## UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## **FORM 10-Q**

(Mark One)

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

For the quarterly period ended March 31, 2018

OR

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

For the transition period from \_\_\_\_\_\_ to \_\_\_\_\_ Commission file number: 001-37471

## PIERIS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Nevada (State or other jurisdiction of incorporation or organization)

255 State Street, 9th Floor Boston, MA United States (Address of principal executive offices)

fices)

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

02109

(Zip Code)

Registrant's telephone number, including area code

857-246-8998

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

<u>Title of each class</u> Common Stock, par value \$0.001 per share Name of each exchange on which registered The Nasdaq Stock Market LLC

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

None

(Title of class)

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  $\mathbb{X}$  No  $\square$ 

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

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

Large accelerated filer		Accelerated filer	
Non-accelerated filer	□ [Do not check if a smaller reporting company]	Smaller reporting company	
Emerging growth compa	any 🗷		

×

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.  $\Box$ 

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 May 9, 2018, the registrant had 53,974,184 shares of common stock outstanding.

## TABLE OF CONTENTS

	Page
PART I: FINANCIAL INFORMATION	
Item 1. Condensed Consolidated Financial Statements	<u>1</u>
Condensed Consolidated Balance Sheets as of March 31, 2018 (unaudited) and December 31, 2017	<u>1</u>
Condensed Consolidated Statements of Operations and Comprehensive Loss for the Three Months Ended March 31,	
<u>2018 and 2017</u>	<u>2</u>
Condensed Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2018 and 2017	<u>3</u>
Notes to the Condensed Consolidated Financial Statements	<u>4</u>
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	<u>13</u>
Item 3. Quantitative and Qualitative Disclosures about Market Risk	<u>19</u>
Item 4. Controls and Procedures	<u>19</u>
PART II: OTHER INFORMATION	
Item 1. Legal Proceedings	<u>21</u>
Item 1A. Risk factors	<u>21</u>
Item 6. Exhibits	<u>21</u>
<u>SIGNATURES</u>	<u>23</u>

#### Forward Looking Statements

This section and other parts of 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 (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (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," "should," "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; 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; and regulatory developments in the United States and foreign countries.

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 year ended December 31, 2017 filed on March 15, 2018, 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 Report to "euro" or "€" are to the currency introduced at the start of the third stage of the European Economic and Monetary Union pursuant to the Treaty establishing the European Community, as amended. We prepare our financial statements in U.S. dollars.

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

Where in this Report we refer to amounts in euros, we have for your convenience also, in certain cases, provided a conversion of those amounts to U.S. dollars in parentheses. Where the numbers refer to a specific balance sheet account date or financial statement account period, we have used the exchange rate that was used to perform the conversions in connection with the applicable financial statement. In all other instances, unless otherwise indicated, the conversions have been made using the noon buying rate of  $\notin$ 1.00 to U.S. \$1.2321 based on Thomson Reuters as of March 31, 2018.

## PIERIS PHARMACEUTICALS, INC.

## CONDENSED CONSOLIDATED BALANCE SHEETS

## (unaudited, in thousands, except share and per share data)

Current assets:         S         109,521         \$         37,878           Short term investments         50,061         34,751           Accounts receivable         3,309         15,546           Prepaid expenses and other current assets         3,190         1,615           Total current assets         3,190         1,615           Total current assets         2,183         89,790           Property and equipment, net         4,445         4,034           Long term investments         2,583         9,922           Other non-current assets         130         130           Total assets         5         173,239         \$         103,876           Liabilities and stockholders' equity         5         1,934         \$         2,452           Accounts payable         \$         1,934         \$         2,452           Accound expenses and other current liabilities         6,170         6,578         6,170           Deferred revenues, current portion         46,251         37,153         37           Total acurrent liabilities         54,763         45,542         37,153           Deferred revenues, current portion         61,704         46,542         37,153           Total acurrent liabilities		I	March 31,	De	cember 31,
Current assets:         S         109,521         \$         37,878           Cash and cash equivalents         \$         00,61         34,751           Accounts receivable         3,309         15,546           Prepaid expenses and other current assets         3,190         1,615           Total current assets         3,190         1,615           Total current assets         2,583         9,922           Other non-current assets         130         130           Total assets         130         130           Cash and tockholders' equity         \$         173,239         \$         103,876           Liabilities and stockholders' equity         \$         1,30         130         130           Total assets         \$         1,73,239         \$         103,876           Liabilities and stockholders' equity         \$         1,445         4,445           Accounts payable         \$         1,934         \$         2,452           Accounte expenses and other current liabilities         6,578         6,170         \$         46,542         37,153           Total current liabilities         \$         1,22,546         92,354         \$         7,755         \$         6,170         \$			2018		2017
Cash and cash equivalents       \$ 109,521       \$ 37,878         Short term investments       50,061       34,751         Accounts receivable       3,309       15,546         Prepaid expenses and other current assets       3,190       1,615         Total current assets       166,081       89,790         Property and equipment, net       4,445       4,034         Long term investments       2,583       9,922         Other non-current assets       130       130         Total assets       \$ 173,239       \$ 103,876         Liabilities and stockholders' equity       Current liabilities       6,578       6,170         Deferred revenues, current portion       44,251       37,153       713,239       \$ 103,876         Liabilities       6,578       6,170       92,251       \$ 37,153       713,239       \$ 103,876         Liabilities       6,578       6,170       92,513       \$ 37,153       713,153       713,153       713,153         Total current liabilities       54,763       45,776       46,542       37,153       73,73       73         Total current liabilities       122,546       92,354       92,354       92,354       92,354       92,354       92,354       92,354	Assets				
Short term investments         50,061         34,751           Accounts receivable         3,309         15,546           Prepaid expenses and other current assets         3,100         1,615           Total current assets         166,081         89,790           Property and equipment, net         4,445         4,034           Long term investments         2,583         9,922           Other non-current assets         130         130           Total assets         \$ 173,239         \$ 103,876           Liabilities and stockholders' equity         -         -           Current liabilities         6,578         6,170           Deferred revenues, current portion         46,251         37,153           Total current liabilities         6,578         6,170           Deferred revenue, ent of current portion         46,251         37,153           Total liabilities         37         37           Total liabilities         37         37           Total liabilities         37         37           Total current liabilities         37         37           Total current liabilities         37         37           Total current liabilities         300,000,000 shares authorized and 53,974,184 and 45,017,062 issued an	Current assets:				
Accounts receivable       3,309       15,546         Prepaid expenses and other current assets       3,190       1,615         Total current assets       166,081       89,790         Property and equipment, net       4,445       4,034         Long term investments       2,583       9,922         Other non-current assets       130       130         Total assets       \$ 173,239       \$ 103,876         Liabilities and stockholders' equity       \$ 1,934       \$ 2,452         Accounts payable       \$ 1,934       \$ 2,452         Accounts payable       \$ 1,934       \$ 2,452         Accounts payable       \$ 1,934       \$ 2,452         Accrued expenses and other current liabilities       6,578       6,170         Deferred revenues, current portion       46,251       37,153         Total labilities       \$ 3,763       45,775         Deferred revenue, net of current portion       67,746       46,542         Other long-term liabilities       \$ 3,77       37         Total labilities       \$ 122,546       92,354         Stockholders' equity:       *       *         Preferred stock, \$0.001 par value per share, 10,000,000 shares authorized and 2,907 and 4,963       \$ 45,017,062 issued and outstanding at March 3	Cash and cash equivalents	\$	109,521	\$	37,878
Prepaid expenses and other current assets         3,190         1,615           Total current assets         166,081         89,790           Property and equipment, net         4,445         4,034           Long term investments         2,583         9,922           Other non-current assets         130         130           Total assets         \$ 173,239         \$ 103,876           Liabilities and stockholders' equity	Short term investments		50,061		34,751
Total current assets         166,081         89,790           Property and equipment, net         4,445         4,034           Long term investments         2,583         9,922           Other non-current assets         130         130           Total assets         \$ 173,239         \$ 103,876           Liabilities and stockholders' equity         \$ 173,239         \$ 103,876           Current liabilities:         \$ 1,934         \$ 2,452           Accounts payable         \$ 1,934         \$ 2,452           Accounts payable         \$ 1,934         \$ 2,452           Account payable         \$ 5,778         6,170           Deferred revenue, current portion         46,251         37,153           Total current liabilities         \$ 37         37           Deferred revenue, net of current portion         \$ 45,775         \$ 92,354           Stockholders' equity:         \$ 122,546         \$ 92,354           Stockholders' outy:         \$ 122,546         \$ 92,354	Accounts receivable		3,309		15,546
Property and equipment, net         1000000000000000000000000000000000000	Prepaid expenses and other current assets		3,190		1,615
Long term investments         2,583         9,922           Other non-current assets         130         130           Total assets         \$ 173,239         \$ 103,876           Liabilities and stockholders' equity         \$ 1,934         \$ 2,452           Accounts payable         \$ 1,934         \$ 2,452           Accrued expenses and other current liabilities         6,578         6,170           Deferred revenues, current portion         46,251         37,153           Total current liabilities         54,763         45,775           Deferred revenue, net of current portion         67,746         46,542           Other long-term liabilities         37         37           Total liabilities         37         37           Total liabilities         122,546         92,354           Stockholders' equity:         -         -           Preferred stock, \$0.001 par value per share, 10,000,000 shares authorized and 2,907 and 4,963         -         -           Sissued and outstanding at March 31, 2018 and December 31, 2017         -         -         -           Common stock, \$0.001 par value per share, 300,000,000 shares authorized and 53,974,184 and 45,017,062 issued and outstanding at March 31, 2018 and December 31, 2017         54         45           Additional paid-in capital         <	Total current assets		166,081		89,790
Other non-current assets         130         130           Total assets         \$ 173,239         \$ 103,876           Liabilities and stockholders' equity         \$ 1,934         \$ 2,452           Accounts payable         \$ 1,934         \$ 2,452           Accrued expenses and other current liabilities         6,578         6,170           Deferred revenues, current portion         46,251         37,153           Total current liabilities         54,763         45,775           Deferred revenue, net of current portion         67,746         46,542           Other long-term liabilities         37         37           Total liabilities         30,000,000 shares authorized and 2,907 and 4,963         -           issued and outstanding at March 31, 2018 and December 31, 2017         -         -           Common stock, \$0.001 par value per share, 300,000,000 shares authorized and 53,974,184 and 45,017,062 issued and outstanding at March 31, 2018 and December 31, 2017         54         45           Additional paid-i	Property and equipment, net		4,445		4,034
Total assets         §         173,239         §         103,876           Liabilities and stockholders' equity         Current liabilities:         S         1,934         §         2,452           Accounts payable         \$         1,934         \$         2,452           Accured expenses and other current liabilities         6,578         6,170           Deferred revenues, current portion         46,251         37,153           Deferred revenue, net of current portion         67,746         46,542           Other long-term liabilities         37         37           Total liabilities         37         37           Stockholders' equity:         -         -           Preferred stock, \$0.001 par value per share, 10,000,000 shares authorized and 2,907 and 4,963         -         -           Stockholders' equity:         -         -         -           Common stock, \$0.001 par value per share, 300,000,000 sh	Long term investments		2,583		9,922
Liabilities and stockholders' equity       5       113,255       5       103,616         Liabilities and stockholders' equity       Current liabilities:       5       1,934       \$       2,452         Accounts payable       \$       1,934       \$       2,452         Accured expenses and other current liabilities       6,578       6,170         Deferred revenues, current portion       46,251       37,153         Total current liabilities       54,763       45,775         Deferred revenue, net of current portion       67,746       46,542         Other long-term liabilities       37       37         Total liabilities       122,546       92,354         Stockholders' equity:       122,546       92,354         Preferred stock, \$0.001 par value per share, 10,000,000 shares authorized and 2,907 and 4,963       54         issued and outstanding at March 31, 2018 and December 31, 2017       -       -         Common stock, \$0.001 par value per share, 300,000,000 shares authorized and 53,974,184 and 45,017,062 issued and outstanding at March 31, 2018 and December 31, 2017       -       -         Additional paid-in capital       185,638       136,484       45         Accumulated other comprehensive loss       (5,973)       (4,695)         Accumulated deficit       (129,026) <td>Other non-current assets</td> <td></td> <td>130</td> <td></td> <td>130</td>	Other non-current assets		130		130
Current liabilities:Accounts payable\$ 1,934\$ 2,452Accrued expenses and other current liabilities6,5786,170Deferred revenues, current portion46,25137,153Total current liabilities54,76345,775Deferred revenue, net of current portion67,74646,542Other long-term liabilities3737Total liabilitiesDeferred stock, \$0.001 par value per share, 10,000,000 shares authorized and 2,907 and 4,963 issued and outstanding at March 31, 2018 and December 31, 2017Common stock, \$0.001 par value per share, 300,000,000 shares authorized and 53,974,184 and 45,017,062 issued and outstanding at March 31, 2018 and December 31, 20175445Additional paid-in capital Accumulated other comprehensive loss Accumulated deficit(5,973)(4,695) (129,026)(129,026)Total stockholders' equityTotal stockholders' equity50,69311,522	Total assets	\$	173,239	\$	103,876
Accounts payable\$ 1,934\$ 2,452Accrued expenses and other current liabilities6,5786,170Deferred revenues, current portion46,25137,153Total current liabilities54,76345,775Deferred revenue, net of current portion67,74646,542Other long-term liabilities3737Total liabilities122,54692,354Stockholders' equity:Preferred stock, \$0.001 par value per share, 10,000,000 shares authorized and 2,907 and 4,963-issued and outstanding at March 31, 2018 and December 31, 2017Common stock, \$0.001 par value per share, 300,000,000 shares authorized and 53,974,184 and 45,017,062 issued and outstanding at March 31, 2018 and December 31, 20175445Additional paid-in capital185,638136,4844ccumulated other comprehensive loss(5,973)(4,695)Accumulated deficit(129,026)(120,312)(120,312)(120,312)(120,312)Total stockholders' equity50,69311,52250,69311,522	Liabilities and stockholders' equity	_			
Accrued expenses and other current liabilities $6,578$ $6,170$ Deferred revenues, current portion $46,251$ $37,153$ Total current liabilities $54,763$ $45,775$ Deferred revenue, net of current portion $67,746$ $46,542$ Other long-term liabilities $37$ $37$ Total liabilities $122,546$ $92,354$ Stockholders' equity: $ -$ Preferred stock, \$0.001 par value per share, 10,000,000 shares authorized and 2,907 and 4,963 $-$ issued and outstanding at March 31, 2018 and December 31, 2017 $ -$ Common stock, \$0.001 par value per share, 300,000,000 shares authorized and 53,974,184 and 45,017,062 issued and outstanding at March 31, 2018 and December 31, 2017 $54$ $45$ Additional paid-in capital $185,638$ $136,484$ $4ccumulated other comprehensive loss(5,973)(4,695)Accumulated deficit(129,026)(120,312)(120,312)(120,312)Total stockholders' equity50,69311,522$	Current liabilities:				
Deferred revenues, current portion $46,251$ $37,153$ Total current liabilities $54,763$ $45,775$ Deferred revenue, net of current portion $67,746$ $46,542$ Other long-term liabilities $37$ $37$ Total liabilities $122,546$ $92,354$ Stockholders' equity: $ -$ Preferred stock, \$0.001 par value per share, 10,000,000 shares authorized and 2,907 and 4,963 $ -$ Stockholders' equity: $ -$ Common stock, \$0.001 par value per share, 300,000,000 shares authorized and 53,974,184 and $45,017,062$ issued and outstanding at March 31, 2018 and December 31, 2017 $ -$ Additional paid-in capital $185,638$ $136,484$ $136,484$ $Accumulated other comprehensive loss(5,973)(4,695)Accumulated deficit(129,026)(120,312)(120,312)(120,312)(120,312)Total stockholders' equity50,69311,522$	Accounts payable	\$	1,934	\$	2,452
Total current liabilities $54,763$ $45,775$ Deferred revenue, net of current portion $67,746$ $46,542$ Other long-term liabilities $37$ $37$ Total liabilities $122,546$ $92,354$ Stockholders' equity: $122,546$ $92,354$ Preferred stock, \$0.001 par value per share, 10,000,000 shares authorized and 2,907 and 4,963 $ -$ common stock, \$0.001 par value per share, 300,000,000 shares authorized and 53,974,184 and $45,017,062$ issued and outstanding at March 31, 2018 and December 31, 2017 $ -$ Common stock, \$0.001 par value per share, 300,000,000 shares authorized and 53,974,184 and $45,017,062$ issued and outstanding at March 31, 2018 and December 31, 2017 $54$ $45$ Additional paid-in capital $185,638$ $136,484$ $136,484$ $(5,973)$ $(4,695)$ Accumulated other comprehensive loss $(5,973)$ $(4,695)$ $(129,026)$ $(120,312)$ Total stockholders' equity $50,693$ $11,522$ $50,693$ $11,522$	Accrued expenses and other current liabilities		6,578		6,170
Deferred revenue, net of current portion0,110Other long-term liabilities37Other long-term liabilities37Total liabilities37Stockholders' equity: Preferred stock, \$0.001 par value per share, 10,000,000 shares authorized and 2,907 and 4,963 issued and outstanding at March 31, 2018 and December 31, 2017Common stock, \$0.001 par value per share, 300,000,000 shares authorized and 53,974,184 and 45,017,062 issued and outstanding at March 31, 2018 and December 31, 201754Additional paid-in capital185,638136,484Accumulated other comprehensive loss Accumulated deficit(5,973)(4,695) (120,312)Total stockholders' equity50,69311,522	Deferred revenues, current portion		46,251		37,153
Other long-term liabilities3737Total liabilities122,54692,354Stockholders' equity:122,54692,354Preferred stock, \$0.001 par value per share, 10,000,000 shares authorized and 2,907 and 4,963 issued and outstanding at March 31, 2018 and December 31, 2017——Common stock, \$0.001 par value per share, 300,000,000 shares authorized and 53,974,184 and 45,017,062 issued and outstanding at March 31, 2018 and December 31, 20175445Additional paid-in capital185,638136,484Accumulated other comprehensive loss(5,973)(4,695)Accumulated deficit(129,026)(120,312)Total stockholders' equity50,69311,522	Total current liabilities		54,763		45,775
Total liabilities122,54692,354Stockholders' equity:122,54692,354Preferred stock, \$0.001 par value per share, 10,000,000 shares authorized and 2,907 and 4,963 issued and outstanding at March 31, 2018 and December 31, 2017——Common stock, \$0.001 par value per share, 300,000,000 shares authorized and 53,974,184 and 45,017,062 issued and outstanding at March 31, 2018 and December 31, 20175445Additional paid-in capital185,638136,484Accumulated other comprehensive loss(5,973)(4,695)Accumulated deficit(129,026)(120,312)Total stockholders' equity50,69311,522	Deferred revenue, net of current portion		67,746		46,542
Stockholders' equity:122,91092,931Preferred stock, \$0.001 par value per share, 10,000,000 shares authorized and 2,907 and 4,963 issued and outstanding at March 31, 2018 and December 31, 2017——Common stock, \$0.001 par value per share, 300,000,000 shares authorized and 53,974,184 and 45,017,062 issued and outstanding at March 31, 2018 and December 31, 20175445Additional paid-in capital185,638136,484Accumulated other comprehensive loss(5,973)(4,695)Accumulated deficit(129,026)(120,312)Total stockholders' equity50,69311,522	Other long-term liabilities		37		37
Preferred stock, \$0.001 par value per share, 10,000,000 shares authorized and 2,907 and 4,963 issued and outstanding at March 31, 2018 and December 31, 2017———Common stock, \$0.001 par value per share, 300,000,000 shares authorized and 53,974,184 and 45,017,062 issued and outstanding at March 31, 2018 and December 31, 20175445Additional paid-in capital185,638136,484Accumulated other comprehensive loss(5,973)(4,695)Accumulated deficit(129,026)(120,312)Total stockholders' equity50,69311,522	Total liabilities		122,546		92,354
issued and outstanding at March 31, 2018 and December 31, 2017 — — — Common stock, \$0.001 par value per share, 300,000,000 shares authorized and 53,974,184 and 45,017,062 issued and outstanding at March 31, 2018 and December 31, 2017 54 45 Additional paid-in capital 185,638 136,484 Accumulated other comprehensive loss (5,973) (4,695) Accumulated deficit (129,026) (120,312) <b>Total stockholders' equity</b> 50,693 11,522	Stockholders' equity:				
45,017,062 issued and outstanding at March 31, 2018 and December 31, 2017       54       45         Additional paid-in capital       185,638       136,484         Accumulated other comprehensive loss       (5,973)       (4,695)         Accumulated deficit       (129,026)       (120,312)         Total stockholders' equity       50,693       11,522					
Additional paid-in capital       185,638       136,484         Accumulated other comprehensive loss       (5,973)       (4,695)         Accumulated deficit       (129,026)       (120,312)         Total stockholders' equity       50,693       11,522	Common stock, \$0.001 par value per share, 300,000,000 shares authorized and 53,974,184 and				
Accumulated other comprehensive loss         (5,973)         (4,695)           Accumulated deficit         (129,026)         (120,312)           Total stockholders' equity         50,693         11,522	45,017,062 issued and outstanding at March 31, 2018 and December 31, 2017		54		45
Accumulated deficit         (129,026)         (120,312)           Total stockholders' equity         50,693         11,522	Additional paid-in capital		185,638		136,484
Total stockholders' equity         50,693         11,522	Accumulated other comprehensive loss		(5,973)		(4,695)
	Accumulated deficit		(129,026)		(120,312)
Total liabilities and stockholders' equity\$ 173,239\$ 103,876	Total stockholders' equity		50,693		11,522
	Total liabilities and stockholders' equity	\$	173,239	\$	103,876

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

## PIERIS PHARMACEUTICALS, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

## (unaudited, in thousands, except per share data)

	Three Month	Three Months Ended March 3		
	2018		2017	
Revenue	\$ 4,152	2 \$	1,343	
Operating expenses				
Research and development	7,930	5	5,360	
General and administrative	4,352	2	3,989	
Total operating expenses	12,288	3	9,349	
Loss from operations	(8,130	5)	(8,006)	
Interest income	32:	;		
Other (expense) income, net	(903	\$)	12	
Loss before income taxes	(8,714	•)	(7,994)	
Provision for income tax	_	-		
Net loss	(8,714	+)	(7,994)	
Foreign currency translation	(74	7)	51	
Unrealized loss on available-for-sale securities	(53)	/	_	
Comprehensive loss	\$ (9,992	2) \$	(7,943)	
Net loss per share				
Basic and diluted	\$ (0.17	7) \$	(0.19)	
Weighted average number of common shares outstanding				
Basic and diluted	50,040	5	43,064	

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

## PIERIS PHARMACEUTICALS, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

## (unaudited, in thousands)

	Three Months Ended March		March 31,	
		2018		2017
Operating activities:				
Net loss	\$	(8,714)	\$	(7,994)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:				
Depreciation		134		100
Stock-based compensation		1,004		752
Other		8		_
Changes in operating assets and liabilities		38,907		32,912
Net cash provided by operating activities		31,339		25,771
Investing activities:				
Purchases of property and equipment		(414)		(179)
Proceeds from maturity of investments		3,600		—
Purchases of investments		(11,479)		_
Net cash used in investing activities		(8,293)		(179)
Financing activities:				
Proceeds from exercise of options		826		_
Proceeds from exercise of warrants		126		_
Issuance of common stock, net of issuance costs		47,207		—
Net cash provided by financing activities		48,159		
Effect of exchange rate change on cash and cash equivalents		438		295
Net increase in cash and cash equivalents		71,643		25,886
Cash and cash equivalents at beginning of year		37,878		29,356
Cash and cash equivalents at end of year	\$	109,521	\$	55,242
Supplemental cash flow disclosures:				
Net unrealized loss on investments	\$	(697)	\$	_
Property and equipment included in accounts payable	\$	65	\$	613

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 (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, MA and its research facility is located in Freising-Weihenstephan, Germany.

Pieris' clinical pipeline includes an immuno-oncology bispecific targeting HER2 and 4-1BB, an inhaled IL-4 receptor alpha antagonist Anticalin protein to treat uncontrolled asthma, 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 a number of major multi-national pharmaceutical companies.

As of March 31, 2018, the Company had cash, cash equivalents, and investments of \$162.2 million. The Company expects that its existing cash, cash equivalents, and investments are sufficient to support operating expense and capital expenditure requirements for at least 12 months from the date of 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, 2017. There have been no material changes to the significant accounting policies during the three months ended March 31, 2018.

#### **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 ("U.S. GAAP") for interim financial information and pursuant to the rules and regulations of the Securities and Exchange Commission (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 months ended March 31, 2018 are not necessarily indicative of results that may be expected for the year ending December 31, 2018. 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, 2017, which was filed with the SEC on March 15, 2018.

#### **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 are considered to be cash equivalents. The Company's current and non-current investments are comprised of money market, asset backed securities, government treasuries, and corporate bonds

that are classified as available-for-sale in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 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 interest income. Approximately \$0.2 million of realized losses were recognized for the three months ended March 31, 2018. No realized gains or losses were recorded for the three months ended March 31, 2017.

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 March 31, 2018, 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*, ("ASC 820") established a hierarchy of inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the financial instrument based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the financial instrument and are developed based on the best information available in the circumstances. The fair value hierarchy applies only to the valuation inputs used in determining the reported or disclosed fair value of the financial instruments and is not a measure of the investment credit quality. Fair value measurements are classified and disclosed in one of the following three categories:

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

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

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

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

#### **Revenue Recognition**

Pieris has entered into several licensing agreements with collaboration partners for the development of Anticalin® therapeutics against a variety of targets in diseases and conditions. The terms of these agreements contain multiple elements and deliverables, which may include: (i) licenses, or options to obtain licenses, to Pieris' Anticalin technology and/or specific programs and (ii) research and development activities to be performed on behalf of or with the 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. Pieris follows the provisions of the FASB ASC Topic 605-25, *Revenue Recognition—Multiple-Element Arrangements* ("ASC 605-25") and FASB ASC Topic 605-28, *Revenue Recognition—Milestone Method* ("ASC 605-28") in accounting for these agreements.

#### Multiple-Element Arrangements

When evaluating multiple-element arrangements, Pieris identifies the deliverables included within the agreement and evaluates which deliverables represent separate units of accounting based on whether the delivered element has stand-alone value to the customer or if the arrangement includes a general right of return for delivered items.

The consideration received is allocated among the separate units of accounting using the relative selling price method, and the applicable revenue recognition criteria are applied to each of the separate units of accounting. Pieris uses the best estimate of selling price ("BESP") methodology to estimate the selling price for each deliverable and unit of accounting because Pieris does not have vendor specific objective evidence ("VSOE") or third-party evidence ("TPE") of selling price for these deliverables. To determine the estimated selling price of a deliverable, Pieris considers market conditions as well as entity-specific factors, including those factors contemplated in negotiating the agreements, terms of previous collaborative agreements, similar agreements entered into by third parties, market opportunity, estimated development costs, probability of success, and the time needed to commercialize a product candidate pursuant to the license. In validating Pieris' BESP, Pieris evaluates whether changes in the key assumptions used to determine the BESP will have a significant effect on the allocation of arrangement consideration among multiple deliverables.

Multiple element arrangements, such as license arrangements, are analyzed to determine whether the deliverables, which often include licenses and performance obligations such as research and development services and governance committee services, can be separated or whether they must be accounted for as a combined unit of accounting in accordance with U.S. GAAP. The Company recognizes the arrangement consideration allocated to licenses as revenue upon delivery of the license only if the license has stand-alone value. If the license is considered not to have stand-alone value, the license would then be combined with other undelivered elements into a combined unit of accounting and the license payments and payments for performance obligations would be recognized as revenue when the revenue recognition criteria have been satisfied for the last deliverable within the unit of accounting. In the case of combined units of accounting that include delivered licenses and undelivered services to be provided over time, revenue would be recognized over the estimated period during which services will be provided. For units of accounting that include licenses to be delivered upon satisfactory completion of certain research services, revenue is deferred until the license is delivered and the performance obligation is satisfied.

If the Company is involved in a governance committee, as part of a multiple element arrangement, it assesses whether its involvement constitutes a performance obligation or a right to participate. When governance committee services are determined to be performance obligations, the Company determines the fair value to be allocated to this deliverable and recognize the revenue over the expected term of the development period of the products. Otherwise, the fair value for participation is combined with other research services or performance obligations and is recognized over the term which the Company expects to complete its aggregate performance obligations.

The Company recognizes arrangement consideration allocated to each unit of accounting when all revenue recognition criteria in ASC 605-25 are satisfied for that particular unit of accounting. For each unit of accounting, the Company must determine the period over which the performance obligations will be performed and revenue will be recognized. If there is no discernible pattern of performance or objectively measurable performance measures do not exist, then the Company recognizes revenue under the arrangement on a straight-line basis over the period the Company is expected to complete its performance obligations. Conversely, if the pattern of performance over which the service is provided to the customer can be determined and objectively measurable performance measures exist, then the Company recognizes revenue under the arrangement using the proportional performance method. Revenue recognized cannot exceed the amount that has been earned and has been billed or is currently billable.

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.

The accounting treatment for options granted to collaborators is dependent upon the nature of the option granted to the collaborative partner. Options are considered substantive if, at the inception of an agreement, Pieris is at risk as to whether the collaborative partner will choose to exercise the option(s) to secure additional goods or services. Factors that are considered in evaluating whether options are substantive include the overall objective of the arrangement, benefit the collaborator might obtain from the agreement without exercising the options, cost to exercise the options relative to the total upfront consideration, and additional financial commitments or economic penalties imposed on the collaborator as a result of exercising the options.

In arrangements where options to obtain additional deliverables are considered substantive, Pieris determines whether the optional licenses are priced at a significant and incremental discount. If the prices include a significant and incremental discount, the option is considered a deliverable in the arrangement. However, if not priced at a significant and incremental discount, the option is not considered a deliverable in the arrangement. When a collaborator exercises an option considered to be at a significant and incremental discount to acquire an additional license, the exercise fee that is attributed to the additional license and any incremental discount allocated at inception are recognized in a manner consistent with the treatment of up-front payments for licenses (*i.e.*, license and research services). In the event an option expires un-exercised, any incremental discounts deferred at the inception of the arrangement are recognized into revenue upon expiration. For options that are non-substantive, the additional licenses to which the options pertain are considered deliverables upon inception of the arrangement; Pieris applies the multiple-element revenue recognition criteria to determine accounting treatment.

Payments or reimbursements resulting from Pieris' research and development efforts in multi-element arrangements, in which Pieris' research and development efforts are considered to be a deliverable, are included in allocable consideration and allocated to the units of accounting. These reimbursements are recognized as the services are performed and are presented on a gross basis, so long as there is persuasive evidence of an arrangement, the fee is fixed or determinable, and collection of the related receivable is reasonably assured. Revenue recognized cannot exceed the amount that has been earned and has been billed or is currently billable. Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the accompanying balance sheets.

