASC 606. The standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. The standard allows for two transition methods -- full retrospective, in which the standard is applied to each prior reporting period presented, or modified retrospective, in which the cumulative effect of initially applying the standard is recognized at the date of initial adoption. The Company elected the modified retrospective approach and applied it to contracts not completed at the date of adoption. Therefore, comparative prior periods have not been adjusted. The reported results for 2019 reflect the application of ASC 606 guidance while the reported results for 2018 were prepared under the guidance of FASB ASC Topic 605, Revenue Recognition, or ASC 605. Furthermore, the Company adopted the contract modification practical expedient set forth in ASC 606 and will reflect the aggregate effect of all modifications that occurred before January 1, 2019 when identifying the satisfied and unsatisfied performance obligations, determining the transaction price and allocating the transaction price to the satisfied and unsatisfied performance obligations. See Note 3 for additional details on these arrangements.

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.

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.

Impact of Adopting ASC 606 on the Financial Statements

As a result of applying the modified retrospective method to adopt the new revenue guidance, the following adjustments were made to the consolidated balance sheet as of January 1, 2019:

| | As Repo | rted, December 31, 2018 | ASC 6 | 06 Adjustment | Adju | isted, January 1, 2019 |
|---|---------|----------------------------|-------|---------------|------|---------------------------|
| Consolidated Balance Sheet Data (in thousands): | | | | | | |
| Prepaid expenses and other current assets | \$ | 4,574 | \$ | 716 | \$ | 5,290 |
| Other non-current assets | | 910 | | 1,120 | | 2,030 |
| Total Assets | \$ | 141,341 | \$ | 1,836 | \$ | 143,177 |
| Deferred revenue, net of current portion | \$ | 53,303 | \$ | 3,477 | \$ | 56,780 |
| Total Liabilities | | 101,406 | | 3,477 | | 104,883 |
| Accumulated deficit | | (147,066) | | (1,641) | | (148,707) |
| Total stockholders' equity | | 39,935 | • | (1,641) | | 38,294 |
| Total liabilities and stockholders' equity | \$ | 141,341 | \$ | 1,836 | \$ | 143,177 |

These changes were primarily caused by the differences in determining and allocating transaction price under ASC 606 and costs to obtain certain contracts.

The adoption of ASC 606 did not impact income taxes, as the Company fully reserves its net deferred tax assets. Therefore, the change to the Company's net deferred tax asset position due to adoption was offset by a corresponding change to the valuation allowance.

The following table compares the reported condensed consolidated balance sheet and statement of operations, as of June 30, 2019 and for the three and six months ended June 30, 2019, to the pro-forma amounts had the previous guidance been in effect:

| | | | June 30, 2019 | | |
|---|-------|-----------------|---------------|-------|-------------------------|
| | As Re | ported, ASC 606 | Adjustments | Adjus | ted Balance, ASC 605 |
| Condensed Consolidated Balance Sheet Data (in thousands): | | | | | |
| Prepaids and other current assets | \$ | 4,605 | \$ (604) | \$ | 4,001 |
| Other non-current assets | | 11,490 | (1,120) | | 10,370 |
| Total Assets | \$ | 130,840 | \$ (1,724) | \$ | 129,116 |
| Deferred revenues, current portion | | 28,406 | 8,689 | | 37,095 |
| Deferred revenue, net of current portion | | 58,110 | (11,644) | | 46,466 |
| Total Liabilities | | 111,355 | (2,955) | | 108,400 |
| Accumulated Deficit | | (170,813) | 1,231 | | (169,582) |
| Total stockholders' equity | | 19,485 | 1,231 | | 20,716 |
| Total liabilities and stockholders' equity | \$ | 130,840 | \$ (1,724) | \$ | 129,116 |

| | | Three | Mon | ths Ended June 30 | , 201 | 9 | | Six | Mont | ths Ended June 30, 2 | 2019 | |
|---|-------|---------------------|-----|-------------------|-------|-----------------------------|----|----------------------|------|----------------------|------|-----------------------------|
| | As Ro | eported, ASC 606 | | Adjustments | A | djusted Balance, ASC 605 | As | Reported, ASC 606 | | Adjustments | Ac | djusted Balance, ASC 605 |
| Condensed Consolidated Statement of Operations Data (in thousands): | | | | | | | | | | | | |
| Revenue | \$ | 5,332 | \$ | (1,199) | \$ | 4,133 | \$ | 13,877 | \$ | (522) | \$ | 13,355 |
| General and administrative expenses | | 4,189 | | (39) | | 4,150 | | 9,121 | | (112) | | 9,009 |
| Loss from operations | | (12,230) | | (1,238) | | (13,468) | | (22,913) | | (634) | | (23,547) |
| Loss before income taxes | | (11,758) | | (1,238) | | (12,996) | | (22,106) | | (634) | | (22,740) |
| Net loss | \$ | (11,758) | \$ | (1,238) | \$ | (12,996) | \$ | (22,106) | \$ | (634) | \$ | (22,740) |
| Comprehensive loss | \$ | (12,409) | \$ | (1,238) | \$ | (13,647) | \$ | (21,831) | \$ | (634) | \$ | (22,465) |

The application of ASC 606 did not have an impact on the Company's net cash used in operating activities for thesix months ended June 30, 2019 but did result in offsetting adjustments to net loss, change in other current and non-current assets, and the change in deferred revenue presented within the condensed consolidated statements of cash flows for that period.

Operating Leases

The Company leases its office and laboratory facilities and certain lease agreements contain free or escalating rent payment provisions. The Company recognizes rent expense under such leases on a straight-line basis over the term of the lease with the difference between the expense and the payments recorded as deferred rent on the consolidated balance sheets. Lease renewal periods are considered on a lease-by-lease basis in determining the lease term. Funding of leasehold improvements by the Company's landlord are accounted for as a tenant improvement allowance and are amortized as a reduction of rent expense over the term of the lease. Leasehold improvements are amortized on a straight-line basis over the shorter of the useful life or the remaining lease term.

Recent Accounting Pronouncements

In February 2016, the FASB issued Accounting Standards Update, or ASU, No. 2016-2, Leases (Topic 842), or ASU 2016-2. Subsequently, the FASB also issued ASU 2019-01, Leases (Topic 842), or ASU 2019-01: Codification Improvements, which updated codification language under the standard. Under the amendments in ASU 2016-2, lessees will be required to recognize (i) a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis and (ii) a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term for all leases (with the exception of short-term leases) at the commencement date. This guidance is effective for public emerging growth companies, like the Company, for fiscal years beginning after December 15, 2019 including interim periods within those fiscal years. Early adoption is permitted. The Company anticipates an effective date of adoption for this standard in the fourth quarter of 2019, retroactive to January 1, 2019, when the Company anticipates losing emerging growth company status. The Company has begun to assess the current state of accounting for leases, to catalog all current leases effected and to review all vendor contracts for the potential existence of a lease in order to understand the gaps between the current state and required future state and to implement the new processes and controls required. The Company currently expects that adoption of this standard will have a material increase on both total assets and liabilities in its condensed consolidated financial statements based upon the Company's current leasing obligations.

In November 2018, the FASB issued ASU No. 2018-18, Collaborative Arrangements (Topic 808):Clarifying the Interaction between Topic 808 and Topic 606, or ASU 2018-18. ASU 2018-18 makes targeted improvements to generally accepted accounting principles for collaborative arrangements, including: (i) clarification that certain transactions between collaborative arrangement participants should be accounted for as revenue under ASC 606 when the collaborative arrangement participant is a customer in the context of a unit of account, (ii) adding unit-of-account guidance in Topic 808 to align with the guidance in ASC 606, and (iii) 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. This guidance is effective for fiscal years beginning after December 15, 2019, including interim periods within that fiscal year. The Company is currently evaluating the impact of adoption, if any, that this standard may have on its condensed consolidated financial statements.

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 (option, license and collaboration agreements), which include upfront payments for licenses or options to obtain licenses, payments for research and development services and milestone payments.

During the three and six months ended June 30, 2019 and 2018, respectively, the Company recognized revenues as follows (in thousands):

| | Three Months | Ended | June 30 | Six Months I | Ended . | June 30 |
|---------------------------------------|------------------|-------|---------|------------------|---------|---------|
| | 2019 | | 2018 | 2019 | | 2018 |
| Revenue from contracts with customers | \$ 4,934 | \$ | 11,224 | \$ 12,468 | \$ | 14,668 |
| Collaboration revenue (ASC 808) | 398 | | 467 | 1,409 | | 1,084 |
| Other revenues | _ | | _ | _ | | 91 |
| Total Revenue | \$ 5,332 | \$ | 11,691 | \$ 13,877 | \$ | 15,843 |

Included in the revenue from contracts with customers for thethree and six months ended June 30, 2019 was \$2.4 million and \$6.5 million, respectively, that was included in the aggregated deferred liability balances at December 31, 2018.

During the three and six months ended June 30, 2019 and 2018, respectively, the Company recognized revenue from the following strategic partnerships and other license agreements (in thousands):

| | 1 | Three Months Ended June 30 | | | | Six Months I | Ended June 30 | |
|------------------|----|----------------------------|----|--------|----|--------------|---------------|--------|
| | | 2019 | | 2018 | | 2019 | | 2018 |
| Seattle Genetics | \$ | 504 | \$ | 2,425 | \$ | 1,429 | \$ | 2,731 |
| AstraZeneca | | 3,888 | | 6,390 | | 9,908 | | 8,937 |
| Servier | | 940 | | 1,419 | | 2,540 | | 2,627 |
| Other | | _ | | 1,457 | | _ | | 1,548 |
| Total Revenue | \$ | 5,332 | \$ | 11,691 | \$ | 13,877 | \$ | 15,843 |

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

| | Research, Development & Commercial Milestones | Sale | Sales Milestones | | |
|------------------------------------|--|------|------------------|--|--|
| Seattle Genetics | \$ 769 | \$ | 450 | | |
| AstraZeneca | 1,111 | | 960 | | |
| Servier | 984 | | 892 | | |
| Total potential milestone payments | \$ 2,864 | \$ | 2,302 | | |

Seattle Genetics

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

Under the terms of the Seattle Genetics Agreements, the companies will pursue multiple antibody-Anticalin fusion proteins during the research phase. The Seattle Genetics Agreements provide Seattle Genetics a base option to select up to three programs for further development. Prior to the initiation of a pivotal trial, the Company may opt into global co-development and U.S.

commercialization of the second program and share in global costs and profits on an equal basis. Seattle Genetics will solely develop, fund and commercialize the othetwo programs. Seattle Genetics may also decide to select additional candidates from the initial research phase for further development in return for the payment to us of additional fees, milestone payments and royalties.

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

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

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

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

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

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

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

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

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

The amounts allocated to the performance obligations for the three research programs will be recognized on a proportional performance basis through the completion of each respective estimated research term of the individual research programs. The amounts allocated to the material right for the antibody target swap option will be recognized either at the time the material right expires or, if exercised, on a proportional performance basis over the estimated research term for that program. The amounts allocated to the participation on each of the committees will be recognized straight-line over the anticipated research term for all research programs. As of June 30, 2019, there was \$26.1 million of aggregate transaction price allocated to remaining performance obligations.

Under the Seattle Genetics 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.

As of June 30, 2019, there is \$6.6 million and \$15.3 million of current and non-current deferred revenue, respectively, related to the Seattle Genetics Agreements.

<u>AstraZeneca</u>

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, 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 the phase 2a study, Pieris has the option to co-develop the AstraZeneca Lead Product and also has the 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.

Prior to the adoption of ASC 606, the budgeted research and development services for the AstraZeneca Lead Product increased and were approved by the JSC. The increases included additional phase 1 services as well as the addition of certain phase 2a services. The Company determined that these increases were contract modifications. Upon the adoption of ASC 606, the Company reflected the aggregate effects of these modifications as of the last modification date.

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) participation on each of the committees, (viii) four research licenses for the AstraZeneca Collaboration Products, (ix) four commercial licenses for the AstraZeneca Collaboration Products, (ix) research services for the AstraZeneca Collaboration Products and (ii) certain phase 2a services for the AstraZeneca Lead Product. Additionally, as the development licenses on the four AstraZeneca Collaboration Products may be granted at a discount in the future, the Company determined such discounts should be assessed as material rights at inception.

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

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

As a result, management concluded that there were 16 performance obligations: (i) combined performance obligation comprised of a non-exclusive platform technology license, research and development license, and commercial licenses for the AstraZeneca Lead Product and research services for the AstraZeneca Lead Product, (ii) combined performance obligation comprised of development and manufacturing services, and technology transfer services for the AstraZeneca Lead Product, (iii) committee participation, (iv-vii) four combined performance obligations each comprised of a non-exclusive platform technology license,

research licenses, and research services for each AstraZeneca Collaboration Product, (viii-xi) four performance obligations comprised of a material right to acquire the development licenses granted for the AstraZeneca Collaboration Products, (xii-xv) four performance obligations comprised of the commercial licenses granted for the AstraZeneca Collaboration Products and (xvi) phase 2a services.

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

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

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

The transaction price is 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 right and delivery of each of the development licenses. As of June 30, 2019, there was \$36.2 million of aggregate transaction price allocated to remaining performance obligations.

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

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

As of June 30, 2019, there is \$12.1 million and \$18.2 million of current and non-current deferred revenue, respectively, related to the AstraZeneca Agreements.

The Company incurred \$1.6 million of third-party success fees to obtain the contract with AstraZeneca. Upon adoption of ASC 606, the Company capitalized \$1.1 million in accordance with ASC 340. As of June 30, 2019, the remaining balance of the asset recognized from transaction costs to obtain the AstraZeneca contract is \$1.0 million. Amortization during the three months ended June 30, 2019 was immaterial and during the six months ended June 30, 2019 was \$0.1 million.

<u>Servier</u>

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 will initially pursue five bispecific therapeutic programs.

Five committed programs have been 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 has the option to co-develop and retain commercial rights in the United States for up to three programs beyond PRS-332, 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 further discussed below.

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 PRS-332, (ii) commercial license for PRS-332, (iii) individual research licenses for each of the four Collaboration Products, and (iv) individual non-exclusive platform technology licenses for each of PRS-332 and four Collaboration Products. Upon achievement of certain development activities, specified by the collaboration for each Servier Agreement, Servier will be granted a development license and a commercial license. For PRS-332 and 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 will be 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 PRS-332 and each of the Collaboration Products.

For PRS-332 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 their 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 ϵ 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 ϵ 0.5 million (approximately \$0.6 million) and another in February 2019 for ϵ 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 PRS-332 and Collaboration Products, shall continue forthree years from the effective date 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 of a material breach, with respect to the Servier Collaboration Agreement and the Servier Platform License, respectively, provided that the applicable party has not cured such breach by the applicable 90-day or 120-day permitted cure period, and dispute resolution procedures specified in the applicable Servier Agreement have been followed. The Servier Agreements may also be terminated due to the other party's insolvency or for a safety issue and may in certain instances be terminated on a product-by-product and/or country-by-country basis. The Servier Platform License will terminate upon termination of the Servier Collaboration Agreement, on a product-by-product and/or country-by-country basis.

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, (ii) development license for PRS-332, (iii) commercial license for PRS-332, (iv) research and development services for PRS-332, (v) participation on each of the committees, (vi) four research licenses for Collaboration Products, and (vii) 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 such goods and services were separate performance obligations. The Company determined the licenses granted, at arrangement inception, should be combined with the research and development services to be provided for PRS-332 and Collaboration Products, over the term of the Servier Agreements, 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 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 there are 14 performance obligations at 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 PRS-332, (ii) four separate performance obligations each comprised of a combined non-exclusive platform technology license, research license and research and development services for each Co-Developed Collaboration Product (iii) one performance obligation comprised of participation in the various governance committees, and (iv) four combined performance obligations comprised of the development and commercial licenses granted for the Co-Developed Collaboration Products (and corresponding discounts) upon the achievement of specified preclinical activities, resulting in material rights. 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 Product, upon the achievement of specified preclinical activities, resulting in material rights.

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 \leq 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 PRS-332 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 PRS-332 and each of the Co-Developed 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-Developed Collaboration Products are granted in the future will be recognized over time upon delivery of each of the licenses through marketing approval. The amounts allocated to the four performance obligations for the material rights to acquire development and commercial licenses for the Servier Developed Collaboration Products are granted in the future will be recognized upon delivery of each of the licenses. As of June 30, 2019, there was \$31.4 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 PRS-332 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.

As of June 30, 2019, there is \$6.8 million and \$24.6 million of current and non-current deferred revenue, respectively, related to the Servier Agreements.

The Company incurred costs to obtain the contract with Servier. Upon adoption of ASC 606, the Company capitalized \$0.5 million of third-party service fees in accordance with ASC 340. As of June 30, 2019, the remaining balance of the asset recognized from costs to obtain the Servier contract is \$0.5 million.

ASKA

On February 27, 2017 the Company entered into an exclusive option agreement, or the ASKA Option Agreement, with ASKA Pharmaceutical Co., Ltd., or ASKA, pursuant to which Pieris granted ASKA an option to acquire (1) a non-exclusive license to certain intellectual property rights associated with the Company's Anticalin platform and (2) an exclusive license to certain intellectual property rights specifically related to the Company's PRS-080 Anticalin protein in order to develop, manufacture, import, sale, export and offer for sale and export any pharmaceutical formulation containing PRS-080, the Company's PEGylated Anticalin protein targeting hepcidin, or the Licensed Product, in Japan and certain other Asian territories.

Pieris is obliged to use commercially reasonable efforts to complete the phase 2a study for PRS-080 and to submit to ASKA, in writing, the final results of the study when available. Upon receipt, ASKA will have 60 days to evaluate the results of the phase 2a study, or the Evaluation Period. ASKA agreed to notify the Company, in writing, of its decision to exercise its option to acquire rights to the Licensed Product. If the phase 2a study meets the applicable success criteria and ASKA fails to provide notification that it will exercise its option, ASKA shall pay the Company an additional fee within 30 days of the end of the Evaluation Period. If ASKA exercises the option, ASKA and the Company will enter into a separate definitive arrangement governing the future development and commercialization activities.

The Company determined that the completed phase 2a study represents the sole good or service to be transferred, and the only performance obligation under the ASKA Option Agreement for which an upfront payment of \$2.75 million was received from ASKA. The \$2.75 million fixed upfront payment represents the transaction price at inception. The additional fee due if the phase 2a study meets the applicable success criteria and ASKA fails to provide notification that it will exercise its option represents variable consideration and will be constrained until it is deemed probable that a significant revenue reversal will not occur.

While the completion of the phase 2a study requires the completion of a number of actions, the Company determined that the finalization of the data and evaluation of results of the phase 2a study is the point at which revenue would be recognized. Therefore, no revenue was recognized in connection with this arrangement for the years ended December 31, 2018 and 2017, respectively. As of June 30, 2019, there is \$2.9 million of current deferred revenue related to the ASKA Option Agreement.

In connection with obtaining the contract with ASKA, the Company additionally incurred \$0.3 million in third-party service fees which were capitalized in accordance with ASC 340. As of June 30, 2019, the remaining balance of the asset recognized from costs to obtain the ASKA contract is\$0.3 million.

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 and six months ended June 30, 2019 and the reductions in deferred revenue of \$2.4 million and \$6.5 million, respectively, were a result of ongoing activities to complete performance obligations under the various agreements.

4. Cash, cash equivalents and investments

As of June 30, 2019 and December 31, 2018, 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) | ob | Significant other servable inputs (Level 2) | i | t unobservable nputs evel 3) |
|--|--------------|----|--|----|---|----|------------------------------------|
| June 30, 2019 | | | | | | | |
| Money market funds, included in cash equivalents | \$ 11,429 | \$ | 11,429 | \$ | _ | \$ | _ |
| Corporate bonds, included in cash equivalents | 2,598 | | _ | | 2,598 | | _ |
| Investments - U.S. treasuries | 6,592 | | 6,592 | | _ | | _ |
| Investments - Asset-backed securities | 10,041 | | _ | | 10,041 | | _ |
| Investments - Corporate bonds | 28,149 | | _ | | 28,149 | | _ |
| Total | \$ 58,809 | \$ | 18,021 | \$ | 40,788 | \$ | _ |
| | | | | | | | |
| December 31, 2018 | | | | | | | |
| Money market funds, included in cash equivalents | \$ 7,791 | \$ | 7,791 | \$ | _ | \$ | _ |
| Corporate bonds, included in cash equivalents | 10,910 | | _ | | 10,910 | | _ |
| Investments - U.S. treasuries | 7,518 | | 7,518 | | _ | | _ |
| Investments - Asset-backed securities | 5,758 | | _ | | 5,758 | | _ |
| Investments - Corporate bonds | 39,964 | | _ | | 39,964 | | _ |
| Total | \$ 71,941 | \$ | 15,309 | \$ | 56,632 | \$ | _ |

Cash equivalents and marketable securities have been initially valued at the transaction price and subsequently valued, at the end of each reporting period, utilizing third party pricing services or other market observable data. The pricing services utilize industry standard valuation models, including both income and market-based approaches and observable market inputs to determine value. The Company validates the prices provided by its third-party pricing services by reviewing their pricing methods and obtaining market values from other pricing sources, as needed. After completing its validation procedures, the Company did not adjust any fair value measurements provided by the pricing services as of June 30, 2019.

Investments at June 30, 2019 consist of the following (in thousands):

| | Contractual maturity (in days) | Amortized Cost U | | Unrealized gains | | realized losses | Fair Value | |
|-------------------------|--------------------------------|------------------|--------|------------------|----|-----------------|------------|--------|
| Investments | | | | | | | | |
| U.S. treasuries | 62-259 | \$ | 6,587 | \$ | 5 | \$ | — \$ | 6,592 |
| Asset-backed securities | 15-233 | | 10,050 | | 5 | | (14) | 10,041 |
| Corporate bonds | 23-242 | | 28,191 | | 8 | | (50) | 28,149 |
| Total | | \$ | 44,828 | \$ | 18 | \$ | (64) \$ | 44,782 |

The Company recorded realized gains of \$0.1 million from the maturity of available-for-sale securities during thethree and six months ended June 30, 2019, respectively. The Company recorded \$0.1 million of realized gains and \$0.1 million in realized losses during the three and six months ended June 30, 2018, respectively.