#### Milestone Payments and Royalties

At the inception of each agreement that includes milestone payments, Pieris evaluates whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone. This evaluation includes an assessment of whether: (a) the consideration is commensurate with either (1) the entity's performance to achieve the milestone, or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone, (b) the consideration relates solely to past performance and (c) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. Pieris evaluates factors such as the scientific, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required to achieve the respective milestone and whether the milestone consideration is reasonable relative to all deliverables and payment.

Pieris 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.

For revenues from research, development, and commercial milestone payments, if the milestones are deemed substantive and the milestone payments are nonrefundable, such amounts are recognized entirely upon successful accomplishment of the milestones, assuming all other revenue recognition criteria are met. Milestones that are not considered substantive are accounted for as contingent revenue and will be recognized when achieved to the extent the Company has no remaining performance obligations under the arrangement. Revenues from sales milestone payments are accounted for as royalties and are

recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met. Royalty payments are recognized in revenues based on the timing of royalty payments earned in accordance with the agreements, which typically is the period when the relevant sales occur, assuming all other revenue recognition criteria are met.

#### **Recent Accounting Pronouncements**

In May 2014, the FASB issued Accounting Standard Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers (Topic 606)* ("ASU 2014-09"). Subsequently, the FASB also issued ASU 2015-14, *Revenue from Contracts with Customers (Topic 606)* ("ASU 2015-14"), which adjusted the effective date of ASU 2014-09; ASU No. 2016-08, *Revenue from Contracts with Customers (Topic 606)* ("ASU 2016-08"): *Principal versus Agent Considerations (Reporting Revenue Gross versus Net)*, which amends the principal-versus-agent implementation guidance and illustrations in ASU 2014-09; ASU No. 2016-10, *Revenue from Contracts with Customers (Topic 606)* ("ASU 2016-10"): *Identifying Performance Obligations and Licensing*, which clarifies identifying performance obligation and licensing implementation guidance and illustrations in ASU 2014-09; and ASU No. 2016-12, *Revenue from Contracts with Customers (Topic 606)* ("ASU 2016-12"): *Narrow-Scope Improvements and Practical Expedients*, which addresses implementation issues and is intended to reduce the cost and complexity of applying the new revenue standard in ASU 2014-09 (collectively, the "Revenue ASUs").

The Revenue ASUs provide an accounting standard for a single comprehensive model for use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance. The accounting standard is effective for public emerging growth companies ("EGC"), like Pieris, for interim and annual periods beginning after December 15, 2018, with an option to early adopt for interim and annual periods beginning after December 15, 2017. The guidance permits two methods of adoption: retrospectively to each prior reporting period presented (the full retrospective method), or retrospectively with the cumulative effect of initially applying the guidance recognized at the date of initial application (the modified retrospective method). The Company is currently evaluating the impact of this pronouncement on its consolidated financial statements and expects to adopt this pronouncement commencing in the first quarter of 2019.

In February 2016, the FASB issued ASU No. 2016-2, *Leases (Topic 842) ("ASU 2016-2")*. 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 fiscal years beginning after December 15, 2019 including interim periods within those fiscal years; early adoption is permitted. The Company is currently evaluating the potential impact the adoption of this standard will have on its financial statements and related disclosures.

In December 2017, the SEC staff issued Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act, or SAB 118, which allows the recording of provisional amounts during a measurement period not to extend beyond one year of the enactment date. In accordance with SAB 118, we determined that our deferred tax asset value and associated valuation allowance reduction of \$3.7 million is a provisional amount and a reasonable estimate at December 31, 2017. The final impact may differ from this provisional amount due to, among other things, changes in interpretations and assumptions we have made thus far and the issuance of additional regulatory or other guidance. We expect to complete the final impact within the measurement period.

Pieris 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 (i) 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, and (ii) government grants.

During the three months ended March 31, 2018 and 2017, respectively, the Company recognized revenues as follows (in thousands):

	Thre	Three Months Ended March 3			
		2018		2017	
License fees	\$	3,444	\$	1,008	
Research and development services		617		335	
Other revenues		91			
Total Revenue	\$	4,152	\$	1,343	

During the three months ended March 31, 2018 and 2017, respectively, the Company recognized revenue from the following strategic partnerships and other license agreements (in thousands):

	Thr	Three Months Ended March 31,		
		2018		2017
Seattle Genetics	\$	308	\$	
AstraZeneca		2,545		_
Servier		1,208		326
Other		91		1,017
Total Revenue	\$	4,152	\$	1,343

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

	Research, Development & Commercial Milestones	Sale	es Milestones
Seattle Genetics	\$ 769	\$	450
AstraZeneca	1,111		960
Servier	1,069		967
Other	353		126
Total potential milestone payments	\$ 3,302	\$	2,503

#### Strategic Partnership with Seattle Genetics, Inc.

On February 8, 2018, the Company entered into a License and Collaboration Agreement and a Non-Exclusive Anticalin Platform Technology License Agreement (collectively the "Seattle Genetics Agreements") with Seattle Genetics, Inc. ("Seattle Genetics"), pursuant to which the parties will develop multiple targeted bispecific immuno-oncology 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 provides Seattle Genetics a base option to select up to three programs for further development. Prior to the initiation of a pivotal trial, Pieris may opt into global co-development and U.S. commercialization of the second program and share in global costs and profits on an equal basis. Seattle Genetics will solely develop, fund and commercialize the other two programs. In addition, Seattle Genetics will have an option to select up to three additional programs for further development.

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

The term of each of the Seattle Genetics Agreements ends upon the expiration of all of Seattle Genetics' payment obligations. The License and 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. If any program is terminated by Seattle Genetics after a pre-defined pre-clinical stage,

Pieris will have full rights to continue such program. If any program is terminated by Seattle Genetics prior to such pre-defined pre-clinical stage, Pieris 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 License and Collaboration Agreement may also be terminated by Seattle Genetics or Pieris 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 License and 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-byproduct 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 License and Collaboration Agreement, whether in its entirety or on a product-by-product basis.

The Company accounted for the Seattle Genetics Agreements as a multiple element arrangement under ASC 605-25. The arrangement with Seattle Genetics contains the following initial deliverables: (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.

Management considered whether any of the deliverables could be considered separate units of accounting. The Company determined each license granted, at arrangement inception, did not have standalone value from the research and development services to be provided for the related antibody target programs due to the specific nature of the intellectual property and knowledge required to perform the research and development services. The Company determined that the participation on the various governance committees did have standalone value from the delivered licenses as the services could be performed by an outside party.

As a result, management concluded there are six units of accounting at inception of the agreement: (i) three combined units of accounting each representing a non-exclusive platform technology license, a co-exclusive candidate research license, and research and development services for first three approved Seattle Genetics antibody target programs, (ii) two units of accounting each representing an antibody target swap right for first and the second approved Seattle Genetics antibody target, and (iii) one unit of accounting representing the participation of the various governance committees.

The Company determined that neither VSOE nor TPE is available for any of the units of accounting identified at arrangement inception. Accordingly, the selling price of each unit of accounting was developed using BESP. The Company developed its best estimate of selling price 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 BESP for committee participation by using management's best estimate of the anticipated participation hours multiplied by a market rate for comparable participants.

Allocable arrangement consideration at inception is comprised of the upfront fees of \$30.0 million and \$4.9 million of estimated research and development services to be reimbursed as research and development occurs through the research term. Therefore, the total allocable arrangement consideration at inception is \$34.9 million and is allocated among the separate units of accounting using the relative selling price method.

The amounts allocated to the combined units of accounting for the three research programs will be recognized on a proportional performance basis through the completion of each respective estimated research term for the individual research programs. However, for the first two programs that contain antibody target swap rights, if the antibody target swap right is exercised, any remaining deferred revenue associated with the two programs at the time of the exercise would be recognized immediately. The amounts allocated to the antibody target swap rights will be recognized either at the time the target right expires, or if exercised, on a proportional performance basis over the estimate research term for that program. The amounts allocated to the participation on each of the committees will be recognized ratably over the anticipated research term for all research programs.

Management determined that all research, development, commercial and sales milestones are deemed non-substantive as they are based solely on the performance of another party. Non-substantive milestones will be treated as contingent revenue and will be recognized when achieved, to the extent the Company has no remaining performance obligations under the arrangement. Milestone payments earned upon the achievement of sales events will be recognized when earned.

The Company will recognize royalty revenue in the period of sale for the related product(s), based on the underlying contract terms, provided that the reported sales are reliably measurable and the Company has no remaining performance obligations, assuming all other revenue recognition criteria are met.

As of March 31, 2018, there is \$11.4 million and \$18.4 million of deferred revenue and non-current deferred revenue, respectively, related to the Seattle Genetics Agreements.

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

As of March 31, 2018 and December 31, 2017, cash, cash equivalents, and investments comprised of funds in depository, money market accounts, U.S. treasury securities, asset backed securities, and corporate bonds. The following table presents the cash equivalents and investments carried at fair value in accordance with the hierarchy defined in Note 2 (in thousands):

	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
March 31, 2018				
Money market funds, included in cash equivalents	\$ 67,752	\$ 67,752	\$ —	\$
U.S. treasuries, included in cash equivalents	6,198	6,198	—	—
Corporate bonds, included in cash equivalents	18,991	—	18,991	_
Asset-backed securities, included in cash equivalents	899	—	899	—
Investments - U.S. treasuries	4,175	4,175	—	—
Investments - Asset-backed securities	7,310	—	7,310	_
Investments - Corporate bonds	41,158	—	41,158	_
Total	\$ 146,483	\$ 78,125	\$ 68,358	\$
December 31, 2017				
Money market funds, included in cash equivalents	\$ 4,583	\$ 4,583	\$ —	\$
Corporate bonds, included in cash equivalents	13,595	—	13,595	—
Investments - U.S. treasuries	4,172	4,172	—	_
Investments - Asset-backed securities	6,384	—	6,384	—
Investments - Corporate bonds	34,117		34,117	_
Total	\$ 62,851	\$ 8,755	\$ 54,096	\$

Cash equivalents and marketable securities have been initially valued at the transaction price and subsequently valued, at the end of each reporting period, utilizing third party pricing services or other market observable data. The pricing services utilize industry standard valuation models, including both income and market based approaches and observable market inputs to determine value. The Company validates the prices provided by its third-party pricing services by reviewing their pricing methods and obtaining market values from other pricing sources, as needed. After completing its validation procedures, the Company did not adjust any fair value measurements provided by the pricing services as of March 31, 2018.

Cash equivalents and investments at March 31, 2018 consist of the following (in thousands):

	Contractual maturity (in days)	Amo	ortized Cost	Unrealized gains	Unrealized losses	Fair Value
Investments						
U.S. treasuries	122-250	\$	4,373	\$	\$ (198)\$	4,175
Asset-backed securities	107-292		5,682		(159)	5,523
Asset-backed securities	greater than 365		1,879		(92)	1,787
Corporate bonds	25-356		41,257	13	(908)	40,362
Corporate bonds	greater than 365		802		(6)	796
Total		\$	53,993	\$ 13	\$ (1,363)\$	52,643

The Company recorded \$0.2 million of realized losses from the maturity of available-for-sale securities during the three months ended March 31, 2018. No realized gains or losses were recognized during the three months ended March 31, 2017.

#### 5. Property and equipment, net

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

	1.7
2018 20	17
Laboratory equipment\$ 6,656	6,101
Office and computer equipment 670	494
Leasehold improvements 326	318
Property and equipment at cost 7,652	6,913
Accumulated depreciation (3,207)	(2,879)
Property and equipment, net \$ 4,445 \$	4,034

#### 6. Accrued Expenses

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

	1	March 31,		cember 31,
	2018		2017	
Compensation expense	\$	1,210	\$	2,325
Professional fees		1,663		1,322
Research and development fees		778		791
Audit and tax fees		402		424
Other current liabilities		2,525		1,308
Total	\$	6,578	\$	6,170

#### 7. Stockholders' Equity

The Company had 53,974,184 shares of common stock and 2,907 shares of preferred stock outstanding as of March 31, 2018, both with a par value of \$0.001 per share. During the three months ended March 31, 2018, 2,056 shares of preferred stock were converted into 2,056,000 shares of common stock. During the three months ended March 31, 2018 the Company issued 512,960 shares of common stock upon option exercises, resulting in cash proceeds of \$0.8 million. No options were exercised during the corresponding 2017 period. During the three months ended March 31, 2018 shares of common stock upon exercise of warrants, resulting in cash proceeds of \$0.1 million. No warrants were exercised during the corresponding 2017 period.

#### **Underwritten Public Offering**

In February 2018, the Company completed an underwritten public offering of its common stock in which it sold 6,325,000 shares of common stock, including the exercise in full by the underwriters of their option to purchase an additional 825,000 shares of common stock, to the public at a price of \$8.00 per share (the "2018 Offering"). The 2018 Offering was completed under the Company's shelf registration statement that was filed on Form S-3 and declared effective by the SEC on August 3, 2016. Net proceeds of the 2018 Offering, after deducting the underwriting discounts and commissions, were \$47.6 million, excluding offering expenses of approximately \$0.4 million incurred by the Company.

#### 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.

For the three months ended March 31, 2018 and 2017, and as calculated using the treasury stock method, approximately 14.7 million and 11.2 million of weighted average shares, respectively, were excluded from the calculation of diluted weighted average shares outstanding as their effect was anti-dilutive.

## 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, 2017, 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 year ended December 31, 2017, filed with the SEC on March 15, 2018. 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 year ended December 31, 2017.

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 immuno-oncology bispecific targeting HER2 and 4-1BB, an inhaled IL-4 receptor alpha antagonist Anticalin protein to treat uncontrolled asthma, and a half-life-optimized hepcidin antagonizing Anticalin protein to treat anemia. Proprietary to Pieris, Anticalin proteins are a novel class of therapeutics validated in the clinic and through partnerships with leading pharmaceutical companies. Our development programs include:

- *PRS-343*, our lead immuno-oncology program, is a fusion protein, comprising a HER2-targeting antibody genetically linked to a 4-1BB-targeting Anticalin protein. PRS-343 is designed to drive tumor localized T cell activation through tumor-targeted drug clustering mediated by HER2 expressed on certain solid tumors. This program is the first bispecific T cell costimulatory agonist to enter clinical development.
  - We are also developing additional immuno-oncology drug candidates that are multispecific Anticalin-based fusion
    proteins designed to engage immunomodulatory targets and consist of a variety of multifunctional biotherapeutics,
    including PRS-332, a bispecific Anticalin-antibody fusion protein comprising an anti-PD-1 antibody genetically fused to
    an Anticalin targeting an undisclosed checkpoint target.
- *PRS-060*, our lead respiratory program partnered with AstraZeneca AB, or AstraZeneca, is a drug candidate that binds to IL-4Rα, thereby inhibiting IL-4 and IL-13, two cytokines known to be key mediators in the inflammatory cascade that causes asthma and other inflammatory diseases.
- *PRS-080* is an Anticalin protein that binds to hepcidin, a natural regulator of iron in the blood. PRS-080 has been designed to target hepcidin for the treatment of functional iron deficiency in anemic patients with chronic kidney disease particularly in end-stage renal disease patients requiring dialysis.

Our programs are in varying stages:

• PRS-343 is currently in a Phase I clinical trial in patients with advanced or metastatic HER2-positive solid tumors for which standard treatment options are not available, are no longer effective, are not tolerated, or the patient has refused standard therapy. The Company intends to report initial safety, tolerability, pharmacokinetic and pharmacodynamic data from this study in the second half of 2018. In addition, Pieris recently signed an agreement with Roche granting the company access to atezolizumab (Tecentriq), an approved PD-L1 inhibitor. The plan is to initiate a combination study of PRS-343 plus atezolizumab (Tecentriq) in HER2-positive cancer patients during the second half of 2018.

- For our other immuno-oncology drug candidates and programs, we are conducting activities relating to candidate identification, optimization, and preclinical evaluation. We intend to file two new INDs for immuno-oncology drug candidates in 2019, one that is proprietary to us and one that is related to a partnered program.
- For our lead respiratory drug candidate, PRS-060, we continue to enroll healthy subjects in a first-in-human study, which was initiated during the fourth quarter of 2017. PRS-060 is part of the Company's respiratory alliance with AstraZeneca. We are sponsoring the Phase I clinical trial, while AstraZeneca is responsible for funding its costs. Initial data from the Phase I trial are expected in the fourth quarter of 2018. AstraZeneca will sponsor and continue to fund clinical development of PRS-060; Pieris will have an option to co-develop PRS-060 with AstraZeneca following completion of the Phase IIa trial. We also have an option for U.S. co-commercialization rights for this program.
- For PRS-080, we continue to enroll dialysis-dependent patients with functional iron deficiency anemia in a Phase IIa trial for PRS-080. We intend to report safety and pharmacodynamic data from this study, including the change in hemoglobin levels after five weekly doses of PRS-080, in the second half of 2018. If data is positive, we will seek to partner PRS-080 in territories outside of those for which ASKA Pharmaceutical Co. Ltd., or Aska, has an exclusive option (Japan and certain other Asian territories).

Our core Anticalin technology and platform were developed in Germany, and we have collaborations with major multi-national pharmaceutical companies. We have established a License and Collaboration Agreement with Les Laboratoires Servier and Institut de Recherches Internationales Servier, or Servier, in January 2017 in immuno-oncology and entered into an Exclusive Option Agreement with Aska, in February 2017 for PRS-080 in Japan and other Asian territories. In May 2017, we entered into an alliance with AstraZeneca to treat respiratory diseases and in February 2018 we entered into a License and Collaboration Agreement with Seattle Genetics, Inc., or Seattle Genetics in immuno-oncology.

Since inception, we have devoted nearly all of our efforts and resources to our research and development activities and have incurred significant net losses. For the three months ended March 31, 2018 and 2017, we reported a net loss of \$8.7 million and \$8.0 million, respectively. As of March 31, 2018, we had an accumulated deficit of \$129.0 million. We expect to continue incurring substantial losses for the next several years as we continue to develop our clinical and preclinical drug candidates and programs. Our operating expenses are comprised of research and development expenses and general and administrative expenses.

We have not generated any revenues from product sales to date, and we do not expect to generate revenues from product sales for the foreseeable future. Our revenues for the three months ended March 31, 2018 and 2017 were primarily 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 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 Servier, AstraZeneca, and Seattle Genetics.

The revenues from Servier, AstraZeneca, and Seattle Genetics have been comprised primarily of upfront payments, research and development services, and milestone payments. We recognized revenues from upfront payments under these agreements based on multipleelement arrangement guidance as we have determined that the licenses to which the payments related did not have standalone value. Research service revenue is recognized when the costs are incurred and the services have been performed. For revenues from research, development, and commercial milestone payments, if the milestones are deemed substantive and the milestone payments are nonrefundable, such amounts are recognized entirely upon successful accomplishment of the milestones, assuming all other revenue recognition criteria are met. Milestones that are not considered substantive are accounted for as contingent revenue and will be recognized when achieved to the extent the Company has no remaining performance obligations under the arrangement. Revenues from sales milestone payments are accounted for as royalties and are recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met. Royalty payments are recognized in revenues based on the timing of royalty payments earned in accordance with the agreements, which typically is the period when the relevant sales occur, assuming all other revenue recognition criteria are met. We expect our revenues for the next several years to consist of upfront payments, research funding and milestone payments from strategic collaborations we currently have or may establish in the future.

#### **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 immuno-oncology programs, currently comprised of the PRS-343 as well as multiple additional proprietary and partnered programs, PRS-060, and PRS-080. 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 labor and fringe benefits, 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 payroll, 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 months ended March 31, 2018 and 2017

The following table sets forth our revenues and operating expenses for the three months ended March 31, 2018 and 2017 (in thousands):

	Three	Three Months Ended March 31,			
	20	018	2017		
Revenues	\$	4,152 \$	1,343		
Research and development expenses		7,936	5,360		
General and administrative expenses		4,352	3,989		
Total operating expenses		12,288	9,349		
Interest Income		325	_		
Other income (expense), net		(903)	12		
Loss before income taxes		(8,714)	(7,994)		
Income tax provision		—			
Net loss	\$	(8,714) \$	(7,994)		

Revenues

The following table provides a comparison of revenues for the three months ended March 31, 2018 and 2017 (in thousands):

	Three Months Ended March 31,					
		2018		2017	Increase/(Decrease)	
License Fees	\$	3,444	\$	1,008	\$	2,436
Research and development services		617		335	\$	282
Other		91			\$	91
Total Revenue	\$	4,152	\$	1,343	\$	2,809

- The \$2.4 million increase in revenues from license fees in the three months ended March 31, 2018 compared to the three months ended March 31, 2017 primarily relates to the recognition of revenue under our collaboration with AstraZeneca which commenced in May 2017 and recognition of revenue under our collaboration with Servier, which commenced in January 2017. In addition, we recorded revenue under our new collaboration with Seattle Genetics, which commenced in February 2018. These amounts are offset by reduced revenues from our other collaborations.
- The \$0.3 million increase in revenues from research and development services in the three months ended March 31, 2018 compared to the three months ended March 31, 2017 relates to increased research and development activities under our collaborations with Servier and Seattle Genetics.

#### Research and Development Expenses

The following table provides a comparison of the research and development expenses for our drug candidates and projects for the three months ended March 31, 2018 and 2017 (in thousands):

	Three Months Ended March 31,					
	2018 2017		Increase/(Decrease)			
PRS-300 series	\$	1,245	\$	1,978	\$	(733)
PRS-060		1,358		816	\$	542
PRS-080		855		403	\$	452
Other research and development activities		4,478		2,163	\$	2,315
Total	\$	7,936	\$	5,360	\$	2,576

- the \$0.7 million decrease in our PRS-300 series period-over-period is due primarily to decreases in preclinical and chemistry and manufacturing control ("CMC") costs as we carried out IND enabling studies for the PRS-343 program in the first quarter of 2017, which dosed its patient in the fourth quarter of 2017;
- the \$0.5 million increase for our PRS-060 program period-over-period is due primarily to an increase of \$0.7 million in our clinical costs as our first-in-human clinical trial for PRS-060 started in December 2017. These amounts were partially offset by a decrease in CMC costs period-over-period;
- the \$0.5 million increase for PRS-080 period-over-period is mainly due to higher CMC costs and license fees related to the Phase IIa study which we initiated in the third quarter of 2017;
- the \$2.3 million increase in other research and development activities is mainly due to increases of \$1.0 million of personnel expenses including bonus and stock compensation, \$0.3 million in preclinical costs, \$0.5 million in general lab supply and DNA expenses, and an additional \$0.5 million for other costs including travel, general R&D expenses, and withholding taxes.

#### General and Administrative Expenses

General and administrative expenses were \$4.4 million for the three months ended March 31, 2018 as compared to \$4.0 million for the three months ended March 31, 2017. The period-over-period increase is due to investments in our general and administrative functions including \$0.3 million in personnel costs, \$0.3 million of professional services (audit, legal and

investor relations) and \$0.3 million in other costs (travel, recruiting, and general office expenses) to support the growing business. These amounts are partially offset by \$0.5 million of transaction fees, recorded in the first quarter of 2017, for our license and collaboration agreements, for which there were none in 2018.

#### Non-operating expense (income), net

Our non-operating expense was \$0.6 million for the three months ended March 31, 2018 as compared to a net non-operating income of \$0.0 million for the three months ended March 31, 2017. This increase in expense is mainly a result of \$0.9 million in net foreign currency transaction losses due to the strengthening of the euro against the U.S. dollar, including foreign currency remeasurement of monetary assets, primarily U.S. dollar cash, investment and, receivable balances in Germany, partially offset by \$0.3 million in interest income related to our investments.

#### Liquidity and Capital Resources

Through March 31, 2018, we have funded our operations with \$373.0 million of cash that has been obtained from the following main sources: \$170.2 million from sales of equity; \$182.1 million in total payments received under license and collaboration agreements, including \$16.8 million for research and development services costs received from our collaboration partners; \$14.2 million from government grants and \$6.5 million from loans.

As of March 31, 2018, we had a total of \$162.2 million in cash, cash equivalents and investments. We have incurred losses in every period since inception including the three months ended March 31, 2018 and 2017, respectively, and have a total accumulated deficit of \$129.0 million as of March 31, 2018.

In February 2018, we completed an underwritten public offering of our common stock in which we sold 6,325,000 shares of Common Stock, including the exercise in full by the underwritters of their option to purchase an additional 825,000 shares of Common Stock, to the public at a price of \$8.00 per share. The offering was completed under the shelf registration statement that was filed on Form S-3 and declared effective by the SEC on August 3, 2016. Net proceeds of the underwritten public offering, after deducting the underwriting discounts and commissions, were \$47.6 million, excluding our offering expenses of approximately \$0.4 million.

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 the three months ended March 31, 2018 and 2017 respectively (in thousands):

	Three	Three Months Ended March 31,			
	2	018	2017		
Net cash provided by operating activities	\$	31,339 \$	25,770		
Net cash used in investing activities		(8,293)	(179)		
Net cash provided by financing activities		48,159			

Net cash provided by operating activities of \$31.3 million for the three months ended March 31, 2018 is comprised principally of operating expenses of \$11.7 million, net of non-cash items and an increase in net working capital of \$1.8 million, offset by aggregate receipts of \$44.9 million from Seattle Genetics and AstraZeneca. Net cash provided by operating activities was \$25.8 million for the three months ended March 31, 2017, comprised principally of operating expenses amounting to \$8.5 million, net of non-cash items and an increase in net working capital of \$0.6 million offset by aggregate receipts of \$34.9 million mainly related to the upfront payment received from Servier.

The increase in net cash used in investing activities for the three months ended March 31, 2018 compared to the same period in 2017 is mainly attributable to higher net investment amounts and to a lesser extent to purchase of property and equipment.

The increase in net cash provided by financing activities for the three months ended March 31, 2018 was primarily due to the issuance of common stock under our 2018 Offering and the exercise of warrants and stock options.

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; and
- 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-343 and PRS-060 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.

#### **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, 2017 for a discussion of our critical accounting policies and estimates. There were no significant changes to our Critical Accounting Policies and Estimates for the three months ended March 31, 2018.

#### **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 Status**

The Jumpstart Our Business Startups Act of 2012, or the JOBS Act, 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 billion during its most recently completed fiscal year. Currently, we qualify as an emerging growth company.

As an emerging growth company, we are eligible to take advantage of certain exemptions from various reporting requirements that are not available to public reporting companies that do not qualify for those classifications, including without limitation 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.
- 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.

For as long as we continue to be an emerging growth company, we expect that we will take advantage of the reduced disclosure obligations available to us as a result of those respective classifications. We will remain an emerging growth company until the earliest of (i) December 31, 2019, 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; (ii) the last day of the fiscal year in which we have total annual gross revenues of \$1 billion or more; (iii) the date on which we have issued more than \$1 billion in nonconvertible debt during the previous three years; or (iv) on the end of the fiscal year on which we are deemed to be a large accelerated filer under applicable SEC rules. We expect that we will remain an emerging growth company for the foreseeable future, but cannot retain our emerging growth company status indefinitely and will no longer qualify as an emerging growth company on or before December 31, 2019.

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.

#### Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

#### Item 4. CONTROLS AND PROCEDURES

#### **Evaluation of Disclosure Controls and Procedures**

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 Form 10-Q. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or 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 a result of the previously reported material weakness discussed below.

In connection with the preparation of our financial statements for the year ended December 31, 2017, we concluded that we had a material weakness relating to the financial statement close process due to the combination of deficiencies. The deficiencies resulted from two separate errors that were not identified by management; one related to the classification of certain operating expenses and one related to the reporting of foreign currency re-measurements on investments. These errors were corrected in the financial statements prior to their issuance.

In response to the identified material weaknesses identified, our management, with the oversight of the Audit Committee of our Board of Directors, has taken action on a number of different remediation initiatives to improve our internal control over financial reporting for the year ended December 31, 2018. We are committed to continuing to improve our internal control processes and will continue to review, optimize, and enhance our internal control environment. These material weaknesses will not be considered remediated until the applicable remedial controls operate for a sufficient period of time and management has concluded that these controls are operating effectively.

Notwithstanding this material weakness, we have 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 internal control over financial reporting identified in connection with the evaluation of such internal control required by Rules 13a-15(d) and 15d-15(d) under the Exchange Act that occurred during the quarter ended March 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### PART II

#### Item 1. LEGAL PROCEEDINGS

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

#### Item 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, 2017.

#### Item 2. UNREGISTERED SALES OF SECURITIES

None.

#### Item 3. DEFAULTS UPON SENIOR SECURITIES

None.

Item 4. MINE SAFETY DISCLOSURE

Not applicable.

**Item 5. OTHER INFORMATION** 

None. Item 6. EXHIBITS

Exhibit			Incorporated by Reference herein from Form or		SEC File / Registration
Number	Exhibit Description	-	Schedule	Filing Date	Number
<u>10.1</u>	License and Collaboration Agreement by and among the Company, Pieris Pharmaceuticals GmbH and Seattle Genetics, Inc., effective as of February 8, 2018	*@			
<u>10.2</u>	Non-Exclusive Anticalin Platform Technology License Agreement by and among the Company, Pieris Pharmaceuticals GmbH and Seattle Genetics, Inc., effective as of February 8, 2018	*@			
<u>31.1</u>	Certification of Stephen S. Yoder, Chief Executive Officer and President, pursuant to Section 302 of the Sarbanes—Oxley Act of 2002	*			
<u>31.2</u>	Certification of Allan Reine, Chief Financial Officer, pursuant to Section 302 of the Sarbanes —Oxley Act of 2002	*			
<u>32.1</u>	Certification of Stephen S. Yoder, Chief Executive Officer and President, pursuant to Section 906 of the Sarbanes—Oxley Act of 2002, 18 U.S.C. Section 1350	**			
<u>32.2</u>	Certification of Allan Reine, Chief Financial Officer, pursuant to Section 906 of the Sarbanes —Oxley Act of 2002, 18 U.S.C. Section 1350	**			
101.INS	XBRL Instance Document	*			
101.SCH	XBRL Taxonomy Extension Schema Document	*			
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				
**	Furnished herewith				
@	Confidential treatment requested as to portions of the exhibit. Confidential materials omitted and filed separately with the SEC				

#### SIGNATURES

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

## PIERIS PHARMACEUTICALS, INC.

By: /s/ Stephen S. Yoder

Stephen S. Yoder Chief Executive Officer and President

By: /s/ Allan Reine Allan Reine Chief Financial Officer

May 10, 2018

May 10, 2018

## LICENSE AND COLLABORATION AGREEMENT BY AND AMONG

## PIERIS PHARMACEUTICALS, INC. AND PIERIS PHARMACEUTICALS GMBH

AND

SEATTLE GENETICS, INC.

## **TABLE OF CONTENTS**

1.Definitions32.License Grants313.Governance & Committees354.Research & Development455.Manufacturing626.Commercialization647.Payments & Royalties668.Royalty Adjustments, Payment Terms & Reconciliation709.Sublicensing and SGEN Rights for CoDev Product7410.Diligence & Exclusivity7711.Intellectual Property8412.Confidentiality9513.Publications98

14. Representations, Warranties & Covenants 103

2

15.Indemnification & Insurance 109

16.Term & Termination 112

17.Miscellaneous 126

This License and Collaboration Agreement is entered into as of February 8, 2018 (the "**Effective Date**") by and among Seattle Genetics, Inc., a Delaware corporation located at 21823 30<sup>th</sup> Drive SE, Bothell, WA 98021 (together with its Affiliates, "**SGEN**"), and Pieris Pharmaceuticals, Inc., a Nevada corporation located at 255 State Street, 9th floor, Boston, MA 02109 and Pieris Pharmaceuticals GmbH, a company organized and existing under the laws of Germany located at Lise-Meitner-str. 30, 85354 Freising, Germany (collectively and together with their Affiliates, "**PIRS**"). SGEN and PIRS are individually referred to herein as a "**Party**" and collectively, as the "**Parties**".

#### RECITALS

WHEREAS, PIRS owns or controls certain proprietary, lipocalin-derived Anticalin® protein technology and has developed other products and technologies that can be used to Research, Develop, Manufacture, and Commercialize (each as defined below) bispecific products, and owns or controls certain patents, proprietary technology, know-how, and information relating to such products or technologies;

WHEREAS, SGEN also owns or controls certain proprietary antibody-derived protein technology and has developed other products or technologies that can be used to Research, Develop, Manufacture and Commercialize (each as defined below) pharmaceutical products and owns or controls certain patents, proprietary technology, know-how and information relating to such products or technologies; and

**WHEREAS**, each Party desires to each grant to the other, and the other Party wishes to obtain, licenses to certain of such granting Party's patents and know-how in order to Research, Develop, Manufacture, and Commercialize certain novel products in accordance with this Agreement (each as defined below).

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

#### 1. Definitions

The following capitalized terms or derivatives thereof (verbs, nouns, singular, plural), when used in this Agreement, shall have the following meanings:

- 1.1. "Accelerated Arbitration" has the meaning set forth in <u>Section 17.2.2.1</u>.
- 1.2. "Accelerated Arbitration Request" has the meaning set forth in <u>Section 17.2.2.1</u>.

1.3. **"Accounting Standards"** means, as applicable, the International Financial Reporting Standards ("**IFRS**"), the U.S. Generally Accepted Accounting Principles ("**U.S. GAAP**"), and any other internationally recognized accounting standards that may be adopted by a Party.

- 1.4. "Acquired Competing Product" has the meaning set forth in <u>Section 10.3</u>.
- 1.5. "Acquisition Transaction" has the meaning set forth in <u>Section 10.3</u>.
- 1.6. "Acquiree" has the meaning set forth in <u>Section 10.3</u>.
- 1.7. "Acquiror" has the meaning set forth in <u>Section 10.3</u>.
- 1.8. "Additional Collaboration Product" has the meaning set forth in <u>Section 4.3.2</u>.
- 1.9. "Additional Collaboration Product Effective Date" has the meaning set forth in <u>Section 4.3.4.3</u>.
- 1.10. "Additional Collaboration Product Option" has the meaning set forth in <u>Section 4.3.2</u>.
- 1.11. **"Additional Collaboration Product Option Exercise Fee**" has the meaning set forth in <u>Section</u> 7.2.
- 1.12. "Additional Collaboration Product Option Exercise Notice" has the meaning set forth in Section 4.3.4.1.
- 1.13. "Additional Study Data" has the meaning set forth in <u>Section 4.4.3.6(b)</u>.
- 1.14. "ADPIC Treaty" has the meaning set forth in <u>Section 12.1</u>.

1.15. **"Affiliate**" means with respect to a Party, any person or entity, which directly or indirectly controls, is controlled by, or is under common control with such Party. Solely as used in this definition, the term "control" means (a) the ownership, directly or indirectly, beneficially or legally, of at least fifty percent (50%) of the outstanding voting securities or capital stock (or such lesser percentage which is the maximum allowed to be owned by a person or entity in a particular jurisdiction) of such Party or other person or entity, as applicable, or such other comparable ownership interest with respect to any person or entity that is not a corporation; or (b) the power, direct or indirect, whether

5

through ownership of voting securities or partnership or other ownership interests, by contract or otherwise of more than fifty percent (50%), to direct the management and policies of a Party or such other person or entity, as applicable.

1.16. **"Agreement**" means this License and Collaboration Agreement together with the recitals and all Exhibits, and attachments hereto, which shall form an integral part of this Agreement.

1.17. "Alliance Manager" has the meaning set forth in <u>Section 3.10</u>.

1.18. "Allowed Target Swap" has the meaning set forth in <u>Section 4.1.1.4</u>.

1.19. **"Antibody**" means any monoclonal or polyclonal antibody, whether multiple or single chain, recombinant or naturally occurring, whole or fragment, and any variants, derivatives or constructs thereof, including but not limited to, antigen binding portions including Fab, Fab', F(ab')2, Fv, dAb and CDR fragments, single chain antibodies (scFv), chimeric antibodies, diabodies and polypeptides (including any humanized versions thereof) that contain at least a portion of an immunoglobulin that is sufficient to selectively bind to a specific Target. For avoidance of doubt, an Antibody Building Block is an Antibody.

6

1.20. "Antibody Building Block" means an Antibody used in a Compound.

1.21. **"Anticalin**" or "**Anticalin Protein**" means, whether in nucleic acid or protein form, (a) any lipocalin mutein isolated from the Anticalin Libraries, or (b) any lipocalin mutein that, in each case, has been derived (either physically, intellectually or by reverse engineering, in one (1) or more steps) from any lipocalin referred to in subsection (a) of this definition, in each case, which selectively binds a specific Target. For the sake of this <u>Section 1.21</u>, "mutein" shall mean a protein arising as a result of a mutation or a recombinant DNA procedure.

1.22. **"Anticalin Affinity Maturation**" means the process of engineering for an Anticalin Protein to enhance its developability profile, such as altering binding affinity, cross-reactivity, or half-life, and specificity by introducing, e.g., one or more amino acid mutations.

1.23. "Anticalin Protein Building Block" means an Anticalin Protein used in a Compound.

1.24. **"Anticalin Characterization**" means the assessment of binding and functional potency and/or the evaluation of the developability profile of Anticalin Proteins and/or fusion proteins that include one or more Anticalin Proteins.

1.25. "Anticalin Expression" means the heterologous expression of an Anticalin Protein in a host cell.

1.26. **"Anticalin Fusion Technology**" means the process of fusing or genetically linking (including through the use of different linkers) one or more Anticalin Proteins to an immunoglobulin or fragment thereof to create bispecific fusion proteins.

1.27. **"Anticalin Libraries**" means any phage display library based on (a) the [\*\*\*] lipocalin ([\*\*\*]) or (b) the [\*\*\*] lipocalin ([\*\*\*]).

1.28. **"Anticalin Selection**" means the process of screening an Anticalin Library with a defined Target through the process of phage display, within a solution, and physically separating the Target bound to Anticalin Proteins from the solution containing non-binding Anticalin Proteins.

1.29. "Arbitration" has the meaning set forth in <u>Section 17.2.1</u>.

1.30. "Arbitration Request" has the meaning set forth in <u>Section 17.2.1</u>.

1.31. "Audited Party" has the meaning set forth in <u>Section 8.5.1</u>.

1.32. "Auditing Party" has the meaning set forth in <u>Section 8.5.1</u>.

1.33. "Authorized Recipients" has the meaning set forth in <u>Section 12.2</u>.

1.34. **"Bankruptcy Code**" has the meaning set forth in <u>Section 16.3.4</u>.

7

1.35. **"Biological License Application**" or "**BLA**" means a Biological License Application in the United States as described in Section 351(a) of the United States Public Health Service Act ("**PHS Act**").

1.36. **"Biosimilar**" means, with respect to a given Collaboration Product in a given country, any biological product on the market in such country that is approved (a) by the applicable Competent Authority in such country under the biosimilarity standard set forth in the United States under 42 U.S.C. §§ 262(i)(2) and (k), or any similar standard under its foreign equivalent applicable Law, on a country-by-country basis where such Collaboration Product is marketed, provided that such applicable Law exists and (b) in reliance in whole or in part, on a prior Marketing Approval (or on any safety or efficacy data submitted in support of such prior Marketing Approval) of such Collaboration Product. For countries or jurisdictions where no explicit biosimilar regulations exist, "Biosimilar" includes products which have been deemed to be a Biosimilar or otherwise deemed interchangeable by a Competent Authority in the United States or European Union. Any product or component thereof (including any Collaboration Product or component thereof) licensed, marketed, sold, manufactured, or produced by or on behalf of a Party, its Affiliates or Sublicensees (to the extent such Sublicensee commercializes a Biosimilar in reliance on or access to the Data, Patents, and Know-How licensed under this Agreement) will not constitute a Biosimilar for the purpose of royalty reduction pursuant to <u>Section 8.1.1</u>.

1.37. **"Building Block**" means, individually, each Antibody and each Anticalin Protein used in a Compound. A Building Block can be either an Antibody Building Block or an Anticalin Protein Building Block.

1.38. **"Building Block IP**" means the PIRS Building Block IP and/or the SGEN Building Block IP, as applicable.

8

1.39. **"Business Day**" means a day that is not a Saturday, Sunday, or a day on which banking institutions in the United States or Munich, Germany, are authorized by applicable Law to remain closed.

1.40. **"Calendar Quarter**" means each three (3) consecutive calendar months ending on each March 31, June 30, September 30, and December 31.

1.41. **"Calendar Year**" means the period of time commencing on January 1 and ending on the next December 31.

1.42. "**CDR**" means complementarity determining region based on the IMGT (ImMunoGeneTics) method.

1.43. "Change of Control" means with respect to a Party, (a) completion of a merger, reorganization, amalgamation, arrangement, share exchange, consolidation, tender or exchange offer, private purchase, business combination, recapitalization, or other transaction involving such Party as a result of which either (1) the stockholders of such Party immediately preceding such transaction hold less than fifty percent (50%) of the outstanding shares, or less than fifty percent (50%) of the outstanding voting power, respectively, of the ultimate company or entity resulting from such transaction immediately after consummation thereof (including a company or entity which as a result of such transaction owns the then-outstanding securities of such Party or all or substantially all of such Party's assets, including such Party's assets related to the Compounds, either directly or through one or more subsidiaries), or (2) any single Third Party person or group (within the meaning of the U.S. Securities Exchange Act of 1934 and the rules of the SEC thereunder as in effect, referred to as a "Group") holds fifty percent (50%) or more of the outstanding shares or voting power of the ultimate company or entity resulting from such transaction immediately after the consummation thereof (including a company or entity which as a result of such transaction owns the then-outstanding securities of such Party or all or substantially all of such Party's assets either directly or through one or more subsidiaries); or (b) the direct or indirect acquisition (including by means of a tender offer or an exchange offer) by any Third Party person or Group of beneficial ownership (within the meaning of the U.S. Securities Exchange Act of 1934 and the rules of the SEC thereunder as in effect), or the right to acquire beneficial ownership, or formation of any Third Party Group which beneficially owns or has the right to acquire beneficial ownership, of fifty percent (50%) or more of either the outstanding voting power or the then outstanding shares of such Party, in each case on a fully-diluted basis. For the avoidance of doubt, a transaction solely to change the domicile of a Party shall not constitute a Change of Control as long as there is no change of direct or indirect shareholding.

1.44. **"Claim**" means any charge, complaint, action, suit, proceeding, hearing, investigation, claim, or demand, including without limitation any investigation by a Government Authority.

9

# 1.45. "Claim Notice" has the meaning set forth in <u>Section 15.3.1</u>.

1.46. **"Clinical Studies**" means research studies in humans that are (a) designed in accordance with international ethical and scientific quality standards for designing, conducting, recording, and reporting research studies involving investigational medicinal products for human use and that involve the participation of human subjects, which standards are established through applicable Laws, and (b) designed to generate clinical data and results regarding a biological molecule in support of Marketing Approval, including any translational research studies. Clinical Studies include, but are not limited to, any Phase 1 Clinical Study, Phase 2 Clinical Study, or Pivotal Clinical Study.

1.47. **"CMC"** means chemistry, manufacturing, and control.

10

1.48. **"CMOs**" means Third Party contract manufacturers that manufacture a Compound under GMP conditions.

1.49. "CMO Supply Agreement" has the meaning set forth in <u>Section 5.3.2.1(b)</u>.

1.50. "Co-Chair" has the meaning set forth in <u>Section 3.6.1.2</u>.

1.51. **"CoDev Decision Point**" has the meaning set forth in <u>Section 4.4.2.2</u>.

1.52. **"CoDev Product**" means a Collaboration Product for which PIRS has exercised a PIRS CoDev Option in accordance with <u>Section 4.4.2</u>. For avoidance of doubt, in the event that PIRS exercises a PIRS CoDev Option, the applicable Collaboration Product shall become a CoDev Product as of the applicable PIRS CoDev Option Exercise Effective Date, and shall no longer be considered an Exclusive Product as of such date.

1.53. **"CoDev Product Amendment**" has the meaning set forth in <u>Section 9.2.3</u>.

1.54. **"CoDev Product Compound Specific Patent**" means any Joint Patent (other than an Initial Compound Specific Patent) that Covers the Research, Development, Manufacture, or Commercialization of a CoDev Product. In addition, any SGEN Compound Specific Patent that Covers the Research, Development, Manufacture, or Commercialization of a CoDev Product shall be considered a CoDev Product Compound Specific Patent as of the PIRS CoDev Option Exercise Effective Date.

1.55. "CoDev Product Opt-Out" has the meaning set forth in Section 16.2.4.

1.56. "CoDev Product Plan" has the meaning set forth in <u>Section 4.4.2.2</u>.

1.57. **"CoDev-Related Dispute**" has the meaning set forth in <u>Section 17.2.2.1</u>.

1.58. **"Collaboration Product(s)**" means a Research Candidate that as of the [\*\*\*] (a) is identified by the Parties under a Research Candidate Plan and (b) SGEN elects for further preclinical and clinical development, and for which SGEN pays the [\*\*\*]. A bispecific Antibody-Anticalin Protein fusion molecule that comprises a portion, fragment, variant, modification or derivative of the Antibody or Anticalin Protein of a Research Candidate that otherwise meets the requirements of the foregoing sentence shall be deemed a Collaboration Product, so long as such portion, fragment, variant, modification or derivative continues to confer binding specificity for the relevant target within the applicable SGEN Antibody Target and PIRS Anticalin Target combination. A Collaboration Product will either be an Exclusive Product or a CoDev Product.

1.59. **"Combination Product**" has the meaning set forth in <u>Section 1.149</u>.

11

1.60. **"Commercialization**" means any and all activities related to obtaining pricing and reimbursement approval, marketing, promoting, distributing, importing, exporting, offering for sale, having sold, selling, or conducting any other commercial exploitation activities relating to a Collaboration Product. For clarity, **"Commercialize**" has a correlative meaning.

1.61. **"Commercialization Expenses**" shall have the meaning set forth in <u>Exhibit 1.189</u> (Profits and Losses).

1.62. **"Commercially Reasonable Efforts**" means, with respect to an obligation of a Party, such level of effort and expenditure of resources required to carry out such obligation in a sustained manner consistent with the efforts and resources of a typical pharmaceutical or biotechnology company of a similar size and with similar resources as SGEN or PIRS together with their respective Affiliates, as applicable, typically devotes at the same stage of development or commercialization, as applicable, for its own internally developed pharmaceutical products in a similar area with similar market potential, at a similar stage of their product life, taking into account all relevant factors including, as applicable, stage of development, mechanism of action, efficacy and safety relative to competitive products in the marketplace, actual or anticipated labeling, the nature and extent of market exclusivity (including patent coverage and regulatory exclusivity), cost and likelihood of obtaining Marketing Approval, and actual or projected profitability. Where applicable, Commercially Reasonable Efforts will be determined on a market-by-market and Indication-by-Indication basis, and it is anticipated that the level of effort will be different for different markets and will change over time reflecting changes in the status of the applicable Compound and the markets involved.

1.63. **"Commercial Manufacturing Costs**" means with respect to a CoDev Product Manufactured by or on behalf of a Party in accordance with the applicable CoDev Product Plan or the Global Commercialization Strategy and related budgets at any time following the first Regulatory Approval of the applicable CoDev Product, such Party's actual costs (including labor and out-of-pocket costs) of Manufacturing such CoDev Product (for both clinical as well as commercial supply) without any mark-up, from the date of the first Regulatory Approval of the applicable CoDev Product until such CoDev Product is no longer Manufactured. Commercial Manufacturing Costs shall be calculated as further defined in <u>Exhibit 1.189</u> (Profits and Losses).

1.64. **"Committee**" has the meaning set forth in <u>Section 3.6.1.1</u>.

1.65. **"Compassionate Use**" means the use of a Collaboration Product as an investigational drug (prior to Marketing Approval) in accordance with applicable Law outside of a Clinical Study to treat a patient with a serious or life-threatening disease or condition who has no comparable or satisfactory alternative treatment options.

1.66. **"Compound**" means any Research Candidate or Collaboration Product.

12

1.67. **"Competent Authority**" means any regulatory agency, department, bureau, commission, council, or other governmental entity of (a) any country, territory, national, federal, state, provincial, county, city, or other political subdivision government, including the FDA, or (b) any supranational body (including the EMA), in any applicable jurisdiction in the world, involved in the granting of Regulatory Approval.

1.68. **"Competing Collaboration Product**" means any [\*\*\*] that [\*\*\*] and [\*\*\*] the [\*\*\*] ([\*\*\*] in terms of [\*\*\*] and [\*\*\*] the [\*\*\*]) as a Collaboration Product. For the avoidance of doubt, no Collaboration Product shall be a "Competing Collaboration Product" with respect to any other Research Candidate or Collaboration Product. For the purposes of this definition "**Biologic**" shall mean a peptide of at least forty (40) amino acids or at least one hundred (100) amino acids if made by entirely synthetic means.

1.69. **"Competing Research Product**" means any bispecific Biologic that specifically binds to and modulates the same Therapeutically [\*\*\*] ([\*\*\*] in terms of [\*\*\*]) as a Research Candidate. For the avoidance of doubt, no Research Candidate shall be a "Competing Research Product" with respect to any other Research Candidate or Collaboration Product. For the purposes of this definition "**Biologic**" shall mean a [\*\*\*] of [\*\*\*] or [\*\*\*] if made by [\*\*\*].

1.70. "Concerned Party" has the meaning set forth in <u>Section 10.3</u>.

1.71. **"Confidential Information**" means any and all Know-How and information of a confidential nature, whether financial, business, legal, technical, or non-technical, whether in oral, written, electronic or other form, including information and data related to a Compound, a Party, or any concepts, discoveries, inventions, data, designs or formulae in relation to this Agreement, that is disclosed, supplied or otherwise made available by or on behalf of one Party or any of its Affiliates or Sublicensees ("**Disclosing Party**") to the other Party or any of its Affiliates or Sublicensees ("**Disclosing Party**") to the other Party or any of its Affiliates or Sublicensees ("**Disclosing Party**") to the other Party or any of its Affiliates or Sublicensees ("**Disclosing Party**") in connection with this Agreement, provided that Joint Know-How shall be deemed the Confidential Information of both Parties. All Confidential Information disclosed by a Party pursuant to the Mutual Confidential Disclosure Agreement between the Parties [\*\*\*], including all amendments thereto (the "**Prior CDA**") shall be deemed to be Confidential Information of such Party pursuant to this Agreement (with the mutual understanding and agreement that any use and disclosure thereof that is authorized under, and consistent with, <u>Section 12</u> and this Agreement shall not be restricted by, or be deemed a violation of, such Prior CDA).

13

1.72. **"Control"**, "**Controlled**", or "**Controlling**" means, with respect to a subject item (including any Intellectual Property Right, Know-How, Regulatory Approvals, or Regulatory Materials) ("**Subject Item**"), the possession (whether arising by ownership, pursuant to a license or sublicense or otherwise, other than pursuant to this Agreement) by a Party of the ability of such Party or its Affiliate to grant a license, sublicense or access to the other Party with respect to such Subject Item, as provided in this Agreement, without violating the terms of any agreement with any Third Party (and subject to <u>Section 8.1.2</u>), in existence as of the time such Party or its Affiliates would first be required hereunder to grant the other Party such license, sublicense, or access. Notwithstanding anything to the contrary hereunder, the PIRS Platform IP and PIRS Platform Improvement IP will not be deemed to be "Controlled" by PIRS or its Affiliates for purposes of this Agreement.

1.73. **"Copyrights**" means all copyrights, and all right, title, and interests in all copyrights, copyright registrations, and applications for copyright registration, certificates of copyright and copyrighted rights and interests throughout the world, and all right, title, and interest in related applications and registrations throughout the world.

1.74. **"Cover"**, **"Covered"** or **"Covering"** with reference to (a) a Patent Right, means that, in the absence of a (sub)license under, or ownership of, such Patent Right, the Research, Development, Manufacture, or Commercialization of a Compound (including the making, using, offering for sale, selling or importing thereof), with respect to a given country, would infringe a Valid Claim of such Patent Right (or, in the case of a Valid Claim that has not yet issued, would infringe such Valid Claim if it were to issue), or (b) Know-How, means that the Research, Manufacture, Development or Commercialization of a Compound incorporates, embodies or otherwise make use of such Know-How.

1.75. "CREATE Act" has the meaning set forth in <u>Section 11.5</u>.

1.76. "**Damages**" has the meaning set forth in <u>Section 15.1</u>.

1.77. **"Data"** means any and all non-aggregated and aggregated research, pharmacology, pre-clinical, clinical, commercial, marketing, process development, manufacturing, and other data or information, including investigator brochures and reports (both preliminary and final), statistical analyses, expert opinions and reports, and safety data, in each case generated from, or related to, Clinical Studies or non-clinical studies, research or testing specifically related or directed to a Compound.

1.78. **"Developed in Competing Indications"** or **"Development in Competing Indications"** has the meaning set forth in <u>Section 4.3.6.2</u>.

#### 14

1.79. **"Development"** or "**Develop"** means, with respect to a Collaboration Product (and any companion diagnostic therefor), any and all pre-clinical, non-clinical and clinical research and development activities after [\*\*\*] and before or after obtaining Marketing Approval for such Collaboration Product, and that are reasonably related to or leading to the development, preparation, and submission of data and information to a Regulatory Authority for the purpose of obtaining, supporting or expanding Marketing Approval or to the appropriate body for obtaining, supporting or expanding pricing approval, including all activities related to pharmacokinetic profiling, design and conduct of Clinical Studies, those Manufacturing related activities that support the Development of the applicable Collaboration Product (such as process development, scale up, test method development, formulation development, delivery system development, quality control development, and validation) and CMC activities, medical affairs, regulatory affairs, statistical analysis, report writing, and regulatory filing creation and submission (including the services of outside advisors and consultants in connection therewith).

1.80. **"Development Costs"** means, on a Collaboration Product-by-Collaboration Product basis, in the in the Field in the Territory, all (i) FTE Costs incurred for the Development and Manufacture of such Collaboration Product and (ii) Out-of-Pocket Costs incurred for the Development and Manufacture of such Collaboration Product, but excluding Commercial Manufacturing Costs. For avoidance of doubt, Development Costs shall not include Commercialization Expenses.

1.81. "Disclosing Party" has the meaning set forth in <u>Section 1.71</u>.

1.82. "Development Plan Overviews" has the meaning set forth in Section 3.3.1.

1.83. "**Dispute**" has the meaning set forth in <u>Section 17.2.1</u>.

1.84. "Divest" or "Divestiture" has the meaning set forth in <u>Section 10.3.6.1</u>.

1.85. **"DMF**" means a drug master file and all equivalents, and related proprietary dossiers, in any country or jurisdiction for a Collaboration Product submitted or to be submitted by a Party to Competent Authorities.

1.86. **"Dollars**" or **"\$**" means the lawful currency of the United States.

1.87. **"Dormant Candidate**" means (i) the remaining [\*\*\*] Research Candidates that have the same SGEN Building Block as a Research Candidate selected by SGEN for further Development at the [\*\*\*] or (ii) a Collaboration Product deemed to be a Dormant Candidate pursuant to <u>Section 4.3.7</u>.

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

1.89. **"EMA**" means the European Medicines Agency or any successor agency thereto.

1.90. "EU[\*\*\*] Market" means any one of [\*\*\*].

15

1.91. **"European Union**" or "**EU**" means the member states of the European Union as of the Effective Date (including for the avoidance of doubt, the United Kingdom), and such other countries as may become part of the European Union after the Effective Date. For clarity, to the extent the United Kingdom and/or any other member state of the European Union would not anymore be a member of the European Union after the Effective Date, it shall still be included in this definition of EU for the purposes of this Agreement.

1.92. **"Exclusive Product**" means a Collaboration Product for which PIRS has not exercised a PIRS CoDev Option in accordance with <u>Section 4.4.2</u>. For avoidance of doubt, unless and until PIRS exercises a PIRS CoDev Option, a Collaboration Product shall be an Exclusive Product.

1.93. **"Exclusive Product Royalties**" has the meaning set forth in <u>Section 7.9</u>.

1.94. **"Existing PIRS Patent Rights**" has the meaning set forth in <u>Section 14.2.1.3</u>.

1.95. "Existing SGEN Know-How" has the meaning set forth in <u>Section 14.3.1.2</u>.

1.96. "Expedited Rules" has the meaning set forth in <u>Section 17.2.2.1</u>.

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

1.98. **"Field**" means, with respect to any Compound, any therapeutic, palliative, prophylactic and diagnostic use for any disease or condition.

1.99. **"Filing Party**" has the meaning set forth in <u>Section 2.6.1</u>.

1.100. **"Final Offer**" has the meaning set forth in <u>Section 9.2.3</u>.

1.101. "First Approved SGEN Antibody Target" has the meaning set forth in <u>Section 4.1.1.2.</u>

1.102. **"First Commercial Sale**" means the first sale to a Third Party of a Collaboration Product by or on behalf of either Party or its Affiliates or Sublicensees, in a country after receipt of the applicable Marketing Approval from the Competent Authorities in that country. For the avoidance of doubt, any Compassionate Use shall not be considered a First Commercial Sale.

1.103. **"FTC**" has the meaning set forth in <u>Section 14.4.5</u>.

16

1.104. **"FTE**" shall mean, with respect to an applicable Compound, a full-time equivalent person-year of work engaged in the direct performance of the applicable Research, Development, Manufacturing, or Commercialization activities for such Compound, determined using an 1,800-hour annual base. In no circumstance can the work of any given person in a given year exceed one (1) FTE. For clarity, indirect personnel (including supervisors and support functions such as legal, finance or business development) shall not constitute FTEs.

1.105. **"FTE Costs**" for a given period and with respect to an applicable Compound, means the product of (a) the total FTEs (proportionately, on a per-FTE basis) dedicated by a Party or its Affiliates in the particular period to the direct performance of the applicable Research, Development, Manufacturing, or Commercialization activities allocated to such Party hereunder and that are Reasonably Allocable to such Compound and (b) the FTE Rate. Notwithstanding the foregoing, FTE Costs shall not include (x) Commercial Manufacturing Costs and (y) Commercialization Expenses.

1.106. **"FTE Rate**" means, unless otherwise agreed between the Parties, a rate per FTE equal to [\*\*\*] Dollars (\$[\*\*\*]) per annum (which may be prorated on a daily or hourly basis (based on a 40-hour workweek) as necessary). The FTE Rate is "fully burdened" and will cover employee salaries, benefits, travel, and such facilities and equipment and other materials and services including ordinary laboratory and Manufacturing consumables (like, for example, growth media, but not larger out-of-pocket expenses that are used in GMP Manufacturing of a Compound, such as chromatography resins) procured from distributors of relevant products as they may use. Commencing upon the first (1<sup>st</sup>) anniversary of the Effective Date and upon every anniversary thereafter, the FTE Rate will be adjusted in accordance with the percentage change over the applicable annual period in the Consumer Price Index (U.S. Bureau of Labor Statistics for all urban consumers, U.S. city average, all items).

1.107. **"Full Sublicense Agreement**" means, with respect to a CoDev Product, a Partnering Agreement between a Party and a Third Party to license or sublicense, transfer, assign or sell all of its rights and obligations to Research, Develop and Commercialize such CoDev Product under this Agreement.

1.108. **"Gatekeeper**" means the Third-Party gatekeeper who will check nominated SGEN Antibody Targets against the Restricted Research Candidate Target List, in accordance with <u>Section 4.1.1.5</u>.

17

1.109. "Global Branding Strategy" has the meaning set forth in <u>Section 6.6</u>.

1.110. "Global Commercialization Agreement" has the meaning set forth in <u>Section 6.1</u>.

1.111. "Global Commercialization Strategy" has the meaning set forth in <u>Section 6.1</u>.

1.112. **"GLP Tox Study**" means, with respect to a Compound, a study conducted in a species using applicable regulatory good laboratory practices for the purposes of assessing the onset, severity, and duration of toxic effects and their dose dependency with the goal of establishing a safety profile required for a regulatory submission supporting the dosing of human subjects as outlined in appropriate ICH guidance. For the avoidance of doubt, preliminary toxicology studies are not regarded as a GLP Tox Study.

1.113. **"Go/No-Go Decision Fee**" means the payment amount for the Go/No-Go DP specified in <u>Section</u> <u>7.4</u> (i.e., [\*\*\*] Dollars (\$[\*\*\*])).

1.114. **"Go/No-Go Decision Point"** or **"Go/No-Go DP"** means, with respect to a Research Candidate, (i) SGEN's written notice to PIRS within [\*\*\*] days of the end of the Research Term with respect to such Research Candidate that it has selected that Research Candidate to become a Collaboration Product and (ii) SGEN's payment of the Go/No Go Decision Fee within [\*\*\*] days of providing such notice.

1.115. **"Government Authority**" means any applicable government authority, court, tribunal, arbitrator, agency, department, legislative body, commission, or other government instrumentality of (a) any country, territory, nation, state, province, county, city, or other political subdivision thereof or (b) any supranational body, including any Competent Authority.

1.116. **"Health Authority Communication**" means any communication from any Competent Authority that concerns significant issues, including any of the following: key product quality attributes (e.g., purity), safety findings affecting the platform (e.g., serious adverse events, emerging safety signals), clinical or non-clinical findings affecting patient safety, or lack of efficacy.

1.117. **"HSR**" has the meaning set forth in <u>Section 14.4.5</u>.

1.118. **"IND"** or **"IND/IMPD**" means (a) an Investigational New Drug Application as defined in the FD&C Act and applicable regulations promulgated thereunder by the FDA, (b) the Investigational Medicinal Product Dossier in the European Union, or (c) the equivalent application to the applicable Competent Authority in any other regulatory jurisdiction, and any amendments to the foregoing (a), (b) or (c), in each case, the filing of which is necessary to initiate or conduct clinical testing of an investigational drug or biological product in humans in such jurisdiction.

1.119. **"IND/IMPD Submission**" means the filing of an IND/IMPD.

18

1.120. **"IND Filing Party**" has the meaning set forth in <u>Section 2.7</u>.

1.121. "Indemnified Party" has the meaning set forth in <u>Section 15.3.1</u>.

1.122. "Indemnifying Party" has the meaning set forth in <u>Section 15.3.1</u>.