5. Property and equipment, net

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

| | June 30 | Do | ecember 31, |
|--------------------------------|-------------|----|-------------|
| | 2019 | | 2018 |
| Laboratory equipment | \$ 8,109 | \$ | 7,431 |
| Office and computer equipment | 692 | | 661 |
| Leasehold improvements | 2,444 | | 323 |
| Property and equipment at cost | 11,245 | | 8,415 |
| Accumulated depreciation | (3,357) | | (3,366) |
| Property and equipment, net | \$ 7,888 | \$ | 5,049 |

6. Accrued Expenses

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

| | June 30 | | December 31, | | |
|-------------------------------|----------|------|--------------|--|--|
| | 2019 | | 2018 | | |
| Accrued license obligations | \$ 2,552 | 2 \$ | 2,523 | | |
| Compensation expense | 1,779 |) | 2,380 | | |
| Professional fees | 1,36 | 5 | 1,945 | | |
| Research and development fees | 1,409 |) | 943 | | |
| Audit and tax fees | 317 | 1 | 378 | | |
| Other current liabilities | 1,068 | 3 | 945 | | |
| Total | \$ 8,49 | \$ | 9,114 | | |

7. Stockholders' Equity

The Company had 49,261,517 shares of common stock and 7,907 shares of preferred stock outstanding as of June 30, 2019, both with a par value of \$0.001 per share.

Series B Preferred Stock

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

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

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 B Preferred Stock are entitled to receive a payment equal to \$0.001 per share of Series B 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 previously issued Series A convertible preferred stock, or the Series A 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 B Preferred Stock and Parity Securities (defined below).

Shares of Series B 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 B Preferred Stock is required to amend the terms of the Series B Certificate of Designation. Holders of Series B Preferred Stock are entitled to receive any dividends payable to holders of the Company's common stock and rank:

- senior to all of the Company's common
- stock;
- senior to any class or series of capital stock of the Company created after the designation of the Series B Preferred Stock specifically ranking by its terms junior to the Series B Preferred Stock, or the Junior Securities;
- on parity with all shares of Series A Preferred Stock and any class or series of capital stock of the Company created after the designation of the Series B Preferred Stock specifically ranking by its terms on parity with the Series B Preferred Stock, or the Parity Securities; and
- junior to any class or series of capital stock of the Company created after the designation of the Series B Preferred Stock specifically ranking by its terms senior to the Series B Preferred Stock, or 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.

2019 Employee, Director and Consultant Equity Incentive Plan

At the Annual Shareholder Meeting, held on July 31, 2019, the shareholders approved the 2019 Employee, Director and Consultant Equity Incentive Plan, or the 2019 Plan. The 2019 Plan permits the Company to issue up to 2,750,000 shares of common stock pursuant to awards granted under the 2019 Plan. Upon approval of the 2019 Plan, the 2018 Employee, Director and Consultant Equity Incentive Plan, or the 2018 Plan, was terminated; all unissued options will be cancelled and no additional awards will be made thereunder. All outstanding awards under the 2018 Plan will remain in effect and any awards forfeited from the outstanding awards will be recycled into the 2019 Plan. There were approximately 931,896 shares remaining and available for grant under the 2018 Plan that terminated with the 2018 Plan.

Open Market Sale Agreement

On August 9, 2019, subsequent to quarter end, the Company entered into an Open Market Sale Agreement® (the "Sale Agreement") with Jefferies LLC ("Jefferies") pursuant to which the Company may offer and sell shares of its common stock, par value \$0.001 per share (the "Common Stock"), having aggregate gross sales proceeds of\$50.0 million (the "Shares"), from time to time, through an "at the market offering" program under which Jefferies will act as sales agent. To date, the Company has not sold any Shares under the Sales Agreement. See Part II, Item 5 "Other Information" for additional information regarding the sale of the Shares.

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 June 30, 2019 and 2018, and as calculated using the treasury stock method, approximately 21.6 million and 14.7 million of weighted average shares, respectively, were excluded from the calculation of diluted weighted average shares outstanding as their effect was anti-dilutive.

9. License and Transfer Agreement

License and Collaboration Agreement with the Technical University of Munich

The Company and the Technical University of Munich, or TUM, initiated discussions in the second quarter of 2018 to clarify, expand and restructure their 2013 research and licensing agreement with TUM, or the TUM License, including the parties' obligations under the TUM License. The TUM License assigns or exclusively licenses to the Company certain intellectual property related to the Company's Anticalin platform technology. The parties' recent discussions relate to revised commercial terms and to reinitiating additional collaborations between faculty at TUM and the Company. While an amended and restated license agreement has not yet been completed, the Company intends to enter into such an amendment. The Company recorded the probable expected impact of the amendment in research and development expense as of December 31, 2018, which is an increase in the Company's financial obligations associated with the TUM License of approximately\$2.3 million, for amounts that would be due in 2019 for 2018 and 2017 sub-licensing activities. These discussions may also lead to an increase in the Company's collaborative research activities with TUM.

10. Leases

In October 2018, Pieris GmbH entered into a new lease for office and laboratory space located in Hallbergmoos, Germany. Under the Lease Agreement, Pieris GmbH will rent approximately 105,000 square feet, of which approximately 96,400 square feet is expected to be delivered by the lessor in the fourth quarter of 2019 and approximately 8,600 square feet is expected to be delivered by the lessor by 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. Pieris GmbH intends to move its operations currently conducted in Freising, Germany to the new leased property.

The Lease Agreement provides for an initial term of 150 months, commencing on the date the lessor first delivers the leased property to Pieris GmbH as agreed under the lease agreement. Pieris GmbH also has an option to extend the term of the Lease Agreement for two additional 60-month periods. 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 terms of the Lease Agreement. Pieris GmbH provided a security deposit of \$0.8 million as of December 31, 2018. The Company will serve as a guarantor for the Lease Agreement.

The Halbergmoos lease included \$11.7 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 FASB ASC 840, *Leases*. The Company recorded straight-line rent expense of \$0.6 million during the six months ended June 30, 2019 and a deferred rent liability of \$12.3 million, inclusive of a tenant improvement allowance of \$11.7 million which the Company is amortizing as a reduction of rent expense over the lease term. As of June 30, 2019, the entire deferred rent liability was classified as non-current deferred rent on the consolidated balance sheet.

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, 2018, 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, 2018, filed with the SEC on March 18, 2019. 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, 2018.

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. Tecentriq® (atezolizumab) is a registered trademark of Genentech, a member of the Roche Group. 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, an immuno-oncology (IO) bispecific targeting HER2 and 4-1BB and a half-life optimized hepcidin-antagonizing Anticalin protein to treat anemia. Proprietary to us, Anticalin proteins are a novel class of therapeutics validated in the clinic and through partnerships with leading pharmaceutical companies. Our development programs include:

- *PRS-060*, our lead respiratory program partnered with AstraZeneca, is 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.
- We are developing additional respiratory drug candidates beyond PRS-060, within and outside of the AstraZeneca alliance. The AstraZeneca alliance includes four
 programs beyond PRS-060. We retain co-development and co-commercialization rights to two out of those four programs. We initiated an additional discovery-stage
 respiratory program in our alliance with AstraZeneca, bringing the total number of active programs to four; AstraZeneca may initiate one additional program within the
 alliance. We also initiated an additional proprietary respiratory discovery-stage program and continue to advance the two proprietary discovery-stage programs
 initiated last year
- *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 costimulatory agonist to enter clinical development.
- We are also developing additional IO drug candidates 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.
- PRS-080 is an Anticalin protein that binds to hepcidin, a natural regulator of iron in the blood. PRS-080 is designed to target hepcidin for the treatment of functional iron deficiency in anemic patients with chronic kidney disease, or CKD, particularly in end-stage renal disease patients requiring dialysis.

Our programs are in varying stages:

- PRS-060 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 single ascending dose, or SAD, study; the drug candidate was safe and well-tolerated in the volunteers in that study. We continue the ongoing multiple ascending dose, or MAD, phase 1 study of a nebulized formulation of PRS-060 versus placebo in mild asthmatics. The MAD study is evaluating safety and tolerability as well as exhaled nitric oxide, an inflammatory marker of allergic asthma. Data from the PRS-060 phase 1 SAD study was presented at the American Thoracic Society International Conference in May 2019 showing that (i) PRS-060 was well tolerated when given as a single inhaled or intravenous doses to healthy volunteers; (ii) there was systemic target engagement (as measured by pSTAT6 inhibition) that will be compared with local lung target engagement (as measured by reduction in FeNO) from the ongoing phase 1 MAD study; and (iii) the overall profile of PRS-060 in the phase 1 SAD study supports its further development as an inhaled drug for the treatment of asthma. We are presenting data from the PRS-060 phase 1 MAD study at the 2019 European Respiratory Society International Congress on October 1, 2019 in a presentation titled 'Multiple ascending dose study of an inhaled IL-4Ra antagonist, AZD1402/PRS-060, in mild asthmatics demonstrates robust FeNO reduction and a promising clinical profile for the treatment of asthma". PRS-060 is the lead drug candidate in Pieris' respiratory collaboration with AstraZeneca. We are sponsoring the phase 1 studies and AstraZeneca is funding the costs. AstraZeneca will conduct and fund the phase 2a study, after which we will have separate options to co-develop and cocommercialize the drug candidate in the United States. Certain statements with respect to the PRS-060 program, including the title of the upcoming presentation at the European Respiratory Society International Congress, are "forward-looking statements". These statements are subject to risks and uncertainties, any one or more of which, including those risk factors set forth in the Company's public filings (including those set forth under the section heading "Risks Related to the Discovery and Development of our Drug Candidates"), could cause actual results to differ materially from those described in such statements. These statements are based on management's current information and expectations. Actual events or results, including the full presentation expected to occur at the European Respiratory Society International Congress and the results or timing of any future PRS-060 study, may differ materially from those contained in these statements. The Company cannot guarantee that it actually will achieve the results, plans, intentions, expectations or guidance disclosed in these statements. Such statements only speak as of the date of this Quarterly Report on Form 10-Q and the Company disclaims any obligation to update information contained in these statements.
- Our other partnered and proprietary respiratory programs are in the discovery stage; the targets and disease areas of these programs are undisclosed.
- We continue to enroll and treat patients in a phase 1 dose-escalation study of PRS-343 and intend to report comprehensive data from the study at a medical meeting later this year, including safety, tolerability, PK data, PD data assessing tumor localized drug effects such as CD8+ expansion, and clinical response data. We also continue to enroll the dose-escalation phase 1 study of PRS-343 in combination with atezolizumab and intend to report data from the study at a medical meeting later this year.
- For our other IO drug candidates and programs, we are conducting activities relating to candidate identification, optimization and preclinical evaluation. We achieved two preclinical milestones in connection with the PRS-344 program, one in December 2018 and another in February 2019, triggering two milestone payments from Servier, and intend to file an IND for the drug candidate in the second half of 2019. We also executed our option to opt-into co-development and United States commercialization of PRS-344 during the first quarter of 2019.
- We completed dosing for the phase 2a study of PRS-080 in anemic, hemodialysis-dependent CKD patients in 2018 and data from that study was presented at the 24th European Hematology Association Congress on June 16, 2019 showing that: (i) PRS-080 was safe and well tolerated at both 4 mg/kg and 8 mg/kg treatment dose levels; (ii) no treatment-related adverse events (AEs) or serious adverse events (SAEs) were observed in the study; (iii) PRS-080 therapy yielded robust iron mobilization with increases in both serum iron and TSAT; (iv) peak iron concentrations were higher in the 8 mg/kg treatment group; (v) while there was no clear difference in hemoglobin (Hb) values between placebo and PRS-080 in 4 mg/kg treatment group over the course of treatment, preliminary evidence of Hb response with separation of Hb values between placebo and PRS-080 was shown in the 8 mg/kg treatment group during the treatment period. We plan to share final data from the phase 2a study with ASKA, at which point ASKA will decide whether to exercise its option to develop and commercialize PRS-080 in Japan and other Asian territories. Additionally, we plan to share the dataset with other parties for potential partnerships outside of the ASKA territories.

Our core Anticalin technology and platform were developed in Germany and we have collaborations with major multi-national pharmaceutical companies. In particular, we have an alliance with AstraZeneca to treat respiratory diseases and partnerships with Servier and Seattle Genetics, both in IO.

Since inception, we have devoted nearly all of our efforts and resources to our research and development activities and have incurred significant net losses. For the three and six months ended June 30, 2019, we reported a net loss of \$11.8 million and \$22.1 million, respectively. For the three and six months ended June 30, 2018, we reported a net loss of \$0.2 million and \$8.9 million, respectively. As of June 30, 2019, we had an accumulated deficit of \$170.8 million. We expect to continue incurring substantial losses for the next several years as we continue to develop our clinical and preclinical drug candidates and programs. Our operating expenses are comprised of research and development expenses and general and administrative expenses.

We have not generated any revenues from product sales to date and we do not expect to generate revenues from product sales for the foreseeable future. Our revenues for the three and six months ended June 30, 2019 and 2018 were from license and collaboration agreements with our partners.

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

Key Financial Terms and Metrics

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

Revenues

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

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

Research and Development Expenses

The process of researching and developing drugs for human use is lengthy, unpredictable and subject to many risks. We expect to continue incurring substantial expenses for the next several years as we continue to develop our clinical and preclinical drug candidates and programs. We are unable, with any certainty, to estimate either the costs or the timelines in which those expenses will be incurred. Our current development plans focus on the following activities: Our lead respiratory program, PRS-060 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; 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.

Results of Operations

Comparison of the three and six months ended June 30, 2019 and 2018

The following table sets forth our revenues and operating expenses for thethree and six months ended June 30, 2019 and 2018 (in thousands):

| | Three Months Ended June 30 | | | | | Six Months E | Ended | nded June 30 | | |
|-------------------------------------|----------------------------|----------|------|--------|----|--------------|-------|--------------|--|--|
| | | 2019 | 2018 | | | 2019 | | 2018 | | |
| Revenues | \$ | 5,332 | \$ | 11,691 | \$ | 13,877 | \$ | 15,843 | | |
| | | | | | | | | | | |
| Research and development expenses | | 13,373 | | 9,155 | | 27,669 | | 17,091 | | |
| General and administrative expenses | | 4,189 | | 4,779 | | 9,121 | | 9,131 | | |
| Total operating expenses | | 17,562 | | 13,934 | | 36,790 | | 26,222 | | |
| | | | | | | | | | | |
| Interest income | | 449 | | 662 | | 955 | | 987 | | |
| Other income (expense), net | | 23 | | 1,230 | | (148) | | 327 | | |
| Loss before income taxes | | (11,758) | | (351) | | (22,106) | | (9,065) | | |
| Provision for income tax | | _ | | (148) | | _ | | (148) | | |
| Net loss | \$ | (11,758) | \$ | (203) | \$ | (22,106) | \$ | (8,917) | | |

Revenues

The following table provides a comparison of revenues for the three months endedJune 30, 2019 and 2018 (in thousands):

| _ | Thi | ee Months | d June 30 | | | |
|---------------------------------------|-----------|-----------|-----------|--------|------------------|---------|
| | 2019 2018 | | | 2018 | Increase/(Decrea | |
| Revenue from contracts with customers | \$ | 4,934 | \$ | 11,224 | \$ | (6,290) |
| Collaboration revenue (ASC 808) | | 398 | | 467 | | (69) |
| Total Revenue | \$ | 5,332 | \$ | 11,691 | \$ | (6,359) |

- The \$6.3 million decrease in revenue from contracts with customers in the three months endedJune 30, 2019 compared to the three months endedJune 30, 2018 partially relates to Roche revenue recorded in the prior period of \$1.5 million due to the recognition of the remaining portion of the upfront payment under this collaboration upon the agreement termination. In addition, level of activities with respect to our collaboration agreements with both Seattle Genetics and AstraZeneca have also decreased.
- The \$0.1 million decrease in collaboration revenue in the three months endedJune 30, 2019 compared to the three months endedJune 30, 2018 relates to slightly lower research and development activities under our collaboration with Servier.

The following table provides a comparison of revenues for the six months ended June 30, 2019 and 2018 (in thousands):

| | Six Months I | Ended | June 30 | | | |
|--------------------------------------|---------------|-------|---------|---------------------|---------|--|
| | 2019 2018 | | | Increase/(Decrease) | | |
| Revenue from contract with customers | \$ 12,468 | \$ | 14,668 | \$ | (2,200) | |
| Collaboration revenue (ASC 808) | 1,409 | | 1,084 | | 325 | |
| Other | _ | | 91 | | (91) | |
| Total Revenue | \$ 13,877 | \$ | 15,843 | \$ | (1,966) | |

- The \$2.2 million decrease in revenues from license fees in thesix months ended June 30, 2019 compared to the six months ended June 30, 2018 primarily relates to Roche revenue recorded in the prior period of \$1.5 million due to the recognition of the remaining portion of the upfront payment under this collaboration upon the agreement termination. In addition, level of activities with respect to our collaboration agreement with Seattle Genetics and AstraZeneca have also decreased to a lesser extent.
- The \$0.3 million increase in collaboration revenues in the six months ended June 30, 2019 compared to the six months ended June 30, 2018 relates to increased research and development activities under our collaboration with Servier.

Research and Development Expenses

The following table provides a comparison of the research and development expenses for the three months endedJune 30, 2019 and 2018 (in thousands):

| | Thr | ee Months | une 30 | | | | |
|----------------------|-----|-----------|--------|-------|---------------------|-------|--|
| | 20 | 2019 2018 | | | Increase/(Decrease) | | |
| Respiratory | \$ | 2,694 | \$ | 1,999 | \$ | 695 | |
| Immuno-oncology | | 4,074 | | 2,558 | | 1,516 | |
| Anemia | | 97 | | 433 | | (336) | |
| Other R&D activities | | 6,508 | | 4,165 | | 2,343 | |
| Total | \$ | 13,373 | \$ | 9,155 | \$ | 4,218 | |
| | | | | | | | |

- The \$0.7 million increase for our respiratory programs period-over-period is due primarily to increases to our ongoing CMC costs incurred for phase 2a readiness for PRS-060 offset by lower clinical costs as the phase 1 SAD study was completed earlier in 2019. We also incurred higher pre-clinical and lab supply expenses as we initiated and we are working on more proprietary and partnered respiratory programs in 2019 compared to 2018;
- The \$1.5 million increase in our immuno-oncology program spending period-over-period is due primarily to an increase in clinical trials costs incurred for PRS-343 and drug product manufacturing for both PRS-343 and PRS-344, all offset by lower spending on other IO programs on a period-over-period basis;
- The \$0.3 million decrease for our anemia program, PRS-080, period-over-period is mainly due to lower clinical costs as the phase 2a study winds down;
- The \$2.3 million increase in other research and development activities expenses is mainly due to higher personnel expenses, including bonus and stock compensation, due to an overall increase in headcount, an increase in recruiting and professional services costs, and an increase in allocated facility costs due to higher non-cash rent charges for the new Halbergmoos facility that is being prepared for occupancy.

The following table provides a comparison of the research and development expenses for thesix months ended June 30, 2019 and 2018 (in thousands):

| 1 | Six Months i | inaea . | June 30 | | | |
|----|--------------|--|---|---|--|--|
| | 2019 | | 2018 | | Increase/(Decrease) | |
| \$ | 5,927 | \$ | 3,301 | \$ | 2,626 | |
| | 9,848 | | 4,564 | | 5,284 | |
| | 222 | | 1,304 | | (1,082) | |
| | 11,672 | | 7,922 | | 3,750 | |
| \$ | 27,669 | \$ | 17,091 | \$ | 10,578 | |
| | \$ | 2019 \$ 5,927 9,848 222 11,672 | 2019 \$ 5,927 \$ 9,848 222 11,672 | \$ 5,927 \$ 3,301 9,848 4,564 222 1,304 11,672 7,922 | 2019 2018 Increase \$ 5,927 \$ 3,301 \$ 9,848 4,564 222 1,304 11,672 7,922 1,304 1,304 | |

Siv Months Ended June 20

- The \$2.6 million increase for our respiratory programs period-over-period is due primarily to increases to our ongoing CMC costs incurred for phase 2a readiness for PRS-060 offset by slightly lower clinical costs as the phase 1 SAD study was completed earlier in 2019. We also incurred higher pre-clinical and lab supply expenses as we initiated and we working on more proprietary and partnered respiratory programs in 2019 compared to 2018;
- The \$5.3 million increase in our immuno-oncology program spending period-over-period is due primarily to an increase in clinical trials costs incurred for PRS-343 and drug product manufacturing for PRS-344 and other proprietary programs;
- The \$1.1 million decrease for our anemia program, PRS-080, period-over-period is mainly due to lower clinical costs as the phase 2a study winds down;
- The \$3.8 million increase in other research and development activities expenses is mainly due to higher personnel expenses, including bonus and stock compensation, due to an overall increase in headcount, an increase in recruiting costs, and an increase in allocated facility costs due to higher non-cash rent charges for the new Halbergmoos facility that is being prepared for occupancy.

General and Administrative Expenses

General and administrative expenses were \$4.2 million for the three months ended June 30, 2019 as compared to \$4.8 million for the three months ended June 30, 2018. The period-over-period decrease is due to lower audit and tax expense and professional services expense.

General and administrative expenses were \$9.1 million for the six months ended June 30, 2019 ad six months ended June 30, 2018. There were no significant fluctuations in expense on a period over period basis.

Non-operating income (expense), net

Our non-operating income was \$0.5 million for the three months endedJune 30, 2019 as compared to \$1.9 million for the three months endedJune 30, 2018. This decrease is due to lower interest income as a result of lower invested amounts and a weakening of the U.S. dollar against the euro, including foreign currency remeasurement of monetary assets, primarily U.S. dollar cash and investment balances in Germany.