1.123. "**Indication**" means a distinct type of disease or medical condition in humans to which a Collaboration Product is directed and eventually approved. To distinguish one Indication from another Indication, the two Indications [\*\*\*] of the [\*\*\*] is in a [\*\*\*], whereas [\*\*\*] to the [\*\*\*] or [\*\*\*] a [\*\*\*] used to [\*\*\*] for [\*\*\*] of the [\*\*\*] would [\*\*\*] a [\*\*\*]. Notwithstanding the foregoing, [\*\*\*] shall be [\*\*\*] and [\*\*\*] of the [\*\*\*] of the [\*\*\*].

1.124. **"Initial Compound Specific Know-How**" means, on a Compound-by-Compound basis, all Know-How developed or generated by or on behalf of PIRS under the Research Candidate Plan that (a) Covers the Research, Development, Manufacture, or Commercialization of such Compound or (b) is reasonably necessary or useful for the Research, Development, Manufacture, or Commercialization of a Compound. Initial Compound Specific Know-How excludes Know-How within the SGEN Building Block IP, PIRS Building Block IP, PIRS Platform IP, or PIRS Platform Improvement IP.

1.125. **"Initial Compound Specific Patents**" means, on a Compound-by-Compound basis, any Patent that includes or otherwise incorporates any Initial Compound Specific Know-How. For avoidance of doubt, Initial Compound Specific Patents excludes Patents within the SGEN Building Block IP, PIRS Building Block IP, PIRS Platform IP, or PIRS Platform IP.

1.126. **"Initial Quantities**" means, for each of the [\*\*\*] Research Candidates that include the same SGEN Building Block, at least [\*\*\*] mg of the respective protein.

1.127. **"Initiation**" or "**Initiated**" means, (i) with respect to a Clinical Study of a Collaboration Product, the first dosing of the first human subject pursuant to the protocol for such Clinical Study or (ii) with respect to a GLP Tox Study, the start date of the in-life phase of such GLP Tox Study.

1.128. "Insolvent Party" has the meaning set forth in <u>Section 16.3.4</u>.

1.129. **"Intellectual Property Rights**" means, collectively, Patent Rights, Copyrights, Trademarks, designs, domain names, moral rights and all other intellectual property and proprietary rights.

1.130. "Joint Development Budget" has the meaning set forth in <u>Section 4.4.2.2</u>.

1.131. "Joint Development Committee" or "JDC" has the meaning set forth in <u>Section 3.3</u>.

19

1.132. **"Joint IP**" means collectively, Joint Know-How and Joint Patents, including all Intellectual Property Rights therein.

1.133. "Joint Intellectual Property Committee" or "JIPC" has the meaning set forth in <u>Section 3.4</u>.

1.134. **"Joint Know-How**" means the (x) Initial Compound Specific Know-How and (y) to the extent not included in (x), Know How created, invented or generated by employees, agents, or independent contractors of (i) both Parties or their Affiliates (or a Third Party acting on any of their behalf) jointly in the course of performing activities under this Agreement, (ii) PIRS or its Affiliates (or a Third Party acting on any of their behalf) in the course of performing activities under this Agreement during the Research Term, including the activities set forth in the applicable Research Candidate Plan, or (iii) either Party or its Affiliates (or a Third Party acting on any of their behalf) in the course of performing activities under this Agreement with respect to a CoDev Product, including the activities set forth in the applicable CoDev Product Plan. Joint Know-How excludes in each case Know-How within the PIRS Platform IP, PIRS Platform Improvement IP, SGEN Building Block IP or PIRS Building Block IP regardless of whether such Know-How would otherwise meet the definition of Joint Know-How hereunder.

1.135. "Joint Patents" means the (x) Initial Compound Specific Patents and (y) to the extent not included in (x), Patents that claim an invention created, invented or generated by employees, agents, or independent contractors of (i) both Parties together or their Affiliates (or a Third Party acting on any of their behalf) in the course of performing activities under this Agreement, (ii) PIRS or its Affiliates (or a Third Party acting on any of their behalf) in the course of performing activities under this Agreement during the Research Term, including the activities set forth in the applicable Research Candidate Plan, or (iii) either Party or its Affiliates (or a Third Party acting on any of their behalf) in the course of performing activities under this Agreement with respect to a CoDev Product, including the activities set forth in the applicable CoDev Product Plan. Joint Patents excludes in each case any Patents within the PIRS Platform IP, PIRS Platform Improvement IP, SGEN Building Block IP or PIRS Building Block IP regardless of whether such Patent would otherwise meet the definition of a Joint Patent hereunder.

1.136. "Joint Research Committee" or "JRC" has the meaning set forth in <u>Section 3.2</u>.

1.137. "Joint Steering Committee" or "JSC" has the meaning set forth in <u>Section 3.1</u>.

20

1.138. **"Key Data"** shall consist of the following Data and information: (a) size and geography of the applicable Clinical Study, including number of sites and identification of main sites, (b) Indications and clinical settings included in such Clinical Study, including lines of therapy and key patient inclusion criteria, (c) summary of safety data from such Clinical Study, including adverse events by severity, dose level and Indication or clinical setting, (d) summary of efficacy data, including Key Endpoints by dose level and Indication or clinical setting, and (e) summary of biomarker analysis by dose level and Indication or clinical setting, including correlation of such biomarker analysis with Key Endpoints (as available at time of publication). For the purposes of this definition, "**Key Endpoints**" shall consist of the following endpoints: overall response rate, complete responses, partial responses if applicable, stable disease, disease control rate, minimal residual disease if applicable, progression free survival, overall survival (as available at the time of publication of Key Data), and any other efficacy endpoint that was not contemplated at the time of this Agreement but was subsequently included as a primary or secondary endpoint in such Clinical Study.

1.139. **"Know-How**" means any and all ideas, concepts, designs, technical information, techniques, Data, database rights, discoveries, inventions, practices, methods, procedures, processes, methods, algorithm, knowledge, skill, experience, test data and any other information or technology, whether in written, electronic, graphic or any other form, including pharmaceutical, chemical, biological and biochemical compositions, formulations, assays, active pharmaceutical ingredients ("**APIs**"), molecules, samples, cell lines, journals, and laboratory notebooks.

1.140. **"Law**" means any applicable national, supranational, federal, state, local or foreign law, statute, ordinance, principle of common law, or any rule, regulation, standard, judgment, order, writ, injunction, decree, arbitration award, agency requirement, license or permit of any applicable Government Authority, including any rules, regulations, guidelines, directives or other requirements of applicable Government Authorities, including good clinical practices, good laboratory practices and good manufacturing practices, as well as all anti-bribery or anti-corruption laws, as applicable.

1.141. "Licensor" has the meaning set forth in <u>Section 9.1.1</u>.

1.142. **"MAA"** means a Marketing Authorization Application, in relation to any Product, filed or to be filed with the EMA (or equivalent national agency), for authorization to place a medicinal product on the market in the European Union (or any other territory).

21

1.143. **"Manufacture**" means, with respect to a Compound, all activities related to the manufacture of the Compound, including, but not limited to, manufacturing supplies for Development or Commercialization, packaging, in-process and finished product testing, release of product or any component or ingredient thereof, quality assurance and quality control activities related to manufacturing and release of product, ongoing stability tests, storage, shipment, import and export as needed, improvement of production, improvement of manufacturing processes, and regulatory activities related to any of the foregoing. For clarity, "Manufacturing" has a correlative meaning.

1.144. "Manufacturing Party" has the meaning set forth in <u>Section 5.3.2.1</u>.

1.145. **"Marketing Approval**" means all approvals, licenses, registrations or authorizations of the Competent Authorities in a country, necessary for the commercial marketing and sale of a Collaboration Product in such country, including (a) the approval of a MAA or a BLA, and (b) a determination or decision establishing prices for a Collaboration Product that can be charged or reimbursed in regulatory jurisdictions where the applicable Competent Authorities approve or determine the price or reimbursement of pharmaceutical products.

1.146. "Material Adverse Effect" has the meaning set forth in <u>Section 4.4.3.6</u>.

1.147. "Medical Journals" has the meaning set forth in <u>Section 13.2.1</u>.

1.148. "**Net Income**" has the meaning set forth in <u>Exhibit 1.189</u>, attached hereto and incorporated herein by reference.

1.149. "Net Sales" means, in the case of sales by or for the benefit of SGEN, its Affiliates, and its Sublicensees (in each case, "Seller") in the Territory to a Third Party, the gross amount invoiced by Seller with respect to Exclusive Products, less the following deductions solely to the extent such deduction: (i) is reasonable and customary, (ii) is included in the gross invoiced sales price for the Exclusive Product or otherwise directly paid, allowed, accrued, or incurred by the Seller with respect to the sale of such Exclusive Product (iii) is applicable and in accordance with standard allocation procedures, (iv) has not already been deducted or excluded, (v) is incurred in the ordinary course of business in type and amount consistent with good industry practice, and (vi) is determined in accordance with, and as recorded in revenues under, applicable Accounting Standards ("Permitted Deductions"):

1.149.1. trade, cash, [\*\*\*] and [\*\*\*] and allowances for Exclusive Products; price reductions (retroactive or otherwise) including [\*\*\*] or otherwise [\*\*\*];

1.149.2. any tax, tariff, duty (including custom duty) or other governmental charge (such as excise, sales or use taxes or value added tax), levied on the sale,

22

transportation or delivery of such Exclusive Products [\*\*\*] and [\*\*\*] or other [\*\*\*] or [\*\*\*] or any [\*\*\*];

1.149.3. customary freight, insurance, packing costs and other transportation charges added to the sales price that are incurred in delivering the Exclusive Product;

1.149.4. amounts repaid or credits taken by reason of rejections, defects, or returns of the Exclusive Products or because of retroactive price reductions, or due to recalls or rebates required by applicable Laws;

1.149.5. any fees for services provided by wholesalers and warehousing chains related to the distribution of such Exclusive Products and the portion of administrative fees paid during the relevant time period to group purchasing organizations, pharmaceutical benefit managers and/or Medicare Prescription Drug Plans relating specifically to such Exclusive Products [\*\*\*] to the [\*\*\*] that such [\*\*\*] in [\*\*\*] the [\*\*\*]; and

1.149.6. the [\*\*\*] that [\*\*\*] to the [\*\*\*] for the [\*\*\*] which as of the [\*\*\*] is [\*\*\*] the [\*\*\*] by the [\*\*\*] and the [\*\*\*] is the [\*\*\*];

1.149.7. [\*\*\*] of a [\*\*\*] with the [\*\*\*] to the [\*\*\*].

For the avoidance of doubt, if a single item falls into more than one of the categories set forth in <u>Section 1.149.1</u> through <u>Section 1.149.6</u> above, such item may not be deducted more than once.

"Net Sales" shall not include any consideration received with respect to a sale, use or other disposition of any Exclusive Product in a country for purposes of conducting Clinical Studies in the course of Development of the Exclusive Product in accordance with this Agreement or as samples (reasonable in number), for Compassionate Use, or for other charitable, promotional, pre-clinical, clinical, regulatory or governmental purposes, in each case to the extent such Exclusive Product is sold at or below cost. Notwithstanding the foregoing, the amounts invoiced by SGEN, its Affiliates, or their Sublicensees for the sale of Exclusive Products among SGEN, its Affiliates or their respective Sublicensees for resale shall not be included in the computation of Net Sales hereunder (except where such Affiliates or Sublicensees are the end users) and Net Sales shall be the gross invoice or contract price charged to the Third Party customer for that Exclusive Product in an arms' length transaction, less the Permitted Deductions. Net Sales calculations shall be determined in accordance with Accounting Standards consistently applied throughout the organization and across all products of the entity whose sales of Exclusive Products are giving rise to Net Sales. In the case of any sale or other transfer for value, such as barter or counter-trade, of an Exclusive Product, or part thereof, other than in an arm's length transaction exclusively for cash, Net Sales shall be calculated as above on the value of the non-cash consideration received or the fair market price (if higher) of such Exclusive Product in the country of sale or transfer,

23

as determined in accordance with Accounting Standards consistently applied (as contemplated above).

In the case where an Exclusive Product is sold as part of a Combination Product in a country in the Territory, Net Sales for the Exclusive Product included in such Combination Product in such country shall be calculated as follows:

(i) if the Exclusive Product is sold separately in such country and the other active ingredient or ingredients in the Combination Product are sold separately in such country, Net Sales for the Collaboration Product shall be calculated by multiplying actual Net Sales of such Combination Product in such country by the fraction A/(A+B), where A is the invoice price of the Exclusive Product when sold separately in such country and B is the total invoice price of the other active ingredient or ingredients in the Combination Product when sold separately in such country and B is the total invoice price of the other active ingredient or ingredients in the Combination Product when sold separately in such country;

(ii) if the Exclusive Product is sold separately in such country but the other active ingredient or ingredients in the Combination Product are not sold separately in such country, Net Sales for the Exclusive Product shall be calculated by multiplying actual Net Sales of such Combination Product in such country by the fraction A/D, where A is the invoice price of the Exclusive Product when sold separately in such country and D is the invoice price of the Combination Product in such country;

(iii) if the Exclusive Product is not sold separately in such country but the other active ingredient or ingredients in the Combination Product are sold separately in such country, Net Sales for the Exclusive Product shall be calculated by multiplying actual Net Sales of such Combination Product by the fraction 1 - (B/D), where B is the invoice price of the other active ingredient or ingredients in the Combination Product when sold separately in such country and D is the invoice price of the Combination Product in such country; notwithstanding the foregoing, if the other active ingredient or ingredient or ingredient or ingredients in the Combination Product are being sold by (a) Seller, then Net Sales for the Collaboration Product shall be calculated by multiplying actual Net Sales of such Combination Product by the fraction 1 - (E/E+1), where E is the number of other active ingredients in the Combination Product, and (b) a Third Party, where such Third Party and Seller have a written agreement on how actual Net Sales of such Combination Product shall be split between Seller and such Third Party, then Net Sales for the Collaboration Product Seller actually receives under such written agreement with such Third Party; or

(iii) if neither the Exclusive Product nor the other active ingredient or ingredients in the Combination Product are sold separately in such country, the Parties shall determine Net Sales for the Exclusive Product in such Combination Product by mutual agreement based on the relative contribution of the Exclusive Product

24

and each other active ingredient to the Combination Product, and shall take into account in good faith any applicable allocations and calculations that may have been made for the same period in other countries.

For purposes of this definition, "**Combination Product**" means a product that includes at least one active ingredient other than a Collaboration Product, when a single sale or reimbursement price is set for such Combination Product.

25

- 1.150. "Non-Competing Indication CoDev Product" has the meaning set forth in <u>Section 4.3.6.2</u>.
- 1.151. "Non-Proposing Party" has the meaning set forth in <u>Section 4.4.3.6</u>.
- 1.152. "Objection Period" has the meaning set forth in <u>Section 4.4.3.6(a)</u>.

1.153. **"Ongoing Internal PIRS Program**" means therapeutic programs for which PIRS has initiated lab work, including all of the following: (i) generation of the genetic constructs, (ii) production of the corresponding protein, and (iii) testing of such protein in at least one (1) in vitro or in vivo assay.

1.154. **"Option Notice**" has the meaning set forth in <u>Section 4.4.2.2</u>.

1.155. **"Out-of-Pocket Costs"** means all direct project costs and expenses paid to Third Parties (or payable to Third Parties) after the Effective Date, which are specifically identifiable for or Reasonably Allocable to services or materials provided by such Third Parties directly in their performance of the Research, Development, Manufacture, or Commercialization of a Compound; such expenses to have been recorded and accrued in accordance with Accounting Standards by the applicable Party and/or its Affiliates, in each case without mark-up. For clarity, Out-of-Pocket Costs do not include capital expenditures (unless mutually agreed by the Parties), travel expenses, idle Manufacturing capacity costs, or items intended to be covered under the definition of FTE Costs. For further clarity, Out-of-Pocket Costs do include otherwise eligible costs for: contract research organizations (CROs); clinical supplies; Manufacturing process development and scale-up; test method development, qualification, and validation; formulation development; and stability testing. Notwithstanding the foregoing, Out-of-Pocket Costs shall not include (x) Commercial Manufacturing Costs and (y) Commercialization Expenses.

1.156. **"Partnering Agreement**" means with respect to any Collaboration Product, an agreement with a Third Party to license or sublicense, transfer, assign or sell (in each case, including an option to do so, but excluding any assignment or sale in connection with a Change of Control of the assigning or selling Party) all or part of its rights and obligations to Research, Develop and Commercialize such Collaboration Product.

1.157. **"Party"** or **"Parties"** has the meaning set forth in the preamble.

1.158. "Party Supply Agreement" has the meaning set forth in <u>Section 5.3.2.1(a)</u>.

26

1.159. **"Patent Right**" or "**Patent**" means any and all patent rights and all right, title and interest in all patent applications and patents that issue from them, all letters patent or equivalent rights and applications in each case to the extent the same has not been held, by a court of competent jurisdiction, to be invalid or unenforceable in a decision from which no appeal can be taken or from which no appeal was taken within the time permitted for appeal. Patent Rights include any extension, registration, confirmation, reissue, continuation, supplementary protection certificate, divisional, continuation-in-part, re-examination, or renewal thereof or foreign counterparts of any of the foregoing.

1.160. "Paying Party" has the meaning set forth in <u>Section 8.4.1</u>.

1.161. "Permitted Deductions" has the meaning set forth in <u>Section 1.148</u>.

1.162. **"Pharmacovigilance Agreement**" has the meaning set forth in <u>Section 4.6.1</u>.

1.163. **"Phase 1 Clinical Study**" means a clinical study of a product in human subjects which provides for the first introduction into humans of a product, conducted in healthy volunteers or patients to obtain information on product safety, tolerability, pharmacological activity, or pharmacokinetics, as described in 21 C.F.R. § 312.21(a) (or the non-United States equivalent thereof).

1.164. **"Phase 1 Clinical Study Expansion Cohort**" means the expansion of a Phase 1 Clinical Study to include additional patient(s) following the selection of a dose during the dose escalation part of the Phase 1 Clinical Study (such as a maximum tolerated dose).

1.165. **"Phase 2 Clinical Study"**, **"Phase 2a Clinical Study**" or **"Phase 2b Clinical Study**" means a clinical study of a product that is prospectively designed to establish the safety, dose ranging and efficacy of a product as further defined in 21 C.F.R. § 312.21(b) (or the non-United States equivalent thereof).

1.166. "**PIRS**" has the meaning set forth in the preamble.

1.167. "PIRS Anticalin Target" means [\*\*\*].

1.168. **"PIRS Background Agreement**" means (i) the Research and License Agreement with [\*\*\*] and (ii) any agreement entered by PIRS to in-license any Intellectual Property Rights necessary or useful for the Research, Development, Manufacturing, or Commercialization of the PIRS Building Block of any Compound.

1.169. **"PIRS Building Block**" means any Anticalin Protein Building Block Controlled by PIRS. For avoidance of doubt, any PIRS Building Block with the same PIRS Anticalin Target shall be deemed to be the same PIRS Building Block under this Agreement.

#### 27

1.170. **"PIRS Building Block IP**" means all Patent Rights and Know-How Controlled by PIRS as of the Effective Date and thereafter during the Term that Cover an Anticalin Protein Building Block individually, including all Intellectual Property Rights therein, but excluding any PIRS Platform IP and PIRS Platform Improvement IP.

1.171. **"PIRS CoDev Option**" has the meaning set forth in <u>Section 4.1.2.1</u>.

1.172. "PIRS CoDev Option Exercise Effective Date" has the meaning set forth in <u>Section 4.4.2.2</u>.

1.173. "PIRS Collaboration Product" has the meaning set forth in <u>Section 16.3.2.4(b)</u>.

1.174. "**PIRS Indemnitees**" has the meaning set forth in <u>Section 15.2</u>.

1.175. **"PIRS IP**" means any and all PIRS Patent Rights and the PIRS Know-How, including any Intellectual Property Rights therein. For avoidance of doubt, PIRS IP shall exclude PIRS Platform IP and PIRS Platform Improvement IP but shall include PIRS Building Block IP.

1.176. **"PIRS Know-How**" means all Know-How that is Controlled by PIRS as of the Effective Date and thereafter during the Term other than pursuant to the licenses granted by SGEN under this Agreement and that (a) Covers the Research, Development, Manufacture, or Commercialization of the Compounds or (b) is reasonably necessary for the Research, Development, Manufacture, or Commercialization of the Compounds, but excludes Know-How within the PIRS Platform IP and PIRS Platform Improvement IP. PIRS Know-How shall include PIRS' interest in Joint Know-How.

1.177. "**PIRS Partner**" has the meaning set forth in <u>Section 9.2.1</u>.

1.178. **"PIRS Patent Rights**" means any Patent Rights that are Controlled by PIRS as of the Effective Date and thereafter during the Term, and that (a) Cover the Research, Development, Manufacture, or Commercialization of the Compounds (including their composition, formulation, combination, product by process, or method of use, manufacture, preparation, or administration), or (b) are reasonably necessary for the Research, Development, Manufacture, or Commercialization of the Compounds pursuant to the terms of this Agreement. PIRS Patent Rights shall include PIRS' interest in Joint Patents that meet the above requirements. PIRS Patent Rights shall exclude Patent Rights within the PIRS Platform IP and PIRS Platform Improvement IP. The PIRS Patent Rights existing as of the Effective Date are set forth in <u>Exhibit 1.178</u> and shall be updated from time to time.

28

1.179. **"PIRS Platform Improvement IP**" means any and all Patent Rights or Know-How created, invented, or generated by or on behalf of employees, agents, or independent contractors of either Party or their Affiliates (whether alone or jointly) in the course of performing activities pursuant to this Agreement that constitutes an improvement, modification, or enhancement to, or derivative of, the PIRS Platform IP, including all Intellectual Property Rights therein. The Patent Rights within the PIRS Platform IP shall be added to <u>Exhibit 1.179</u> from time to time.

1.180. **"PIRS Platform IP**" means (a) the Know-How Controlled by PIRS that is necessary or useful for the practice of the PIRS Platform Technology, and (b) those Patent Rights Controlled by PIRS directed to the PIRS Platform Technology as set forth in Exhibit 1.180.

1.181. **"PIRS Platform Technology**" means Anticalin Libraries, Anticalin Selection, Anticalin Expression, Anticalin Characterization, Anticalin Fusion Technology, and Anticalin Affinity Maturation methods, all to the extent Controlled by PIRS.

1.182. **"PIRS Sublicense Notice**" has the meaning set forth in <u>Section 9.2.3</u>.

29

1.183. **"PIRS Territory**" means (a) with respect to a CoDev Product, the United States of America, and (b) with respect to a Research Candidate, the entire world.

1.184. "PIRS Territory Commercialization Plan" has the meaning set forth in <u>Section 6.5</u>.

1.185. **"Pivotal Clinical Study**" means a clinical study of a product that is designed to generate statistically significant evidence of the efficacy of a product for a particular Indication or use (as well as additional safety information) and that is intended to form the primary scientific support for filing a BLA to obtain Marketing Approval to market the product (or any MAA for the non-United States equivalent thereof).

1.186. **"Platform Agreement**" means that certain non-exclusive license agreement to the PIRS Platform Technology entered into between SGEN and PIRS on the date hereof.

1.187. **"Potential CoDev Product**" means each Collaboration Product unless and until it would be impossible for such Collaboration Product to become a CoDev Product.

1.188. "**Prior CDA**" has the meaning set forth in <u>Section 1.71</u>.

1.189. **"Profits and Losses"** means all profits and losses associated with the Commercialization of a CoDev Product. Profits and Losses will be calculated as outlined in <u>Exhibit 1.189</u>.

1.190. **"Promotional Materials**" has the meaning set forth in <u>Exhibit 6.2</u>.

1.191. **"Proposed Study(ies)**" has the meaning set forth in <u>Section 4.4.3.6</u>.

1.192. **"Proposed Terms**" has the meaning set forth in <u>Section 17.2.2.2</u>.

1.193. **"Proposing Party**" has the meaning set forth in <u>Section 4.4.3.6</u>.

1.194. **"Qualified Sublicensee**" means any Third Party that, at the time of the PIRS Sublicense Notice [\*\*\*].

1.195. "**Raw Data**" has the meaning set forth in <u>Section 2.6.4</u>.

1.196. "**Receiving Party**" has the meaning set forth in <u>Section 1.71</u>.

1.197. **"Reasonably Allocable**" means, with respect to FTE Costs or Out-of-Pocket Costs that are associated with an applicable Compound and something else (such as another product or Compound) and where such costs are not separately accounted for or invoiced for such Compound, only the pro-rated portion of such costs that are attributable to such Compound (based on head-count, time-spent or other activity-based method) and calculated and documented in good faith using Accounting Standards.

1.198. **"Reconciliation Report**" has the meaning set forth in <u>Section 8.3.2</u>.

30

1.199. **"Regulatory Approval"** means any and all approvals, licenses, registrations, or authorizations by a Competent Authority necessary for the Development activities (including any IND/IMPD approval), Manufacturing activities or Commercialization activities (including, where applicable, Marketing Approval, pricing, labeling and reimbursement determinations or approvals).

1.200. **"Regulatory Exclusivity**" means any exclusive marketing rights or data exclusivity rights conferred by any applicable Competent Authority, other than an issued and unexpired Patent, including any regulatory data protection exclusivity and/or any other exclusivity afforded by restrictions which prevent the granting by a Competent Authority of Regulatory Approval to market for any indication a Biosimilar.

1.201. **"Regulatory Materials**" means regulatory applications, submissions, dossiers, notifications, registrations, case report forms, trial master file, DMF, common technical documents, question and answers with Competent Authorities, Marketing Approvals or other filings or communications made to or with, or other approvals granted by, a Competent Authority that are necessary or reasonably desirable in order to Develop, Manufacture or Commercialize a Collaboration Product in a particular country or regulatory jurisdiction.

1.202. **"Reimbursable** [\*\*\*]" means [\*\*\*] between [\*\*\*] and the [\*\*\*].

1.203. **"Research"** or "**Researching**" means activities related to the design, discovery, generation, identification, profiling, characterization, production, process development, cell line development, pre-clinical development or non-clinical or pre-clinical studies of Research Candidates prior to [\*\*\*].

1.204. **"Research Candidate"** means a bispecific Antibody-Anticalin Protein fusion molecule Researched by the Parties under this Agreement. Each Research Candidate shall include [\*\*\*] PIRS Building Block and [\*\*\*] SGEN Building Block.

1.205. **"Research Candidate Target Combination**" means the [\*\*\*] Targets against which a single Research Candidate is directed.

1.206. "**Research Collaboration**" has the meaning set forth in <u>Section 4.1</u>.

1.207. "Research Candidate Plan" has the meaning set forth in <u>Section 4.1.2.1</u>.

31

1.208. "**Research Term**" means, with respect to the [\*\*\*] Research Candidates for an Approved SGEN Antibody Target, the period of time commencing on (I) the Effective Date for the First Approved SGEN Antibody Target, and (II) the date a nominated SGEN Antibody Target becomes approved (as notified by the Gatekeeper in accordance with <u>Section 4.1.1.5(c)</u>) for the Second and Third Approved SGEN Antibody Targets, and, continuing until the earliest of (i) with respect to (x) the First Approved SGEN Antibody Target, [\*\*\*] years after SGEN's receipt of [\*\*\*] of the Research Candidate directed to the [\*\*\*] PIRS Anticalin Target, or (y) the Second and Third Approved SGEN Antibody Targets, [\*\*\*] years after SGEN's receipt of [\*\*\*] of such Research Candidates, respectively and (ii) with respect to all Approved SGEN Antibody Targets, the [\*\*\*].

1.209. **"Restricted Research Candidate Target List**" means the list of Targets that PIRS will submit to the Gatekeeper within [\*\*\*] days of the Effective Date (and keep updated on an ongoing basis) that shall include (i) the Targets that PIRS would be contractually restricted from Researching, Developing, Manufacturing, or Commercializing under this Agreement, and (ii) Targets for which PIRS has a bona fide Ongoing Internal PIRS Programs, which PIRS shall provide to the Gatekeeper from time to time.

1.210. **"Royalty Bearing Net Sales**" means on a country-by-country and Exclusive Product-by-Exclusive Product basis, the Net Sales generated during the Royalty Term for such Collaboration Product in such country.

1.211. **"Royalty Term**" means, on a country-by-country basis and Exclusive Product-by-Exclusive Product basis, the period commencing on the First Commercial Sale of such Exclusive Product in a country and ending with respect to such Exclusive Product in such country on the later of (a) [\*\*\*] years thereafter in such country of sale; (b) [\*\*\*] in such country of sale; or (c) expiration of the [\*\*\*], in each case, Covering the import, use, sale or offer for sale (but, for clarity, not the Manufacturing) of such Exclusive Product in such country of sale, including by 35 U.S.C. § 271(g) or any foreign equivalent.

- 1.212. "**Rules**" has the meaning set forth in <u>Section 17.2.1</u>.
- 1.213. "Scientific Meeting" has the meaning set forth in <u>Section 13.2.2</u>.
- 1.214. "Scientific Paper" has the meaning set forth in <u>Section 13.2.1</u>.
- 1.215. "SEC" has the meaning set forth in <u>Section 12.6.2</u>.
- 1.216. "Second Approved SGEN Antibody Target" has the meaning set forth in <u>Section 4.1.1.3</u>.
- 1.217. "Seller" has the meaning set forth in <u>Section 1.148</u>.

32

1.218. **"Senior Executives"** means the Chief Executive Officer of PIRS and the Chief Executive Officer of SGEN, or their duly authorized respective designees with equivalent decision-making authority with respect to matters under this Agreement.

1.219. "Sensitive Information" has the meaning set forth in <u>Section 10.3.6.2</u>.

1.220. **"SGEN**" has the meaning set forth in the preamble.

1.221. **"SGEN Antibody Target**" means an antibody Target that SGEN has nominated and the Gatekeeper has approved for use in the collaboration in accordance with <u>Section 4.1.1</u>.

1.222. **"SGEN Antibody Target-Dependent T Cell Activation"** is deemed to be achieved if the criteria described in Exhibit 1.222 have been met by the applicable Research Candidate.

1.223. **"SGEN Background Agreement**" means any agreement entered by SGEN, whether before or after the Effective Date, to in-license any Intellectual Property Rights necessary or useful for the Research, Development, Manufacturing, or Commercialization of the SGEN Building Block of any Compound.

1.224. **"SGEN Building Block**" means any Antibody Building Block Controlled by SGEN. For avoidance of doubt, any Antibody Building Block with the same SGEN Antibody Target shall be deemed to be the same SGEN Building Block under this Agreement.

1.225. **"SGEN Building Block IP**" means all Patent Rights and Know-How Controlled by SGEN as of the Effective Date and thereafter during the Term that Cover an Antibody Building Block individually, including all Intellectual Property Rights therein.

1.226. **"SGEN Compound Specific Patents**" has the meaning set forth in <u>Section 11.1.3.1</u>.

1.227. **"SGEN Indemnitees**" has the meaning set forth in <u>15.1</u>.

1.228. **"SGEN IP**" means any and all SGEN Patent Rights and SGEN Know-How, including any Intellectual Property Rights therein. For the avoidance of doubt, SGEN IP shall include SGEN Building Block IP.

1.229. **"SGEN Know-How**" means all Know-How that is Controlled by SGEN as of the Effective Date and thereafter during the Term other than pursuant to the licenses granted by PIRS under this Agreement and that (a) Covers the Research, Development, Manufacture, or Commercialization of the Compounds or (b) is reasonably necessary for the Research, Development, Manufacture, or Commercialization of the Compounds. SGEN Know-How shall include SGEN's interest in Joint Know-How.

1.230. **"SGEN Partner**" has the meaning set forth in <u>Section 9.3.1.</u>

33

1.231. **"SGEN Patent Rights**" means any Patent Rights that are Controlled by SGEN as of the Effective Date and thereafter during the Term, and that that (a) Cover the Research, Development, Manufacture, or Commercialization of the Compounds (including their composition, formulation, combination, product by process, or method of use, manufacture, preparation, or administration), or (b) are reasonably necessary for the Research, Development, Manufacture, or Commercialization of the Compounds pursuant to the terms of this Agreement. SGEN Patent Rights shall include SGEN's interest in Joint Patents that meet the above requirements. The SGEN Patent Rights existing as of the Effective Date (if any) are set forth in <u>Exhibit 1.231</u> and shall be updated from time to time.

1.232. **"SGEN Territory**" means (a) with respect to a CoDev Product, the entire world except for the United States of America, (b) with respect to an Exclusive Product, the entire world, and (c) with respect to a Research Candidate, the entire world.

1.233. "SGEN Territory Commercialization Plan" has the meaning set forth in <u>Section 6.4</u>.

1.234. **"Shared Costs**" means (a) Development Costs, (b) Commercial Manufacturing Costs, (c) Commercialization Expenses, and (d) any Third Party license payments in accordance with <u>Section 8.1.2.2(b)</u>; in each case for (a) through (d) as such costs are incurred by either Party or their Affiliates in connection with a Collaboration Product on or following the date that PIRS receives the Option Notice for such Collaboration Product in accordance with the applicable CoDev Product Plan and Joint Development Budget for such Collaboration Product, subject to [\*\*\*] as set forth in <u>Section 9.1.2</u>. For clarity, Shared Costs shall not include costs incurred by a Party in the performance of any Unsponsored Work.

1.235. "Shared Cost Report" has the meaning set forth in <u>Section 8.3.1</u>.

1.236. "Significant Study" has the meaning set forth in <u>Section 4.3.7</u>.

1.237. **"Subject Item**" has the meaning set forth in <u>Section 1.72</u>.

1.238. **"Sublicensee**" means a Third Party which is a licensee or sublicensee of the rights granted to SGEN or PIRS, as applicable, under this Agreement, in accordance with the terms and conditions of this Agreement. For sake of clarity, Sublicensees do not include (a) wholesalers, Distributors or similar entities performing similar functions, even if such Third Party is granted a limited right to promote and resell a Collaboration Product sold to it and (b) Affiliates of the Party that has been granted the license (i.e., SGEN or PIRS, as applicable). For avoidance of doubt, neither Party shall be permitted to sublicense their rights under this Agreement with respect to a Compound until after achievement of the [\*\*\*] with respect to such Compound.

34

1.239. "Sublicensing Income" means all consideration and payments, including without limitation, [\*\*\*]. Notwithstanding the foregoing, Sublicensing Income shall not include amounts such Party receives from a Third Party for the purchase of an equity interest in such Party generally (for clarity, an equity investment that is not solely related to a Compound(s)), [\*\*\*]. For avoidance of doubt, Sublicensing Income shall also include the [\*\*\*]. For the purposes of this <u>Section 1.239</u>, "[\*\*\*]" means the [\*\*\*].

1.240. "Supplied Party" has the meaning set forth in Section 5.3.2.1.

1.241. "Supply Agreement" means a Party Supply Agreement or a CMO Supply Agreement.

1.242. "Support Memorandum" has the meaning set forth in <u>Section 17.2.2.2</u>.

1.243. **"Target**" means the biological target of a pharmacologically active drug compound.

1.244. "**Term**" has the meaning set forth in <u>Section 16.1</u>.

1.245. **"Territory**" means either the SGEN Territory or the PIRS Territory, as applicable given the context of the use of the term.

1.246. **"Therapeutically Relevant**" means that the modulation of a given Target is reasonably believed to be responsible, in whole or in part, for a specific aspect of the safety or efficacy of such product and would not, for example, include modulation of a given Target solely to achieve or improve a pharmacokinetic attribute, such as [\*\*\*]. **"Third Approved SGEN Antibody Target**" has the meaning set forth in <u>Section 4.1.1.3</u>.

1.247. "Third Party" means any person or entity other than PIRS, SGEN, and their respective Affiliates.

1.248. "Third Party Claim" has the meaning set forth in <u>Section 15.1</u>.

1.249. **"Third Party License**" has the meaning set forth in <u>Section 8.1.2</u>.

1.250. **"Trademarks**" means all trademarks, service marks, trade names, rights in trade dress, logos, symbols, brand names and all trademark rights and interests throughout the world, and all right, title and interest in related applications and registrations throughout the world under common law, state law, federal law, or laws of foreign countries.

1.251. **"Transferring Party**" has the meaning set forth in <u>Section 2.5.2</u>.

1.252. "Unsponsored Work" has the meaning set forth in <u>Section 4.4.3.6(a)</u>.

36

1.253. "Valid Claim" means (a) a claim of an issued and unexpired Patent Right, which claim has not been revoked or held invalid or unenforceable by a final court without the possibility of appeal or other government agency of competent jurisdiction by a final determination without the possibility of appeal or has not been held (through a final determination without the possibility of appeal) or admitted to be invalid or unenforceable through re-examination or disclaimer, reissue, opposition procedure, nullity suit or otherwise by a final determination without the possibility of appeal or (b) a claim of a pending Patent Right application that has not been abandoned, finally rejected or expired without the possibility of appeal or refiling; provided, however, that Valid Claim will exclude any such pending claim in an application that has not been granted within [\*\*\*] years following the earliest priority filing date for such application, excluding, however, any pending Patent Right that does not have a reasonable bona fide basis for patentability (such reasonable bona fide basis to be determined by an outside counsel selected in good faith by the Parties, in the event that the Parties disagree as to whether there is a reasonable bona fide basis for patentability for such a claim). For purposes of the definition of Valid Claim, "determination" means a determination with respect to a Patent Right that would prevent a Party from enforcing or continuing to enforce such Patent Right. To the extent that any Patent Right is issued, restored, or otherwise deemed valid and enforceable, then it once again shall be considered a Valid Claim as from the date of such issuance, restoration, or determination.

1.254. "Withholding Taxes" has the meaning set forth in <u>Section 8.4.3</u>.

1.255. "Working Group" has the meaning set forth in <u>Section 3.9</u>.

# 2. License Grants

2.1. <u>Collaboration Product Licenses</u>. Subject to the terms and conditions set forth in this Agreement, on a Collaboration Product-by-Collaboration Product basis (unless and until PIRS exercises a PIRS CoDev Option for such Collaboration Product pursuant to <u>Section 4.4.2</u>, in which case such Collaboration Product would become a CoDev Product), PIRS hereby grants to SGEN an exclusive (even as to PIRS) sublicensable (subject to <u>Section 2.4</u>), non-transferable (except as set forth in <u>Section 17.4</u>), right and license under the PIRS IP to Develop, Manufacture, have Manufactured, and Commercialize such Collaboration Product in the Territory and in the Field. For clarity, the license grant to SGEN under this <u>Section 2.1</u> with respect to any PIRS Building Block IP within the PIRS IP is exclusive solely with respect to the applicable Collaboration Product, and no other right or license is granted to SGEN under such PIRS Building Block IP (e.g., to develop and commercialize the applicable PIRS Building Block as a standalone product or as a component of an unrelated product).

2.2. <u>Research Candidate Research Licenses</u>.

37

2.2.1. <u>License Grant to SGEN</u>. Subject to the terms and conditions set forth in this Agreement, on an Research Candidate-by-Research Candidate basis, during the Research Term for such Research Candidate, PIRS hereby grants to SGEN a co-exclusive (with PIRS), non-sublicensable, non-transferable (except as set forth in <u>Section 17.4</u>), right and license under the PIRS IP for the Research and Manufacturing activities in relation to such Research Candidate Plan in the Field and anywhere in the Territory. For clarity, the license grant to SGEN under this <u>Section 2.2.1</u> with respect to any PIRS Building Block IP within the PIRS IP is co-exclusive (with PIRS) solely with respect to the applicable Research Candidate, and no other right or license is granted to SGEN under such PIRS Building Block IP (e.g., to develop and commercialize the applicable PIRS Building Block as a standalone product or as a component of an unrelated product).

2.2.2. <u>License Grant to PIRS</u>. Subject to the terms and conditions set forth in this Agreement, on an Research Candidate-by-Research Candidate basis, during the Research Term for such Research Candidate, SGEN hereby grants to PIRS a co-exclusive (with SGEN), non-sublicensable, non-transferable (except as set forth in <u>Section 17.4</u>), right and license under the SGEN IP for the Research and Manufacturing activities in relation to such Research Candidate Plan in the Field and anywhere in the Territory. For clarity, the license grant to PIRS under this <u>Section 2.2.2</u> with respect to any SGEN Building Block IP within the SGEN IP is co-exclusive (with SGEN) solely with respect to the applicable Research Candidate, and no other right or license is granted to PIRS under such SGEN Building Block IP (e.g., to develop and commercialize the applicable SGEN Building Block as a standalone product or as a component of an unrelated product).

#### 2.3. <u>CoDev Product Licenses</u>.

2.3.1. License Grant to SGEN. Subject to the terms and conditions of this Agreement, PIRS hereby grants to SGEN, commencing on the PIRS CoDev Option Exercise Effective Date, a co-exclusive (with PIRS), sublicensable (subject to Section 2.4 below), non-transferable (except as set forth in Section 17.4), right and license under the PIRS IP to Develop (subject to Section 4), Manufacture and have Manufactured (subject to Section 5) and Commercialize (subject to Section 6) a CoDev Product in the Field and anywhere in the world. For clarity, the license grant to SGEN under this Section 2.3.1 with respect to any PIRS Building Block IP within the PIRS IP is co-exclusive (with PIRS) solely with respect to the applicable CoDev Product, and no other right or license is granted to SGEN under such PIRS Building Block IP (e.g., to develop and

38

commercialize the applicable PIRS Building Block as a standalone product or as a component of an unrelated product). For avoidance of doubt, upon PIRS CoDev Option Exercise Effective Date the applicable Collaboration Product shall be considered a CoDev Product and the exclusive license under <u>Section 2.1</u> with respect to such CoDev Product shall terminate.

2.3.2. <u>License Grant to PIRS</u>. Subject to the terms and conditions of this Agreement, SGEN hereby grants to PIRS, commencing on PIRS CoDev Option Exercise Effective Date, a co-exclusive (with SGEN), sublicensable (subject to <u>Section 2.4</u> below), non-transferable (except as set forth in <u>Section 17.4</u>), right and license under the SGEN IP to Develop (subject to <u>Section 4</u>), Manufacture and have Manufactured (subject to <u>Section 5</u>) and Commercialize (subject to <u>Section 6</u>) a CoDev Product in the Field and anywhere in the world. For clarity, the license grant to PIRS under this <u>Section 2.3.2</u> with respect to any SGEN Building Block IP within the SGEN IP is co-exclusive (with SGEN) solely with respect to the applicable CoDev Product, and no other right or license is granted to PIRS under such SGEN Building Block IP (e.g., to develop and commercialize the applicable SGEN Building Block as a standalone product or as a component of an unrelated product). For avoidance of doubt, upon PIRS CoDev Option Exercise Effective Date the applicable Collaboration Product shall be considered a CoDev Product and the exclusive license under <u>Section 2.1</u> with respect to such CoDev Product shall terminate.

2.4. <u>Sublicense Rights</u>. SGEN or PIRS may sublicense (through multiple tiers) all or part of the rights and licenses granted to them under this <u>Section 2</u> to a Third Party solely in accordance with the terms set forth in <u>Section 9</u>.

2.5. Know-How Transfer & Information Sharing.

2.5.1. <u>Electronic Data Exchange</u>. Promptly following the Effective Date, the Parties will establish a secure electronic data exchange system through which the Parties may share Know-How to be exchanged by the Parties under this Agreement, including the Know-How transfer obligations of this <u>Section 2.5</u>.

2.5.2. <u>Research Term</u>. Within [\*\*\*] days following the Effective Date (and for SGEN, within [\*\*\*] days of approval of an SGEN Antibody Target under <u>Section 4.1.1</u>) or any other schedule unanimously agreed upon by the Parties in a Research Candidate Plan, [\*\*\*] that [\*\*\*] or [\*\*\*] a [\*\*\*] been [\*\*\*]. For avoidance of doubt and subject to <u>Section 2.6</u> below [\*\*\*] <u>Section 2.5.2</u>, [\*\*\*].

2.5.3. <u>Ongoing Transfer & Information Sharing</u>.

2.5.3.1. <u>Research Candidates</u>. With respect to each Research Candidate, during the Research Term with respect to such Research Candidate, the Transferring Party shall promptly [\*\*\*] to the [\*\*\*] that is [\*\*\*].

39

2.5.3.2. <u>Potential CoDev Products</u>. With respect to each Potential CoDev Product, SGEN will provide PIRS with Development Plan Overviews as set forth in <u>Section 3.3.1</u>, and [\*\*\*], CMC [\*\*\*]. In addition, at least [\*\*\*] months in advance (as determined by SGEN in good faith) of [\*\*\*] for a [\*\*\*], SGEN shall provide a [\*\*\*] of all Reimbursable [\*\*\*] to date and an [\*\*\*] of future Reimbursable [\*\*\*] through the estimated PIRS CoDev Option Exercise Effective Date for such Potential CoDev Product.

2.5.3.3. <u>CoDev Products</u>. With respect to each CoDev Product, to the extent not already provided, a Party shall make available to the other Party as soon as practicable all material Know-How (or, at the request of the other Party, any other Know-How) Controlled by such Party at the time of the PIRS CoDev Option Exercise Effective Date and that comes into existence from time to time thereafter that is relevant to the continued Development, Manufacturing or Commercialization of the CoDev Product, including Know-How generated pursuant to the applicable CoDev Product Plan or under any Unsponsored Work in accordance with <u>Section 4.4.3</u>.

# 2.6. <u>CoDev Product Rights of Reference; Use of Data</u>.

2.6.1. Where applicable, each Party (the "**Beneficiary**") shall have the right to cross-reference, file or incorporate by reference in its respective Territory any Regulatory Materials (and any Data contained therein) filed or owned by the other Party or its Sublicensees (the "**Filing Party**") for a CoDev Product, for use by the Beneficiary (and its Affiliates and Sublicensees) solely in connection therewith. The Filing Party shall, on written request by the Beneficiary, provide to the Beneficiary, and to any specified Competent Authority, a letter, in the form reasonably required by the Beneficiary, acknowledging that the Beneficiary (and its Affiliates and Sublicensees) has the above rights with respect to any such Regulatory Materials.

2.6.2. The Filing Party will provide, and cause its Affiliates and Sublicensees to provide, reasonable cooperation to the Beneficiary to affect the foregoing rights (including permitting the Beneficiary (and its Affiliates' and Sublicensees') and/or any relevant Competent Authority to inspect any such Regulatory Materials upon reasonable notice).

2.6.3. In the event that the Regulatory Materials to be cross-referenced, filed, or incorporated by reference include any DMF of a Third Party manufacturer, such rights of cross-reference, filing or incorporation by reference shall be subject to such obligations and restrictions as the Filing Party may have to such Third Party manufacturer with respect to the use or disclosure of its DMF.

#### *40*

2.6.4. The Beneficiary shall have the right to request primary source data ("**Raw Data**") for any Data intended for submission by the Beneficiary (or its Affiliates and Sublicensees) to the Competent Authorities or to request that the Filing Party make such Raw Data available for inspection by any applicable Competent Authorities, such right to be exercised in good faith but at the Beneficiary's (or its Affiliates' and Sublicensees') sole discretion. The Filing Party agrees to conduct appropriate quality control and verification procedures and such other processes as may be required to confirm that the Data accurately describes the experimental methods and results of any study. Such quality control and verification procedures shall include verification against Raw Data to ensure that supporting statements and conclusions embodied in any documents submitted by the Beneficiary (and its Affiliates and Sublicensees) to the Competent Authorities are accurately represented. The Filing Party will ensure that quality control and verification procedures are conducted by individuals and entities with the appropriate technical expertise and experience, and that quality control and verification procedures are documented appropriately in compliance with the industry standard operating procedures and all applicable laws and regulations.

2.6.5. <u>Other</u>. Subject to the terms and conditions of this Agreement, including the non-compete provisions of <u>Section 10</u>, either Party may use any Data generated pursuant to this Agreement to research products that are not Compounds.

2.6.6. <u>Disclaimer</u>. Other than as expressly set forth in this Agreement, any Data disclosed or materials (other than pursuant to a Party Supply Agreement) provided by a Party to the other Party under this Agreement is provided on an "as is" basis, without any warranty (express or implied) of any kind, and the disclosing Party expressly disclaims all such warranties to the maximum extent permitted under applicable Law. The Beneficiary on behalf of itself and its Affiliates and Sublicensees accepts all risk and liability in relation to the use of the Data or materials received from the Filing Party under this Agreement. For avoidance of doubt, this <u>Section 2.6.6</u> does not limit either Party's rights with respect to the other Party's breach of this Agreement.

2.7. <u>Building Block Right of IND Reference</u>. To the extent that a Party has filed and Controls an IND/IMPD for a product (including any Collaboration Product) that includes a Party's Building Block (such product the "**Reference Product**", and such Party the "**IND Filing Party**"), then, upon the written request of the other Party (the "**IND Beneficiary**"), such Party shall provide a copy of such IND/IMPD to the IND Beneficiary, provided, however, that such written request can only be made within [\*\*\*] months of the IND Beneficiary's good faith anticipated [\*\*\*] for the product (including any Collaboration Product) that includes the same Building Block as the Reference Product. In addition, upon written request of the IND Beneficiary, the IND Filing Party

41

shall take all actions necessary to permit the IND Beneficiary to cross-reference such IND/IMPD (in its entirety) in its own Regulatory Materials (including any IND) for a product (including any Collaboration Product) that includes the same Building Block as the Reference Product.

#### 3. Governance & Committees

3.1. <u>Joint Steering Committee</u>. Within [\*\*\*] days after the Effective Date, the Parties shall establish a joint steering committee (the "**Joint Steering Committee**" or "**JSC**").

3.1.1.1. The JSC will assume a general role of leadership in the collaboration, to oversee the other Committees and guide the implementation of the strategic objectives of the collaboration and will be responsible for:

3.1.1.1. reviewing and approving a CoDev Product Plan and Joint Development Budget for each CoDev Product and any annual or interim updates and proposed amendments thereto;

3.1.1.2. attempting to resolve issues presented to it in accordance with <u>Section 3.6.2;</u>

3.1.1.3. establishing, as appropriate, any additional sub-committees and Working Groups (subject to Section 3.9); and

3.1.1.4. making such other determinations as are expressly delegated to it under the terms of this Agreement.

3.1.2. Unless otherwise agreed upon between the Parties, the JSC shall be comprised of an equal number of representatives from each of SGEN and PIRS, which unless otherwise agreed upon between the Parties, shall be comprised of [\*\*\*] members of each Party. Decision-making by the JSC shall be as set forth in Section 3.6.2.1.

3.1.3. The JSC will meet at least [\*\*\*] times each Calendar Year (or more if agreed upon) and all meetings of the JSC shall be virtual unless the Parties agree otherwise.

3.2. <u>Joint Research Committee</u>. Within [\*\*\*] days after the Effective Date until [\*\*\*], the Parties shall establish a joint research committee for all Research Candidates (the "**Joint Research Committee**" or "**JRC**").

3.2.1. The JRC will be responsible for:

3.2.1.1. preparing and approving each Research Candidate Plan (including work splits and budget) and any updates and proposed amendments thereto;

3.2.1.2. initiating, implementing, and overseeing the conduct of any Research Candidate Plan;

42

3.2.1.3. reviewing, resolving, and approving any matters or disputes related to the Research of any Research Candidate prior to [\*\*\*];

3.2.1.4. establishing a core joint research team to ensure work under each Research Candidate Plan is executed efficiently;

3.2.1.5. discussing and exchanging relevant Research Data for the Research Candidates in accordance with <u>Section 2.5.3.1</u>; and

3.2.1.6. making such determinations as are expressly delegated to it under the terms of this Agreement.

3.2.2. Unless otherwise agreed upon between the Parties, the JRC shall be comprised of an equal number of representatives from each of SGEN and PIRS, which unless otherwise agreed upon between the Parties, shall be comprised of [\*\*\*] members of each Party.

3.2.3. The JRC will meet [\*\*\*] times per Calendar Year during the Research Term (or as often as otherwise agreed upon), and all meetings of the JRC shall be virtual unless the Parties agree otherwise.

3.2.4. Decision-making by the JRC shall be as set forth in <u>Section 3.6.2</u>.

3.3. <u>Joint Development Committee</u>. Within [\*\*\*] days of the [\*\*\*] for a Research Candidate, the Parties shall establish a joint development committee for all Potential CoDev Products (the "**Joint Development Committee**" or "**JDC**").

3.3.1. <u>Potential CoDev Products</u>. For so long as there is no CoDev Product, unless otherwise agreed upon between the Parties, the JDC shall be comprised of an equal number of representatives from each of SGEN and PIRS, which unless otherwise agreed upon between the Parties, shall be comprised of [\*\*\*] members of each Party. The JDC for all Potential CoDev Products will meet at least [\*\*\*] times per year (or more if agreed upon in good faith if needed, for example, in the case of [\*\*\*] during which time the [\*\*\*]. Furthermore, the [\*\*\*]:

3.3.1.1. [\*\*\*]; and

3.3.1.2. [\*\*\*];

For the purposes of this <u>Section 3.3.1</u>, [\*\*\*] which shall consist of [\*\*\*]. For the avoidance of doubt, [\*\*\*].

3.3.2. <u>CoDev Product JDC</u>. After PIRS has exercised a PIRS CoDev Option for a Potential CoDev Product, the JDC will be reorganized to focus on the CoDev Product (and any additional Co-Dev Products pursuant to Section 4.3.6.2) within [\*\*\*] days. After such reorganization, the JDC will meet at least [\*\*\*] times per Calendar Year during the Term (or more if agreed upon), with the Co-Chairs

43

attending in person at least [\*\*\*] per Calendar Year. Unless otherwise agreed upon between the Parties, the reorganized JDC shall be comprised of an equal number of representatives from each of SGEN and PIRS, which unless otherwise agreed upon between the Parties, shall be comprised of [\*\*\*] members of each Party. The CoDev Product JDC will be responsible for:

3.3.2.1. receiving and discussing updates for Potential CoDev Products in accordance with <u>Section 3.3.1</u>;

3.3.2.2. reviewing and discussing any material Data generated by either Party in the course of Researching and Developing any CoDev Product;

3.3.2.3. reviewing and discussing ongoing and anticipated Manufacturing activities with respect to each CoDev Product;

3.3.2.4. initiating, implementing and overseeing the conduct of each CoDev Product Plan;

3.3.2.5. conducting annual review of the CoDev Product Plan and related Joint Development Budget for the CoDev Product and prepare any annual or interim updates and proposed amendments thereto to be submitted to the JSC and in accordance with <u>Section 4.4.3.1</u>;

3.3.2.6. establishing a core joint development and regulatory team to ensure work under the CoDev Product Plan is executed efficiently;

3.3.2.7. reviewing any proposed Unsponsored Work;

3.3.2.8. coordinating the activities of the Parties under the CoDev Product Plan, including facilitating communications between the Parties with respect to the Development and Manufacture of a CoDev Product;

3.3.2.9. providing a forum for discussion of the Development, Manufacture, and regulatory strategies of the CoDev Product;

3.3.2.10. coordinating the sharing of data under <u>Section 2.5.3.3</u>;

3.3.2.11. preparing and approving a global medical affairs plan that addresses, for example, study recruitment, enhancement, and disease awareness, as well as corresponding medical affairs plans for each Party's respective Territory; and

3.3.2.12. making such determinations as are expressly delegated to it under the terms of this Agreement.

3.3.3. <u>Role of JDC for Potential CoDev Products</u>. For clarity, the [\*\*\*].

44

3.3.4. <u>Role of JDC for Exclusive Products</u>. For Exclusive Products that are no longer Potential CoDev Products, the JDC shall provide a forum for discussion of the annual reports provided by SGEN as set forth in <u>Section 3.7</u>. PIRS shall have the opportunity to ask questions related to such annual reports and SGEN will make good faith efforts to answer such questions. For the avoidance of doubt, the JDC shall have no decision-making authority for such Exclusive Products that are no longer Potential CoDev Products and SGEN shall have no obligation to consider or implement any comments and suggestions PIRS may have.

3.3.5. The votes of each Party's representatives to the JDC shall have equal weight. Decision-making by the JDC shall be as set forth in <u>Section 3.6.2</u>.

3.4. <u>Joint Intellectual Property Committee</u>. Within [\*\*\*] days after the Effective Date, the Parties shall establish a joint intellectual property committee (the "**Joint Intellectual Property Committee**" or "**JIPC**").

3.4.1. The JIPC will be responsible for:

3.4.1.1. Consistent with Section 11, overseeing all intellectual property related issues arising under this Agreement, including strategies for prosecution and maintenance of all Joint IP and CoDev Product Compound Specific Patents;

3.4.1.2. preparing reports and guidance related to such intellectual property issues; and

3.4.1.3. making such determinations as are expressly delegated to it under the terms of this Agreement.

3.4.2. Unless otherwise agreed upon between the Parties, the JIPC shall be comprised of [\*\*\*] member of each Party. All JIPC representatives will have appropriate expertise, seniority, decision-making authority, and ongoing familiarity with the subject matter of this Agreement and each Party's representatives collectively will have relevant expertise in intellectual property portfolio management. Decision-making by the JIPC shall be as set forth in <u>Section 3.6.2</u>.

3.4.3. The JIPC will meet at least [\*\*\*] each Calendar Year (or more if agreed upon), with the Co-Chairs (and optional the Alliance Managers) attending in person at least [\*\*\*] per Calendar Year.

45

3.5. Joint Commercialization Committee. The Parties shall establish a joint commercialization committee (the "Joint Commercialization Committee" or "JCC") at an appropriate time, reasonably in advance of the first potential Marketing Approval of a CoDev Product and reasonably in advance of the time required for the Global Commercialization Strategy to be prepared as set forth in <u>Section 6.1</u>.

3.5.1. If formed, the JCC will be charged solely with commercial governance of a CoDev Product, including:

3.5.1.1. receiving updates for a CoDev Product relative to the applicable Global Commercialization Agreement or Global Commercialization Strategy;

3.5.1.2. developing the Global Commercialization Strategy and the Global Branding Strategy for the CoDev Product and any annual or interim updates and proposed amendments thereto in accordance with <u>Section 6.3</u> and <u>Section 6.6</u>;

3.5.1.3. establishing a core joint commercialization team to ensure work under the Global Commercialization Agreement and Global Commercialization Strategy is executed efficiently;

3.5.1.4. reviewing the PIRS Territory Commercialization Plan and the SGEN Territory Commercialization Plan;

3.5.1.5. coordinating the activities of the Parties under the Global Commercialization Agreement and Global Commercialization Strategy, including facilitating communications between the Parties with respect to the Commercialization of a CoDev Product;

3.5.1.6. providing a forum for discussion of the Commercialization of the CoDev Product; and

3.5.1.7. making such determinations as are expressly delegated to it under the terms of this Agreement.

3.5.2. PIRS and SGEN shall have equal membership on the JCC and their votes shall have equal weight. Decision-making by the JCC shall be as set forth in <u>Section 3.6.2</u>.

# 3.6. Governance and Decision-Making.

3.6.1. General Rules.

3.6.1.1. <u>Committee Membership</u>. Each of the Joint Steering Committee, Joint Research Committee, Joint Development Committee, Joint Intellectual Property Committee, and Joint Commercialization Committee (each, a

46

"Committee") will have solely the roles and responsibilities assigned to it in this <u>Section 3</u> and as otherwise expressly set forth in this Agreement. Either Party may replace its respective Committee representatives at any time with prior written notice to the other Party. In the event a Committee member from either Party is unable to attend or participate in a Committee meeting, the Party who designated such representative may designate a substitute representative for the meeting in its sole discretion. The Alliance Managers (as defined below) appointed by SGEN and PIRS are ex-officio members of each of the Committees. For avoidance of doubt, the Alliance Manager may also be a member of one or more Committees and either Party may include the same individual on one or more Committees.

3.6.1.2. <u>Co-Chairs</u>. Each Party shall appoint one of its members in each Committee to co-chair such Committee's meetings (each, a "**Co-Chair**"). The Co-Chairs shall attend each Committee meeting (either in-person, by videoconference or telephonically, unless otherwise expressly provided herein). Unless otherwise agreed, the Co-Chairs shall have relevant decision-making authority from each Party such that the Committee is able to effectuate all of its decisions within the scope of its responsibilities. In the event the Co-Chair from either Party is unable to attend or participate in a Committee meeting, the Party who designated such Co-Chair may designate a substitute Co-Chair for the meeting in its sole discretion.

3.6.1.3. <u>Committee Meetings</u>. All Committee meetings may be conducted by telephone, videoconference or in person as determined by the Co-Chairs in consultation with the Alliance Managers. Each Party shall bear its own personnel and travel costs and expenses relating to Committee meetings. With the consent of the Parties (not to be withheld unreasonably), other employee representatives of the Parties may attend any Committee meeting as non-voting observers. Either Party may also call a special meeting of a Committee (by videoconference or teleconference) by at least [\*\*\*] Business Days prior written notice to the other Party in the event such Party reasonably believes that a significant matter must be addressed prior to the next regularly scheduled meeting, and no later than [\*\*\*] Business Days prior to the special meeting, such Party shall provide the Committee with materials reasonably adequate to enable an informed decision.

3.6.2. <u>Decision Making</u>. Other than as set forth herein, in order to make any decision required of it hereunder with respect to any approval, a Committee must have present (in person, by videoconference or telephonically) at least the Co-Chair of each Party (or his/her designee for such meeting). The Parties will endeavor to make decisions where required with respect to any approval of a Committee by consensus of the Co-Chairs. Notwithstanding the foregoing:

3.6.2.1. JSC. The JSC shall attempt in good faith to resolve any dispute or failure to agree (including those escalated from the JRC, JDC, JCC or JIPC) by unanimous consent (with the Co-Chairs having each one vote). If the JSC cannot resolve such dispute or failure to agree within [\*\*\*] days of the matter being referred to it, then SGEN shall have final decision-making authority on all matters except that any decision that relates to a CoDev Product after PIRS has exercised a PIRS CoDev Option or any matter that falls within the purview of the JIPC shall be escalated to the Senior Executives followed by accelerated dispute resolution pursuant to <u>Section 17.2.2</u>.