Our non-operating income was \$0.8 million for the six months ended June 30, 2019 as compared to \$1.3 million for the six months ended June 30, 2018. This decrease is due to a weakening of the U.S. dollar against the euro, offset slightly by a higher yield on the lower amounts invested.

Liquidity and Capital Resources

Through June 30, 2019, we have funded our operations primarily through private and public sales of equity, payments received under our license and collaboration agreements (including research and development services costs, upfront and milestone payments), government grants and loans.

As of June 30, 2019, we had a total of \$99.7 million in cash, cash equivalents and investments. We have incurred losses in every period since inception including the three months ended June 30, 2019 and 2018, respectively, and have a total accumulated deficit of \$170.8 million as of June 30, 2019.

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 for thesix months ended June 30, 2019 and 2018 respectively (in thousands):

| | Six Months Ende | ed June 30 |
|---|-----------------|------------|
| | 2019 | 2018 |
| Net cash (used in) provided by operating activities | (25,841) | 22,351 |
| Net cash provided by (used in) investing activities | 7,596 | (57,056) |
| Net cash provided by financing activities | 280 | 48,228 |

There was a \$48.2 million change in net cash from operating activities, as the net cash used in operating activities was\$25.8 million for the six months ended June 30, 2019 compared to net cash provided by operating activities of \$22.4 million for the six months ended June 30, 2018. The change is primarily driven by lower accounts receivable and higher deferred revenue as a result of upfront payments from Seattle Genetics and milestone payments from AstraZeneca, which totaled \$37.1 million, offset slightly by other working capital changes during the six months ended June 30, 2019. Additionally, there was an \$13.2 million increase in the net loss in 2019 compared to 2018.

The change in net cash due to investing activities for thesix months ended June 30, 2019 compared to the same period in 2018 is mainly attributable to more investment maturities than investment purchases in the current year compared to 2018.

Financing activities for the six months ended June 30, 2019 were \$0.3 million due to exercises of options and warrants and proceeds from the employee stock purchase plan. This is compared to \$47.2 million in proceeds due to the issuance of common stock under our 2018 Offering along with\$1.0 million of proceeds from the exercise of warrants and stock options for the six months ended June 30, 2018.

On August 9, 2019, subsequent to our quarter end, we entered into an Open Market Sale Agreement (the "Sale Agreement") with Jefferies LLC ("Jefferies") pursuant to which we may offer and sell shares of our common stock, par value \$0.001 per share (the "Common Stock"), having aggregate gross sales proceeds of \$50.0 million (the "Shares"), from time to time, through an "at the market offering" program under which Jefferies will act as sales agent. To date, we have not sold any Shares under the Sales Agreement. See Part II, Item 5 "Other Information" for additional information regarding the sale of the Shares.

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.

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-060 and PRS-343 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, 2018 for a discussion of our critical accounting policies and estimates. There has been one material change to the critical accounting policies during the six months ended June 30, 2019. This change is related to revenue recognition and is 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, 2018. 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.

Emerging Growth Company and Smaller Reporting Company Status

The Jumpstart Our Business Startups Act of 2012 establishes a class of company called an "emerging growth company," which generally is a company whose initial public offering was completed after December 8, 2011 and had total annual gross revenues of less than \$1.07 billion during its most recently completed fiscal year.

Additionally, Section 12b-2 of the Exchange Act establishes a class of company called a "smaller reporting company" which, effective September 10, 2018, was amended to include companies with a public float of less than \$250 million as of the last business day of its most recently completed second fiscal quarter or, if such public float is less than \$700 million, had annual revenues of less than \$100 million during the most recently completed fiscal year for which audited financial statements are available. Currently, we qualify as both an emerging growth company and a smaller reporting company.

As an emerging growth company and a smaller reporting company, we are eligible and have taken advantage of certain exemptions from various reporting requirements that are not available to public reporting companies that do not qualify for those classifications, including, but not limited to, the following:

- Any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's
 report providing additional information about the audit and financial statements, commonly known as an "auditor discussion and analysis."
- A requirement to hold a non-binding advisory stockholder vote on executive compensation or any golden parachute payments not previously approved by stockholders.
- A requirement to comply with the requirement of auditor attestation of management's assessment of internal control over financial reporting, which is required for other public reporting companies by Section 404 of the Sarbanes-Oxley Act of 2002, as amended.
- 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.

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

For as long as we continue to be an emerging growth company and/or a smaller reporting company, we expect that we will take advantage of the reduced disclosure obligations available to us as a result of those respective classifications. We expect that we will no longer qualify as an emerging growth company on December 31, 2019 as this is the last day of the fiscal year following the fifth anniversary of the date of the first sale of our common stock pursuant to an effective registration statement under the Securities Act.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer have evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act means controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and such information is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Our principal executive officer and principal financial officer have concluded that, based on such evaluation, our disclosure controls and procedures were not effective as of June 30, 2019 as a result of the previously reported material weakness discussed below.

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

In connection with the preparation of our financial statements for the year ended December 31, 2018, we concluded that we had a material weakness relating to our income tax provision process, including the evaluation of any changes resulting from the recently enacted Tax Cuts and Jobs Act, or the TCJA. The material weakness created a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements may not be prevented or detected on a timely basis. The material weakness did not result in any misstatement or correction in the provision for income taxes prior to the issuance of the 2018 consolidated financial statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018.

Management has undertaken a remediation plan to address the control deficiency that led to the material weakness. The remediation plan includes enhancing our tax provision process, including the ongoing impact from the TCJA. We may also retain additional expert assistance, as needed, in the preparation and review of our tax provision.

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

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting identified in connection with the evaluation of such internal control required by Rules 13a-15(d) and 15d-15(d) under the Exchange Act that occurred during the quarter ended June 30, 2019 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.

There have been no material changes from the risk factors previously disclosed in Part I, Item 1A (Risk Factors) of our Annual Report on Form 10-K for the fiscal year ended December 31, 2018.

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.

On August 9, 2019, we entered into the Sale Agreement with Jefferies pursuant to which the Company may offer and sell our Common Stock having aggregate gross sales proceeds of \$50.0 million (the "Shares"), from time to time, through an "at the market offering" program under which Jefferies will act as sales agent. The shares of Common Stock that may be sold pursuant to the Sale Agreement will be issued pursuant to our shelf registration statement on Form S-3 (File No. 333-226725) (the "Registration Statement"), as supplemented by the prospectus supplement dated August 9, 2019 relating to the sale of the Shares (the "Prospectus Supplement").

Under the Sale Agreement, we will set the parameters for the sale of Shares, including the number of Shares to be issued, the time period during which sales are requested to be made, limitations on the number of Shares that may be sold in any one trading day and any minimum price below which sales may not be made. Subject to the terms and conditions of the Sale Agreement, Jefferies may sell the Shares by methods deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act including sales made directly on or through the Nasdaq Capital Market or any other existing trading market for the Common Stock. We have agreed to pay Jefferies a commission of 3.0% of the gross sales proceeds of any Shares sold through Jefferies under the Sale Agreement, and also have provided Jefferies with customary indemnification and contribution rights. The Sale Agreement may be terminated at any time by either party upon prior written notice to the other party.

The representations and warranties contained in the Sale Agreement were made only for purposes of the transactions contemplated by the Sale Agreement as of specific dates and may have been qualified by certain disclosures between the parties and a contractual standard of materiality different from those generally applicable under securities laws, among other limitations. The representations and warranties were made for purposes of allocating contractual risk between the parties to the Sale Agreement and should not be relied upon as a disclosure of factual information relating to us, Jefferies or the transactions described in this Quarterly Report on Form 10-Q.

The foregoing description of the material terms of the Sale Agreement is qualified in its entirety by reference to the full agreement, a copy of which is filed as Exhibit 10.1 to this Quarterly Report on Form 10-Q and is incorporated herein by reference.

Brownstein Hyatt Farber Schreck, LLP, counsel to us, has issued a legal opinion relating to the Shares. A copy of such legal opinion, including the consent included therein, is attached as Exhibit 5.1 hereto.

The Shares will be sold pursuant to the Registration Statement, and offerings of the Shares will be made only by means of the Prospectus Supplement. This Quarterly Report on Form 10-Q shall not constitute an offer to sell or the solicitation of any offer to buy the securities discussed herein, nor shall there be any offer, solicitation or sale of the securities in any state in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state.

Item 6. Exhibits.

| Exhibit Number | Exhibit Description | | Incorporated by Reference herein from Form or Schedule | Filing Date | SEC File / Registration Number |
|-------------------|--|----|---|-------------|--------------------------------------|
| <u>5.1</u> | Opinion of Brownstein Hyatt Farber Schreck, LLP | * | | | |
| 10.1 | Open Market Sale Agreement, dated as of August 9, 2019, by and between Pieris Pharmaceuticals, Inc. and Jefferies LLC. | * | | | |
| 10.2 | Pieris Pharmaceuticals, Inc. Amended and Restated Non- Employee Director Compensation Policy. | * | | | |
| 10.29.1 | Subtenant Recognition and Attornment Agreement, by and among Pieris Pharmaceuticals, Inc., 225 State Street, LLC, and Berenberg Capital Markets LLC, dated as of May 31, 2019 | * | | | |
| 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 | XBRL Instance Document | * | | | |
| 101.SCH | XBRL Taxonomy Extension Schema Document | * | | | |
| | | 3 | 6 | | |

| Exhibit <u>Number</u> | Exhibit Description | | Incorporated by Reference herein from Form or Schedule | Filing Date | SEC File / Registration Number |
|--------------------------|--|---|---|-------------|--------------------------------------|
| 101.CAL | XBRL Taxonomy Extension Calculation Linkbase Document | * | | | |
| 101.DEF | XBRL Taxonomy Extension Definition Linkbase Document | * | | | |
| 101.LAB | XBRL Taxonomy Extension Label Linkbase Document | * | | | |
| 101.PRE | XBRL Taxonomy Extension Presentation Linkbase Document | * | | | |
| * | Filed herewith. | | | | |
| ** | 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. | | | | |

SIGNATURES

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

PIERIS PHARMACEUTICALS, INC.

August 9, 2019 By: /s/ Stephen S. Yoder

Stephen S. Yoder

Chief Executive Officer and President

(Principal Executive Officer)

August 9, 2019 By: /s/ Allan Reine

Allan Reine

Chief Financial Officer

(Principal Financial and Accounting Officer)

Brownstein Hyatt Farber Schreck

August 9, 2019

Pieris Pharmaceuticals, Inc. 255 State Street, 9th Floor Boston. MA 02109

Ladies and Gentlemen:

We have acted as local Nevada counsel to Pieris Pharmaceuticals, Inc., a Nevada corporation (the "Company"), in connection with that certain Open Market Sale Agreement, dated August 9, 2019 (the "Sale Agreement"), by and between the Company and Jefferies LLC, as sales agent and/or principal, relating to the issuance and sale by the Company from time to time of shares of the Company's common stock, par value \$0.001 per share (the "Common Stock"), having an aggregate offering price of up to \$50,000,000 (the "Shares"), as more fully described in the base prospectus, dated August 24, 2018 (the "Base Prospectus"), contained in the Registration Statement on Form S-3 (File No. 333-226725) (as amended through and including the date hereof, the "Registration Statement"), as supplemented by the prospectus supplement, dated August 9, 2019 (together with the Base Prospectus, the "Prospectus"), each as filed with the Securities and Exchange Commission under the Securities Act of 1933, as amended (the "Act"). This opinion letter is being delivered at your request pursuant to the requirements of Item 601(b)(5) of Regulation S-K under the Act.

In our capacity as such counsel, we are familiar with the proceedings taken and proposed to be taken by the Company in connection with the authorization, issuance and sale of the Shares as contemplated by the Sale Agreement and as described in the Registration Statement and the Prospectus. For purposes of this opinion letter, and except to the extent set forth in the opinion set forth below, we have assumed that all such proceedings have been or will be timely completed in the manner presently proposed in the Sale Agreement and the Registration Statement and the Prospectus.

For purposes of issuing the opinion hereinafter expressed, we have made such legal and factual examinations and inquiries, including an examination of originals or copies certified or otherwise identified to our satisfaction as being true copies of (i) the Registration Statement, including the Prospectus, (ii) the Sale Agreement, (iii) the Company's articles of incorporation and bylaws, each as amended to date, (iv) the resolutions of the board of directors of the Company authorizing and approving, among other things, the consummation of the transactions contemplated by the Sale Agreement, and (v) such agreements, instruments, corporate records and other documents as we have deemed necessary or appropriate. We have also obtained from officers, representatives and agents of the Company and from public officials, and have relied upon, such certificates, representations, assurances and public fillings, as we have deemed necessary and appropriate for the purpose of issuing this opinion letter.

Without limiting the generality of the foregoing, in our examination, we have, with your permission, assumed without independent verification, that (i) the obligations of each party to any such document we examined are or will be its valid and binding obligations, enforceable in accordance with its terms; (ii) each natural person executing any of the documents we reviewed has sufficient legal capacity to do so; (iii) all documents submitted to us as originals are authentic, the signatures on all documents that we examined

Las Vegas, NV 89106-4614 main 702.382.2101

bhfs.com Brownstein Hyatt Farber Schreck, LLP

Pieris Pharmaceuticals, Inc. August 9, 2019 Page 2

are genuine, and all documents submitted to us as certified, conformed, photostatic, electronic or facsimile copies conform to the original document; (iv) all corporate records made available to us by the Company, and all public records we have reviewed, are accurate and complete; and (v) after any issuance of the Shares, the total number of issued and outstanding shares of Common Stock, together with the total number of shares of Common Stock then reserved for issuance or obligated to be issued by the Company pursuant to any agreement or arrangement or otherwise, will not exceed the total number of shares of Common Stock then authorized under the Company's articles of incorporation.

We are qualified to practice law in the State of Nevada. The opinion set forth herein is expressly limited to and based exclusively on the general corporate laws of the State of Nevada as in effect as of the date hereof, and we do not purport to be experts on, or to express any opinion with respect to the applicability or effect of, the laws of any other jurisdiction. We express no opinion concerning, and we assume no responsibility as to laws or judicial decisions related to, or any orders, consents or other authorizations or approvals as may be required by, any federal laws, rules or regulations, including, without limitation, any federal securities laws, rules or regulations, or any state securities or "Blue Sky" laws, rules or regulations.

Based on the foregoing and in reliance thereon, having regard to legal considerations and other information that we deem relevant, and subject to the qualifications, limitations and assumptions set forth herein, we are of the opinion that the Shares have been duly authorized by the Company and if, when and to the extent any Shares are issued and sold in accordance with all applicable terms and conditions set forth in, and in the manner contemplated by, the Sale Agreement (including payment in full of all consideration required therefor as prescribed under the Sale Agreement), and as described in the Registration Statement and the Prospectus, such Shares will be validly issued, fully paid and non-assessable.

The opinion expressed herein is based upon the applicable laws, rules and regulations of the State of Nevada and the facts in existence on the date of this opinion letter. In delivering this opinion letter to you, we disclaim any obligation to update or supplement the opinion set forth herein or to apprise you of any changes in any laws, rules, regulations or facts after the date hereof. No opinion is offered or implied as to any matter, and no inference may be drawn, beyond the strict scope of the specific issues expressly addressed by the opinion set forth herein.

We consent to your filing this opinion letter as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, that is to be incorporated by reference into the Registration Statement and to the reference to our firm contained under the heading "Legal Matters" in the Prospectus. In giving this consent, we do not admit that we are within the category of persons whose consent is required under Section 7 of the Act or the rules and regulations of the Commission promulgated thereunder.

Very truly yours, /s/ Brownstein Hyatt Farber Schreck, LLP

OPEN MARKET SALE AGREEMENTSM

August 9, 2019

JEFFERIES LLC 520 Madison Avenue New York, New York 10022

Ladies and Gentlemen:

Pieris Pharmaceuticals, Inc., a Nevada corporation (the "Company"), proposes, subject to the terms and conditions stated herein, to issue and sell from time to time through Jefferies LLC, as sales agent and/or principal (the "Agent"), shares of the Company's common stock, par value \$0.001 per share (the "Common Shares"), having an aggregate offering price of up to \$50,000,000 on the terms set forth in this agreement (this "Agreement").

Section 1. DEFINITIONS

- (a) <u>Certain Definitions</u>. For purposes of this Agreement, capitalized terms used herein and not otherwise defined shall have the following respective meanings:
- "Affiliate" of a Person means another Person that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, such first-mentioned Person. The term "control" (including the terms "controlling," "controlled by" and "under common control with") means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, by contract or otherwise.
- "Agency Period" means the period commencing on the date of this Agreement and expiring on the earliest to occur of (x) the date on which the Agent shall have placed the Maximum Program Amount pursuant to this Agreement and (y) the date this Agreement is terminated pursuant to Section 7.
 - "Commission" means the U.S. Securities and Exchange Commission.
- **"Exchange Act"** means the Securities Exchange Act of 1934, as amended, and the rules and regulations of the Commission thereunder.
- "Floor Price" means the minimum price set by the Company in the Issuance Notice below which the Agent shall not sell Shares during the applicable period set forth in the Issuance Notice, which may be adjusted by the Company at any time during the period set forth in the Issuance Notice by delivering written notice of such change to the Agent and which in no event shall be less

SM "Open Market Sale Agreement" is a service mark of Jefferies LLC

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than \$1.00 without the prior written consent of the Agent, which may be withheld in the Agent's sole discretion.

"Issuance Amount" means the aggregate Sales Price of the Shares to be sold by the Agent pursuant to any Issuance Notice.

"Issuance Notice" means a written notice delivered to the Agent by the Company in accordance with this Agreement in the form attached hereto as <u>Exhibit A</u> that is executed by its Chief Executive Officer, President or Chief Financial Officer.

"Issuance Notice Date" means any Trading Day during the Agency Period that an Issuance Notice is delivered pursuant to Section 3(b)(i).

"Issuance Price" means the Sales Price less the Selling Commission.

"Maximum Program Amount" means Common Shares with an aggregate Sales Price of the lesser of (a) the number or dollar amount of Common Shares registered under the effective Registration Statement (defined below) pursuant to which the offering is being made, (b) the number of authorized but unissued Common Shares (less Common Shares issuable upon exercise, conversion or exchange of any outstanding securities of the Company or otherwise reserved from the Company's authorized capital stock), (c) the number or dollar amount of Common Shares permitted to be sold under Form S-3 (including General Instruction I.B.6 thereof, if applicable), or (d) the number or dollar amount of Common Shares for which the Company has filed a Prospectus (defined below).

"**Person**" means an individual or a corporation, partnership, limited liability company, trust, incorporated or unincorporated association, joint venture, joint stock company, governmental authority or other entity of any kind.

"Principal Market" means the Nasdaq Capital Market or such other national securities exchange on which the Common Shares, including any Shares, are then listed.

"Sales Price" means the actual sale execution price of each Share placed by the Agent pursuant to this Agreement.

"Securities Act" means the Securities Act of 1933, as amended, and the rules and regulations of the Commission thereunder.

"Selling Commission" means three percent (3.0%) of the gross proceeds of Shares sold pursuant to this Agreement, or as otherwise agreed between the Company and the Agent with respect to any Shares sold pursuant to this Agreement.

"Settlement Date" means the second business day following each Trading Day during the period set forth in the Issuance Notice on which Shares are sold pursuant to this Agreement, when the Company shall deliver to the Agent the amount of Shares sold on such Trading Day and the Agent shall deliver to the Company the Issuance Price received on such sales.

"Shares" shall mean the Company's Common Shares issued or issuable pursuant to this Agreement.

"Trading Day" means any day on which the Principal Market is open for trading.

Section 2. REPRESENTATIONS AND WARRANTIES OF THE COMPANY

The Company represents and warrants to, and agrees with, the Agent that as of (1) the date of this Agreement, (2) each Issuance Notice Date, (3) each Settlement Date, (4) each Triggering Event Date with respect to which the Company is required to deliver a certificate pursuant to Section 4(0) and (5) as of each Time of Sale (each of the times referenced above is referred to herein as a "Representation Date"), except as may be disclosed in the Prospectus (including any documents incorporated by reference therein and any supplements thereto) on or before a Representation Date:

(a) Registration Statement. The Company has prepared and filed with the Commission a shelf registration statement on Form S-3 (File No. 333-226725) that contains a base prospectus (the "Base Prospectus"). Such registration statement registers the issuance and sale by the Company of the Shares under the Securities Act. The Company may file one or more additional registration statements from time to time that will contain a base prospectus and related prospectus or prospectus supplement, if applicable, with respect to the Shares. Except where the context otherwise requires, such registration statement(s), including any information deemed to be a part thereof pursuant to Rule 430B under the Securities Act, including all financial statements, exhibits and schedules thereto and all documents incorporated or deemed to be incorporated therein by reference pursuant to Item 12 of Form S-3 under the Securities Act as from time to time amended or supplemented, is herein referred to as the "Registration Statement," and the prospectus constituting a part of such registration statement(s) specifically relating to the Shares, together with any prospectus supplement filed with the Commission pursuant to Rule 424(b) under the Securities Act relating to a particular issuance of the Shares, including all documents incorporated or deemed to be incorporated therein by reference pursuant to Item 12 of Form S-3 under the Securities Act, in each case, as from time to time amended or supplemented, is referred to herein as the "Prospectus," except that if any revised prospectus is provided to the Agent by the Company for use in connection with the offering of the Shares that is not required to be filed by the Company pursuant to Rule 424(b) under the Securities Act, the term "Prospectus" shall refer to such revised prospectus from and after the time it is first provided to the Agent for such use. The Registration Statement at the time it originally became effective is herein called the "Original Registration Statement." As used in this Agreement, the terms "amendment" or "supplement" when applied to the Registration Statement or the Prospectus shall be deemed to include the filing by the Company with the Commission of any document under the Exchange Act after the date hereof that is or is deemed to be incorporated therein by reference. All references in this Agreement to the Registration Statement, the Prospectus or any amendments or supplements thereto, or any Free Writing Prospectus (as defined herein), shall be deemed to include any copy filed with the Commission pursuant to EDGAR (as defined herein).