3.6.2.2. Notwithstanding the foregoing, PIRS shall have final decision-making authority with respect to deployment of its internal resources and FTEs under any Research Candidate Plan, provided, however, that PIRS shall have the obligation to make available the internal resources and FTEs set forth in the Research Candidate Plan for the First Approved SGEN Antibody Target attached hereto as <u>Exhibit 4.1.2</u> as well as a similar level of resources and internal FTEs for each of the [\*\*\*]. Further notwithstanding, the Parties shall mutually agree the criteria for [\*\*\*].

3.6.2.3. For the avoidance of doubt, for a CoDev Product, neither Party shall be required to commit resources or funds towards Clinical Studies that it has not agreed to include in a CoDev Product Plan. If a Party desires to conduct additional Clinical Study(ies) (beyond what the Parties jointly agree), then it may do so at its own expense in accordance with <u>Section 4.4.3.5</u> and <u>Section 4.4.3.6</u>.

3.6.2.4. <u>JRC</u>. Decisions by the JRC shall be by consensus, and any disputes shall be escalated to the JSC;

3.6.2.5. <u>JDC</u>. Decisions by the JDC shall be by consensus, provided that (i) any concerns of PIRS related to SGEN's Development of a Potential CoDev Product shall be escalated to the JSC for final determination (i.e., no further escalation), and (ii) any disputes related to a CoDev Product shall be escalated to the JSC;

3.6.2.6. <u>JIPC</u>. Decisions by the JIPC shall be by consensus, and any disputes shall be escalated to the JSC; and

3.6.2.7. <u>JCC</u>. Decisions by the JCC shall be by consensus, and any disputes shall be escalated to the JSC, except that each Party shall have final decision-making authority on decisions specific to territories where such Party is leading Commercialization of a CoDev Product, subject to compliance with the Global Commercialization Strategy and Global Commercialization Agreement;

3.6.3. Notwithstanding the foregoing, day-to-day operational level decisions concerning tasks or activities shall be made by the Party to which responsibility for such task or activity has been allocated under this Agreement; *provided that* such decisions are not inconsistent with the Research Candidate Plan, Co-Dev Product Plan, Global Commercialization Strategy, PIRS Territory commercialization Plan or SGEN Territory Commercialization Plan, as applicable, or the express terms and conditions of this Agreement.

3.7. Exclusive Products. The governance structure set forth in this Section 3 shall not apply to an Exclusive Product (except that the JDC shall provide a forum for discussion pursuant to Section 3.3.1 and Section 3.3.2.1 for Potential CoDev Products and pursuant to Section 3.3.4 for Exclusive Products that are no longer Potential CoDev Products), and SGEN shall have sole responsibility and decision making authority for the Research, Development, Manufacturing, and Commercialization of such Exclusive Product. Subject to the foregoing, SGEN shall provide PIRS a written annual report (in a format to be selected by SGEN) no later than [\*\*\*] days following the end of every Calendar Year summarizing SGEN's Research, Development, Manufacturing, and Commercialization activities for Exclusive Products that are no longer Potential CoDev Products, including general timelines with regard to anticipated milestones intended to be achieved within [\*\*\*] months following such report (to the extent SGEN has such visibility). For each such applicable Exclusive Product, such report shall include information (except for SGEN [\*\*\*]) on:

3.7.1. Clinical Studies (including development phase, Indications, anticipated size and duration, primary endpoints, and top-line results, as available and applicable) that (a) have been conducted in the prior [\*\*\*] months or (b) are intended to be conducted or Initiated in the next [\*\*\*] months;

3.7.2. anticipated launch dates by country;

3.7.3. in the event of [\*\*\*] successive Calendar Quarters of [\*\*\*] of such Exclusive Product, [\*\*\*] of promotional efforts that have been spent in the prior [\*\*\*] months; and

3.7.4. activities and plans (if any) for such Exclusive Product in [\*\*\*].

3.8. For the avoidance of doubt, failure to meet the projected timelines for Clinical Studies and anticipated launch dates described in <u>Section 3.7.1</u> and <u>Section 3.7.2</u> above shall not, taken alone, constitute a failure by SGEN to exercise Commercially Reasonable Efforts in the Development and Commercialization of such Exclusive Products.

49

3.9. <u>Working Groups</u>. From time to time, a Committee may establish and delegate duties to sub-committees or teams (each, a "**Working Group**") to oversee projects or activities within their respective authority. Each Working Group and its activities shall be subject to the oversight, review, and approval of, and shall report to, the Committee that established such Working Group. In no event shall the authority of any Working Group exceed that specified for the Committee under which such Working Group is established.

3.10. <u>Alliance Managers</u>. Within [\*\*\*] days following the Effective Date, each Party shall appoint an individual to act as alliance manager for such Party (each, an "**Alliance Manager**"). Each Alliance Manager shall be a representative of the applicable Party in connection with this Agreement. The Alliance Managers shall (a) coordinate all contacts between the Parties regarding the activities contemplated by this Agreement, (b) facilitate all such activities hereunder, (c) be responsible for progressing the alliance activities, (d) ensure the orderly conduct of Committee meetings, (e) prepare and issue written minutes of each Committee meeting within [\*\*\*] days thereafter accurately reflecting the discussions and decisions of such Committee meeting, and (f) otherwise facilitate communication and be the first line of dispute resolution between the Parties. The Alliance Manager shall have the right to attend all Committee meetings and shall be responsible for assisting the Co-Chair in performing its oversight responsibilities. The name and contact information for each Party's Alliance Manager, as well as any replacement(s) chosen by such Party, in its sole discretion, from time to time shall be provided to the other Party. Each Party shall provide its Alliance Manager with sufficient resources for the Alliance Manager to perform his or her role under this Agreement.

3.11. <u>Scope of Governance</u>. Notwithstanding the creation of the Committees, each Party shall retain the rights, powers and discretion granted to it hereunder, and no Committee shall be delegated or vested with rights, powers, or discretion unless such delegation or vesting is expressly provided herein, or the Parties expressly so agree in writing. No Committee shall have the power to amend or modify this Agreement, and no decision of any Committee shall be in contravention of any terms and conditions of this Agreement. The Alliance Managers shall not have any rights, powers or discretion except as expressly granted to the Alliance Managers hereunder, and in no event shall the Alliance Managers have any right or power to modify or amend this Agreement. It is understood and agreed that issues to be formally decided by any of the Committees are only those specific issues that are expressly provided in this Agreement to be decided by such Committee.

# 4. Research & Development

4.1. <u>Research</u>. On a Research Candidate-by-Research Candidate basis, during the Research Term, the Parties shall jointly collaborate to generate, evaluate and Research such Research Candidate (individually and collectively, the "**Research Collaboration**").

50

There will be up to [\*\*\*] Research Candidates under this Agreement, [\*\*\*] for each SGEN Building Block.

4.1.1. SGEN Antibody Target Nomination, Gatekeeping, and Target Swap.

4.1.1.1. <u>Research Candidate Target Combinations</u>. There will be up to [\*\*\*]. There will be [\*\*\*] SGEN Antibody Targets, not counting potential substitutions of Approved SGEN Antibody Targets in accordance with <u>Section 4.1.1.4</u>. All SGEN Antibody Targets shall be [\*\*\*].

4.1.1.2. <u>First SGEN Antibody Target</u>. The first SGEN Antibody Target has been defined and is listed in <u>Exhibit 4.1.1.2</u> (the "**First Approved SGEN Antibody Target**").

4.1.1.3. <u>Second and Third SGEN Antibody Targets</u>. SGEN shall nominate the second and third SGEN Antibody Targets (provided, that SGEN shall be obligated to nominate the [\*\*\*] but shall not be obligated to nominate the [\*\*\*]) within [\*\*\*] months of the date that SGEN receives the [\*\*\*] of each of the Research Candidates for the First Approved SGEN Antibody Target, or such other time period as unanimously decided by the JRC, in each case in accordance with the Target gatekeeping procedure as set forth in <u>Section 4.1.1.5</u>. The second SGEN Antibody Target clearing such procedures shall be the "Second Approved SGEN Antibody Target " and shall be added to <u>Exhibit 4.1.1.3(a)</u>. The third SGEN Antibody Target clearing such procedures shall be the "Third Approved SGEN Antibody Target" and shall be added to <u>Exhibit 4.1.1.3 (b)</u>.

4.1.1.4. <u>Target Swap</u>.

(a) SGEN shall have the right, [\*\*\*], to [\*\*\*] the [\*\*\*] with a [\*\*\*] time during the first [\*\*\*] months of the applicable Research Term of the [\*\*\*] Research Candidates that include such First Approved SGEN Antibody, but only if [\*\*\*] can be demonstrated for the Research Candidate that includes the [\*\*\*]. SGEN shall have the right, [\*\*\*], to [\*\*\*] time during the first [\*\*\*] months of the applicable Research Term of the [\*\*\*] Research Candidates that include such Second Approved SGEN Antibody Target, [\*\*\*]. Any Target swap under this <u>Section 4.1.1.4</u> shall be subject to the Target gatekeeping procedure as set forth in <u>Section 4.1.1.5</u>. Upon a successful swap, the replacement SGEN Antibody Target or the Second Approved SGEN Antibody Target or the Second Approved SGEN Antibody Target or the Second Approved SGEN Antibody Target swap, (i) SGEN shall immediately [\*\*\*].

51

(b) The Target swaps as set forth in <u>Section 4.1.1.4(a)</u> are individually or collectively referred to as an "Allowed Target Swap".

# 4.1.1.5. <u>Target Gatekeeping Procedure</u>.

(a) The Parties shall enter into a tri-party agreement with the Gatekeeper within [\*\*\*] days of [\*\*\*], such triparty agreement to contain appropriate confidentiality provisions. The Gatekeeper's identity and contact information is set forth in Exhibit 4.1.1.5(a). Such tri-party agreement shall be in place [\*\*\*].

(b) SGEN shall submit its nomination for the second and any nomination for the third SGEN Antibody Target and for any Allowed Target Swap to the Gatekeeper in writing during the timeframes set forth in in <u>Section 4.1.1.3</u>, <u>4.1.1.4(a)</u> or <u>Section 4.1.1.5</u>, as applicable. [\*\*\*] pursuant to this <u>Section 4.1.1.5</u>, SGEN may submit up to [\*\*\*]. The Gatekeeper shall, within [\*\*\*] Business Days, provide SGEN and PIRS the [\*\*\*] of proposed SGEN Antibody Targets that are [\*\*\*] in the Research Collaboration (i.e., the [\*\*\*] of such proposed Antibody Targets that do not appear on the Restricted Research Candidate Target List). SGEN may [\*\*\*] up to [\*\*\*] proposed SGEN Antibody Targets [\*\*\*], provided that if the Gatekeeper reports that [\*\*\*] of the proposed SGEN Antibody Targets are free for use in the Research Collaboration, then SGEN may submit up to [\*\*\*] additional proposed SGEN Antibody Targets to the Gatekeeper for [\*\*\*] as set forth herein. Furthermore, if there is at least [\*\*\*] proposed SGEN Antibody Target free for use in the Research Collaboration, then SGEN Antibody Target free for use in the Research Collaboration [\*\*\*] proposed SGEN Antibody Target free for use in the Research Collaboration, then SGEN Antibody Target free for use in the Research Collaboration, then SGEN Antibody Target free for use in the Research Collaboration, then SGEN Antibody Target free for use in the Research Collaboration, then SGEN Antibody Target free for use in the Research Collaboration, then SGEN Antibody Target free for use in the Research Collaboration, then SGEN Antibody Target free for use in the Research Collaboration such list of [\*\*\*] proposed SGEN Antibody Targets until one of them gets approved by the Gatekeeper.

(c) The Gatekeeper shall, within [\*\*\*] Business Days, notify SGEN whether such nominated SGEN Antibody Target is free for use in the Research Collaboration (i.e., such SGEN Antibody Target does not appear on the Restricted Research Candidate Target List), in which case it would become the First Approved Antibody Target, Second Approved SGEN Antibody Target or the Third Approved SGEN Antibody Target, as applicable, as of the date of such notice. If the Target is free for use, the Gatekeeper shall also inform PIRS within such [\*\*\*] Business Day period.

(d) If the Gatekeeper declined a nominated SGEN Antibody Target because such Target appears on the Restricted Research Candidate Target Combination List, then SGEN may decide

to (a) disclose such nominated SGEN Antibody Target to PIRS and discuss with PIRS in good faith whether and under what terms such nominated SGEN Antibody Target could be included in the Collaboration, or (b) nominate an alternative SGEN Antibody Target (provided, that SGEN shall be obligated to nominate an alternative for the [\*\*\*] but shall not be obligated to nominate an alternative for the [\*\*\*] SGEN Antibody Target) within [\*\*\*] days of notification by the Gatekeeper with the process set forth in this <u>Section 4.1.1.5</u> repeating.

# 4.1.2. <u>Research Candidate Plan</u>.

4.1.2.1. <u>Research Candidate Plan</u>. The Parties shall establish a Research plan for the [\*\*\*] Research Candidates associated with a particular SGEN Antibody Target, which may be supplemented and amended from time to time by the Joint Research Committee, as described in <u>Section 3.1</u> (each, a "**Research Candidate Plan**"). Each Research Candidate Plan shall include a workplan and budget for the activities to be conducted by each Party for the Research Candidates during the applicable Research Term. The Parties shall endeavor to ensure that each Research Candidate Plan is at all times be in compliance with all applicable Laws and in accordance with professional and ethical standards customary in the biopharmaceutical industry.

4.1.2.2. <u>First Approved SGEN Antibody Target Research Candidate Plan</u>. The initial Research Candidate Plan for the Research Candidates that include the First Approved SGEN Antibody Target is attached hereto as <u>Exhibit 4.1.2</u>. In the event of an Approved Target Swap, a new Research Candidate Plan for the new First Approved SGEN Antibody Target shall be prepared within [\*\*\*] days of notification by the Gatekeeper of availability of a nominated SGEN Antibody Target for use in the Research Collaboration.

4.1.2.3. <u>Second and Third Approved SGEN Antibody Target Research Candidate Plan</u>. The Parties shall, within [\*\*\*] days of notification by the Gatekeeper of the availability of a nominated SGEN Antibody Target for use in the Collaboration, prepare an initial Research Candidate Plan for the Second and Third Approved SGEN Antibody Target, as applicable, each of which shall be attached hereto as <u>Exhibit 4.1.2.3(a)</u> and <u>Exhibit 4.1.2.3(b)</u>, respectively. The Parties shall discuss and agree in good faith the dates on which the work under each Research Candidate Plan will commence, taking into account resource availabilities of each Party, provided, however, that (i) work under the Research Candidate Plan for the Second Approved SGEN Antibody Target shall begin no later than [\*\*\*] days of availability of such Research Candidate Plan, and (ii) neither Party shall be obligated to commit

53

resources to work under the Research Candidate Plan for the Third Approved SGEN Antibody Target until [\*\*\*] months after work under the Research Candidate Plan for the Second Approved Antibody Target has been started (but each Party shall use Commercially Reasonable efforts to initiate work under such Research Candidate Plan as soon as feasible). In the event of an Approved Target Swap, a new Research Candidate Plan for the new Approved SGEN Antibody Target shall be prepared within [\*\*\*] days of notification by the Gatekeeper of availability of a nominated SGEN Antibody Target for use in the Research Collaboration.

## 4.1.3. <u>Research Term Collaboration Obligations</u>.

4.1.3.1. Each Party shall provide to the other written reports regarding the progress and results of their activities under the Research Candidate Plan through the JRC. Each Party shall (and shall cause its Affiliates, subcontractors and consultants to) maintain complete and accurate records (in the form of technical notebooks and/or electronic files where appropriate) of all work conducted by it or on its behalf (including by its Affiliates, subcontractors, and consultants) under the Research Candidate Plan. Such records, including any electronic files, shall fully and properly reflect all work done and results achieved in sufficient detail and in a good scientific manner appropriate for patent and regulatory purposes. To the extent not already provided via the JRC, each Party shall have the right to review and receive a copy of such records maintained by the other Party (including its Affiliates, subcontractors, and consultants) at reasonable times, but no more than twice in any one Calendar Year, and to obtain access to source documents to the extent needed for patent and regulatory purposes or for other legal proceedings.

### 4.2. <u>Research Funding</u>.

4.2.1. In connection with PIRS' Research and Manufacturing activities under the Research Candidate Plans, SGEN shall be responsible for all PIRS Out-of-Pocket Costs in an amount not to exceed [\*\*\*] Dollars (\$[\*\*\*]) per Research Candidate Plan (such cap may be amended by mutual agreement) and PIRS internal FTE Costs in an amount not to exceed [\*\*\*] Dollars (\$[\*\*\*]) in the aggregate (across all Research Candidate Plans). For the avoidance of doubt, PIRS shall not be obligated to (i) spend Out-of-Pocket Costs in excess of the above mentioned cap without written agreement by SGEN to cover such additional Out-of-Pocket Costs, and (ii) deploy more internal FTE resources than those included in the Research Candidate Plan for the First Approved SGEN Antibody Target (attached hereto as Exhibit 4.1.2) and similar levels of internal FTE resources for each of the Research Candidate Plans for the Second and Third Approved SGEN Antibody Target.

54

4.2.2. PIRS shall provide an invoice to SGEN within [\*\*\*] days of the end of each Calendar Quarter setting forth the Out-of-Pocket Costs as well as PIRS internal FTE Costs expended in connection with PIRS' activities under an approved Research Candidate Plan for each such Calendar Quarter; SGEN shall provide payment of such Costs to PIRS within [\*\*\*] days of recipient of such invoice.

# 4.3. <u>Collaboration Products and Additional Collaboration Products</u>.

4.3.1. <u>Collaboration Products</u>. There will be up to [\*\*\*] Collaboration Products, i.e., [\*\*\*] for each SGEN Antibody Target, unless SGEN exercises [\*\*\*] or more Additional Collaboration Product Option(s) pursuant to this <u>Section 4.3</u>, in which case there will be up to [\*\*\*] Collaboration Products.

4.3.2. <u>Additional Collaboration Product Option</u>. Subject to the terms and conditions of this <u>Section 4.3</u>, SGEN shall have the option to add up to [\*\*\*] additional Collaboration Products (each, an "Additional Collaboration Product") to this Agreement by providing notice with respect to a Compound meeting the requirements of this <u>Section 4.3</u> and during the time periods set forth in this <u>Section 4.3</u> (such option the "Additional Collaboration Product Option").

4.3.3. <u>Identity of the Additional Collaboration Products</u>. The Additional Collaboration Products shall each be a Compound which (i) is a Dormant Candidate, and (ii) for which PIRS has not already initiated a Competing Research Product as permitted under <u>Section 10.2</u>.

# 4.3.4. Additional Collaboration Product Option Exercise .

4.3.4.1. SGEN may exercise the Additional Product Option by providing written notice to PIRS identifying the Dormant Candidate for which SGEN seeks to exercise the Additional Collaboration Product Option (the "Additional Collaboration Product Option Exercise Notice").

4.3.4.2. Within [\*\*\*] days of receipt of the Additional Collaboration Product Option Exercise Notice, PIRS shall inform SGEN as to whether or not a Competing Research Candidate as described in <u>Section 4.3.3</u> exists (as of the date of receipt of the Additional Collaboration Product Option Exercise Notice) and, if an authorized officer of PIRS certifies that there is such a Competing Research Candidate, SGEN shall not be permitted to designate that Dormant Candidate as an Additional Collaboration Product.

4.3.4.3. On the date of notice from PIRS that there is no Competing Research Candidate with respect to the Dormant Candidate, the applicable Dormant Candidate shall become an Additional Collaboration Product (the date of such

#### 55

notice, the "Additional Collaboration Product Effective Date"). As of the Additional Collaboration Product Effective Date, such Dormant Candidate shall be considered a Collaboration Product under this Agreement.

4.3.5. <u>Additional Collaboration Product Option Exercise Fee</u>. With respect to each Additional Collaboration Product SGEN shall pay the [\*\*\*] and the Additional Collaboration Product Option Exercise Fee set forth in <u>Section 7.2</u> within [\*\*\*] days of the Additional Collaboration Product Effective Date.

## 4.3.6. Additional Collaboration Product CoDev Option .

4.3.6.1. <u>Treatment as a Collaboration Product</u>. As set forth in <u>Section 4.3.4.3</u>, the Additional Collaboration Product shall be treated as a Collaboration Product in all respects under this Agreement as of the Additional Collaboration Product Effective Date. For example, in the event that an Additional Collaboration Product is the first Collaboration Product to reach the [\*\*\*], then SGEN shall have the [\*\*\*] to issue an Option Notice with respect to such Collaboration Product to reach the [\*\*\*], then SGEN shall be required to issue an Option Notice with respect to such Collaboration Product to reach the [\*\*\*], then SGEN shall be required to issue an Option Notice with respect to such Collaboration Product.

4.3.6.2. Additional CoDev Options. In the event that PIRS has exercised a PIRS CoDev Option with respect to a Collaboration Product, then SGEN shall have the obligation to issue an Option Notice for any Collaboration Product(s) (including, for avoidance of doubt, Additional Collaboration Products) that has the [\*\*\*] as the CoDev Product at the time that such Collaboration Product reaches the [\*\*\*], but only if such Collaboration Product is being (or is intended to be) Developed in [\*\*\*] with respect to the corresponding CoDev Product. The process for the issuance of such Option Notice shall be as set forth in Section 4.4.2.2. In the event that PIRS exercises a PIRS CoDev Option for a Collaboration Product as contemplated under this Section 4.3.6.2, the resulting CoDev Product shall be treated the same as the first CoDev Product under this Agreement. If PIRS does not exercise a PIRS CoDev Option for a Collaboration Product as set forth above, such Collaboration Product shall become an Exclusive Product. For the avoidance of doubt, SGEN shall have no obligation to issue an Option Notice for (i) any Collaboration Product that does not include the [\*\*\*] as a CoDev Product, or (ii) any Collaboration Product that includes the [\*\*\*] as a CoDev Product but is not being Developed in [\*\*\*] (with (ii) being a "[\*\*\*] **CoDev Product**"). For the purpose of this Agreement, "[\*\*\*]" or "[\*\*\*]" shall mean that [\*\*\*] being or planned to be evaluated in a Pivotal Clinical Study for such CoDev Product and such Collaboration Product, as determined in good faith by the Parties at the time of the (potential) Option Notice for such Collaboration Product, overlap in at

56

least [\*\*\*] (including, for avoidance of doubt, different [\*\*\*] within the same Indication). For any [\*\*\*] CoDev Product, SGEN shall not Initiate a Pivotal Clinical Study in [\*\*\*] that would have represented a Development in [\*\*\*] with respect to the corresponding CoDev Product until the earlier of (i) [\*\*\*] years after the Initiation of the first Pivotal Clinical Study for the [\*\*\*] CoDev Product or (ii) termination of the clinical Development of the corresponding CoDev Product in the [\*\*\*] that would have represented a Development in [\*\*\*]. Any dispute regarding whether a Collaboration Product is being (or is intended to be) Developed in a [\*\*\*] shall be referred to Accelerated Arbitration.

Additional Collaboration Product Diligence. If at any time there is more than one 4.3.7. Collaboration Product that includes the [\*\*\*] and such Collaboration Products are being Developed in [\*\*\*], then Commercially Reasonable Efforts regarding the Development and Commercialization of such Collaboration Products will be determined for [\*\*\*] Collaboration Products [\*\*\*], meaning that if activities performed for [\*\*\*] Collaboration Products are deemed to satisfy Commercially Reasonable Efforts for diligence, then the other Collaboration Product(s) shall [\*\*\*] have been performed for such other Collaboration Product(s), provided, however, once a first Pivotal Clinical Study had been initiated for one of the Collaboration Products, then for each such other Collaboration Product (i) SGEN must initiate a [\*\*\*] within [\*\*\*] year of completion of such first Pivotal Clinical Study, and (ii) thereafter, there cannot be a [\*\*\*] conducted by SGEN for each such other Collaboration Product for a period of more than [\*\*\*] years, provided that in each case the timeframe may be reasonably extended to account for one or more material delays outside of SGEN's reasonable control due to a Regulatory Authority's actions (or inaction), provided that SGEN shall provide sufficient documentation to PIRS to substantiate the basis for such material delay(s). In the event that SGEN fails to comply with either of the diligence obligations set forth in (i) and (ii) above, then such other Collaboration Product shall cease to be a Collaboration Product and as of the applicable time shall be deemed a [\*\*\*]. For the purposes of this Section 4.3.7, "Significant Study" shall mean any GLP Tox Study or Clinical Study. For the avoidance of doubt, if at any time [\*\*\*] or more Collaboration Products that include the [\*\*\*] are not being Developed in [\*\*\*], then Commercially Reasonable Efforts regarding Development and Commercialization of such Collaboration Products shall be determined separately for each Collaboration Product. For clarity, if the [\*\*\*] or more Collaboration Products are all Exclusive Products that include the [\*\*\*], then Commercially Reasonable Efforts regarding the Development and Commercialization of such Exclusive Products will be determined for [\*\*\*] Exclusive Products [\*\*\*], even if such Exclusive Products are not being Developed in [\*\*\*].

### 4.4. <u>Development</u>.

### 4.4.1. <u>Generally</u>.

4.4.1.1. Following [\*\*\*], SGEN shall be responsible for all subsequent Research, Development and Commercialization of each Collaboration Product unless and until, where applicable, PIRS exercises a PIRS CoDev Option as described below with respect to such Collaboration Product. SGEN shall prepare and present to PIRS Development Plan Overviews for each Collaboration Product at the JDC in accordance with <u>Section 3.3.1</u>. SGEN shall be responsible for all costs associated with the Development, Manufacture, and Commercialization of such Collaboration Products subject to the cost sharing provisions for a CoDev Product as outlined below upon PIRS exercise of a PIRS CoDev Option. In the event that SGEN requests and PIRS agrees to perform activities for the Research, Development or Manufacture of a Collaboration Product, then SGEN shall reimburse PIRS for all costs and expenses (including all Out-of-Pocket and FTE Costs) incurred by PIRS in connection therewith.

4.4.1.2. With respect to each Research Candidate for which SGEN has not paid the Go/No-Go Fee within [\*\*\*] days of the conclusion of the Research Term for such Research Candidate, SGEN shall not Research, Develop, Manufacture, or Commercialize such Research Candidate (which will become a Dormant Candidate at such time) and all licenses from PIRS to SGEN with respect to such Dormant Candidate shall terminate (for clarity, once a Dormant Candidate becomes an Additional Collaboration Product then it shall be a Collaboration Product for purposes of the license grant under <u>Section 2.1</u>). Notwithstanding the foregoing, for so long as SGEN is Researching, Developing, Manufacturing or Commercializing a Collaboration Product with the same SGEN Building Block, then it shall be permitted to use Dormant Candidates comprising that SGEN Building Block, but only as an experimental control in *in vitro* or *in vivo* assays directed to the Development of a Collaboration Product including the same SGEN Building Block.

### 4.4.2. <u>PIRS CoDev Option</u>.

4.4.2.1. <u>PIRS CoDev Option</u>. PIRS shall have—and SGEN hereby grants to PIRS as of the Effective Date—the exclusive option (exercisable in PIRS' sole discretion) to opt into [\*\*\*] global co-Development and co-Commercialization as set forth in the CoDev Product Plan of [\*\*\*] Collaboration Product, which would then become a CoDev Product and would no longer be an Exclusive Product, in accordance with the selection procedure set forth below (the "**PIRS CoDev Option**"). Notwithstanding the foregoing, in the event that SGEN exercises one of its [\*\*\*] Additional Collaboration

Product Option(s), then PIRS may have additional PIRS CoDev Options with respect to other Collaboration Products as set forth in <u>Section 4.3.6</u>.

PIRS CoDev Option Notice. Subject to Section 4.3.6.2, and pursuant to the 4422 applicable guidelines set forth in Section 4.4.2.3, for applicable Collaboration Products, SGEN may or shall (depending on the Collaboration Product) issue a written notice ("Option Notice") triggering a PIRS CoDev Option after Key Data from the Clinical Study preceding the first Pivotal Clinical Study is available and prior to initiating such Pivotal Clinical Study with respect to such Collaboration Product (the "CoDev Decision Point"). Concurrently with the Option Notice, to the extent not already provided to PIRS, SGEN shall provide to PIRS: (a) all material clinical Data to be included in the clinical study report (CSR), but in no case less than Key Data, for all Clinical Studies conducted prior to initiation of the first Pivotal Study in the form then available (i.e., even if a final CSR may not yet be available for all Clinical Studies, but including the final CSR for Clinical Studies, for which it is available), including, upon PIRS' reasonable request, providing PIRS with access to the underlying raw data (which may require a PIRS employee to travel to Clinical Study sites), (b) all material preclinical Data as well as all material Data related to CMC Development work conducted on such Collaboration Product (including, upon PIRS' reasonable request, providing PIRS with access to the underlying raw data), (c) documentation of all substantive interactions with Competent Authorities as well as Regulatory Materials (e.g. the IND/IMPD), (d) a written report on the market potential for such Collaboration Product, including the competitive landscape with a form and content as decided by SGEN, but no less detailed than the report that SGEN has prepared for its internal use, (e) a Development plan and related budget for the Collaboration Product including a regulatory strategy for obtaining Marketing Approval from the FDA for the United States and the EMA for the EU[\*\*\*] Markets for the Collaboration Product (the "CoDev Product Plan" and corresponding budget, the "Joint Development Budget"), provided that such initial CoDev Product Plan shall not contain Pivotal Clinical Studies in more than [\*\*\*] Indication and not more than [\*\*\*] Pivotal Clinical Studies in such Indication for such Collaboration Product, and (f) an accounting of the Reimbursable [\*\*\*]. The initial CoDev Product Plan shall also include an estimate of the number of field sales representatives and medical science liaisons required for the continued Development and Commercialization of the Collaboration Product in the United States, provided that such estimate shall not be binding but may serve as a basis for negotiating the Global Commercialization Agreement. The Parties shall in good faith discuss such initial CoDev Product Plan and Joint Development Budget reasonably in advance of the anticipated [\*\*\*] through the JDC. If

59

an Option Notice is issued, PIRS must exercise a PIRS CoDev Option in writing within the later of: (i) [\*\*\*] days following receipt of the Option Notice and (ii) [\*\*\*] days of public release of Key Data from the Clinical Study immediately preceding such Pivotal Clinical Study (the date of such written notice by PIRS being the "**PIRS CoDev Option Exercise Effective Date**"). SGEN shall issue such public release without undue delay after such Key Data becomes available. PIRS shall pay to SGEN, within [\*\*\*]) days of PIRS' exercise of a PIRS CoDev Option, an amount equal to [\*\*\*] percent ([\*\*\*]%) of SGEN's Reimbursable [\*\*\*].

4.4.2.3. <u>Option Notice Procedures</u>. Subject to <u>Section 4.3.6</u>, SGEN may, in its sole discretion, issue an Option Notice for the [\*\*\*] Collaboration Product to reach the [\*\*\*], but must (unless PIRS exercised a PIRS CoDev Option as to the [\*\*\*] Collaboration Product) do so for the [\*\*\*] Collaboration Product to reach the [\*\*\*]. For clarity, (i) if SGEN issues an Option Notice for the [\*\*\*] Collaboration Product to reach the [\*\*\*] but PIRS does not exercise a PIRS CoDev Option, SGEN will be obligated to issue an Option Notice for the [\*\*\*] Collaboration Product to reach the [\*\*\*] Collaboration Product to reach the [\*\*\*] but PIRS does not exercise a PIRS CoDev Option, SGEN will be obligated to issue an Option Notice for the [\*\*\*] Collaboration Product to reach the [\*\*\*] but PIRS does not exercise a PIRS CoDev Option, SGEN shall not be obligated to issue an Option Notice for the [\*\*\*] Collaboration Product to reach the [\*\*\*] Collaboration Product to reach the [\*\*\*] but PIRS does not exercise a PIRS CoDev Option, SGEN shall not be obligated to issue an Option Notice as to the [\*\*\*]. If PIRS does not exercise a PIRS CoDev Option with respect to a Collaboration Product, such Product shall remain an Exclusive Product.

4.4.2.4. <u>Joint Development</u>. Beginning on a PIRS CoDev Option Exercise Effective Date, the Parties shall jointly Develop a CoDev Product in accordance with the applicable CoDev Product Plan.

## 4.4.3. <u>Development under a CoDev Product Plan</u>.

4.4.3.1. <u>Updates</u>. Each CoDev Product Plan (together with the corresponding Joint Development Budget) shall be updated and approved annually (on an annual cycle ending on September 30<sup>th</sup>) for the upcoming Calendar Year (the " **Annual CoDev Plan Date**"), such update subject to review and approval by the JDC. Either Party can propose an amendment to a CoDev Product Plan which shall be subject to review and approval by the JDC, provided that if a PIRS CoDev Option Exercise Effective Date is less than [\*\*\*] days in advance of the next Annual CoDev Plan Date for the initial CoDev Product Plan provided with the Option Notice, then SGEN may update the initial CoDev Plan on the next Annual CoDev Plan Date and approval of the JDC shall not be required, provided, however, that (i) SGEN shall not be allowed to make material changes to the initial CoDev Plan (such as changing the number of Clinical Studies or Indications, including lines of therapy, of

60

such Clinical Studies) or increase the Joint Development Budget by more than [\*\*\*] percent ([\*\*\*]%) for the applicable Calendar Year compared to the initial CoDev Product Plan without the prior written consent of PIRS, and (ii) from the PIRS CoDev Option Exercise Effective Date until the second Annual CoDev Plan Date for the CoDev Product Plan, SGEN shall consider in good faith any amendments to the CoDev Product Plan proposed by PIRS, but shall not be obligated to amend the CoDev Product Plan accordingly.

Responsibilities. Subject Section 4.4.5 and Section 4.5, and subject to the 4.4.3.2. activities allocated to each Party under a CoDev Product Plan, PIRS shall be primarily responsible for obtaining Regulatory Approvals for a CoDev Product in the PIRS Territory, and SGEN shall be primarily responsible for obtaining Regulatory Approvals for a CoDev Product in the SGEN Territory. Notwithstanding the foregoing, SGEN shall be the sponsor of the [\*\*\*] Pivotal Clinical Study under the CoDev Product Plan. For each CoDev Product Clinical Study, the Party that is the sponsor of such Clinical Study shall have and maintain operational control and responsibility for such Clinical Study, provided, however, that the non-sponsoring Party shall have equal input and participation in strategic level decisions (including via participation and membership in all major global program teams and sub-teams) relating to such Clinical Study, including the extent to which the non-sponsoring Party will actively participate in any substantive interactions with regulatory authorities and substantive key opinion leader (KOL) interactions. In addition, for any CoDev Product Clinical Study, the sponsoring Party shall provide notice of, and the non-sponsoring Party shall have the ability to attend, all substantive interactions with regulatory authorities and all substantive KOL interactions including investigator meetings and advisory boards. In addition, the medical affairs plan contemplated by Section 3.3.2.11 will specifically address the introduction of PIRS to KOLs in the PIRS Territory for the purpose of enabling PIRS to prepare for launch. Furthermore, the Parties agree that Clinical Studies under a CoDev Product Plan may be conducted globally with one sponsor per study (which shall include responsibility for clinical operations for such study worldwide) and unless otherwise mutually agreed by the Parties in writing, on a Clinical Study-by-Clinical Study basis (i) PIRS shall be the sponsor for each Clinical Study conducted in the United States under a CoDev Product Plan other than as part of a global Clinical Study, (ii) SGEN shall be the sponsor for each Clinical Study conducted in the SGEN Territory other than as part of a global Clinical Study, and (iii) the Parties shall mutually agree which party shall lead for each global Clinical Study conducted in both the SGEN Territory and PIRS Territory under a CoDev Product Plan with the goal of equal participation of each party in terms of study size. For example, several smaller global trials

61

may be grouped together and considered to be equivalent to one larger global trial. For avoidance of doubt, each Party shall be solely responsible for any Unsponsored Work.

4.4.3.3. <u>Overages</u>. For a CoDev Product, neither Party shall be required to commit resources or funds towards Clinical Studies that are not included in a CoDev Product Plan, provided that:

(a) In the event that a Party anticipates that the actual amount of aggregate annual Shared Costs set forth in the Joint Development Budget included in the current applicable CoDev Product Plan will increase by up to [\*\*\*] percent ([\*\*\*]%) over the aggregate annual amount set forth in the initial approved Joint Development Budget for such year, such Party shall bring such information to the JDC which will engage in a good faith discussion of the reason(s) for such anticipated increase but approval of the JDC shall not be required and the applicable Joint Development Budget shall be automatically updated to reflect such increase and such increased amount shall be shared by the Parties pursuant to Section 4.4.3.5(a). For clarity, if the foregoing process occurs multiple times with respect to a year, then the [\*\*\*] percent ([\*\*\*]%) threshold is the aggregate amount of all expected increases.

(b) In the event that a Party anticipates that the actual amount of aggregate annual Shared Costs set forth in the relevant Joint Development Budget included in the current applicable CoDev Product Plan will increase more than [\*\*\*] percent ([\*\*\*]%) over the aggregate annual amount set forth in the initial approved Joint Development Budget for such year, such Party shall bring such information to the JDC for approval.

4.4.3.4. <u>Database</u>. Before commencement of each Clinical Study pursuant to a CoDev Product Plan, the Parties shall use the applicable regulatory database format in order to fulfill both FDA and EMA requirements.

# 4.4.3.5. <u>Development Funding</u>.

(a) <u>CoDev Product Plan</u>. For each CoDev Product, beginning on the date PIRS receives the Option Notice for the Collaboration Product corresponding to the CoDev Product, each Party shall be responsible for fifty percent (50%) of the Shared Costs for such CoDev Product as set forth in the associated Joint Development Budget. Each Party shall be responsible for any other

62

costs such Party incurs in connection with the Development of a CoDev Product.

(b) <u>Unsponsored Work</u>. Each Party shall be solely responsible for costs it incurs in the performance of any Unsponsored Work.

4.4.3.6. <u>Additional Studies; Additional Study Data</u>.

(a) Additional Studies. If a Party (including its Affiliates or Sublicensees) wishes to conduct one or more additional Clinical Studies or Development activities for a CoDev Product (beyond the Pivotal Clinical Study or other Clinical Studies included in the thencurrent CoDev Product Plan), such Party (the "Proposing Party") shall notify the other Party (the "Non-Proposing Party") of such proposed studies (the "Proposed Study(ies)") and provide the Non-Proposing Party with any Data or publications supporting any such proposal. In such event, the JDC shall consider such proposal and evaluate the supporting Data and information in good faith. If the Parties both wish to collaborate in the conduct of such Proposed Study(ies), the Proposing Party shall prepare an amendment to a CoDev Product Plan and Joint Development Budget to include the Proposed Study(ies) for review and approval by the JDC, and subsequently the JSC. If, after consideration in good faith by the JDC and the JSC, as applicable, the Parties do not, within [\*\*\*] days of the first applicable JSC meeting, mutually agree to include the Proposed Study(ies) in a CoDev Product Plan, the Proposing Party may elect to conduct such rejected Proposed Study(ies) (such study(ies), in such event, "Unsponsored Work"), rather than escalate further as described in <u>Section 3.6.2.1</u>. Notwithstanding the foregoing, the Non-Proposing Party may, within [\*\*\*] days following the failure of the JDC to mutually agreed to include the Proposed Study(ies) in a CoDev Product Plan (the "Objection Period"), provide reasonable written objection to such Unsponsored Work on the basis of likely potential Material Adverse Effect upon the procurement or maintenance of Marketing Approval or Commercialization of a CoDev Product. If the Non-Proposing Party makes such an objection, the Proposing Party shall not be permitted to proceed with such Unsponsored Work, provided that if the Proposing Party disputes the stated likely potential Material Adverse Effect upon the procurement or maintenance of Marketing Approval or Commercialization of a CoDev Product by the Unsponsored Work, then such dispute shall be subject to Accelerated Arbitration. The

63

Proposing Party shall deliver to the JDC regular updates on such Unsponsored Work, and promptly following completion of the Unsponsored Work, a top-line summary of all Data resulting from such Unsponsored Work. For the purposes of this <u>Section 4.4.3.6</u>, "**Material Adverse Effect**" shall mean any materially adverse impact on the value of a CoDev Product, including but not limited to restriction on a CoDev Product's label or adverse impact to the safety or efficacy of a CoDev Product.

(b) Additional Study Data. All Data resulting from any Unsponsored Work (collectively, "Additional Study Data") shall be solely owned by the Party that performed the Unsponsored Work that produced such Data, subject to the rights and licenses, if any, granted to the other Party herein. Each Party shall have access to and the right to use, at no cost to such Party, all Additional Study Data solely as necessary to comply with safety reporting or other similar regulatory requirements in its respective Territory, but not, for example, for Marketing Approval or pricing approval. If the Additional Study Data is later included in the label of a CoDev Product that has received Marketing Approval anywhere in the world (whether or not such Marketing Approval is for the Non-Proposing Party's respective Territory), the Non-Proposing Party shall reimburse the Proposing Party for [\*\*\*] percent ([\*\*\*]%) of the Development Costs associated with such Unsponsored Work, such amount to be deducted from any amounts owed to the Non-Proposing Party under Section 4(b) of Exhibit 1.189.

4.4.4. <u>Reporting: Development Records</u>. Each Party shall provide to the other written reports regarding the progress and results of their activities under a CoDev Product Plan through the JDC. Each Party shall (and shall cause its Affiliates, Sublicensees, subcontractors and consultants to) maintain complete and accurate records (in the form of technical notebooks and/or electronic files where appropriate) of all work conducted by it or on its behalf (including by its Affiliates, Sublicensees, subcontractors and consultants) under a CoDev Product Plan. Such records, including any electronic files where such Data may also be contained, shall fully and properly reflect all work done and results achieved in sufficient detail and in a good scientific manner appropriate for patent and regulatory purposes. Each Party shall have the right to review and receive a copy of such records (including a copy of the databases) maintained by the other Party (including its Affiliates, Sublicensees, subcontractors and consultants) at reasonable times, but no more than

64

[\*\*\*] in any one Calendar Year, and to obtain access to source documents to the extent needed for patent or regulatory purposes or for other legal proceedings.

#### 4.4.5. <u>Regulatory Matters</u>.

4.4.5.1. <u>Ownership</u>. Subject to <u>Section 4.4.5.2</u> and <u>Section 4.5</u> below, PIRS will own all IND/IMPDs, BLAs, Regulatory Approvals and related regulatory documentation submitted to any Competent Authority in the PIRS Territory with respect to a CoDev Product. At PIRS' request, SGEN will transfer to PIRS ownership of any IND/IMPDs or related regulatory documents submitted by or on behalf of SGEN to any Competent Authority in the PIRS Territory with respect to a CoDev Product (for clarity, SGEN shall have the right to cross-reference or incorporate by reference such transferred IND/IMPDs or related regulatory documents pursuant to <u>Section 2.6</u>). SGEN will own all IND/IMPDs, MAAs, Regulatory Approvals and related regulatory documentation submitted to any Competent Authority in the SGEN Territory with respect to a CoDev Product as well as any drug master files maintained by or on behalf of SGEN anywhere in the world with respect to a CoDev Product.

4.4.5.2. <u>Responsibility</u>. Unless otherwise set forth in a CoDev Product Plan and subject to <u>Section 4.4.5.1</u>, <u>Section 4.4.6.3</u> and <u>Section 4.5</u>, each Party will be primarily responsible for all regulatory matters relating to a CoDev Product in its Territory, including (i) overseeing, monitoring and coordinating all regulatory actions, communications and filings with, and submissions to, each Competent Authority; (ii) interfacing, corresponding and meeting with each Competent Authority; (iii) seeking and maintaining all regulatory filings; and (iv) maintaining and submitting all records required to be maintained or required to be submitted to any Competent Authority, provided that, as the Party primarily responsible for Manufacturing, SGEN shall be responsible for preparing and defending the CMC section of the BLA for such CoDev Product. Each Party will keep the other Party informed of their strategy with respect to the regulatory matters set forth in this <u>Section 4.4.5.2</u>, including through the applicable Committees, establishment of material sharing portals (e.g., SharePoint) or through the establishment of Working Groups.

# 4.4.6. <u>Communications</u>.

4.4.6.1. Within [\*\*\*] Business Days after receipt of any Health Authority Communication from a Competent Authority with respect to a Collaboration Product, the recipient Party will provide the other Party, through its Alliance Manager, with a brief written description of the principal issues raised in such Health Authority Communication and, upon such other Party's request, the

65

recipient Party will also provide complete copies of such correspondence within a reasonable period of time following such request. In the case of a CoDev Product, the recipient Party will additionally allow such other Party a reasonable opportunity to review and comment on any proposed response to such Health Authority Communications in advance of the transmission of such response, and will reasonably consider all comments timely provided in connection therewith.

4.4.6.2. With respect to each Collaboration Product, within twenty-four (24) hours after receipt of any Health Authority Communications from a Competent Authority related to a Clinical Study hold or potential Clinical Study hold for safety reasons or for a potential withdrawal from the market for a safety issue or a report of a serious safety finding by a Competent Authority, the recipient Party will provide the other Party, through its Alliance Manager, with a brief written description of the principal issues raised in such Health Authority Communication.

4.4.6.3. <u>Meetings</u>. In connection with any regulatory matters for which a Party is responsible as set forth in <u>Section 4.4.5.2</u> or a CoDev Product Plan, as applicable, each Party shall provide the other Party with reasonable advance notice of all formal meetings and teleconferences with a Competent Authority and pertaining to a CoDev Product, or with as much advance notice as practicable under the circumstances. The notifying Party shall use reasonable efforts to permit the other Party to have, at such other Party's expense, mutually acceptable representatives attend as observers, such formal meetings and teleconferences with FDA or EMA pertaining to such CoDev Product, provided that for any formal meetings and teleconferences with the FDA that address any CMC-related issues for such CoDev Product, SGEN shall have representatives attend such formal meetings and teleconferences as any CMC-related questions as well as for defending the CMC section of the BLA of such CoDev Product towards the FDA.

66

4.5. <u>Submissions</u>. With respect to a CoDev Product, each Party will allow the other Party a reasonable opportunity to review and comment on all filings and other submissions to a Competent Authority related to such CoDev Product in advance of such submission or filing, and such first Party will reasonably consider in good faith all comments timely provided by such other Party in connection therewith. Notwithstanding the foregoing, SGEN shall prepare and defend the CMC section of the BLA for such CoDev Product, provide PIRS with a reasonable opportunity to review and comment on such CMC section, and reasonably consider in good faith all comments timely provided by PIRS in connection therewith.

# 4.6. <u>Pharmacovigilance Agreement/Safety Data Exchange Agreement</u>.

4.6.1. <u>Agreement</u>. After the Effective Date, the Parties shall mutually agree on a reasonably practicable date to enter into an agreement setting forth the worldwide pharmacovigilance procedures for the Parties with respect to a CoDev Product (the "**Pharmacovigilance Agreement**"). The Pharmacovigilance Agreement shall be executed before the initiation of the first Clinical Study conducted by either of the Parties for a CoDev Product that requires the other Party to report pharmacovigilance data generated by such Clinical Study to the Competent Authorities. When executed, the Pharmacovigilance Agreement shall remain a stand-alone document, independent from this Agreement to enable amendment thereto as required independently of this Agreement.

4.6.2. <u>Specifications</u>. The Pharmacovigilance Agreement shall be in accordance with, and enable both Parties to fulfill, all local, national, and regional regulatory reporting obligations under applicable Laws.

67

4.7. Subcontractors. Each Party will have the right to use its Affiliates or Third Parties to perform the Research, Development, Manufacturing, or Commercialization activities for the benefit of such Party under this Agreement; provided that: (a) such Party remains responsible for the work allocated to such Party hereunder (including under each Research Candidate Plan, Collaboration Product Plan or CoDev Product Plan) to the same extent it would if it had done such work itself; and (b) such Party will enter into a binding written agreement with each such Affiliate and/or Third Party, prior to commencing such activities, which agreement includes the following terms (i) the subcontractors undertake in writing obligations of confidentiality and non-use regarding Confidential Information that are substantially the same as those undertaken by the Parties pursuant to Section 12 (except for a commercially reasonable term for confidentiality obligations), and (ii) such Party Controls all Intellectual Property Rights developed by the subcontractors in the course of performing any such work and owns all such intellectual property that is specifically related to, or otherwise necessary for Research, Development, Manufacture, or Commercialization of a Collaboration Product, which includes, prior to commencing any such activities, having such subcontractor execute an agreement licensing or assigning (or committing to sublicense or assign), as applicable, any inventions and related Intellectual Property Rights to the Party by whom they are employed or for whom they are providing services (or its designated Affiliate). Notwithstanding the foregoing in this Section 4.7, where the Third Party is an academic or academic institution, the Parties shall consider in good faith to agree to waive clause (ii); for all other Third Parties, the Parties must mutually consent to waive or limit clause (ii), such consent not to be unreasonably withheld.

### 5. Manufacturing

68

5.1. <u>Research Candidate Supply</u>. For each Research Candidate, PIRS shall be responsible for providing Initial Quantities of such Research Candidates under a mutually-agreed timeline and as set forth in the applicable Research Candidate Plan. PIRS shall also be responsible for providing additional quantities of such Research Candidate in a reasonable amount, as agreed by the JRC, during the first [\*\*\*] months of the applicable Research Term. For avoidance of doubt, and subject to <u>Section 4.2</u>, SGEN shall be responsible for the FTE Costs and Out-of-Pocket Costs associated with providing such Initial Quantities or such additional quantities of the Research Candidates. For further avoidance of doubt, PIRS shall not be required to conduct any cell line development work, research cell bank or master cell bank generation activities and SGEN shall be responsible for such activities for each Research Candidate and Exclusive Product.

5.2. <u>Exclusive Product Supply</u>. Subject to the terms and conditions of this Agreement, SGEN shall be solely responsible, at its own expense, for the Manufacture and supply of any Exclusive Product.

5.3. <u>CoDev Product Supply</u>.

5.3.1. <u>Generally</u>. With respect to each CoDev Product, upon the PIRS CoDev Option Exercise Effective Date, SGEN will continue to be responsible for the Manufacture and supply of such CoDev Product for continued Development and Commercialization. The Parties will enter into an appropriate Supply Agreement as set forth below in Section 5.3.2 to supply PIRS with any quantities of the CoDev Product necessary for Development (including any activities allocated to PIRS under the applicable CoDev Product Plan and any Unsponsored Work) and Commercialization activities. In the event that (i) the Parties mutually determine that it would be beneficial to have a second source for the Manufacture of the CoDev Product and that responsibility for such second source should be allocated to PIRS (taking into account the guiding principles of cost, quality, and speed of manufacture) or (ii) SGEN fails to meet any mutually binding supply commitments pursuant to a Supply Agreement, then SGEN shall use Commercially Reasonable Efforts to conduct a technology transfer pursuant to Section 5.3.2.1(c) below to enable such Manufacture of the CoDev Product in-house with PIRS or its designated Third Party CMO. To the extent that quantities of the CoDev Product Manufactured by PIRS or its Third Party CMO are supplied to SGEN, then the Parties shall enter an appropriate Supply Agreement as set forth in Section 5.3.2. More generally, The CoDev Product Plan shall include details regarding Manufacture and supply of the CoDev Product until Marketing Approval of the CoDev Product and thereafter, details regarding the Manufacture and supply of the CoDev Product shall be included in the Global Commercialization Agreement as set forth in Section 6 and Exhibit 6.2.

69

#### 5.3.2. Supply Agreements.

5.3.2.1. In the event that a Party (the "**Manufacturing Party**") is supplying the CoDev Product to the other Party (the "**Supplied Party**") in accordance with the principles set forth in <u>Section</u> 5.3.1, then the Parties shall enter into a Supply Agreement as set forth in this <u>Section 5.3.2</u>.

(a) If the Manufacturing Party is Manufacturing the CoDev Product in-house, then within [\*\*\*] days of a written request of the Supplied Party, the Parties will negotiate in good faith and enter into a supply agreement (and any other necessary ancillary agreements including a quality technical agreement) for Development or Commercialization supply of such CoDev Product (each, a "**Party Supply Agreement**") which will be on commercially reasonable terms customary for parties similarly situated and shall include key performance indicators (including criteria regarding manufacturing capacity, quantity, timeliness of delivery, quality and cost that are consistent with prevailing industry standards for Third Party contract manufacturing agreements) as well as appropriate liabilities for failure to supply agreed quantities of such CoDev Product. Any CoDev Product supplied for clinical purposes prior to commercial scale Manufacturing or on a commercial scale under a Party Supply Agreement, will be supplied at a price no greater than a CoDev Product's [\*\*\*] and will be included in Shared Costs pursuant to <u>Section 1.234</u>, except for supply for any Unsponsored Work, which shall be fully paid by the Proposing Party.

(b) If the Manufacturing Party is Manufacturing the CoDev Product through a Third Party CMO, then at the request and option of the Supplied Party, the Supplied Party shall enter into an agreement directly with the Third Party CMO or with the Manufacturing Party to govern the terms and conditions of the supply of such CoDev Product (each such agreement, a ("**CMO Supply Agreement**"). In the event of a CMO Supply Agreement directly with the Third Party CMO, the Parties will use good faith efforts to coordinate the activities under this <u>Section 5.3.2.1(b)</u> and to take advantage of any volume discounts or economies of scale. Each Party agrees that, in its CMO Supply Agreement with a Third Party CMO, such Party shall not include any limitations on such Third Party CMO's ability to supply the other Party with such CoDev Product, and upon the request of the other Party, such Party shall facilitate initial business discussions between the other Party

70

and such Third Party CMO. Any CMO Supply Agreement shall (i) be consistent with the terms included in this Agreement, including with regard to confidentiality, (ii) shall assign to the Manufacturing Party such Third Party's entire right, title and interest in, or provide a perpetual, fully-paid, worldwide, fully sublicensable (through multiple tiers) exclusive (other than with respect to such Third Party's background technology and improvements thereof) license under and to, any Know-How or Patent Rights made, developed or invented by such Third Party specifically related to the Manufacture of such CoDev Product, and (iii) shall be subject to review by the other Party prior to execution. The cost of any CoDev Product supplied for clinical purposes prior to commercial scale Manufacturing or on a commercial scale with a Third Party CMO will be shared equally by the Parties and will be included in Shared Costs pursuant to <u>Section 1.234</u>, except for supply for any Unsponsored Work, which shall be fully paid by the Proposing Party.

(c) Under the circumstances described in <u>Section 5.3.1 (i)</u> and (ii) at PIRS' reasonable request, a CoDev Product Plan shall include a technology transfer of manufacturing process(es) Controlled by SGEN, and in SGEN or its Third Party CMOs' possession for a CoDev Product to PIRS or its Third Party subcontractor. If quantities of the CoDev Product are Manufactured by PIRS or its Third Party CMO and supplied to SGEN, and PIRS fails to meet any mutually binding supply commitments pursuant to a Supply Agreement with SGEN, at SGEN's reasonable request, a CoDev Product Plan shall include a technology transfer of any manufacturing process(es) Controlled by PIRS (if such processes are not already Controlled or in the possession of SGEN or its Third Party CMO), and in PIRS or its Third Party CMOs' possession for a CoDev Product, to SGEN or its Third Party subcontractor. Each Party shall include in any contract with a CMO for Manufacture of any Potential CoDev Product or CoDev Product, as applicable, customary provisions requiring the CMO to conduct such technology transfer, including making available its qualified technical personnel on a reasonable basis to consult with the other Party with respect to such Know-How.

#### 6. Commercialization

71

6.1. <u>Generally</u>. For each CoDev Product, PIRS will have operational control of Commercialization activities and book sales in the United States and SGEN will have operational control of Commercialization activities and book sales outside the United States. Within [\*\*\*] months after Initiation of the first Pivotal Study for such CoDev Product, the Parties shall negotiate in good faith and enter into an agreement to define the Parties' responsibilities and obligations with respect to Commercialization of the CoDev Product (a "Global Commercialization Agreement"). Appended to the Global Commercialization Agreement shall be an initial plan setting forth the specific strategy for Commercialization of the Product ("Global Commercialization Strategy").

6.2. <u>Global Commercialization Agreement</u>. The Global Commercialization Agreement shall include the items set forth in <u>Exhibit 6.2</u>, as well any other customary provisions as agreed by the Parties in good faith.

6.3. <u>Global Commercialization Strategy</u>. The JCC shall prepare for the approval of the JSC the initial draft of such Global Commercialization Strategy within [\*\*\*] months after initiation of the first Pivotal Clinical Study for a CoDev Product, which shall be updated and approved annually thereafter. Amendments to any Global Commercialization Strategy will become effective following review and approval by the JSC.

6.4. SGEN Territory Commercialization Plan. No less than [\*\*\*] months in advance of the reasonably expected First Commercial Sale in the SGEN Territory with respect to a CoDev Product, and on an annual basis thereafter, SGEN shall prepare and deliver to the JCC for review a written plan that summarizes the Commercialization activities to be undertaken by SGEN with respect to a CoDev Product in the SGEN Territory in the next Calendar Year (the "SGEN Territory Commercialization Plan"). Each SGEN Territory Commercialization Plan shall at all times be consistent with the most recent Global Commercialization Strategy approved by the JCC and the Global Commercialization Agreement. The initial SGEN Territory Commercialization Plan will outline plans for establishing, training and qualifying the appropriate number of sales representatives and medical science liaisons prior to applicable Marketing Approval. The initial SGEN Territory Commercialization Plan for a CoDev Product shall subsequently be updated and modified by SGEN, from time to time at its discretion and no less frequently than [\*\*\*] per Calendar Year, based upon, among other things, SGEN's Commercialization activities with respect to a CoDev Product in the SGEN Territory, a copy of which updated plan will be provided to the JCC. Notwithstanding the foregoing, in the event of any disagreement between the Parties regarding the SGEN Territory Commercialization Plan for a CoDev Product, the SGEN representatives on the JCC shall have final decision-making authority over the preparation and updating of such SGEN Territory Commercialization Plan, provided that such decisions do not materially adversely affect the Commercialization of a CoDev Product in the PIRS Territory and such SGEN Territory Commercialization Plan is consistent with the then-currently approved Global Commercialization Strategy and the Global Commercialization Agreement.

72

6.5. <u>PIRS Territory Commercialization Plan</u>. No less than [\*\*\*] months in advance of the reasonably expected First Commercial Sale in the PIRS Territory with respect to a CoDev Product, and on an annual basis thereafter, PIRS shall prepare and deliver to the JCC for review a written plan that summarizes the Commercialization activities to be undertaken by PIRS with respect to a CoDev Product in the PIRS Territory in the next Calendar Year (the "PIRS Territory Commercialization Plan"). The PIRS Territory Commercialization Plan shall at all times be consistent with the most recent Global Commercialization Strategy approved by the JCC and the Global Commercialization Agreement. The initial PIRS Territory Commercialization Plan will outline plans for establishing, training and qualifying the appropriate number of sales representatives and medical science liaisons prior to the applicable Marketing Approval. The initial PIRS Territory Commercialization Plan for a CoDev Product shall subsequently be updated and modified by PIRS, from time to time at its discretion and no less frequently than once per Calendar Year, based upon, among other things, PIRS' Commercialization activities with respect to a CoDev Product in the PIRS Territory, a copy of which updated plan will be provided to the JCC. Notwithstanding the foregoing, in the event of any disagreement between the Parties regarding the PIRS Territory Commercialization Plan for a CoDev Product, the PIRS representatives on the JCC shall have final decision-making authority over the preparation and updating of such PIRS Territory Commercialization Plan, provided that such decisions do not materially adversely affect the Commercialization of a CoDev Product in the SGEN Territory and such PIRS Territory Commercialization Plan is consistent with the then-currently approved Global Commercialization Strategy and the Global Commercialization Agreement.

6.6. <u>Global Branding</u>. The JCC shall, from time to time during the Term, develop (and thereafter modify and update) for approval by the JSC a high-level global branding strategy (including global positioning and promotional messages) for a CoDev Product for use throughout the world (the "**Global Branding Strategy**"), which shall be consistent with the applicable Global Commercialization Strategy and the Global Commercialization Agreement.

6.7. <u>Exclusive Products</u>. SGEN shall be solely responsible for and have sole control over all aspects of the Commercialization of the Exclusive Products in the Territory, including planning and implementation, distribution, promotion, booking of sales, pricing, reimbursement, and costs.

73

# 7. Payments & Royalties

7.1. <u>Technology Access Fee</u>. In partial consideration for the rights granted under this Agreement regarding the Compounds, SGEN shall pay PIRS a one-time, non-refundable, and non-creditable lump sum payment of [\*\*\*] Dollars (\$[\*\*\*]) within [\*\*\*] days following receipt of the corresponding invoice from PIRS after the Effective Date. For avoidance of doubt, this technology access fee shall not be [\*\*\*] to SGEN even if a Compound is later is designated a CoDev Product.

7.2. <u>Additional Collaboration Product Option Exercise Fee</u>. On an Additional Collaboration Product-by-Additional Collaboration Product basis, SGEN shall pay the fee set forth below in <u>Section 7.2.1</u>, <u>Section 7.2.2</u>, or <u>Section 7.2.3</u>, as applicable, within [\*\*\*] days following receipt of the corresponding invoice from PIRS after the Additional Collaboration Product Effective Date (the "**Additional Collaboration Product Option Exercise Fee**"). The Additional Collaboration Product Option Exercise Fee shall be a one-time, non-refundable, and noncreditable lump sum payment.

7.2.1. The Additional Collaboration Product Option Exercise Fee for the [\*\*\*] Additional Collaboration Product shall be [\*\*\*] Dollars (\$[\*\*\*]).

7.2.2. The Additional Collaboration Product Option Exercise Fee for the [\*\*\*] Additional Collaboration Product shall be [\*\*\*] Dollars (\$[\*\*\*]).

7.2.3. The Additional Collaboration Product Option Exercise Fee for the [\*\*\*] Additional Collaboration Product shall be [\*\*\*] Dollars (\$[\*\*\*]).