All references in this Agreement to financial statements and schedules and other information which is "contained," "included," "stated" in or "part of" the Registration Statement or the Prospectus (and all other references of like import) shall be deemed to mean and include all such

financial statements and schedules and other information which is or is deemed to be incorporated by reference in or otherwise deemed under the Securities Act to be a part of or included in the Registration Statement or the Prospectus, as the case may be, as of any specified date; and all references in this Agreement to amendments or supplements to the Registration Statement or the Prospectus shall be deemed to mean and include, without limitation, the filing of any document under the Exchange Act which is or is deemed to be incorporated by reference in or otherwise deemed under the Securities Act to be a part of or included in the Registration Statement or the Prospectus, as the case may be, as of any specified date.

At the time the Original Registration Statement was declared effective and at the time the Company's most recent annual report on Form 10-K was filed with the Commission, if later, the Company met the then-applicable requirements for use of Form S-3 under the Securities Act. During the Agency Period, each time the Company files an annual report on Form 10-K the Company will meet the then-applicable requirements for use of Form S-3 under the Securities Act.

(b) <u>Compliance with Registration Requirements</u>. The Original Registration Statement and any Rule 462(b) Registration Statement have been declared effective by the Commission under the Securities Act. The Company has complied, to the Commission's satisfaction, with all requests of the Commission for additional or supplemental information, if any. No stop order suspending the effectiveness of the Registration Statement or any Rule 462(b) Registration Statement is in effect and no proceedings for such purpose have been instituted or are pending or, to the best knowledge of the Company, are contemplated or threatened by the Commission.

The Prospectus when filed complied or will comply in all material respects with the Securities Act and, if filed with the Commission through its Electronic Data Gathering, Analysis and Retrieval system ("EDGAR") (except as may be permitted by Regulation S-T under the Securities Act), was identical to the copy thereof delivered to the Agent for use in connection with the issuance and sale of the Shares. Each of the Registration Statement, any Rule 462(b) Registration Statement and any post-effective amendment thereto, at the time it became or becomes effective and at each Representation Date, complied and will comply in all material respects with the Securities Act and did not and will not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. As of the date of this Agreement, the Prospectus and any Free Writing Prospectus (as defined below) considered together (collectively, the "Time of Sale Information") did not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading. The Prospectus, as amended or supplemented, as of its date and at each Representation Date, did not and will not contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The representations and warranties set forth in the three immediately preceding sentences do not apply to statements in or omissions from the Registration Statement, any Rule 462(b) Registration Statement, or any post-effective amendment thereto, or the Prospectus, or any amendments or supplements thereto, made in reliance upon and in conformity with information relating to the Agent furnished to the Company in writing by the Agent expressly for use therein, it being understood and agreed that the only such information furnished by the Agent to the Company consists of the information described in <u>Section 6</u> below. There are no contracts or other documents required to be described in the Prospectus or to be filed There are no continuous or other accuments required to be accurated in the rappersist of to be incu-

as exhibits to the Registration Statement which have not been described or filed as required. The Registration Statement and the offer and sale of the Shares as contemplated hereby meet the requirements of Rule 415 under the Securities Act and comply in all material respects with said rule.

- (c) Ineligible Issuer Status. The Company is not an "ineligible issuer" in connection with the offering of the Shares pursuant to Rules 164, 405 and 433 under the Securities Act. Any Free Writing Prospectus that the Company is required to file pursuant to Rule 433(d) under the Securities Act, if applicable, has been, or will be, filed with the Commission in accordance with the requirements of the Securities Act. If applicable, each Free Writing Prospectus that the Company has filed, or is required to file, pursuant to Rule 433(d) under the Securities Act or that was prepared by or on behalf of or used or referred to by the Company complies or will comply in all material respects with the requirements of Rule 433 under the Securities Act including timely filing with the Commission or retention where required and legending, and each such Free Writing Prospectus, as of its issue date and at all subsequent times through the completion of the issuance and sale of the Shares did not, does not and will not include any information that conflicted, conflicts with or will conflict with the information contained in the Registration Statement or the Prospectus, including any document incorporated by reference therein. Except for the Free Writing Prospectuses, if any, and electronic road shows, if any, furnished to the Agent before first use, the Company has not prepared, used or referred to, and will not, without the Agent's prior consent, which consent shall not be unreasonably withheld or delayed, prepare, use or refer to, any Free Writing Prospectus.
- (d) <u>Incorporated Documents</u>. The documents incorporated or deemed to be incorporated by reference in the Registration Statement and the Prospectus, at the time they were filed with the Commission, complied in all material respects with the requirements of the Exchange Act, as applicable, and, when read together with the other information in the Prospectus, do not contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading.
- (e) Exchange Act Compliance. The documents incorporated or deemed to be incorporated by reference in the Prospectus, at the time they were or hereafter are filed with the Commission, and any Free Writing Prospectus or amendment or supplement thereto complied and will comply in all material respects with the requirements of the Exchange Act, and, when read together with the other information in the Prospectus, at the time the Registration Statement and any amendments thereto become effective and at each Representation Date, as the case may be, will not contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.
- (f) <u>Statistical and Market-Related Data</u>. All statistical, demographic and market-related data included in the Registration Statement or the Prospectus are based on or derived from sources that the Company believes, after reasonable inquiry or investigation, to be reliable and accurate. To the extent required, the Company has obtained the written consent for the use of such data from such sources.

- Disclosure Controls and Procedures; Deficiencies in or Changes to Internal Control (g) Over Financial Reporting. Except as otherwise disclosed in the Registration Statement and the Prospectus, the Company has established and maintains disclosure controls and procedures (as defined in Rules 13a-15 and 15d-15 under the Exchange Act), which (i) are designed to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to the Company's principal executive officer and its principal financial officer by others within those entities, particularly during the periods in which the periodic reports required under the Exchange Act are being prepared; (ii) have been evaluated by management of the Company for effectiveness as of the end of the Company's most recent fiscal quarter; and (iii) are effective in all material respects to perform the functions for which they were established. Except as otherwise disclosed in the Registration Statement and the Prospectus, since the end of the Company's most recent audited fiscal year, there have been no significant deficiencies or material weaknesses in the Company's internal control over financial reporting (whether or not remediated) and no change in the Company's internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting. The Company is not aware of any change in its internal control over financial reporting that has occurred during its most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.
- (h) <u>This Agreement</u>. This Agreement has been duly authorized, executed and delivered by the Company.
- (i) <u>Authorization of the Shares</u>. The Shares have been duly authorized for issuance and sale pursuant to this Agreement and, when issued and delivered by the Company against payment therefor pursuant to this Agreement, will be validly issued, fully paid and nonassessable, and the issuance and sale of the Shares is not subject to any preemptive rights, rights of first refusal or other similar rights to subscribe for or purchase the Shares.
- (j) No Applicable Registration or Other Similar Rights. There are no persons with registration or other similar rights to have any equity or debt securities registered for sale under the Registration Statement or included in the offering contemplated by this Agreement, except for such rights as have been duly waived.
- (k) No Material Adverse Change. Except as otherwise disclosed in the Registration Statement and the Prospectus, subsequent to the respective dates as of which information is given in the Registration Statement and the Prospectus: (i) there has been no material adverse change, or any development that would reasonably be expected to result in a material adverse change, in the condition, financial or otherwise, or in the earnings, business, properties, operations, assets, liabilities or prospects, whether or not arising from transactions in the ordinary course of business, of the Company and its subsidiaries, considered as one entity (any such change being referred to herein as a "Material Adverse Change"); (ii) the Company and its subsidiaries, considered as one entity, have not incurred any material liability or obligation, indirect, direct or contingent, including without limitation any losses or interference with its business from fire, explosion, flood, earthquakes, accident or other calamity, whether or not covered by insurance, or from any strike, labor dispute or court or governmental action, order or decree, that are material, individually or in the aggregate, to the Company and its subsidiaries, considered as one entity, and has not entered into any transactions not in the ordinary course of business; and (iii) there has not been any material

decrease in the capital stock or any material increase in any short-term or long-term indebtedness of the Company or its subsidiaries and there has been no dividend or distribution of any kind declared, paid or made by the Company or, except for dividends paid to the Company or other subsidiaries, by any of the Company's subsidiaries on any class of capital stock, or any repurchase or redemption by the Company or any of its subsidiaries of any class of capital stock.

- (I) <u>Independent Accountants</u>. Ernst & Young LLP, which has expressed its opinion with respect to the financial statements (which term as used in this Agreement includes the related notes thereto) filed with the Commission as a part of the Registration Statement and the Prospectus, is (i) an independent registered public accounting firm as required by the Securities Act, the Exchange Act, and the rules of the Public Company Accounting Oversight Board ("**PCAOB**"), (ii) in compliance with the applicable requirements relating to the qualification of accountants under Rule 2-01 of Regulation S-X under the Securities Act and (iii) a registered public accounting firm as defined by the PCAOB whose registration has not been suspended or revoked and who has not requested such registration to be withdrawn.
- <u>Financial Statements</u>. The financial statements filed with the Commission as a part of the Registration Statement and the Prospectus present fairly, in all material respects, the consolidated financial position of the Company and its subsidiaries as of and at the dates indicated and the results of their operations, changes in stockholders' equity and cash flows for the periods specified. Such financial statements have been prepared in conformity with generally accepted accounting principles as applied in the United States applied on a consistent basis throughout the periods involved, except as may be expressly stated in the related notes thereto. The interactive data in eXtensible Business Reporting Language included or incorporated by reference in the Registration Statement fairly presents the information called for in all material respects and has been prepared in accordance with the Commission's rules and guidelines applicable thereto. No other financial statements or supporting schedules are required to be included in the Registration Statement or the Prospectus. The financial data set forth in each of the Registration Statement and the Prospectus under the captions "Capitalization" fairly present, in all material respects, the information set forth therein on a basis consistent with that of the audited financial statements contained in the Registration Statement and the Prospectus. To the Company's knowledge, no person who has been suspended or barred from being associated with a registered public accounting firm, or who has failed to comply with any sanction pursuant to Rule 5300 promulgated by the PCAOB, has participated in or otherwise aided the preparation of, or audited, the financial statements or other financial data filed with the Commission as a part of the Registration Statement and the Prospectus.
- (n) Company's Accounting System. The Company and each of its subsidiaries make and keep accurate books and records and maintain a system of internal accounting controls designed to provide reasonable assurance that: (i) transactions are executed in accordance with management's general or specific authorization; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles as applied in the United States and to maintain accountability for assets; (iii) access to assets is permitted only in accordance with management's general or specific authorization; (iv) the recorded accountability for assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences; and (v) the interactive data in extensible Business Reporting Language included or incorporated by reference in the Registration

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Statement and the Prospectus fairly presents the information called for in all material respects and is prepared in accordance with the Commission's rules and guidelines applicable thereto.

- (o) Incorporation and Good Standing of the Company. The Company has been duly incorporated and is validly existing as a corporation in good standing under the laws of the State of Nevada and has the corporate power and authority to own, lease and operate its properties and to conduct its business as described in the Registration Statement and the Prospectus and to enter into and perform its obligations under this Agreement. The Company is duly qualified as a foreign corporation to transact business and is in good standing in the Commonwealth of Massachusetts and each other jurisdiction in which such qualification is required, whether by reason of the ownership or leasing of property or the conduct of business except where the failure to so qualify or be in good standing would not reasonably be expected, individually or in the aggregate, to have a material adverse effect on the condition (financial or otherwise), earnings, business, properties, operations, assets, liabilities or prospects of the Company and its subsidiaries, taken as a whole(a "Material Adverse Effect").
- Subsidiaries. Each of the Company's "subsidiaries" (for purposes of this (p) Agreement, as defined in Rule 405 under the Securities Act) has been duly incorporated or organized, as the case may be, and is validly existing as a corporation, partnership or limited liability company, as applicable, in good standing under the laws of the jurisdiction of its incorporation or organization and has the power and authority (corporate or other) to own, lease and operate its properties and to conduct its business as described in the Registration Statement and the Prospectus. Each of the Company's subsidiaries is duly qualified as a foreign corporation, partnership or limited liability company, as applicable, to transact business and is in good standing in each jurisdiction in which such qualification is required, whether by reason of the ownership or leasing of property or the conduct of business, except where the failure to so qualify or be in good standing would not reasonably be expected to, individually or in the aggregate, result in a Material Adverse Event. All of the issued and outstanding capital stock or other equity or ownership interests of each of the Company's subsidiaries have been duly authorized and validly issued, are fully paid and nonassessable and are owned by the Company, directly or through subsidiaries, free and clear of any security interest, mortgage, pledge, lien, encumbrance or adverse claim. The Company does not own or control, directly or indirectly, any corporation, association or other entity other than the subsidiaries listed in Exhibit 21.1 to the Company's most recently filed Annual Report on Form 10-K.
- outstanding capital stock of the Company is as set forth in the Registration Statement and the Prospectus under the caption "Capitalization" (other than for subsequent issuances, if any, pursuant to employee benefit plans described in the Prospectus or upon the exercise of outstanding preferred stock, options or warrants, in each case described in the Registration Statement and the Prospectus). The Common Shares (including the Shares) conform in all material respects to the description thereof contained in the Prospectus. All of the issued and outstanding Common Shares have been duly authorized and validly issued, are fully paid and nonassessable and have been issued in compliance with all federal and state securities laws. None of the outstanding Common Shares was issued in violation of any preemptive rights, rights of first refusal or other similar rights to subscribe for or purchase securities of the Company that have not been duly waived or satisfied. There are no authorized or outstanding ontions warrants, preemptive rights, rights of first refusal

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or other rights to purchase, or equity or debt securities convertible into or exchangeable or exercisable for, any capital stock of the Company or any of its subsidiaries other than those described in the Registration Statement and the Prospectus. The descriptions of the Company's stock option, stock bonus and other stock plans or arrangements, and the options or other rights granted thereunder, set forth in the Registration Statement and the Prospectus accurately and fairly presents in all material respects the information required to be shown with respect to such plans, arrangements, options and rights.

- (r) Stock Exchange Listing. The Common Shares are registered pursuant to Section 12(b) or 12(g) of the Exchange Act and are listed on the Principal Market, and the Company has taken no action designed to, or likely to have the effect of, terminating the registration of the Common Shares under the Exchange Act or delisting the Common Shares from the Principal Market, nor has the Company received any notification that the Commission or the Principal Market is contemplating terminating such registration or listing. To the Company's knowledge, it is in compliance with all applicable listing requirements of the Principal Market.
- Non-Contravention of Existing Instruments; No Further Authorizations or Approvals Required. Neither the Company nor any of its subsidiaries is in violation of its amended and restated articles of incorporation or its amended and restated by-laws, charter, by-laws, partnership agreement or operating agreement or similar organizational documents, as applicable, or is in default (or, with the giving of notice or lapse of time, would be in default) ("**Default**") under any indenture, loan, credit agreement, note, lease, license agreement, contract, franchise or other instrument (including, without limitation, any pledge agreement, security agreement, mortgage or other instrument or agreement evidencing, guaranteeing, securing or relating to indebtedness) to which the Company or any of its subsidiaries is a party or by which it or any of them may be bound, or to which any of their respective properties or assets are subject (each, an "Existing Instrument"), except for such Defaults as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect. The Company's execution, delivery and performance of this Agreement, consummation of the transactions contemplated hereby and by the Registration Statement and the Prospectus and the issuance and sale of the Shares (including the use of proceeds from the sale of the Shares as described in the Registration Statement and the Prospectus under the caption "Use of Proceeds") (i) have been duly authorized by all necessary corporate action and will not result in any violation of the provisions of the charter or by-laws, partnership agreement or operating agreement or similar organizational documents, as applicable, of the Company or any subsidiary (ii) will not conflict with or constitute a breach of, or Default or a Debt Repayment Triggering Event (as defined below) under, or result in the creation or imposition of any lien, charge or encumbrance upon any property or assets of the Company or any of its subsidiaries pursuant to, or require the consent of any other party to, any Existing Instrument and (iii) will not result in any violation of any law, administrative regulation or administrative or court decree applicable to the Company or any of its subsidiaries except for such conflicts, breaches, Defaults, violations, Debt Repayment Triggering Event, lien, charge or encumbrance specified in clauses (ii) and (iii) above that would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect. No consent, approval, authorization or other order of, or registration or filing with, any court or other governmental or regulatory authority or agency, is required for the Company's execution, delivery and performance of this Agreement and consummation of the transactions contemplated hereby and by the Parietration Statement and the Drachactus excent such as have been obtained or made by the

Company and are in full force and effect under the Securities Act and such as may be required under applicable state securities or blue sky laws or FINRA (as defined below). As used herein, a "Debt Repayment Triggering Event" means any event or condition which gives, or with the giving of notice or lapse of time would give, the holder of any note, debenture or other evidence of indebtedness (or any person acting on such holder's behalf) the right to require the repurchase, redemption or repayment of all or a portion of such indebtedness by the Company or any of its subsidiaries.

- (t) No Material Actions or Proceedings. There is no action, suit, proceeding, inquiry or investigation brought by or before any governmental entity now pending or, to the knowledge of the Company, threatened, against or affecting the Company or any of its subsidiaries, which would reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect or materially and adversely affect the consummation of the transactions contemplated by this Agreement or the performance by the Company of its obligations hereunder; and the aggregate of all pending legal or governmental proceedings to which the Company or any such subsidiary is a party or of which any of their respective properties or assets is the subject, including ordinary routine litigation incidental to the business, would not reasonably be expected to have a Material Adverse Effect. No labor dispute with the employees of the Company or any of its subsidiaries, or with the employees of any principal supplier, manufacturer, customer or contractor of the Company, exists or, to the knowledge of the Company, is threatened or imminent that would reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect.
- Intellectual Property Rights. The Company and its subsidiaries own, or have obtained valid and enforceable licenses for, the inventions, patent applications, patents, trademarks, trade names, service names, copyrights, trade secrets and other intellectual property described in the Registration Statement and the Prospectus as being owned or licensed by them or that are necessary for the conduct of their respective businesses as currently conducted or as currently proposed to be conducted as described in the Registration Statement and the Prospectus (collectively, "Intellectual Property"). To the Company's knowledge: (i) the Registration Statement and the Prospectus accurately, in all material respects, sets forth third party ownership and other interests (including, e.g., co-exclusive license rights) in the Intellectual Property; there are no material third party rights in any Intellectual Property that are not identified in the Registration Statement and the Prospectus other than customary reversion rights of third party licensors, customary, limited licenses to the Company's service providers and academic and other collaborators, and customary rights with respect to prosecution, maintenance and enforcement with respect to third party licensees; and (ii) to the Company's knowledge, there is no infringement by third parties of any Intellectual Property. Except as otherwise disclosed in the Registration Statement and the Prospectus, there is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others: (A) challenging the Company's ownership of, or rights in or to, any Intellectual Property, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim; (B) challenging the validity, enforceability or scope of any Intellectual Property, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim that, if asserted on the date hereof, would reasonably be expected to succeed; or (C) asserting that the Company or any of its subsidiaries infringes or otherwise violates, or would, through pursuing the discovery and development programs described in the Registration Statement or the Prospectus infringe or violate any valid natent trademark trade name convice name convirient trade corret or other

proprietary rights of others, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim. Except as otherwise disclosed in the Registration Statement and the Prospectus, the Company and its subsidiaries have complied in all material respects with the terms of each agreement pursuant to which Intellectual Property has been licensed to the Company or any subsidiary, and all such agreements are in full force and effect. The Intellectual Property includes claims that cover various valuable aspects and features of the discovery and development programs described in the Registration Statement and the Prospectus as being pursued by the Company and/or its subsidiaries. All patents and patent applications owned by, or exclusively licensed to, the Company have been duly and properly filed and maintained (other than cases where the Company has, for strategic reasons, chosen to no longer pursue a patent application or continue payment of a maintenance fee or annuity). To the knowledge of the Company, the parties prosecuting such patents and patent applications have complied with their duty of candor and disclosure to the U.S. Patent and Trademark Office, and the Company is not aware of any violation of such duty which would preclude the grant of a patent in connection with any such application or would reasonably be expected to form the basis of a finding of invalidity with respect to any patents that have issued from such applications.

- (v) All Necessary Permits, etc. Except as otherwise disclosed in the Prospectus, the Company and each subsidiary possess such valid and current certificates, authorizations or permits required by state, federal or foreign regulatory agencies or bodies to conduct their respective businesses as currently conducted and as described in the Registration Statement or the Prospectus ("Permits"), except where failure to so possess would not reasonably be expected to, individually or in the aggregate, result in a Material Adverse Effect. Neither the Company nor any of its subsidiaries is in violation of, or in default under, any of the Permits or has received any notice of proceedings relating to the revocation or modification of, or non-compliance with, any such certificate, authorization or permit except as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect.
- (w) <u>Title to Properties</u>. Except as otherwise disclosed in the Prospectus, the Company and its subsidiaries do not own any real property. The Company and its subsidiaries have good and marketable title to all of the personal property and other assets reflected as owned in the financial statements referred to in Section 2(m) above (or elsewhere in the Registration Statement or the Prospectus), in each case free and clear of any security interests, mortgages, liens, encumbrances, equities, adverse claims and other defects, except such as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect. The equipment and personal property held under lease by the Company or any of its subsidiaries are held under valid and enforceable leases, with such exceptions as are not material and do not materially interfere with the use made or proposed to be made of such equipment or personal property by the Company or such subsidiary.
- (x) <u>Tax Law Compliance</u>. The Company and its subsidiaries have filed all necessary federal, local, state and foreign income and franchise tax returns or have properly requested extensions thereof, except as would reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect, and have paid all taxes required to be paid by any of them and, if due and payable, any related or similar assessment, fine or penalty levied against any of them except for any such taxes being contested in good faith and by appropriate proceedings, and except as would reasonably be expected individually or in the aggregate to have a Material Adverse

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Effect. The Company has made adequate charges, accruals and reserves (excluding reserves for deferred taxes with respect to differences between United States generally accepted accounting principles and tax basis accounting) in the applicable financial statements referred to in Section 2(m) above in respect of all federal, local, state and foreign income and franchise taxes for all periods as to which the tax liability of the Company or any of its subsidiaries has not been finally determined, except as would reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect.

- (y) <u>Company Not an "Investment Company."</u> The Company is not, and will not be, either after receipt of payment for the Shares or after the application of the proceeds therefrom as described under "Use of Proceeds" in the Registration Statement or the Prospectus, required to register as an "investment company" under the Investment Company Act of 1940, as amended (the "Investment Company Act").
- (z) <u>Insurance</u>. Except as otherwise disclosed in the Prospectus, each of the Company and its subsidiaries are insured by recognized, financially sound and reputable institutions with policies in such amounts and with such deductibles and covering such risks as are generally deemed adequate and customary for their businesses including, but not limited to, policies covering real and personal property owned or leased by the Company and its subsidiaries against theft, damage, destruction, acts of vandalism and earthquakes and policies covering the Company and its subsidiaries for product liability claims and clinical trial liability claims. The Company has no reason to believe that it or any of its subsidiaries will not be able (i) to renew its existing insurance coverage as and when such policies expire or (ii) to obtain comparable coverage from similar institutions as may be necessary or appropriate to conduct its business as now conducted and at a cost that would not reasonably be expected to have a Material Adverse Effect. Neither the Company nor any of its subsidiaries has been denied any insurance coverage which it has sought or for which it has applied.
- (aa) No Price Stabilization or Manipulation; Compliance with Regulation M. Neither the Company nor any of its subsidiaries has taken, directly or indirectly, any action designed to or that might cause or result in stabilization or manipulation of the price of the Common Shares or of any "reference security" (as defined in Rule 100 of Regulation M under the Exchange Act ("Regulation M")) with respect to the Common Shares, whether to facilitate the sale or resale of the Shares or otherwise, and has taken no action which would directly or indirectly violate Regulation M.
- (bb) <u>Related Party Transactions</u>. There are no business relationships or related-party transactions involving the Company or any of its subsidiaries or any other person required to be described in the Registration Statement or the Prospectus which have not been described as required.
- (cc) <u>FINRA Matters</u>. All of the information provided to the Agent or to counsel for the Agent by the Company, its counsel, its officers and directors and the holders of any securities (debt or equity) or options to acquire any securities of the Company in connection with the offering of the Shares is true, complete, correct and compliant with Financial Industry Regulatory Authority, Inc.'s ("FINRA") rules and any letters, filings or other supplemental information provided to FINRA pursuant to FINRA Rules or NASD Conduct Rules is true, complete and correct. The

Company meets the requirements for use of Form S-3 under the Securities Act specified in FINRA Rule 5110(b)(7)(C)(i).

- (dd) <u>No Unlawful Contributions or Other Payments</u>. Except as otherwise disclosed in the Prospectus, neither the Company nor any of its subsidiaries nor, to the best of the Company's knowledge, any employee or agent of the Company or any subsidiary, has made any contribution or other payment to any official of, or candidate for, any federal, state or foreign office in violation of any law or of the character required to be disclosed in the Registration Statement and the Prospectus.
- Compliance with Environmental Laws. Except as described in the Prospectus and except as could not be expected, individually or in the aggregate, to result in a Material Adverse Effect; (i) neither the Company nor any of its subsidiaries is in violation of any federal, state, local or foreign statute, law, rule, regulation, ordinance, code, policy or rule of common law or any judicial or administrative interpretation thereof, including any judicial or administrative order, consent, decree or judgment, relating to pollution or protection of human health, the environment (including, without limitation, ambient air, surface water, groundwater, land surface or subsurface strata) or wildlife, including, without limitation, laws and regulations relating to the release or threatened release of chemicals, pollutants, contaminants, wastes, toxic substances, hazardous substances, petroleum or petroleum products (collectively, "Hazardous Materials") or to the manufacture, processing, distribution, use, treatment, storage, disposal, transport or handling of Hazardous Materials (collectively, "Environmental Laws"), (ii) the Company and its subsidiaries have all permits, authorizations and approvals required under any applicable Environmental Laws and are each in compliance with their requirements, (iii) there are no pending or, to the Company's knowledge, threatened administrative, regulatory or judicial actions, suits, demands, demand letters, claims, liens, notices of noncompliance or violation, investigation or proceedings relating to any Environmental Law against the Company or any of its subsidiaries and (iv) to the Company's knowledge, there are no events or circumstances that would reasonably be expected to form the basis of an order for clean-up or remediation, or an action, suit or proceeding by any private party or governmental body or agency, against or affecting the Company or any of its subsidiaries relating to Hazardous Materials or any Environmental Laws.
- (ff) ERISA Compliance. To the extent applicable, except as otherwise disclosed in the Prospectus, the Company and its subsidiaries and any "employee benefit plan" (as defined under the Employee Retirement Income Security Act of 1974, as amended, and the regulations and published interpretations thereunder (collectively, "ERISA")) established or maintained by the Company, its subsidiaries or their "ERISA Affiliates" (as defined below) are in compliance with ERISA, except as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect. "ERISA Affiliate" means, with respect to the Company or any of its subsidiaries, any member of any group of organizations described in Sections 414(b), (c), (m) or (o) of the Internal Revenue Code of 1986, as amended, and the regulations and published interpretations thereunder (the "Code") of which the Company or such subsidiary is a member. No "reportable event" (as defined under ERISA) has occurred or is reasonably expected to occur with respect to any "employee benefit plan" established or maintained by the Company, its subsidiaries or any of their ERISA Affiliates. No "employee benefit plan" established or maintained by the Company, its subsidiaries or any of their ERISA Affiliates, if such "employee benefit plan" were terminated, would have any "amount of unfunded benefit liabilities" (as defined

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- under ERISA). Neither the Company, its subsidiaries nor any of their ERISA Affiliates has incurred or reasonably expects to incur any liability under (i) Title IV of ERISA with respect to termination of, or withdrawal from, any "employee benefit plan" or (ii) Sections 412, 4971, 4975 or 4980B of the Code. Each "employee benefit plan" established or maintained by the Company, its subsidiaries or any of their ERISA Affiliates that is intended to be qualified under Section 401(a) of the Code is so qualified and nothing has occurred, whether by action or failure to act, which would cause the loss of such qualification.
- (gg) <u>Brokers</u>. Except as otherwise disclosed in the Prospectus, there is no broker, finder or other party that is entitled to receive from the Company any brokerage or finder's fee or other fee or commission as a result of any transactions contemplated by this Agreement.
- (hh) No Outstanding Loans or Other Extensions of Credit. The Company does not have any outstanding extension of credit, in the form of a personal loan, to or for any director or executive officer (or equivalent thereof) of the Company except for such extensions of credit as are expressly permitted by Section 13(k) of the Exchange Act.
- (ii) <u>Compliance with Laws</u>. The Company and its subsidiaries have been and are in compliance with all applicable laws, rules and regulations, except where failure to be so in compliance could not be expected, individually or in the aggregate, to result in a Material Adverse Effect.
- (jj) <u>Dividend Restrictions</u>. Except as disclosed in the Prospectus, no subsidiary of the Company is prohibited or restricted, directly or indirectly, from paying dividends to the Company, or from making any other distribution with respect to such subsidiary's equity securities or from repaying to the Company or any other subsidiary of the Company any amounts that may from time to time become due under any loans or advances to such subsidiary from the Company or from transferring any property or assets to the Company or to any other subsidiary.
- (kk) Anti-Corruption and Anti-Bribery Laws. Neither the Company nor any of its subsidiaries or any of their respective officers, directors nor, to the knowledge of the Company, any agent, employee, affiliate or other person acting on behalf of the Company or any of its subsidiaries has, in the course of its actions for, or on behalf of, the Company or any of its subsidiaries (i) used any corporate funds for any unlawful contribution, gift, entertainment or other unlawful expenses relating to political activity; (ii) made or taken any act in furtherance of an offer, promise, or authorization of any direct or indirect unlawful payment or provision of anything of value to any domestic government official, "foreign official" (as defined in the U.S. Foreign Corrupt Practices Act of 1977, as amended, and the rules and regulations thereunder (collectively, the "FCPA"), or official or employee of any government-owned or controlled entity or public international organization, or political party, party official, or candidate for political office, from corporate funds; (iii) violated or is in violation of any provision of the FCPA, the U.K. Bribery Act 2010 or any applicable law or regulation implementing the OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions, or any other applicable non-U.S. anti-bribery statute or regulation; or (iv) made, offered, authorized, requested, or taken an act in furtherance of any unlawful bribe, rebate, payoff, influence payment, kickback or other unlawful payment or benefit to any domestic government official, foreign official as defined in the FCPA, or official or employee of any government-owned or controlled entity or public

international organization, or political party, party official, or candidate for political office; and the Company and its subsidiaries and, to the knowledge of the Company, the Company's affiliates have conducted their respective businesses in compliance with the FCPA and any other applicable anti-corruption laws and have instituted and maintain policies and procedures designed to ensure, and which are reasonably expected to continue to ensure, continued compliance therewith.

- (II) Money Laundering Laws. The operations of the Company and its subsidiaries are, and have been conducted at all times, in compliance with applicable financial recordkeeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the money laundering statutes of all applicable jurisdictions, the rules and regulations thereunder and any related or similar applicable rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the "Money Laundering Laws") and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any of its subsidiaries with respect to the Money Laundering Laws is pending or, to the best knowledge of the Company, threatened.
- (mm) Clinical Data and Regulatory Compliance. The preclinical studies and clinical trials, and other studies (collectively, "studies") that are described in, or the results of which are referred to in, the Registration Statement or the Prospectus were and, if still pending, are being conducted in all material respects in accordance with the protocols, procedures and controls designed and approved for such studies and with standard medical and scientific research procedures; each description of the results of such studies is accurate and complete in all material respects and fairly presents the data derived from such studies, and the Company and its subsidiaries have no knowledge of any other studies the results of which are materially inconsistent with, or otherwise call into question, the results described or referred to in the Registration Statement or the Prospectus; where required, the Company and its subsidiaries have made all such filings and obtained all such approvals as may be required by the Food and Drug Administration of the U.S. Department of Health and Human Services or any committee thereof or from any other U.S. or foreign government or drug or biologic regulatory agency, or health care facility Institutional Review Board (collectively, the "Regulatory Agencies"); neither the Company nor any of its subsidiaries has received any notice of, or correspondence from, any Regulatory Agency requiring the termination, suspension or modification of any clinical trial that is described or referred to in the Registration Statement or the Prospectus; and the Company and its subsidiaries have each operated and currently are in compliance in all material respects with all applicable rules, regulations and policies of the Regulatory Agencies.
- (nn) <u>Sanctions.</u> Neither the Company nor any of its subsidiaries or any of their respective officers, directors, or affiliates, nor, to the knowledge of the Company, any agent, employee or other person acting on behalf of the Company or any of its subsidiaries is currently the subject or the target of any sanctions administered by the Office of Foreign Assets Control of the U.S. Department of the Treasury ("**OFAC**"), the United Nations Security Council, the European Union, Her Majesty's Treasury of the United Kingdom, or other relevant sanctions authority (collectively, "**Sanctions**"), nor located, organized or resident in a country or territory that is the subject or the target of Sanctions (including, without limitation, Cuba, Iran, North Korea, Syria and the Crimea Region of the Ukraine); and the Company will not directly or indirectly use any of the proceeds from the sale of the Shares by the Company in the offering contemplated by this Agreement or lend contribute or otherwise make available any such proceeds to any

and regreement, or tend, continues or otherwise make available any owen proceeds to any

subsidiary, joint venture partner or other person or entity, for the purpose of financing the activities of or business with any person or country or territory that, at the time of such financing, is subject to, or the target of, any Sanctions or in any other manner that will result in a violation by any person (including any person participating in the offering contemplated by this Agreement, whether as underwriter, advisor, investor or otherwise) of Sanctions. For the past five years, the Company and its subsidiaries have not knowingly engaged in, are not now knowingly engaged in, and will not engage in any dealings or transactions with any person or country or territory that at the time of the dealing or transaction is or was the subject or the target of Sanctions.

- (oo) <u>Sarbanes-Oxley</u>. The Company is in compliance, in all material respects, with all applicable provisions of the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated thereunder.
- (pp) <u>Duties, Transfer Taxes, Etc.</u> No stamp or other issuance or transfer taxes or duties and no capital gains, income, withholding or other taxes are payable by the Agent in the United States or any political subdivision or taxing authority thereof or therein in connection with the execution, delivery or performance of this Agreement by the Company or the sale and delivery by the Company of the Shares.
- Cybersecurity. The Company and its subsidiaries' information technology assets and equipment, computers, systems, networks, hardware, software, websites, applications, and databases (collectively, "IT Systems") are adequate for, and operate and perform in all material respects as required in connection with the operation of the business of the Company and its subsidiaries as currently conducted, and to the knowledge of the Company free and clear of all material bugs, errors, defects, Trojan horses, time bombs, malware and other corruptants. The Company and its subsidiaries have implemented and maintained commercially reasonable physical, technical and administrative controls, policies, procedures, and safeguards to maintain and protect their material confidential information and the integrity, continuous operation, redundancy and security of all IT Systems and data, including "Personal Data," used in connection with their businesses. "Personal Data" means (i) a natural person's name, street address, telephone number, e-mail address, photograph, social security number or tax identification number, driver's license number, passport number, credit card number, bank information, or customer or account number; (ii) any information which would qualify as "personally identifying information" under the Federal Trade Commission Act, as amended; (iii) "personal data" as defined by GDPR; (iv) any information which would qualify as "protected health information" under the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act (collectively, "HIPAA"); and (v) any other piece of information that allows the identification of such natural person, or his or her family, or permits the collection or analysis of any data related to an identified person's health or sexual orientation. There have been no breaches, violations, outages or unauthorized uses of or accesses to same, except for those that have been remedied without material cost or liability or the duty to notify any other person, nor any incidents under internal review or investigations relating to the same. The Company and its subsidiaries are presently in material compliance with all applicable laws or statutes and all judgments, orders, rules and regulations of any court or arbitrator or governmental or regulatory authority, and contractual obligations relating to the privacy and security of IT Systems and Personal Data and to the protection of such IT Systems and Personal Data from unauthorized use access misappropriation or modification

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- Compliance with Data Privacy Laws. The Company and its subsidiaries are, and at (rr) all prior times were, in material compliance with all applicable state and federal data privacy and security laws and regulations, including without limitation HIPAA, and the Company and its subsidiaries have taken commercially reasonable actions to prepare to comply with, and since May 25, 2018, have been and currently are in material compliance with, the European Union General Data Protection Regulation ("GDPR") (EU 2016/679) (collectively, the "Privacy Laws"). The Company and its subsidiaries have in place, comply with, and take appropriate steps reasonably designed to support compliance in all material respects with their policies and procedures relating to data privacy and security and the collection, storage, use, disclosure, handling, and analysis of Personal Data (the "Policies"). The Company and its subsidiaries have at all times made all disclosures to users or customers required by applicable laws, and none of such disclosures made or contained in any Policy have, to the knowledge of the Company, been materially inaccurate or in violation of any applicable law in any material respect. The Company further certifies that neither it nor any subsidiary: (i) has received notice of any actual or potential liability under or relating to, or actual or potential violation of, any of the Privacy Laws, and has no knowledge of any event or condition that would reasonably be expected to result in any such notice; (ii) is currently conducting or paying for, in whole or in part, any investigation, remediation, or other corrective action pursuant to any Privacy Law; or (iii) is a party to any order, decree, or agreement that imposes any obligation or liability under any Privacy Law.
- (ss) Other Underwriting Agreements. The Company is not a party to any agreement with an agent or underwriter for any other "at the market" or continuous equity transaction.
- (tt) Regulatory Permits and Compliance. The Company holds, and is operating in material compliance with, such Permits of the FDA and any other Regulatory Agency that may be required for the conduct of its business as currently conducted (collectively, the "FDA Permits"), and all such FDA Permits are in full force and effect. The Company has fulfilled and performed all of its material obligations with respect to the FDA Permits, and no event has occurred which allows, or after notice or lapse of time would allow, revocation or termination thereof or results in any other material impairment of the rights of the holder of any FDA Permit. The Company has operated and currently is in compliance with applicable statutes and implementing regulations administered or enforced by the FDA or other Regulatory Agency, including the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.) and applicable regulations promulgated thereunder, except where the failure to so comply would not result in a Material Adverse Effect. The Company has not received notice of any pending or threatened claim, suit, proceeding, hearing, enforcement, audit, investigation, arbitration or other action from the FDA or comparable foreign Regulatory Agency alleging that any operation or activity of the Company is in violation of any applicable law, rule or regulation.

Any certificate signed by any officer or representative of the Company or any of its subsidiaries and delivered to the Agent or counsel for the Agent in connection with an issuance of Shares shall be deemed a representation and warranty by the Company to the Agent as to the matters covered thereby on the date of such certificate.

The Company acknowledges that the Agent and, for purposes of the opinions to be delivered pursuant to Section 4(o) hereof, counsel to the Company and counsel to the Agent, will

rely upon the accuracy and truthfulness of the foregoing representations, including any officers certificate representation, and hereby consents to such reliance.

Section 3. ISSUANCE AND SALE OF COMMON SHARES

(a) <u>Sale of Securities</u>. On the basis of the representations, warranties and agreements herein contained, but subject to the terms and conditions herein set forth, the Company and the Agent agree that the Company may from time to time seek to sell Shares through the Agent, acting as sales agent, or directly to the Agent, acting as principal, as follows, with an aggregate Sales Price of up to the Maximum Program Amount, based on and in accordance with Issuance Notices as the Company may deliver, during the Agency Period.

(b) Mechanics of Issuances.

- (i) <u>Issuance Notice</u>. Upon the terms and subject to the conditions set forth herein, on any Trading Day during the Agency Period on which the conditions set forth in <u>Section 5(a)</u> and <u>Section 5(b)</u> shall have been satisfied, the Company may exercise its right to request an issuance of Shares by delivering to the Agent an Issuance Notice; *provided, however*, that (A) in no event may the Company deliver an Issuance Notice to the extent that the sum of (x) the aggregate Sales Price of the requested Issuance Amount, plus (y) the aggregate Sales Price of all Shares issued under all previous Issuance Notices effected pursuant to this Agreement, would exceed the Maximum Program Amount; and (B) prior to delivery of any Issuance Notice, the period set forth for any previous Issuance Notice shall have expired or been terminated. An Issuance Notice shall be considered delivered on the Trading Day that it is received by e-mail to the persons set forth in Schedule A hereto and confirmed by the Company by telephone (including a voicemail message to the persons so identified), with the understanding that, with adequate prior written notice, the Agent may modify the list of such persons from time to time.
- (ii) Agent Efforts. Upon the terms and subject to the conditions set forth in this Agreement, upon the receipt of an Issuance Notice, the Agent will use its commercially reasonable efforts consistent with its normal sales and trading practices to place the Shares with respect to which the Agent has agreed to act as sales agent, subject to, and in accordance with the information specified in, the Issuance Notice, unless the sale of the Shares described therein has been suspended, cancelled or otherwise terminated in accordance with the terms of this Agreement. For the avoidance of doubt, the parties to this Agreement may modify an Issuance Notice at any time provided they both agree in writing to any such modification.
- (iii) Method of Offer and Sale. The Shares may be offered and sold (A) in privately negotiated transactions with the consent of the Company or (B) by any other method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) under the Securities Act, including block transactions, sales made directly on the Principal Market or sales made into any other existing trading market of the Common Shares. Nothing in this Agreement shall be deemed to require either party to agree to the method of offer and sale specified in the preceding sentence, and the method of placement of any Shares by the Agent shall be at the Agent's discretion.

- (iv) <u>Confirmation to the Company</u>. If acting as sales agent hereunder, the Agent will provide written confirmation to the Company no later than the opening of the Trading Day next following the Trading Day on which it has placed Shares hereunder setting forth the number of shares sold on such Trading Day, the corresponding Sales Price and the Issuance Price payable to the Company in respect thereof.
- (v) <u>Settlement.</u> Each issuance of Shares will be settled on the applicable Settlement Date for such issuance of Shares and, subject to the provisions of <u>Section 5</u>, on or before each Settlement Date, the Company will, or will cause its transfer agent to, electronically transfer the Shares being sold by crediting the Agent's or its designee's account at The Depository Trust Company through its Deposit/Withdrawal At Custodian (DWAC) System, or by such other means of delivery as may be mutually agreed upon by the parties hereto and, upon receipt of such Shares, which in all cases shall be freely tradable, transferable, registered shares in good deliverable form, the Agent will deliver, by wire transfer of immediately available funds, the related Issuance Price in same day funds delivered to an account designated by the Company prior to the Settlement Date. The Company may sell Shares to the Agent as principal at a price agreed upon at each relevant time Shares are sold pursuant to this Agreement (each, a "**Time of Sale**").
- Suspension or Termination of Sales. Consistent with standard market settlement (vi) practices, the Company or the Agent may, upon notice to the other party hereto in writing or by telephone (confirmed immediately by verifiable email), suspend any sale of Shares, and the period set forth in an Issuance Notice shall immediately terminate; provided, however, that (A) such suspension and termination shall not affect or impair either party's obligations with respect to any Shares placed or sold hereunder prior to the receipt of such notice; (B) if the Company suspends or terminates any sale of Shares after the Agent confirms such sale to the Company, the Company shall still be obligated to comply with Section 3(b)(v) with respect to such Shares; and (C) if the Company defaults in its obligation to deliver Shares on a Settlement Date, the Company agrees that it will hold the Agent harmless against any loss, claim, damage or expense (including, without limitation, penalties, interest and reasonable legal fees and expenses), as incurred, arising out of or in connection with such default by the Company. The parties hereto acknowledge and agree that, in performing its obligations under this Agreement, the Agent may borrow Common Shares from stock lenders in the event that the Company has not delivered Shares to settle sales as required by subsection (v) above, and may use the Shares to settle or close out such borrowings. The Company agrees that no such notice shall be effective against the Agent unless it is made to the persons identified in writing by the Agent pursuant to Section 3(b)(i).
- (vii) No Guarantee of Placement, Etc. The Company acknowledges and agrees that (A) there can be no assurance that the Agent will be successful in placing Shares; (B) the Agent will incur no liability or obligation to the Company or any other Person if it does not sell Shares; and (C) the Agent shall be under no obligation to purchase Shares on a principal basis pursuant to this Agreement, except as otherwise specifically agreed by the Agent and the Company.
- (viii) <u>Material Non-Public Information.</u> Notwithstanding any other provision of this Agreement, the Company and the Agent agree that the Company shall not deliver any Issuance Notice to the Agent, and the Agent shall not be obligated to place any Shares, during any period in which the Company is in possession of material non-public information.

- (c) <u>Fees.</u> As compensation for services rendered, the Company shall pay to the Agent, on the applicable Settlement Date, the Selling Commission for the applicable Issuance Amount (including with respect to any suspended or terminated sale pursuant to <u>Section 3(b)(vi)</u>) by the Agent deducting the Selling Commission from the applicable Issuance Amount.
- (d) Expenses. The Company agrees to pay all costs, fees and expenses incurred in connection with the performance of its obligations hereunder and in connection with the transactions contemplated hereby, including without limitation (i) all expenses incident to the issuance and delivery of the Shares (including all printing and engraving costs); (ii) all fees and expenses of the registrar and transfer agent of the Shares; (iii) all necessary issue, transfer and other stamp taxes in connection with the issuance and sale of the Shares; (iv) all fees and expenses of the Company's counsel, independent public or certified public accountants and other advisors; (v) all costs and expenses incurred in connection with the preparation, printing, filing, shipping and distribution of the Registration Statement (including financial statements, exhibits, schedules, consents and certificates of experts), the Prospectus, any Free Writing Prospectus (as defined below) prepared by or on behalf of, used by, or referred to by the Company, and all amendments and supplements thereto, and this Agreement; (vi) all filing fees, attorneys' fees and expenses incurred by the Company or the Agent in connection with qualifying or registering (or obtaining exemptions from the qualification or registration of) all or any part of the Shares for offer and sale under the state securities or blue sky laws or the provincial securities laws of Canada, and, if requested by the Agent, preparing and printing a "Blue Sky Survey" or memorandum and a "Canadian wrapper,, and any supplements thereto, advising the Agent of such qualifications, registrations, determinations and exemptions; (vii) the reasonable and documented fees and disbursements of the Agent's counsel, including the reasonable and documented fees and expenses of counsel for the Agent in connection with, FINRA review, if any, and approval of the Agent's participation in the offering and distribution of the Shares; (viii) the filing fees incident to FINRA review, if any; (ix) the costs and expenses of the Company relating to investor presentations on any "road show" undertaken in connection with the marketing of the offering of the Shares, including, without limitation, expenses associated with the preparation or dissemination of any electronic road show, expenses associated with the production of road show slides and graphics, fees and expenses of any consultants engaged in connection with the road show presentations with the prior approval of the Company, travel and lodging expenses of the representatives, employees and officers of the Company and of the Agent and any such consultants, and the cost of any aircraft chartered in connection with the road show; and (x) the fees and expenses associated with listing the Shares on the Principal Market. The fees and disbursements of Agent's counsel pursuant to subsections (vi) and (vii) above shall not exceed (A) \$50,000 in connection with the first Issuance Notice and (B) \$15,000 in connection with each Triggering Event Date (as defined below) on which the Company is required to provide a certificate pursuant to Section 4(o).

Section 4. ADDITIONAL COVENANTS

The Company covenants and agrees with the Agent as follows, in addition to any other covenants and agreements made elsewhere in this Agreement:

(a) <u>Exchange Act Compliance</u>. During the Agency Period, the Company shall (i) file, on a timely basis, with the Commission all reports and documents required to be filed under Section 13, 14 or 15 of the Exchange Act in the manner and within the time periods required by

the Exchange Act; and (ii) either (A) include in its quarterly reports on Form 10-Q and its annual reports on Form 10-K, a summary detailing, for the relevant reporting period, (1) the number of Shares sold, if any, through the Agent pursuant to this Agreement and (2) the net proceeds, if any, received by the Company from such sales or, in the Company's sole discretion, (B) prepare a prospectus supplement containing, or include in such other filing permitted by the Securities Act or Exchange Act (each an "Interim Prospectus Supplement"), such summary information and, at least once a quarter and subject to this Section 4, file such Interim Prospectus Supplement pursuant to Rule 424(b) under the Securities Act (and within the time periods required by Rule 424(b) and Rule 430B under the Securities Act)); provided, however, that prior notice is given to the Agent of any such filing of an Interim Prospectus Supplement.

- Securities Act Compliance. After the date of this Agreement, the Company shall promptly advise the Agent in writing (i) of the receipt of any comments of, or requests for additional or supplemental information from, the Commission; (ii) of the time and date of any filing of any post-effective amendment to the Registration Statement, any Rule 462(b) Registration Statement or any amendment or supplement to the Prospectus, or any Free Writing Prospectus; (iii) of the time and date that any post-effective amendment to the Registration Statement or any Rule 462(b) Registration Statement becomes effective; and (iv) of the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or any post-effective amendment thereto, any Rule 462(b) Registration Statement or any amendment or supplement to the Prospectus or of any order preventing or suspending the use of any Free Writing Prospectus or the Prospectus, or of any proceedings to remove, suspend or terminate from listing or quotation the Common Shares from any securities exchange upon which they are listed for trading or included or designated for quotation, or of the threatening or initiation of any proceedings for any of such purposes. If the Commission shall enter any such stop order at any time, the Company will use its best efforts to obtain the lifting of such order as soon as practicable. Additionally, the Company agrees that it shall comply with the provisions of Rule 424(b) and Rule 433, as applicable, under the Securities Act and will use its reasonable efforts to confirm that any filings made by the Company under such Rule 424(b) or Rule 433 were filed in a timely manner with the Commission.
- Amendments and Supplements to the Prospectus and Other Securities Act Matters. If any event shall occur or condition exist as a result of which it is necessary to amend or supplement the Prospectus so that the Prospectus does not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances when the Prospectus is delivered to a purchaser, not misleading, or if in the opinion of the Agent or counsel for the Agent it is otherwise necessary to amend or supplement the Prospectus to comply with applicable law, including the Securities Act, the Company agrees (subject to Sections 4(d) and 4(f)) to promptly prepare, file with the Commission and furnish at its own expense to the Agent, such amendments or supplements to the Prospectus so that the statements in the Prospectus as so amended or supplemented will not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances when the Prospectus is delivered to a purchaser, not misleading or so that the Prospectus, as amended or supplemented, will comply with applicable law including the Securities Act. Neither the Agent's consent to, nor delivery of, any such amendment or supplement shall constitute a waiver of any of the Company's obligations under Sections 4(d) and 4(f) Notwithstanding the foregoing the Company shall not be required to file such amendment or

supplement if there is no pending Issuance Notice and the Company believes that it is in its best interest not to file such amendment or supplement.

- (d) Agent's Review of Proposed Amendments and Supplements. Prior to amending or supplementing the Registration Statement (including any registration statement filed under Rule 462(b) under the Securities Act) or the Prospectus (excluding any amendment or supplement through incorporation of any report filed under the Exchange Act), the Company shall furnish to the Agent for review, a reasonable amount of time prior to the proposed time of filing or use thereof, a copy of each such proposed amendment or supplement, insofar as such proposed amendment or supplement relates to the transactions contemplated hereby, and the Company shall not file or use any such proposed amendment or supplement without the Agent's prior consent, and the Company shall file with the Commission within the applicable period specified in Rule 424(b) under the Securities Act any prospectus required to be filed pursuant to such Rule.
- (e) <u>Use of Free Writing Prospectus</u>. Neither the Company nor the Agent has prepared, used, referred to or distributed, or will prepare, use, refer to or distribute, without the other party's prior written consent, any "written communication" that constitutes a "free writing prospectus" as such terms are defined in Rule 405 under the Securities Act with respect to the offering contemplated by this Agreement (any such free writing prospectus being referred to herein as a "Free Writing Prospectus").
- Free Writing Prospectuses. The Company shall furnish to the Agent for review, a (f) reasonable amount of time prior to the proposed time of filing or use thereof, a copy of each proposed free writing prospectus or any amendment or supplement thereto to be prepared by or on behalf of, used by, or referred to by the Company insofar as such proposed free writing prospectus or amendment or supplement relates to the transactions contemplated hereby, and the Company shall not file, use or refer to any such proposed free writing prospectus or any such amendment or supplement thereto without the Agent's consent. The Company shall furnish to the Agent, without charge, as many copies of any free writing prospectus prepared by or on behalf of, or used by the Company insofar as such proposed free writing prospectus relates to the transactions contemplated hereby, as the Agent may reasonably request. If at any time when a prospectus is required by the Securities Act (including, without limitation, pursuant to Rule 173(d)) to be delivered (whether physically or through compliance with Rule 172 under the Securities Act or any similar rule) in connection with sales of the Shares (but in any event if at any time through and including the date of this Agreement) there occurred or occurs an event or development as a result of which any free writing prospectus prepared by or on behalf of, used by, or referred to by the Company conflicted or would conflict with the information contained in the Registration Statement or included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances prevailing at that subsequent time, not misleading, the Company shall promptly amend or supplement such free writing prospectus to eliminate or correct such conflict or so that the statements in such free writing prospectus as so amended or supplemented will not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances prevailing at such subsequent time, not misleading, as the case may be; provided, however, that prior to amending or supplementing any such free writing prospectus, the Company shall furnish to the Agent for review, a reasonable amount of time prior to the proposed time of filing or use thereof, a copy of such proposed amended or supplemented free

writing prospectus and the Company shall not file, use or refer to any such amended or supplemented free writing prospectus without the Agent's consent, which consent shall not be unreasonably withheld or delayed.

- (g) <u>Filing of Agent Free Writing Prospectuses</u>. The Company shall not take any action that would result in the Agent or the Company being required to file with the Commission pursuant to Rule 433(d) under the Securities Act a free writing prospectus prepared by or on behalf of the Agent that the Agent otherwise would not have been required to file thereunder.
- (h) Copies of Registration Statement and Prospectus. After the date of this Agreement through the last time that a prospectus is required by the Securities Act (including, without limitation, pursuant to Rule 173(d)) to be delivered in connection with sales of the Shares, the Company agrees to furnish the Agent with copies (which may be electronic copies) of the Registration Statement and each amendment thereto, and with copies (which may be electronic copies) of the Prospectus and each amendment or supplement thereto in the form in which it is filed with the Commission pursuant to the Securities Act or Rule 424(b) under the Securities Act, both in such quantities as the Agent may reasonably request from time to time; and, if the delivery of a prospectus is required under the Securities Act or under the blue sky or securities laws of any jurisdiction at any time on or prior to the applicable Settlement Date for any period set forth in an Issuance Notice in connection with the offering or sale of the Shares and if at such time any event has occurred as a result of which the Prospectus as then amended or supplemented would include an untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made when such Prospectus is delivered, not misleading, or, if for any other reason it is necessary during such same period to amend or supplement the Prospectus or to file under the Exchange Act any document incorporated by reference in the Prospectus in order to comply with the Securities Act or the Exchange Act, to notify the Agent and to request that the Agent suspend offers to sell Shares (and, if so notified, the Agent shall cease such offers as soon as practicable); and if the Company decides to amend or supplement the Registration Statement or the Prospectus as then amended or supplemented, to advise the Agent promptly by telephone (with confirmation in writing) and to prepare and cause to be filed promptly with the Commission an amendment or supplement to the Registration Statement or the Prospectus as then amended or supplemented that will correct such statement or omission or effect such compliance; provided, however, that if during such same period the Agent is required to deliver a prospectus in respect of transactions in the Shares, the Company shall promptly prepare and file with the Commission such an amendment or supplement.
- (i) <u>Blue Sky Compliance</u>. The Company shall cooperate with the Agent and counsel for the Agent to qualify or register the Shares for sale under (or obtain exemptions from the application of) the state securities or blue sky laws or Canadian provincial securities laws of those jurisdictions designated by the Agent, shall comply with such laws and shall continue such qualifications, registrations and exemptions in effect so long as required for the distribution of the Shares. The Company shall not be required to qualify as a foreign corporation or to take any action that would subject it to general service of process in any such jurisdiction where it is not presently qualified or where it would be subject to taxation as a foreign corporation. The Company will advise the Agent promptly of the suspension of the qualification or registration of (or any such exemption relating to) the Shares for offering, sale or trading in any jurisdiction or any initiation or threat of any proceeding for any such purpose, and in the event of the issuance of any order

suspending such qualification, registration or exemption, the Company shall use its best efforts to obtain the withdrawal thereof as soon as practicable.

- (j) <u>Earnings Statement</u>. As soon as practicable, the Company will make generally available to its security holders and to the Agent an earnings statement (which need not be audited) covering a period of at least 12 months beginning with the first fiscal quarter of the Company occurring after the date of this Agreement which shall satisfy the provisions of Section 11(a) of the Securities Act and Rule 158 under the Securities Act.
- (k) <u>Listing</u>; <u>Reservation of Shares</u>. (a) The Company will use its best efforts to maintain the listing of the Shares on the Principal Market; and (b) the Company will reserve and keep available at all times, free of preemptive rights, Shares for the purpose of enabling the Company to satisfy its obligations under this Agreement.
- Transfer Agent. The Company shall engage and maintain, at its expense, a registrar and transfer agent for the Shares.
- (m) <u>Due Diligence</u>. During the term of this Agreement, the Company will reasonably cooperate with any reasonable due diligence review conducted by the Agent in connection with the transactions contemplated hereby, including, without limitation, providing information and making available documents and senior corporate officers, during normal business hours and at the Company's principal offices, as the Agent may reasonably request from time to time.
- (n) Representations and Warranties. The Company acknowledges that each delivery of an Issuance Notice and each delivery of Shares on a Settlement Date shall be deemed to be (i) an affirmation to the Agent that the representations and warranties of the Company contained in or made pursuant to this Agreement are true and correct as of the date of such Issuance Notice or of such Settlement Date, as the case may be, as though made at and as of each such date, except as may be disclosed in the Prospectus (including any documents incorporated by reference therein and any supplements thereto); and (ii) an undertaking that the Company will advise the Agent if any of such representations and warranties will not be true and correct as of the Settlement Date for the Shares relating to such Issuance Notice, as though made at and as of each such date (except that such representations and warranties shall be deemed to relate to the Registration Statement and the Prospectus as amended and supplemented relating to such Shares).
- (o) <u>Deliverables at Triggering Event Dates; Certificates.</u> The Company agrees that on or prior to the date of the first Issuance Notice and, during the term of this Agreement after the date of the first Issuance Notice, upon:
- (A) the filing of the Prospectus or the amendment or supplement of any Registration Statement or Prospectus (other than a prospectus supplement relating solely to an offering of securities other than the Shares or a prospectus filed pursuant to Section 4(a)(ii)(B)), by means of a post-effective amendment, sticker or supplement, but not by means of incorporation of documents by reference into the Registration Statement or Prospectus;
- (B) the filing with the Commission of an annual report on Form 10-K or a quarterly report on Form 10-Q (including any Form 10-K/A or Form 10-Q/A containing amended

financial information or a material amendment to the previously filed annual report on Form 10-K or quarterly report on Form 10-Q), in each case, of the Company; or

- (C) the filing with the Commission of a current report on Form 8-K of the Company containing amended financial information (other than information "furnished" pursuant to Item 2.02 or 7.01 of Form 8-K or to provide disclosure pursuant to Item 8.01 of Form 8-K relating to reclassification of certain properties as discontinued operations in accordance with Statement of Financial Accounting Standards No. 144) that is material to the offering of securities of the Company in the Agent's reasonable discretion; (any such event, a "Triggering Event **Date**"), the Company shall furnish the Agent (but in the case of clause (C) above only if the Agent reasonably determines that the information contained in such current report on Form 8-K of the Company is material) with a certificate as of the Triggering Event Date, in the form and substance satisfactory to the Agent and its counsel, substantially similar to the form previously provided to the Agent and its counsel, modified, as necessary, to relate to the Registration Statement and the Prospectus as amended or supplemented, (A) confirming that the representations and warranties of the Company contained in this Agreement are true and correct, (B) that the Company has performed all of its obligations hereunder to be performed on or prior to the date of such certificate and as to the matters set forth in Section 5(a)(iii) hereof, and (C) containing any other certification that the Agent shall reasonably request. The requirement to provide a certificate under this Section 4(o) shall be waived for any Triggering Event Date occurring at a time when no Issuance Notice is pending or a suspension is in effect, which waiver shall continue until the earlier to occur of the date the Company delivers instructions for the sale of Shares hereunder (which for such calendar quarter shall be considered a Triggering Event Date) and the next occurring Triggering Event Date. Notwithstanding the foregoing, if the Company subsequently decides to sell Shares following a Triggering Event Date when a suspension was in effect and did not provide the Agent with a certificate under this Section 4(o), then before the Company delivers the instructions for the sale of Shares or the Agent sells any Shares pursuant to such instructions, the Company shall provide the Agent with a certificate in conformity with this Section 4(o) dated as of the date that the instructions for the sale of Shares are issued.
- <u>Legal Opinions.</u> On or prior to the date of the first Issuance Notice and on or prior to each Triggering Event Date with respect to which the Company is obligated to deliver a certificate pursuant to Section 4(o) for which no waiver is applicable and excluding the date of this Agreement, a negative assurances letter and the written legal opinion of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo P.C., counsel to the Company, Brownstein Hyatt Farber Schreck, LLP, local Nevada counsel for the Company, Dentons Europe LLP, local German counsel for the Company, Schiweck Weinzierl Koch, Patentanwälte Partnerschaft mbH, intellectual property counsel to the Company, and Choate Hall & Stewart LLP, U.S. intellectual property counsel for the Company, each dated the date of delivery, in form and substance reasonably satisfactory to the Agent and its counsel, substantially similar to the form previously provided to the Agent and its counsel, modified, as necessary, to relate to the Registration Statement and the Prospectus as then amended or supplemented, shall be furnished to the Agent; provided, however, no more than one of each opinion shall be required to be furnished hereunder per annual report on Form 10-K and quarterly report on Form 10-Q filed by the Company. In lieu of such opinions for subsequent periodic filings, in the discretion of the Agent, the Company may furnish a reliance letter from such counsel to the Agent, permitting the Agent to rely on a previously delivered opinion letter,

in such prior opinion shall be deemed to relate to the Registration Statement and the Prospectus as amended or supplemented as of such Triggering Event Date).

- Comfort Letter. On or prior to the date of the first Issuance Notice and on or prior to each Triggering Event Date with respect to which the Company is obligated to deliver a certificate pursuant to Section 4(o) for which no waiver is applicable and excluding the date of this Agreement, the Company shall cause Ernst & Young LLP, the independent registered public accounting firm who has audited the financial statements included or incorporated by reference in the Registration Statement, to furnish the Agent a comfort letter, dated the date of delivery, in form and substance reasonably satisfactory to the Agent and its counsel, substantially similar to the form previously provided to the Agent and its counsel; provided, however, that any such comfort letter will only be required on the Triggering Event Date specified to the extent that it contains financial statements filed with the Commission under the Exchange Act and incorporated or deemed to be incorporated by reference into a Prospectus. If requested by the Agent, the Company shall also cause a comfort letter to be furnished to the Agent within ten (10) Trading Days of the date of occurrence of any material transaction or event requiring the filing of a current report on Form 8-K containing material amended financial information of the Company, including the restatement of the Company's financial statements. The Company shall be required to furnish no more than one comfort letter hereunder per calendar quarter.
- (r) <u>Secretary's Certificate</u>. On or prior to the date of the first Issuance Notice and on or prior to each Triggering Event Date with respect to which the Company is obligated to deliver a certificate pursuant to Section 4(o) for which no waiver is applicable and excluding the date of this Agreement, the Company shall furnish the Agent a certificate executed by the Secretary of the Company, signing in such capacity, dated the date of delivery (i) certifying that attached thereto are true and complete copies of the resolutions duly adopted by the Board of Directors of the Company authorizing the execution and delivery of this Agreement and the consummation of the transactions contemplated hereby (including, without limitation, the issuance of the Shares pursuant to this Agreement), which authorization shall be in full force and effect on and as of the date of such certificate, (ii) certifying and attesting to the office, incumbency, due authority and specimen signatures of each Person who executed this Agreement for or on behalf of the Company, and (iii) containing any other certification that the Agent shall reasonably request.
- (s) Agent's Own Account; Clients' Account. The Company consents to the Agent trading, in compliance with applicable law, in the Common Shares for the Agent's own account and for the account of its clients at the same time as sales of the Shares occur pursuant to this Agreement.
- (t) <u>Investment Limitation</u>. The Company shall not invest, or otherwise use the proceeds received by the Company from its sale of the Shares in such a manner as would require the Company or any of its subsidiaries to register as an investment company under the Investment Company Act.
- (u) <u>Market Activities</u>. The Company will not take, directly or indirectly, any action designed to or that might be reasonably expected to cause or result in stabilization or manipulation of the price of the Shares or any other reference security, whether to facilitate the sale or resale of the Shares or otherwise, and the Company will, and shall cause each of its affiliates to, comply

with all applicable provisions of Regulation M. If the limitations of Rule 102 of Regulation M ("Rule 102") do not apply with respect to the Shares or any other reference security pursuant to any exception set forth in Section (d) of Rule 102, then promptly upon notice from the Agent (or, if later, at the time stated in the notice), the Company will, and shall cause each of its affiliates to, comply with Rule 102 as though such exception were not available but the other provisions of Rule 102 (as interpreted by the Commission) did apply. The Company shall promptly notify the Agent if it no longer meets the requirements set forth in Section (d) of Rule 102.

Notice of Other Sale. Without the written consent of the Agent, the Company will not, directly or indirectly, offer to sell, sell, contract to sell, grant any option to sell or otherwise dispose of any Common Shares or securities convertible into or exchangeable for Common Shares (other than Shares hereunder), warrants or any rights to purchase or acquire Common Shares, during the period beginning on the third Trading Day immediately prior to the date on which any Issuance Notice is delivered to the Agent hereunder and ending on the third Trading Day immediately following the Settlement Date with respect to Shares sold pursuant to such Issuance Notice; and will not directly or indirectly enter into any other "at the market" or continuous equity transaction offer to sell, sell, contract to sell, grant any option to sell or otherwise dispose of any Common Shares (other than the Shares offered pursuant to this Agreement) or securities convertible into or exchangeable for Common Shares, warrants or any rights to purchase or acquire, Common Shares prior to the termination of this Agreement; provided, however, that such restrictions will not be required in connection with the Company's (i) issuance or sale of Common Shares, options to purchase Common Shares or Common Shares issuable upon the exercise of options or other equity awards pursuant to any employee, consultant, or director share, option, incentive or benefit plan, share purchase or ownership plan, long-term incentive plan, dividend reinvestment plan, inducement award under Principal Market rules or other compensation plan of the Company or its subsidiaries, as in effect on the date of this Agreement, (ii) issuance or sale of Common Shares issuable upon exchange, conversion or redemption of preferred stock or other securities or the exercise or vesting of warrants, options or other equity awards outstanding at the date of this Agreement, (iii) issuance or sale of Common Shares or securities convertible into or exchangeable for Common Shares as consideration for mergers, acquisitions, other business combinations, joint ventures, collaborations, licensing arrangements or strategic alliances occurring after the date of this Agreement which are not used for capital raising purposes and (iv) modification of any outstanding options, warrants of any rights to purchase or acquire Common Shares.

Section 5. CONDITIONS TO DELIVERY OF ISSUANCE NOTICES AND TO SETTLEMENT

(a) <u>Conditions Precedent to the Right of the Company to Deliver an Issuance Notice</u> and the Obligation of the Agent to Sell Shares. The right of the Company to deliver an Issuance Notice hereunder is subject to the satisfaction, on the date of delivery of such Issuance Notice, and the obligation of the Agent to use its commercially reasonable efforts to place Shares during the applicable period set forth in the Issuance Notice is subject to the satisfaction, on each Trading Day during the applicable period set forth in the Issuance Notice, of each of the following conditions:

- (i) Accuracy of the Company's Representations and Warranties; Performance by the Company. The Company shall have delivered the certificate required to be delivered pursuant to Section 4(o) on or before the date on which delivery of such certificate is required pursuant to Section 4(o). The Company shall have performed, satisfied and complied with all covenants, agreements and conditions required by this Agreement to be performed, satisfied or complied with by the Company at or prior to such date, including, but not limited to, the covenants contained in Section 4(p), Section 4(q) and Section 4(r).
- (ii) No Injunction. No statute, rule, regulation, executive order, decree, ruling or injunction shall have been enacted, entered, promulgated or endorsed by any court or governmental authority of competent jurisdiction or any self-regulatory organization having authority over the matters contemplated hereby that prohibits or directly and materially adversely affects any of the transactions contemplated by this Agreement, and no proceeding shall have been commenced that may have the effect of prohibiting or materially adversely affecting any of the transactions contemplated by this Agreement.
- (iii) Material Adverse Changes. Except as disclosed in the Prospectus and the Time of Sale Information, (a) in the judgment of the Agent there shall not have occurred any Material Adverse Change; and (b) there shall not have occurred any downgrading, nor shall any notice have been received by the Company of any intended or potential downgrading or of any review for a possible change that does not indicate the direction of the possible change, in the rating accorded any securities of the Company or any of its subsidiaries by any "nationally recognized statistical rating organization" as such term is defined for purposes of Section 3(a)(62) of the Exchange Act.
- (iv) No Suspension of Trading in or Delisting of Common Shares; Other Events. The trading of the Common Shares (including without limitation the Shares) shall not have been suspended by the Commission, the Principal Market or FINRA and the Common Shares (including without limitation the Shares) shall have been approved for listing or quotation on and shall not have been delisted from the Nasdaq Stock Market, the New York Stock Exchange or any of their constituent markets. There shall not have occurred (and be continuing in the case of occurrences under clauses (i) and (ii) below) any of the following: (i) trading or quotation in any of the Company's securities shall have been suspended or limited by the Commission or by the Principal Market or trading in securities generally on either the Principal Market shall have been suspended or limited, or minimum or maximum prices shall have been generally established on any of such stock exchanges by the Commission or FINRA; (ii) a general banking moratorium shall have been declared by any of federal or New York, authorities; or (iii) there shall have occurred any outbreak or escalation of national or international hostilities or any crisis or calamity, or any change in the United States or international financial markets, or any substantial change or development involving a prospective substantial change in United States' or international political, financial or economic conditions, as in the judgment of the Agent is material and adverse and makes it impracticable to market the Shares

in the manner and on the terms described in the Prospectus or to enforce contracts for the sale of securities.

- (b) <u>Documents Required to be Delivered on each Issuance Notice Date</u>. The Agent's obligation to use its commercially reasonable efforts to place Shares hereunder shall additionally be conditioned upon the delivery to the Agent on or before the Issuance Notice Date of a certificate in form and substance reasonably satisfactory to the Agent, executed by the Chief Executive Officer, President or Chief Financial Officer of the Company, to the effect that all conditions to the delivery of such Issuance Notice shall have been satisfied as at the date of such certificate as required to be delivered pursuant to Section 4(o) (which certificate shall not be required if the foregoing representations shall be set forth in the Issuance Notice).
- (c) No Misstatement or Material Omission. Agent shall not have advised the Company that the Registration Statement, the Prospectus or the Time of Sale Information, or any amendment or supplement thereto, contains an untrue statement of fact that in the Agent's reasonable opinion is material, or omits to state a fact that in the Agent's reasonable opinion is material and is required to be stated therein or is necessary to make the statements therein not misleading.
- (d) Agent Counsel Legal Opinion. Agent shall have received from Cooley LLP, counsel for Agent, such opinion or opinions, on or before the date on which the delivery of the Company counsel legal opinion is required pursuant to Section 4(p), with respect to such matters as Agent may reasonably require, and the Company shall have furnished to such counsel such documents as they reasonably request for enabling them to pass upon such matters.

Section 6. INDEMNIFICATION AND CONTRIBUTION

(a) Indemnification of the Agent. The Company agrees to indemnify and hold harmless the Agent, its officers and employees, and each person, if any, who controls the Agent within the meaning of the Securities Act or the Exchange Act against any loss, claim, damage, liability or expense, as incurred, to which the Agent or such officer, employee or controlling person may become subject, under the Securities Act, the Exchange Act, other federal or state statutory law or regulation, or the laws or regulations of foreign jurisdictions where Shares have been offered or sold or at common law or otherwise (including in settlement of any litigation), insofar as such loss, claim, damage, liability or expense (or actions in respect thereof as contemplated below) arises out of or is based upon (i) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, or any amendment thereto, including any information deemed to be a part thereof pursuant to Rule 430B under the Securities Act, or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein not misleading; or (ii) any untrue statement or alleged untrue statement of a material fact contained in any Free Writing Prospectus that the Company has used, referred to or filed, or is required to file, pursuant to Rule 433(d) of the Securities Act or the Prospectus (or any amendment or supplement thereto), or the omission or alleged omission therefrom of a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading and to reimburse the Agent and each such officer, employee and controlling person for any and all expenses (including the fees and disbursements of counsel chosen by the Agent) as such expenses are reasonably incurred and documented by the Agent or such officer, employee or controlling person in connection with investigating, defending, settling,

compromising or paying any such loss, claim, damage, liability, expense or action; provided, however, that the foregoing indemnity agreement shall not apply to any loss, claim, damage, liability or expense to the extent, but only to the extent, arising out of or based upon any untrue statement or alleged untrue statement or omission or alleged omission made in reliance upon and in conformity with written information furnished to the Company by the Agent expressly for use in the Registration Statement, any such Free Writing Prospectus or the Prospectus (or any amendment or supplement thereto), it being understood and agreed that the only such information furnished by the Agent to the Company consists of the information set forth in the first sentence of the ninth paragraph under the caption "Plan of Distribution" in the Prospectus. The indemnity agreement set forth in this Section 6(a) shall be in addition to any liabilities that the Company may otherwise have.

- (b) Indemnification of the Company, its Directors and Officers. The Agent agrees to indemnify and hold harmless the Company, each of its directors, each of its officers who signed the Registration Statement and each person, if any, who controls the Company within the meaning of the Securities Act or the Exchange Act against any loss, claim, damage, liability or expense, as incurred, to which the Company or any such director, officer or controlling person may become subject, under the Securities Act, the Exchange Act, or other federal or state statutory law or regulation, or the laws or regulations of foreign jurisdictions where Shares have been offered or sold or at common law or otherwise (including in settlement of any litigation), that arises out of or is based upon (i) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, or any amendment thereto, including any information deemed to be a part thereof pursuant to Rule 430B under the Securities Act, or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein not misleading; or (ii) any untrue statement or alleged untrue statement of a material fact contained in any Free Writing Prospectus that the Company has used, referred to or filed, or is required to file, pursuant to Rule 433(d) of the Securities Act or the Prospectus (or any amendment or supplement thereto), or the omission or alleged omission therefrom of a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; but, for each of (i) and (ii) above, only to the extent arising out of or based upon any untrue statement or alleged untrue statement or omission or alleged omission made in reliance upon and in conformity with written information furnished to the Company by the Agent expressly for use in the Registration Statement, any such Free Writing Prospectus or the Prospectus (or any amendment or supplement thereto), it being understood and agreed that the only such information furnished by the Agent to the Company consists of the information set forth in the first sentence of the ninth paragraph under the caption "Plan of Distribution" in the Prospectus, and to reimburse the Company and each such director, officer and controlling person for any and all expenses (including the fees and disbursements of one counsel chosen by the Company) as such expenses are reasonably incurred by the Company or such officer, director or controlling person in connection with investigating, defending, settling, compromising or paying any such loss, claim, damage, liability, expense or action. The indemnity agreement set forth in this Section 6(b) shall be in addition to any liabilities that the Agent may otherwise have.
- (c) <u>Notifications and Other Indemnification Procedures</u>. Promptly after receipt by an indemnified party under this <u>Section 6</u> of notice of the commencement of any action, such indemnified party will, if a claim in respect thereof is to be made against an indemnifying party

under this Section 6, notify the indemnifying party in writing of the commencement thereof, but the omission so to notify the indemnifying party will not relieve it from any liability which it may have to any indemnified party for contribution or otherwise than under the indemnity agreement contained in this <u>Section 6</u> or to the extent it is not prejudiced as a proximate result of such failure. In case any such action is brought against any indemnified party and such indemnified party seeks or intends to seek indemnity from an indemnifying party, the indemnifying party will be entitled to participate in, and, to the extent that it shall elect, jointly with all other indemnifying parties similarly notified, by written notice delivered to the indemnified party promptly after receiving the aforesaid notice from such indemnified party, to assume the defense thereof with counsel reasonably satisfactory to such indemnified party; provided, however, if the defendants in any such action include both the indemnified party and the indemnifying party and the indemnified party shall have reasonably concluded that a conflict may arise between the positions of the indemnifying party and the indemnified party in conducting the defense of any such action or that there may be legal defenses available to it and/or other indemnified parties which are different from or additional to those available to the indemnifying party, the indemnified party or parties shall have the right to select separate counsel to assume such legal defenses and to otherwise participate in the defense of such action on behalf of such indemnified party or parties. Upon receipt of notice from the indemnifying party to such indemnified party of such indemnifying party's election so to assume the defense of such action and approval by the indemnified party of counsel, the indemnifying party will not be liable to such indemnified party under this Section 6 for any legal or other expenses subsequently incurred by such indemnified party in connection with the defense thereof unless (i) the indemnified party shall have employed separate counsel in accordance with the proviso to the preceding sentence (it being understood, however, that the indemnifying party shall not be liable for the fees and expenses of more than one separate counsel (together with local counsel), representing the indemnified parties who are parties to such action), which counsel (together with any local counsel) for the indemnified parties shall be selected by the indemnified party (in the case of counsel for the indemnified parties referred to in Section 6(a) and Section 6(b) above), (ii) the indemnifying party shall not have employed counsel satisfactory to the indemnified party to represent the indemnified party within a reasonable time after notice of commencement of the action or (iii) the indemnifying party has authorized in writing the employment of counsel for the indemnified party at the expense of the indemnifying party, in each of which cases the fees and expenses of counsel shall be at the expense of the indemnifying party and shall be paid as they are incurred.

(d) Settlements. The indemnifying party under this Section 6 shall not be liable for any settlement of any proceeding effected without its written consent, but if settled with such consent or if there be a final judgment for the plaintiff, the indemnifying party agrees to indemnify the indemnified party against any loss, claim, damage, liability or expense by reason of such settlement or judgment. Notwithstanding the foregoing sentence, if at any time an indemnified party shall have requested an indemnifying party to reimburse the indemnified party for fees and expenses of counsel as contemplated by Section 6(c) hereof, the indemnifying party agrees that it shall be liable for any settlement of any proceeding effected without its written consent if (i) such settlement is entered into more than 30 days after receipt by such indemnifying party of the aforesaid request; and (ii) such indemnifying party shall not have reimbursed the indemnified party in accordance with such request prior to the date of such settlement. No indemnifying party shall, without the prior written consent of the indemnified party, effect any settlement, compromise or consent to the

| entry of judgment in any | pending or inreatened action. | suit or proceeding in respect | of which any |
|--------------------------|-------------------------------|-------------------------------|--------------|

indemnified party is or could have been a party and indemnity was or could have been sought hereunder by such indemnified party, unless such settlement, compromise or consent includes an unconditional release of such indemnified party from all liability on claims that are the subject matter of such action, suit or proceeding.

(e) <u>Contribution</u>. If the indemnification provided for in this <u>Section 6</u> is for any reason held to be unavailable to or otherwise insufficient to hold harmless an indemnified party in respect of any losses, claims, damages, liabilities or expenses referred to therein, then each indemnifying party shall contribute to the aggregate amount paid or payable by such indemnified party, as incurred, as a result of any losses, claims, damages, liabilities or expenses referred to therein (i) in such proportion as is appropriate to reflect the relative benefits received by the Company, on the one hand, and the Agent, on the other hand, from the offering of the Shares pursuant to this Agreement; or (ii) if the allocation provided by clause (i) above is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) above but also the relative fault of the Company, on the one hand, and the Agent, on the other hand, in connection with the statements or omissions which resulted in such losses, claims, damages, liabilities or expenses, as well as any other relevant equitable considerations. The relative benefits received by the Company, on the one hand, and the Agent, on the other hand, in connection with the offering of the Shares pursuant to this Agreement shall be deemed to be in the same respective proportions as the total gross proceeds from the offering of the Shares (before deducting expenses) received by the Company bear to the total Selling Commissions received by the Agent. The relative fault of the Company, on the one hand, and the Agent, on the other hand, shall be determined by reference to, among other things, whether any such untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company, on the one hand, or the Agent, on the other hand, and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission.

The amount paid or payable by a party as a result of the losses, claims, damages, liabilities and expenses referred to above shall be deemed to include, subject to the limitations set forth in Section 6(c), any legal or other fees or expenses reasonably incurred by such party in connection with investigating or defending any action or claim. The provisions set forth in Section 6(c) with respect to notice of commencement of any action shall apply if a claim for contribution is to be made under this Section 6(e); provided, however, that no additional notice shall be required with respect to any action for which notice has been given under Section 6(b) for purposes of indemnification.

The Company and the Agent agree that it would not be just and equitable if contribution pursuant to this Section 6(e) were determined by pro rata allocation or by any other method of allocation which does not take account of the equitable considerations referred to in this Section 6(e).

Notwithstanding the provisions of this <u>Section 6(e)</u>, the Agent shall not be required to contribute any amount in excess of the Selling Commission received by the Agent in connection with the offering contemplated hereby. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. For purposes of this Section 6(e), each

officer and employee of the Agent and each person, if any, who controls the Agent within the meaning of the Securities Act or the Exchange Act shall have the same rights to contribution as the Agent, and each director of the Company, each officer of the Company who signed the Registration Statement, and each person, if any, who controls the Company within the meaning of the Securities Act and the Exchange Act shall have the same rights to contribution as the Company.

Section 7. TERMINATION & SURVIVAL

- (a) <u>Term.</u> Subject to the provisions of this <u>Section 7</u>, the term of this Agreement shall continue from the date of this Agreement until the end of the Agency Period, unless earlier terminated by the parties to this Agreement pursuant to this <u>Section 7</u>.
 - (b) <u>Termination</u>; <u>Survival Following Termination</u>.
 - (i) Either party may terminate this Agreement prior to the end of the Agency Period, by giving written notice as required by this Agreement, upon ten (10) Trading Days' notice to the other party; provided that, (A) if the Company terminates this Agreement after the Agent confirms to the Company any sale of Shares, the Company shall remain obligated to comply with Section 3(b)(v) with respect to such Shares and (B) Section 2, Section 3(d), Section 6, Section 7 and Section 8 shall survive termination of this Agreement. If termination shall occur prior to the Settlement Date for any sale of Shares, such sale shall nevertheless settle in accordance with the terms of this Agreement.
 - (ii) In addition to the survival provision of Section 7(b)(i), the respective indemnities, agreements, representations, warranties and other statements of the Company, of its officers and of the Agent set forth in or made pursuant to this Agreement will remain in full force and effect, regardless of any investigation made by or on behalf of the Agent or the Company or any of its or their partners, officers or directors or any controlling person, as the case may be, and, anything herein to the contrary notwithstanding, will survive delivery of and payment for the Shares sold hereunder and any termination of this Agreement.

Section 8. MISCELLANEOUS

(a) Press Releases and Disclosure. The Company may issue a press release describing the material terms of the transactions contemplated hereby as soon as practicable following the date of this Agreement, and may file with the Commission a Current Report on Form 8-K or, if this Agreement is signed within four days of the Company's filing of a periodic report, its Quarterly Report on Form 10-Q, with this Agreement attached as an exhibit thereto, describing the material terms of the transactions contemplated hereby, and the Company shall consult with the Agent prior to making such disclosures, and the parties hereto shall use all commercially reasonable efforts, acting in good faith, to agree upon a text for such disclosures that is reasonably satisfactory to all parties hereto. No party hereto shall issue thereafter any press release or like public statement (including, without limitation, any disclosure required in reports filed with the Commission pursuant to the Exchange Act) related to this Agreement or any of the transactions contemplated hereby without the prior written approval of the other party hereto, except as may

be necessary or appropriate in the reasonable opinion of the party seeking to make disclosure to comply with the requirements of applicable law or stock exchange rules and except for the disclosure required pursuant to Section 4(a) of this Agreement in the Company's quarterly reports on Form 10-Q or annual reports on Form 10-K. If any such press release or like public statement is so required, the party making such disclosure shall consult with the other party prior to making such disclosure, and the parties shall use all commercially reasonable efforts, acting in good faith, to agree upon a text for such disclosure that is reasonably satisfactory to all parties hereto.

- (b) No Advisory or Fiduciary Relationship. The Company acknowledges and agrees that (i) the transactions contemplated by this Agreement, including the determination of any fees, are arm's-length commercial transactions between the Company and the Agent, (ii) when acting as a principal under this Agreement, the Agent is and has been acting solely as a principal and is not the agent or fiduciary of the Company, or its stockholders, creditors, employees or any other party, (iii) the Agent has not assumed nor will assume an advisory or fiduciary responsibility in favor of the Company with respect to the transactions contemplated hereby or the process leading thereto (irrespective of whether the Agent has advised or is currently advising the Company on other matters) and the Agent does not have any obligation to the Company with respect to the transactions contemplated hereby except the obligations expressly set forth in this Agreement, (iv) the Agent and its affiliates may be engaged in a broad range of transactions that involve interests that differ from those of the Company, and (v) the Agent has not provided any legal, accounting, regulatory or tax advice with respect to the transactions contemplated hereby and the Company has consulted its own legal, accounting, regulatory and tax advisors to the extent it deemed appropriate.
- (c) Research Analyst Independence. The Company acknowledges that the Agent's research analysts and research departments are required to and should be independent from their respective investment banking divisions and are subject to certain regulations and internal policies, and as such the Agent's research analysts may hold views and make statements or investment recommendations and/or publish research reports with respect to the Company or the offering that differ from the views of their respective investment banking divisions. The Company understands that the Agent is a full service securities firm and as such from time to time, subject to applicable securities laws, may effect transactions for its own account or the account of its customers and hold long or short positions in debt or equity securities of the companies that may be the subject of the transactions contemplated by this Agreement.
- (d) <u>Notices</u>. All communications hereunder shall be in writing and shall be mailed, hand delivered or telecopied and confirmed to the parties hereto as follows:

If to the Agent:

Jefferies LLC 520 Madison Avenue New York, NY 10022

Attention: General Counsel.

with a copy (which shall not constitute notice) to:

Cooley LLP 55 Hudson Yards New York, New York 10001 Facsimile: (212) 479-6275 Attention: Daniel I. Goldberg.

If to the Company:

Pieris Pharmaceuticals, Inc. 255 State Street, 9th Floor Boston, Massachusetts 02109

Attention: Ahmed Mousa, Vice President and General Counsel.

with a copy (which shall not constitute notice) to:

Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. One Financial Center Boston, Massachusetts 02111

Attention: William C. Hicks and Marc. D. Mantell

Any party hereto may change the address for receipt of communications by giving written notice to the others in accordance with this Section 8(d).

- (e) <u>Successors</u>. This Agreement will inure to the benefit of and be binding upon the parties hereto, and to the benefit of the affiliates, agents, employees, officers and directors and controlling persons referred to in <u>Section 6</u>, and in each case their respective successors, and no other person will have any right or obligation hereunder. The term "successors" shall not include any purchaser of the Shares as such from the Agent merely by reason of such purchase.
- (f) Partial Unenforceability. The invalidity or unenforceability of any Article, Section, paragraph or provision of this Agreement shall not affect the validity or enforceability of any other Article, Section, paragraph or provision hereof. If any Article, Section, paragraph or provision of this Agreement is for any reason determined to be invalid or unenforceable, there shall be deemed to be made such minor changes (and only such minor changes) as are necessary to make it valid and enforceable.
- in accordance with the internal laws of the State of New York applicable to agreements made and to be performed in such state. Any legal suit, action or proceeding arising out of or based upon this Agreement or the transactions contemplated hereby ("Related Proceedings") may be instituted in the federal courts of the United States of America located in the Borough of Manhattan in the City of New York or the courts of the State of New York in each case located in the Borough of Manhattan in the City of New York (collectively, the "Specified Courts"), and each party irrevocably submits to the exclusive jurisdiction (except for proceedings instituted in regard to the

microcardy administration of the excitative landarenon (except for proceedings mathematica in regard to the

enforcement of a judgment of any such court (a "Related Judgment"), as to which such jurisdiction is non-exclusive) of such courts in any such suit, action or proceeding. Service of any process, summons, notice or document by mail to such party's address set forth above shall be effective service of process for any suit, action or other proceeding brought in any such court. The parties irrevocably and unconditionally waive any objection to the laying of venue of any suit, action or other proceeding in the Specified Courts and irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such suit, action or other proceeding brought in any such court has been brought in an inconvenient forum.

(h) General Provisions. This Agreement constitutes the entire agreement of the parties to this Agreement and supersedes all prior written or oral and all contemporaneous oral agreements, understandings and negotiations with respect to the subject matter hereof. This Agreement may be executed in two or more counterparts, each one of which shall be an original, with the same effect as if the signatures thereto and hereto were upon the same instrument, and may be delivered by facsimile transmission or by electronic delivery of a portable document format (PDF) file. This Agreement may not be amended or modified unless in writing by all of the parties hereto, and no condition herein (express or implied) may be waived unless waived in writing by each party whom the condition is meant to benefit. The Article and Section headings herein are for the convenience of the parties only and shall not affect the construction or interpretation of this Agreement.

[Signature Page Immediately Follows]

If the foregoing is in accordance with your understanding of our agreement, kindly sign and return to the Company the enclosed copies hereof, whereupon this instrument, along with all counterparts hereof, shall become a binding agreement in accordance with its terms

Very truly yours,

PIERIS PHARMACEUTICALS, INC.

By: /s/ Stephen Yoder

Name: Stephen Yoder

Title: CEO

The foregoing Agreement is hereby confirmed and accepted by the Agent in New York, New York as of the date first above written.

JEFFERIES LLC

By: /s/ Donald Lynaugh

Name: Donald Lynaugh Title: Managing Director

EXHIBIT A

ISSUANCE NOTICE

| [Date] | | |
|---|--|-------|
| Jefferies LLC 520 Madison Avenue New York, New York 10022 | | |
| Attn: [] | | |
| "Company") and Jefferies LLC (the | rket Sale Agreement between Pieris Pharmaceuticals, Inc e "Agent") dated as of August 9, 2019. The Company con f this Issuance Notice are satisfied as of the date hereof. | |
| Date of Delivery of Issuance Notice | e (determined pursuant to <u>Section 3(b)(i)</u>): | |
| Issuance Amount (equal to the total | l Sales Price for such Shares): | |
| | \$ | |
| Number of days in selling period: | | |
| First date of selling period: | | |
| Last date of selling period: | | |
| Settlement Date(s) if other than star | ndard T+2 settlement: | |
| | | |
| | less than \$1.00 without the prior written consent of the A the Agent's sole discretion): \$ per share | gent, |
| Other Limitations: | | |
| Comments: | | |
| | | |
| | 3 | |
| | By:Name: | _ |
| | Title: | |

Schedule A Notice Parties

The Company

Stephen Yoder

Allan Reine

Ahmed Mousa

The Agent

Donald Lynaugh

Jack Fabbri

Matthew Kim

PIERIS PHARMACEUTICALS, INC.

AMENDED AND RESTATED NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

The Board of Directors of Pieris Pharmaceuticals, Inc. (the "Company") has approved the following Amended and Restated Non-Employee Director Compensation Policy (this "Policy") which establishes compensation to be paid to non-employee directors of the Company, effective as of April 30, 2019 ("Effective Time"), to provide an inducement to obtain and retain the services of qualified persons to serve as members of the Company's Board of Directors.

Applicable Persons

This Policy shall apply to each director of the Company who is not an employee of the Company or any Affiliate (each, a "Non-Employee Director"). "Affiliate" shall mean an entity which is a direct or indirect parent or subsidiary of the Company, as determined pursuant to Section 424 of the Internal Revenue Code of 1986, as amended.

Stock Option Grants

All stock option amounts set forth herein shall be subject to automatic adjustment in the event of any stock split or other recapitalization affecting the Company's common stock, par value \$0.001 per share (the "Common Stock").

Interim Stock Option Grant

On January 25, 2020, (i) each Non-Employee Director shall be automatically granted a non-qualified stock option to purchase 10,000 shares of Common Stock under the Company's then-current Stock Incentive Plan, as of the Effective Time the 2018 Stock Incentive Plan (the "Stock Plan"), and (ii) the Chairperson of the Board of Directors (the "Chairperson") shall be automatically granted an additional non-qualified stock option to purchase 2,500 shares of Common Stock under the Stock Plan (together, the "Interim Director Awards").

Annual Stock Option Grants

Beginning in calendar 2020, each calendar year, (i) each Non-Employee Director shall be automatically granted a non-qualified stock option to purchase 20,000 shares of Common Stock under the Stock Plan on the date of the annual meeting of the Board of Directors coincident with or immediately following the Company's annual meeting of stockholders (the "Annual Stockholders Meeting"), and (ii) the Chairperson shall be automatically granted an additional non-qualified stock option to purchase 5,000 shares of Common Stock under the Stock Plan (together, the "Annual Director Awards").

Initial Stock Option Grant for Newly Appointed or Elected Directors and Chairperson

Each new Non-Employee Director shall be automatically granted a non-qualified stock option to purchase 30,000 shares of Common Stock under the Stock Plan at the first regularly scheduled meeting of the Board of Directors on or after his or her initial appointment or election to the Board of Directors (the "Initial Director Award"). The Chairperson shall be automatically granted an additional non-qualified stock option to purchase 40,000 shares of Common Stock under the Stock Plan at the first regularly scheduled meeting of the Board of Directors on or after his or her initial appointment or election as Chairperson (the "Initial Chairperson Award").

Terms for All Option Grants

Unless otherwise specified in this Policy or by the Board of Directors or the Compensation Committee at the time of grant, all options granted under this Policy shall: (i) vest, in the case of (A) the Annual Director Awards, at the end of the "Directors' Compensation Year", which shall be defined as the approximately one-year period beginning on the date of each regular Annual Stockholders Meeting and ending on the date of the next regular Annual Stockholders Meeting, subject to the Non-Employee Director's continued service on the Board of Directors through the applicable Directors' Compensation Year, and (B) the Interim Director Awards and the Initial Director Award, one (1) year after the date of grant of such option, subject to the Non-Employee Director's continued service on the Board of Directors on the vesting date, and (C) the Initial Chairperson Award, as to twenty-five percent (25%) of the shares underlying the Initial Chairperson Award on the first anniversary of the date of the Chairperson's appointment or election as Chairperson (the "Initial Vesting Date"), with the remaining seventy-five percent (75%) of the shares underlying the Initial Chairperson Award vesting in twelve (12) equal quarterly installments at the end of each full calendar quarter following the Initial Vesting Date, subject to the Chairperson's continued service as Chairperson on the vesting date; (ii) have an exercise price equal to the fair market value of the Common Stock on the grant date, as determined in the Stock Plan; (iii) terminate ten years after the grant date; and (iv) contain such other terms and conditions as set forth in the form of option agreement approved by the Board of Directors or the Compensation Committee prior to the grant date.

Annual Fees

Each Non-Employee serving on the Board of Directors and the Audit Committee, Compensation Committee, Nominating and Corporate Governance Committee, and/or Science and Technology Committee, as applicable, shall be entitled to the following annual amounts (the "Annual Fees"):

| | Annual Retainer Amount for Member | Annual Retainer Amount for Chair |
|-------------------------------------|-----------------------------------|----------------------------------|
| Board of Directors | \$35,000 | \$30,000* |
| Audit Committee | \$7,500 | \$15,000** |
| Science and Technology Committee | \$5,000 | \$10,000** |

| Compensation Committee | \$5,000 | \$10,000** | |
|---|---------|------------|--|
| Nominating and Corporate Governance Committee | \$3,750 | \$7,500** | |

^{*} The annual retainer amount for the Chair of the Board of Directors is in addition to the annual retainer amount for a Member of the Board of Directors.

Except as otherwise set forth in this Policy, all Annual Fees shall be paid for the period from January 1 through December 31 of each year. Such Annual Fees shall be paid in cash or a grant of an option to purchase Common Stock under the Stock Plan, at the election of each Non-Employee Director, as follows:

- cash in the amount of each Non-Employee Director's Annual Fees; or
- an option to purchase such number of shares of Common Stock as is equal to the full dollar amount of each Non-Employee Director's Annual Fees (as calculated below under "Calculation of Shares and Grant Terms").

Election

Each Non-Employee Director shall make an annual election on the form provided by the Company, indicating the combination of cash and/or Common Stock elected in the year prior to the payment, indicating his or her election for the following calendar year. If no election has been made prior to the first date of the calendar year, then the Non-Employee Director shall receive all Annual Fees in cash. Each newly elected or appointed Non-Employee Director shall make an election prior to the beginning of the next calendar quarter after his or her initial appointment or election.

Payments

Payments payable to Non-Employee Directors shall be paid quarterly in arrears promptly following the end of each calendar quarter, provided that (i) the amount of such payment shall be prorated for any portion of such quarter that such director was not serving on the Board or a committee or, in the case of the Annual Fees paid for service as a chairperson, as a chairperson, and (ii) no fee shall be payable in respect of any period prior to the date such director was elected to the Board or a committee or, in the case of the Annual Fees paid for service as a chairperson, as a chairperson.

Calculation of Shares and Grant Terms

If an option to purchase Common Stock is to be received as payment, the number of shares underlying such option shall equal the Black Scholes value of the options computed in accordance with FASB Topic 718 on the 25th day of the month following the end of each calendar quarter (the "Calculation Date") (rounded down to the nearest whole number so that no fractional shares

^{**} Annual retainer amounts for the Chair of Committees of the Board of Directors are in lieu of the annual retainer amount for a Member of the applicable Committee of the Board of Directors.

shall be issued). The option shall be automatically and without any further action required by the Board of Directors issued as of the Calculation Date and shall be fully vested as of the date of grant.

Expenses

Upon presentation of documentation of such expenses reasonably satisfactory to the Company, each Non-Employee Director shall be reimbursed for his or her reasonable out-of-pocket business expenses incurred in connection with attending meetings of the Board of Directors and committees thereof or in connection with other business related to the Board of Directors.

Amendments

The Compensation Committee shall periodically review this Policy to assess whether any amendments in the type and amount of compensation provided herein should be made and shall make recommendations to the Board of Directors for its approval of any amendments to this Policy.

SUBTENANT RECOGNITION AND ATTORNMENT AGREEMENT

This Sublease Recognition and Attornment Agreement (this "Agreement") is made as of the 3 day of May, 2019 (the "Effective Date"), by and among 255 STATE STREET, LLC, a Delaware limited liability company, with an address c/o Pembroke Real Estate LLC, 255 State Street, Boston, Massachusetts 02109 ("New Sublandlord"), BERENBERG CAPITAL MARKETS LLC, a Delaware limited liability company ("Existing Sublandlord"), and PIERIS PHARMACEUTICALS INC., a Nevada corporation, having a business address of Lise-Meitna-Strasse 30, Freising-Weihenstephan, Germany ("Subtenant").

WITNESSETH:

Reference is hereby made to the following facts:

- A. The New Sublandlord, as landlord, and Existing Sublandlord, as tenant, entered into that certain Lease, originally dated as of May 12, 2011 (the "Lease"), for certain premises (the "Existing Premises") containing approximately 9,105 rentable square feet of Rentable Area located on the ninth (9th) floor of the building commonly known as 255 State Street in Boston, Massachusetts (as more particularly described in the Lease, the "Building"). The Lease will be amended by that certain First Amendment to Lease, of even date herewith (the "First Amendment").
- B. Existing Sublandlord, as sublandlord, and Subtenant, as subtenant, entered into that certain Sublease, dated as of August 27, 2015 (the "Sublease"), pursuant to which Existing Sublandlord subleased to Subtenant approximately 3,905 rentable square feet located on the ninth (9th) floor of the Building (as more particularly described in the Sublease, the "Subleased Premises").
- C. Effective as of the Replacement Premises Commencement Date (as defined in the First Amendment), pursuant to the terms of the First Amendment, the term of the Lease will be terminated with respect to the Subleased Premises. Concurrent herewith, pursuant to the terms of that certain Sublease Assignment Agreement (the "Sublease Assignment Agreement"), dated as of the Effective Date, Existing Sublandlord has assigned to New Sublandlord all of its right, title, interest, claim, and demand in, to, and under the Sublease, and New Sublandlord has accepted such assignment and assumed the obligations of Existing Sublandlord as sublandlord under the Sublease, to the extent arising or accruing from and after the Replacement Premises Commencement Date (as defined in the First Amendment). Notwithstanding such assignment and assumption by New Sublandlord, Existing Sublandlord agrees nothing herein or in the Sublease Assignment Agreement shall release or cause to be released, Existing Sublandlord from any of its obligations under the Sublease to the extent arising or accruing prior to the Replacement Premises Commencement Date.
- D. As a result of the termination of the term of the Lease with respect to the Subleased Premises, and the assignment of the Sublease pursuant to the Sublease Assignment Agreement, New Sublandlord and Subtenant desire to confirm the existence of a direct lease between New Sublandlord and Subtenant, subject to and in accordance with the terms and conditions of the Sublease, all as more particularly set forth herein.

4832-1322-5864.3

NOW, THEREFORE, in consideration of the mutual promises herein made, and other good and valuable consideration, the receipt, sufficiency and delivery of which are hereby acknowledged, the parties agree as follows:

- 1. Recognition; Attornment. Effective as of the Replacement Premises Commencement Date, New Sublandlord hereby recognizes Subtenant as the tenant under a direct lease with New Sublandlord, and Subtenant hereby attorns to and recognizes New Sublandlord as the landlord under a direct lease with Subtenant, all subject to and in accordance with the terms and conditions of the Sublease, provided, however, New Sublandlord and any of its successors and assigns shall not be (i) liable for any misrepresentation, act or omission of Existing Sublandlord, (ii) subject to any counterclaim or offset which Subtenant may have against Existing Sublandlord; (iii) liable for the return of any security deposit or letters of credit excepting only to the extent actually received by New Sublandlord and with respect to which Subtenant agrees to look solely to Existing Sublandlord for refund or reimbursement; provided, however, concurrent with the execution of the First Amendment, Existing Sublandlord shall transfer to New Sublandlord that certain security deposit in the amount of \$48,555.37 to New and Subtenant shall look to New Sublandlord for the return of said security deposit from and after the Replacement Premises Commencement Date, in accordance with and subject to the terms and conditions of the Sublease; unless delivered by Existing Sublandlord to New Sublandlord, bound by any advance payment of rent or additional rent or any other sums made by Subtenant to Existing Sublandlord, except for rent or additional rent paid not more than thirty (30) days in advance; (v) obligated with respect to any duties, obligations, or liabilities of Existing Sublandlord under the Sublease, to the extent arising or accruing prior to the Replacement Premises Commencement Date, or (vi) bound by any covenant to undertake, complete or pay for any improvements to the Subleased Premises.
- 2. <u>Ratification of Sublease</u>. Notwithstanding that, pursuant to the terms of the First Amendment, effective as of the Replacement Premises Commencement Date the term of the Lease with respect to the Subleased Premises will be terminated, the Sublease is hereby ratified and confirmed, and all of the terms, covenants, agreements and provisions of the Sublease shall remain unaltered and unmodified and in full force and effect throughout the balance of the term of the Sublease, including, without limitation, the terms and conditions of the Lease that were incorporated by reference in the Sublease.
- 3. <u>Estoppel Certifications</u>. Subtenant does hereby certify, represent and warrant to New Sublandlord, as of the Replacement Premises Commencement Date, as follows:
 - (a) Subtenant is the owner of Subtenant's interest in the Sublease and has not transferred or assigned the Sublease, or subsublet any portion of the Subleased Premises.
 - (b) A true, correct and complete copy of the Sublease is attached hereto as <u>Exhibit A</u>. The Sublease is presently in full force and effect and has not been changed, modified, amended or supplemented.
 - (c) To Subtenant's knowledge, Subtenant is not in breach or default of any of its obligations, agreements, or covenants contained in the Sublease.

- (d) To Subtenant's knowledge, Existing Sublandlord is not in breach or default of any of its obligations, agreements, or covenants contained in the Sublease.
- (e) No rent under the Sublease has been paid more than thirty (30) days in advance of the date due.
- (f) All improvements to the Subleased Premises required to be built by the sublandlord under the Sublease (if any) have been fully and satisfactorily completed by Existing Sublandlord; all allowances and contributions (if any) payable by the sublandlord under the Sublease for Subtenant's improvements (or for any other purpose) have been paid in full; Subtenant is not, as of the date hereof, entitled to any reduction, offset or abatement of the rent payable under the Sublease; and Subtenant has accepted the Subleased Premises and is paying rent with respect thereto.
- 4. <u>No Merger</u>. Subtenant acknowledges and agrees that there shall be no merger of the Sublease or of the estate created by the Sublease with the Lease or the leasehold interest created by the Lease by reason of the fact that the same person, corporation, firm or other entity may now or hereafter acquire, assume, hold or own, directly or indirectly, both (a) the interest of landlord under the Lease, and (b) the interest of sublandlord under the Sublease.
- 5. Miscellaneous. The submission of drafts of this Agreement for examination and negotiation does not constitute an offer for any of the other terms and conditions set forth in this Agreement, and this Agreement shall not be binding upon New Sublandlord or Subtenant unless and until New Sublandlord shall have executed and delivered a fully executed copy of this Agreement to Subtenant. If any provision of this Agreement is invalid or unenforceable in any circumstances, the remainder of this Agreement, and the application of such provision in any other circumstances, shall not be affected thereby. This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts. The covenants, terms, conditions, agreements, and obligations in this Agreement shall be binding upon and inure to the benefit of the heirs, successors and permitted assigns of the parties hereto. This Agreement may be executed in any number of counterparts and shall constitute an agreement binding on all parties notwithstanding that all parties are not signatories to the original or the same counterpart provided that all parties are furnished a copy or copies thereof reflecting the signature of all parties. Delivery of such counterparts by facsimile or other electronic transmission shall constitute delivery of originals for all purposes.

[Signature page follows]

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4832-1322-5864.3

IN WITNESS WHEREOF, the undersigned has caused this Agreement to be executed under seal as of the date first set forth above.

NEW SUBLANDLORD:

255 STATE STREET, LLC, a Delaware limited liability company

By: Pembroke Real Estate LLC, its manager

| By:_ | | |
|------|-------|--|
| | Name: | |
| | Ite. | |

SUBTENANT:

PIERIS PHARMACEUTICALS INC., a Nevada

corporation

Approved as to Form Legal Department

By: Tresident CEO

EXISTING SUBLANDLORD:

BERENBERG CAPITAL MARKETS LLC, a Delaware limited liability company

| By: | | | |
|------|--|--|--|
| Its: | | | |

IN WITNESS WHEREOF, the undersigned has caused this Agreement to be executed under seal as of the date first set forth above.

NEW SUBLANDLORD:

255 STATE STREET, LLC, a Delaware limited liability company

By: Pembroke Real Estate LLC, its manager

By: John Chila Its: Ut

SUBTENANT:

PIERIS PHARMACEUTICALS INC., a Nevada corporation

| By: | |
|------|--|
| its: | |

EXISTING SUBLANDLORD:

BERENBERG CAPITAL MARKETS LLC, a Delaware limited liability company

By:_

Its:_

: Peter Nichols, Co-

Hanaging Partner

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4838-4003-1127.1

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-1q5(f)) for the registrant and have:
 - a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: August 9, 2019

/s/ Stephen S. Yoder

Stephen S. Yoder

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

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

I, Allan Reine, certify that:

- 1. I have reviewed this quarterly report on Form 10-Q of Pieris Pharmaceuticals, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: August 9, 2019

/s/ Allan Reine

Allan Reine

Title: Chief Financial Officer (principal financial officer)

CERTIFICATIONS UNDER SECTION 906

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

- (i) the accompanying Quarterly Report on Form 10-Q of the Company for the fiscal quarter endedJune 30, 2019 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
 - (ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 9, 2019 /s/ Stephen S. Yoder

Stephen S. Yoder

Title: Chief Executive Officer and President

(principal executive officer)

CERTIFICATIONS UNDER SECTION 906

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

- (i) the accompanying Quarterly Report on Form 10-Q of the Company for the fiscal quarter endedJune 30, 2019 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
 - (ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 9, 2019 /s/ Allan Reine

Allan Reine

Title: Chief Financial Officer

(principal financial officer)