#### 74

7.3. <u>Go/No-Go Fee for Additional Collaboration Products</u>. For avoidance of a doubt, on an Additional Collaboration Product-by-Additional Collaboration Product basis, SGEN shall pay to PIRS the Go/No-Go Fee in addition to the Additional Collaboration Product Option Exercise Fee. The Go/No-Go Fee with respect to each Additional Collaboration Product shall be due at the same time as the Additional Collaboration Product Option Exercise Fee.

7.4. <u>Development and Regulatory Milestones</u>. In partial consideration for the rights granted under this Agreement regarding the Collaboration Products, in each case upon initial achievement of the applicable milestone by or on behalf of SGEN or its Sublicensees for each Collaboration Product, SGEN will pay PIRS the corresponding non-refundable (subject to <u>Section 4.4.2.2</u>) and non-creditable lump sum payments set forth below.

Development Front	Payment Amount		
Development Event	[***]	[***]	[***]
[***]	[***] Dollars (\$[***])		
Initiation of Phase 1 Clinical Study	[***] Dollars (\$[***])	[***][***]	
Initiation of Phase 2a Clinical Study or Initiation of Phase 1 Clinical Study Expansion Cohorts (whichever comes first)	[***] Dollars (\$[***])		[***]
Initiation of Pivotal Clinical Study	[***] Dollars (\$[***])	[***] Dollars (\$[***])	[***] Dollars (\$[***])
[***] filing with [***]	[***] Dollars (\$[***])	[***] Dollars (\$[***])	[***] Dollars (\$[***])
[***] filing with [***]	[***] Dollars (\$[***])	[***] Dollars (\$[***])	[***] Dollars (\$[***])
[***] filing in [***]	[***] Dollars (\$[***])	[***] Dollars (\$[***])	[***] Dollars (\$[***])
Marketing Approval in the [***]	[***] Dollars (\$[***])	[***] Dollars (\$[***])	[***] Dollars (\$[***])
Marketing Approval in the [***]	[***] Dollars (\$[***])	[***] Dollars (\$[***])	[***] Dollars (\$[***])
Marketing Approval in [***]	[***] Dollars (\$[***])	[***] Dollars (\$[***])	[***] Dollars (\$[***])
Maximum Total	[***] Dollars (\$[***])	[***] Dollars (\$[***])	[***] Dollars (\$[***])

75

7.5. <u>Marketing Approval in Europe</u>. Notwithstanding the above, with respect to each Marketing Approval in the EU, the respective milestone payment will be due upon [\*\*\*] or [\*\*\*], whichever comes earlier.

7.6. <u>Skipped Development and Regulatory Milestones</u>. If any of the above development and regulatory milestones are skipped (i.e. a later milestone payment is payable before an earlier milestone payment in the same jurisdiction, if applicable), or if Marketing Approval is achieved in any jurisdiction with respect to a Collaboration Product without all of the preceding milestone payments applicable to such Product in such jurisdiction, if applicable, having been achieved, then the skipped milestone(s) will be deemed to have been achieved upon the achievement of the subsequent milestone or upon Marketing Approval, as applicable.

7.7. <u>CoDev Product</u>.

7.7.1. [\*\*\*]

7.7.2. <u>Profit and Loss Sharing</u>. In lieu of [\*\*\*], the Parties will share [\*\*\*] the Profits and Losses arising from the Commercialization of a CoDev Product on a global basis, as set forth in <u>Exhibit 1.189</u>. For avoidance of doubt, Parties will share the Profits and Losses arising from the Commercialization of the CoDev Product for so long as such CoDev Product is being [\*\*\*].

7.8. <u>Sales Milestones</u>. On an Exclusive Product-by-Exclusive Product basis, as partial consideration for the rights granted hereunder regarding such Exclusive Product, SGEN shall make the non-refundable, non-creditable, one-time sales milestone payments to PIRS based upon achievement of the following worldwide annual Calendar Year cumulative Royalty Bearing Net Sales for each such Exclusive Product.

Annual Calendar Year - Royalty Bearing Net Sales Threshold	Payment
First equal or exceeding [***] Dollars (\$[***])	[***] Dollars (\$[***])
First equal or exceeding [***] Dollars (\$[***])	[***] Dollars (\$[***])
First equal or exceeding [***] Dollars (\$[***])	[***] Dollars (\$[***])
Maximum Total	[***] Dollars (\$[***])

For clarity, one or more of the above sales milestones may be achieved during the same Calendar Year.

76

7.9. <u>Royalties</u>. On an Exclusive Product-by-Exclusive Product basis, as partial consideration for the rights granted hereunder regarding such Exclusive Product, during the Royalty Term for each such Exclusive Product, SGEN shall pay PIRS royalties equal to the following percentages of the Royalty Bearing Net Sales of such Exclusive Product in a Calendar Year in the SGEN Territory (**"Exclusive Product Royalties**").

Annual Calendar Year Royalty Bearing Net Sales	Royalty Rates Owed by SGEN
Portion of Royalty Bearing Net Sales up to and including [***] Dollars (\$[***])	[***] Percent ([***]%)
Portion of Royalty Bearing Net Sales greater than [***] Dollars (\$[***])to and including [***] Dollars (\$[***])	[***] Percent ([***]%)
Portion of Royalty Bearing Net Sales greater than[***] Dollars (\$[***]) ) up to and including [***] Dollars (\$[***])	[***] Percent ([***]%)
Portion of Royalty Bearing Net Sales greater than[***] Dollars (\$[***])	[***] Percent ([***]%)

#### 8. Royalty Adjustments, Payment Terms & Reconciliation

# 8.1. <u>Royalty Adjustments</u>.

8.1.1. <u>Biosimilar Drug Competition</u>. Subject to <u>Section 8.1.3</u>, if in any Calendar Quarter total sales of any Biosimilar(s) of a Royalty Bearing Exclusive Product in any country reaches more than [\*\*\*] percent ([\*\*\*]%) in units of the total sales of the applicable Exclusive Product and the Biosimilar(s) in such country, then the Royalties payable to PIRS for such Exclusive Product in such country for such Calendar Quarter shall be reduced by [\*\*\*] percent ([\*\*\*]%) of the amount otherwise payable hereunder. Notwithstanding the foregoing, in the event of Biosimilar sales that are later enjoined by a court or otherwise halted (such as on the basis of patent or regulatory exclusivity), then subsequent Royalties shall be restored to the level otherwise contemplated under this Agreement.

77

# 8.1.2. <u>Third Party Licenses</u>.

Exclusive Products. If it is necessary for SGEN to license one or more Patent 8.1.2.1. Rights from one or more Third Parties in order to Develop, Manufacture or Commercialize the Anticalin Building Block of any Exclusive Product (but excluding Patents owned or Controlled by a Third Party service provider selected by SGEN, such as a CMO, and Patents related to any aspect or use of the Antibody Building Block) whether directly or through any Affiliate or Sublicensee, in the SGEN Territory, then SGEN may negotiate and obtain a license under such Patent Right(s) (each such Third Party license referred to herein as a "Third Party License"). If any royalty payments are due to a Third Party pursuant to a Third Party License or in the context of proceedings brought by any Third Party alleging that one or more Patent Rights of such Third Party is infringed by the Development, Manufacture, Commercialization or use of the Anticalin Building Block of any Exclusive Product in the Field under this Agreement, then subject to Section 8.1.3, SGEN may deduct [\*\*\*] percent ([\*\*\*]%) of such payment(s) from the Royalties associated with such Exclusive Product otherwise payable under Section 7.9, but in no event shall Royalties be reduced by greater than [\*\*\*] percent ([\*\*\*]%) under this <u>Section 8.1.2</u>. For avoidance of doubt, SGEN shall be responsible for any Third Party license payments associated with a SGEN Antibody Target or a SGEN Building Block, without any reduction of the Royalties payable to PIRS under Section 7.9. For avoidance of doubt, nothing this Section 8.1.2.1 precludes SGEN from negotiating and obtaining any licensee it deems necessary or desirable in connection with any Exclusive Product.

# 8.1.2.2. <u>CoDev Product</u>.

(a) For a CoDev Product, (i) PIRS shall be responsible for any Third Party license payments associated with a PIRS Building Block, including under any PIRS Background Agreement, and (ii) SGEN shall be responsible for any Third Party license payments associated with a SGEN Building Block, including under any SGEN Background Agreement.

(b) In the event that either Party reasonably determines that it is necessary or useful to license any additional Patent Rights from one or more Third Parties in order to Develop, Manufacture, or Commercialize a CoDev Product (except for such Third Party Patent Rights that relate solely to a Party's Building Block), it shall promptly notify the other Party and one Party shall be designated the lead Party to negotiate such Third Party license

78

under the following guidelines: (1) if the Third Party license is expected to apply (x) only within the SGEN Territory or (y) within both the SGEN Territory and PIRS Territory, then SGEN shall be the lead negotiating party, and if the Third Party license is expected to apply only within the PIRS Territory, then PIRS shall be the lead negotiating party, (2) the Party which is the lead negotiating party shall, as between the Parties, be the Party which executes the Third Party license, and (3) the Party which is the lead negotiating party shall include the other Party in the negotiations for such Third Party license if requested by the other Party. Any Third Party license negotiated by a Party shall be subject to the prior consent of other Party, which consent shall not be unreasonably withheld or delayed, unless such Third Party license applies only within such Party's respective Territory, in which case no consent will be required. In the event such Third Party license is obtained, then any associated payments will be shared [\*\*\*] as part of Shared Costs.

8.1.3. <u>Maximum Deduction</u>. Notwithstanding anything to the contrary herein, under no circumstances shall the combined effect of all reductions to the Royalties permitted under Section 8.1.1 and Section 8.1.2, on a country-by-country and Exclusive Product-by-Exclusive Product basis, reduce the effective Royalties payable by SGEN to PIRS under this Agreement for any Calendar Quarter below [\*\*\*] percent ([\*\*\*]%) of the Royalties that would otherwise be payable pursuant to <u>Section 7.9</u>, as applicable, for such Exclusive Product in such country.

79

8.2. <u>Sales Payment Reports and Royalty Payments</u>. After the First Commercial Sale by the Seller of a Royalty Bearing Exclusive Product requiring the payments due to PIRS pursuant to <u>Section 7</u> and ending, on an Exclusive Product-by-Exclusive Product basis, following the last to expire Royalty Term with respect to such Exclusive Product, SGEN shall send to PIRS within [\*\*\*] days after the end of each Calendar Quarter (a) a written report which shall state, for the previous Calendar Quarter, on a country-by-country and Exclusive Product-by-Exclusive Product basis, the description of the Exclusive Product sold, the corresponding amount of gross sales of Exclusive Products, an itemized calculation of Net Sales showing deductions provided for in the definition of Net Sales and the calculation of any milestones fees and Royalties due, including any reductions made in accordance with this Agreement, as well as the exchange rate for such country, and (b) payment (in Dollars) of all royalty payments due to PIRS hereunder for such Calendar Quarter.

# 8.3. <u>Shared Cost Reconciliation for CoDev Product</u>.

8.3.1. Within [\*\*\*] Business Days after the end of each Calendar Quarter, each Party will provide the other Party with a detailed, itemized accounting of Shared Costs actually incurred by such Party, its Partners (if applicable) and their Affiliates in its performance of a CoDev Product Plan for a CoDev Product during such Calendar Quarter (the "Shared Cost Report").

8.3.2. With respect to each Calendar Quarter, no later than the later of (i) [\*\*\*] days following the end of such Calendar Quarter and (ii) [\*\*\*] days following each Party' receipt of the Shared Cost Report, the Parties shall calculate the reconciliation amount to be paid by each Party (the "**Reconciliation Report**").

8.3.3. Within [\*\*\*] days after the Parties' agreement as to the Reconciliation Report, the Party having paid less than [\*\*\*] percent ([\*\*\*]%) of the actual Shared Costs (on a cumulative basis) shall deliver to the other Party an invoice for such amount to be paid within [\*\*\*] days.

## 8.4. <u>Payment Terms</u>.

8.4.1. <u>Generally</u>. All payments made by a Party under this Agreement ("**Paying Party**") shall be made in immediately available funds by wire transfer to such bank and account as may be designated from time to time by the other Party. Except as otherwise set forth herein, all other payments due under this Agreement will be paid within [\*\*\*] days following receipt of an invoice requesting such payment. All invoices provided to the Paying Party hereunder shall include the other Party's bank details, the contact name for issue resolution and will be marked for the attention of the Alliance Manager.

8.4.2. <u>Late Payments</u>. Interest shall accrue on any late payment of fees owed to a Party not made on the date such payment is due, at an annual interest rate equal

80

to the [\*\*\*] percent ([\*\*\*]%) above LIBOR per annum or the maximum applicable legal rate, if less, calculated on the total number of days such payment is delinquent.

8.4.3. <u>Taxes and Withholding</u>. All payments under this Agreement shall be made without any deduction or withholding for or on account of any tax, except as set forth in this <u>Section 8.4.3</u>. The Parties agree to cooperate with one another and use reasonable efforts to minimize under applicable Law obligations for any and all income or other taxes required by applicable Law to be withheld or deducted from any of the royalty and other payments made by or on behalf of the Paying Party hereunder ("**Withholding Taxes**"). The Paying Party shall, if required by applicable Law, deduct from any amounts that it is required to pay to the other Party hereunder an amount equal to such Withholding Taxes. Such Withholding Taxes shall be paid to the proper taxing authority for such other Party's account and, if available, evidence of such payment shall be secured and sent to the other Party within [\*\*\*] days of such payment. The Paying Party shall, at the other Party's sole cost and expense, as mutually agreed by the Parties, do all such lawful acts and things, and sign all such lawful deeds and documents as such other Party may reasonably request to enable such other Party to avail itself of any applicable legal provision or any double taxation treaties with the goal of paying the sums due to such other Party hereunder without deducting any Withholding Taxes.

8.4.4. <u>Conversions</u>. With respect to amounts required to be converted into another currency for calculation of the Net Sales amount and the Royalty payments, such amount shall be converted using a rate of exchange which corresponds to the rate used by SGEN or PIRS, as applicable, for conversion between the relative currencies for its reporting period in its books and records that are maintained in accordance with Accounting Standards, as applicable, for its external reporting.

# 8.5. <u>Record and</u>

Audit.

8.5.1. <u>Generally</u>. Each Party shall keep complete, true and accurate books of account and records for the purpose of determining the amounts payable under this Agreement (including, for avoidance of doubt, Development Costs, Commercial Manufacturing Costs, Commercialization Expenses, Sublicensing Income, Third Party license payments, Shared Costs, and Profits and Losses). Such books and records shall be kept at the principal place of business of each Party, as the case may be, for at least [\*\*\*] years (or such longer period as required by applicable Law) following the end of the Calendar Year to which they pertain, provided that SGEN shall keep such books and records that are related to Reimbursable [\*\*\*] for a Collaboration Product for at least [\*\*\*] years following

81

the [\*\*\*] for such Collaboration Product. Each Party (the "Audited Party") shall make such account and records available, on reasonable notice sent by the other Party (the "Auditing Party"), for inspection during normal business hours, with not less than [\*\*\*] Business Days' advance written notice, by an independent certified public accounting firm nominated by such and reasonably acceptable for the Audited Party, for the purpose of verifying the accuracy of any statement or report given by the Audited Party and to verify the accuracy of the payments due hereunder for any Calendar Year. Such auditor shall advise the Parties simultaneously promptly upon its completion of its audit whether or not the payments due hereunder have been accurately recorded, calculated, and reported, and, if not, then the amount of such discrepancy. A Party's financial records with respect to a given period of time shall only be subject to [\*\*\*] audit per Calendar Year except in the case of willful misconduct or fraud. The Auditing Party's right to perform an audit pertaining to any Calendar Year shall expire [\*\*\*] years after the end of such Calendar Year, provided that PIRS shall have the right to perform an audit of Reimbursable [\*\*\*] for a Collaboration Product for a period of [\*\*\*] years following the [\*\*\*] for such Collaboration Product (which, for the avoidance of doubt, shall include all such Reimbursable [\*\*\*] even if incurred more than [\*\*\*] years prior to the audit). The auditor shall be required to keep confidential all information learned during any such inspection, and to disclose to the Auditing Party only such details as may be necessary to report the accuracy of the Audited Party's statement or report. The Auditing Party shall be responsible for the auditor's costs, unless the auditor certifies that there was a variation or error of underpayment or overpayment of Shared Costs by the Auditing Party exceeding [\*\*\*] percent ([\*\*\*]%) of the amount stated for any period covered by the inspection, in which case all reasonable costs relating to the inspection for such period shall be borne by the Audited Party. If such accounting firm correctly identifies a discrepancy made during such period, any unpaid amounts or overpaid amounts that are discovered shall be paid/refunded promptly but in any event within [\*\*\*] days of the date of delivery of such accounting firm's written report so correctly concluding, or as otherwise agreed upon by the Parties.

# 9. Sublicensing and SGEN Rights for CoDev Product

## 9.1. General Partnering Agreement Obligations.

9.1.1. Subject to this <u>Section 9</u>, a Party shall have the right to enter into a Partnering Agreement provided that: (a) such Party (each, a "**Sublicensing Party**") provides the other Party with prompt written notice of the execution of the Partnering Agreement, (b) the Partnering Agreement is consistent with, and fully implements the relevant provisions of, this Agreement and each Party's rights under this Agreement and (c) each Sublicensee is obligated to fulfill the applicable obligations of the Sublicensing Party set forth in this Agreement.

82

Each Partnering Agreement shall preserve the original licensing Party's ("Licensor") rights and interests in such Party's intellectual property as set forth in this Agreement, by including, without limitation, provisions for the benefit of the Licensor substantially similar in language and scope to, as applicable, the license provisions set forth in <u>Section 2</u>, the ownership provisions in <u>Section 11</u>, the confidentiality provisions set forth in <u>Section 12</u>, and the publication provisions set forth in <u>Section 13</u>. The Sublicensing Party shall, subject to <u>Section 9.2.2</u> and <u>Section 9.3.2</u> below (Full Sublicense Agreement), remain liable to the other Party for any act or omission of its Sublicensee (including the payment of milestone and royalties). For avoidance of doubt, the Partnering Agreement shall prohibit the applicable Sublicensee from taking any action that the Sublicensing Party is not permitted to take under this Agreement, including, conducting a Clinical Study with respect to a CoDev Product without first complying with <u>Section 4.4.3.6</u>. Notwithstanding the foregoing but subject to <u>Section 9.2.2</u> and <u>Section 9.3.2</u> below.

9.1.2. Except where a Party has entered into a Full Sublicense Agreement pursuant to <u>Section 9.2.2</u> and <u>Section 9.3.2</u> below, as applicable, the Parties intend to share [\*\*\*] in any Sublicensing Income received by a Sublicensing Party pursuant to a Partnering Agreement and shall in good faith agree upon a method for allocating such Sublicensing Income for purposes of calculating Reimbursable [\*\*\*], Shared Costs and Profit and Losses as set forth in <u>Exhibit 1.189</u>.

# 9.2. PIRS Specific Sublicensing Obligations and SGEN Rights for CoDev Product .

9.2.1. <u>Generally</u>. Subject to the obligations set forth in <u>Section 9.1</u> and this <u>Section 9.2</u>, PIRS may enter into any Partnering Agreement for a CoDev Product in the PIRS Territory with a Third Party (the "**PIRS Partner**").

9.2.2. <u>Full Sublicense</u>. Following the PIRS CoDev Option Exercise Effective Date and subject to <u>Section 9.1</u> and <u>Section 9.2.3</u>, PIRS may enter into a Full Sublicense Agreement with a Qualified Sublicensee, provided that PIRS shall include in such Full Sublicense Agreement (i) the obligation of the PIRS Partner to [\*\*\*] share with SGEN all Shared Costs and Profits and Losses associated with the applicable CoDev Product on and after the effective date of the Full Sublicense Agreement, and (ii) the right of the PIRS Partner to replace the PIRS representatives on all Committees for such CoDev Product with its own representatives upon written notice to SGEN. Furthermore, the PIRS Partner shall expressly assume all of the obligations (including diligence) and liabilities of PIRS applicable to the further Research, Development, Manufacture, and Commercialization of such CoDev Product. Following such assumption, PIRS and SGEN shall no longer be responsible or liable to each other for any of their

respective obligations (including diligence) and liabilities applicable to the further Research, Development, Manufacture, and Commercialization of such CoDev Product (including, without limitation, that SGEN shall no longer have any governance or reporting obligations to PIRS with respect to the applicable CoDev Product). As a condition to entering into a Full Sublicense hereunder, PIRS shall require the PIRS Partner, within [\*\*\*] days of the date of execution of such Full Sublicense Agreement, to enter into a direct agreement with SGEN, acknowledging the respective rights, obligations and liabilities of the PIRS Partner and SGEN with respect to such CoDev Product, and providing for the transition of any PIRS CoDev Product related activities and governance from PIRS to the PIRS Partner. PIRS shall have no obligation to share with SGEN any [\*\*\*] received from such PIRS Partner under such Full Sublicense Agreement, and such [\*\*\*] shall not be included in the calculation of Profit and Losses as set forth in Exhibit 1.189.

9.2.3. <u>SGEN Partnering Agreement Rights</u>. In the event that PIRS desires to enter into any Partnering Agreement (including a Full Sublicense) with a Third Party regarding a CoDev Product in accordance with this Section 9.2, PIRS shall include SGEN in the partnering process from the beginning and discuss with SGEN in good faith the terms and conditions under which PIRS would be willing to sublicense its rights to such CoDev Product to SGEN. In addition, prior to [\*\*\*] regarding any such Partnering Agreement, PIRS shall provide SGEN with a written notice identifying [\*\*\*] under which PIRS would be willing [\*\*\*] (the "PIRS Sublicense Notice"). If, within [\*\*\*] Business Days following its receipt of the PIRS Sublicense Notice, SGEN notifies PIRS of its interest in licensing such CoDev Product under such [\*\*\*], PIRS and SGEN shall negotiate in good faith for a period of up to [\*\*\*] days an amendment to this Agreement that incorporates a license to such CoDev Product under such [\*\*\*] ("CoDev Product Amendment"). If (a) SGEN does not provide such written notice to PIRS within [\*\*\*] Business Days following its receipt of the PIRS Sublicense Notice or (b) SGEN provides such written notice to PIRS but the Parties fail execute a CoDev Product Amendment within [\*\*\*] days following PIRS' receipt of SGEN's written notice, then (i) SGEN shall provide PIRS with [\*\*\*] as to the terms on which it would be willing to execute such a CoDev Product Amendment (the "[\*\*\*]") and (ii) PIRS shall be free to enter into a Partnering Agreement with a Third Party on terms that, in the reasonable discretion of PIRS, are [\*\*\*] (when taken as a whole and without consideration of any Compound or product other than the CoDev Product included in the PIRS Sublicense Notice) to such Third Party than those set forth in the [\*\*\*] and PIRS shall otherwise shall have no further obligations to SGEN with respect to the potential Partnering Agreement described in the PIRS Sublicense Notice. The Parties acknowledge and agree that any Change of Control transaction involving PIRS shall not be subject to this Section 9.2.3 and

84

this <u>Section 9.2.3</u> shall not be deemed to limit, prohibit or restrict in any way the right of PIRS to solicit, negotiate, facilitate and execute any Change of Control transaction.

## 9.3. SGEN Specific Sublicensing Obligations.

9.3.1. <u>Generally</u>. Subject to the obligations set forth in <u>Section 9.1</u> and this <u>Section 9.3</u>, SGEN may enter into any Partnering Agreement for a Collaboration Product with a Third Party (the "SGEN **Partner**"), except that on a Potential CoDev Product-by-Potential CoDev Product basis, SGEN shall not enter into a Partnering Agreement with a SGEN Partner that includes the right to Commercialize such Potential CoDev Product in the United States.

9.3.2. Full Sublicense. Subject to Section 9.1, SGEN may enter into a Full Sublicense Agreement for a CoDev Product, provided that SGEN shall include in such Full Sublicense Agreement (i) the obligation of the SGEN Partner to [\*\*\*] share with PIRS all Shared Costs and Profits and Losses associated with the applicable CoDev Product on and after the effective date of the Full Sublicense Agreement, and (ii) the right of the SGEN Partner to replace the SGEN representatives on all Committees for such CoDev Product with its own representatives upon written notice to PIRS. Furthermore, the SGEN Partner shall expressly assume all of the obligations (including diligence) and liabilities of SGEN applicable to the further Research, Development, Manufacture and Commercialization of such CoDev Product. Following such assumption, SGEN and PIRS shall no longer be responsible or liable to each other for any of their respective obligations (including diligence) and liabilities applicable to the further Research, Development, Manufacture, and Commercialization of such CoDev Product (including, without limitation, that PIRS shall no longer have any governance or reporting obligations to SGEN with respect to the applicable CoDev Product). As a condition to entering into a Full Sublicense hereunder, SGEN shall require the SGEN Partner, within [\*\*\*] days of the date of execution of such Full Sublicense Agreement, to enter into a direct agreement with PIRS acknowledging the respective rights, obligations and liabilities of the SGEN Partner and PIRS with respect to such CoDev Product, and providing for the transition of any SGEN CoDev Product related activities and governance from SGEN to the SGEN Partner. SGEN shall have no obligation to share with PIRS any [\*\*\*] received from such SGEN Partner under such Full Sublicense Agreement, and such [\*\*\*] shall not be included in the calculation of Profit and Losses as set forth in Exhibit 1.189.

85

#### 10. Diligence & Exclusivity

# 10.1. Diligence Obligation.

10.1.1. <u>Generally</u>. PIRS and SGEN shall use Commercially Reasonable Efforts to perform their respective activities contemplated by this Agreement with respect to the subject matter hereof, including but not limited to any activities under the then-current Research Candidate Plan and CoDev Product Plan and any other plans or tasks approved by a Committee.

#### 10.1.2. <u>SGEN</u>.

10.1.2.1. <u>Generally</u>. SGEN shall use Commercially Reasonable Efforts to Research and Develop each Research Candidate to achieve the [\*\*\*]. SGEN shall further use Commercially Reasonable Efforts to Develop and Commercialize each (subject to <u>Section 4.3.7</u>) Collaboration Product in the Field, including Commercialization activities (such as booking sales) for each Collaboration Product Commercialized in the SGEN Territory. In particular, SGEN shall use Commercially Reasonable Efforts to Commercialize each Collaboration Product in the following: each [\*\*\*] and, with respect to Exclusive Products, the [\*\*\*].

# 10.1.2.2. Collaboration Products.

(a) <u>IND/IMPD Filing</u>. For each Collaboration Product, SGEN shall file an IND/IMPD no later than [\*\*\*] years after the [\*\*\*] for such Collaboration Product. In the event of one or more material delays outside of SGEN's reasonable control (e.g., for technical, including manufacturing, scientific or regulatory reasons), then such [\*\*\*] year period shall be reasonably extended to account for such delay(s), provided that SGEN shall provide sufficient documentation to PIRS to substantiate the basis for the material delay(s).

(b) <u>Ongoing Clinical Studies.</u> For each Collaboration Product that is not a CoDev Product, there shall not be a period of longer than [\*\*\*] year during which there is no ongoing Clinical Study being conducted by SGEN for such Collaboration Product. In the event of one or more material delays outside of SGEN's reasonable control (e.g., for technical, including manufacturing, scientific or regulatory reasons), then such [\*\*\*] year period shall be reasonably extended to account for such delay(s), provided that SGEN shall provide sufficient documentation to PIRS to substantiate the basis for the material delay(s).

86

(c) <u>Remediation Plan</u>. Notwithstanding anything to the contrary in this <u>Section</u> 10.1.2.2, if SGEN believes it is will be unable to meet the timelines set forth under <u>Section 10.2.1.2(a)</u> or <u>Section 10.2.1.2(b)</u> above (as may be extended as set forth in such Sections), SGEN may notify PIRS of such belief, which notice shall contain a reasonably detailed explanation of the relevant facts and will include in reasonable detail, specific steps that SGEN will take to remedy the diligence failure within [\*\*\*] year of the deadlines set forth under <u>Section 10.2.1.2(a)</u> or <u>Section 10.2.1.2(b)</u> above (as may be extended as set forth in such SGEN will take to remedy the diligence failure within [\*\*\*] or resuming Clinical Studies, as applicable (each a "**Remediation Plan**"), which Remediation Plan may be updated (but for clarity, not further extended) from time to time. SGEN shall use Commercially Reasonably Efforts to promptly carry out the Remediation Plan.

(d) <u>Failure to Implement</u>. Notwithstanding anything to the contrary in this <u>Section 10.1.2.2</u>, if SGEN fails to implement a Remediation Plan (including failing to meet a specified deadline contained therein for submitting an IND/IMPD or resuming Clinical Studies), as determined by the JSC, then, solely with respect to the applicable Collaboration Product, SGEN shall be required to terminate for convenience pursuant to <u>Section 16.2.3</u> effective immediately. Notwithstanding <u>Section 3.6.2</u>, in the event the JSC cannot reach agreement as to whether SGEN has failed to implement a Remediation Plan, then such dispute shall be escalated to the Senior Executives followed by accelerated dispute resolution pursuant to <u>Section 17.2.2</u> if the Senior Executives cannot resolve the issue within [\*\*\*] days upon referral.

10.1.3. <u>PIRS</u>. PIRS shall use Commercially Reasonable Efforts to Research each Research Candidate. PIRS shall use Commercially Reasonable Efforts to co-Develop and Commercialize each CoDev Product in the Field, including Commercialization activities (such as booking sales) for each CoDev Product Commercialized in the PIRS Territory.

## 10.2. Non-Compete.

10.2.1. <u>Research Candidate Exclusivity</u>. On a Research Candidate-by-Research Candidate basis, during the Research Term with respect to such Research Candidate, each Party covenants not to Research, Develop, Manufacture, itself or with its Affiliate or any Third Party, a Competing Research Product with respect

87

to such Research Candidate anywhere in the world except as expressly permitted under this Agreement.

10.2.1.1. Competing Research Product ROFN. On a Dormant Candidate-by-Dormant Candidate basis, for a period of [\*\*\*] year after the [\*\*\*] applicable to such Dormant Candidate, each Party covenants not to Research, Develop, Manufacture, itself or with its Affiliate or any Third Party, a Competing Research Product with respect to such Dormant Candidate anywhere in the world except as expressly permitted under this Agreement. After such [\*\*\*] year period has lapsed, either Party may Research, Develop or Manufacture a Competing Research Product with respect to such Dormant Candidate (such Party the "CRP Initiating Party"), except that for a period of [\*\*\*] years after the [\*\*\*] year period set forth in this Section 10.2.1 has lapsed, the CRP Initiating Party shall provide the other Party, prior to initiating any laboratory experiments with respect to such Competing Research Product, with written notice describing the Competing Research Product that the CRP Initiating Party seeks to Research, Develop, Manufacture or Commercialize ("CRP ROFN Notice"). If, within [\*\*\*] days following receipt of the CRP ROFN Notice, the other Party notifies the CRP Initiating Party of its interest to license or include in this collaboration such Competing Research Product, PIRS and SGEN shall enter into good faith negotiations on an exclusive basis for a period of [\*\*\*] days to attempt to negotiate the financial and key terms for a collaboration and license with respect to such rights and, if the Parties are able to reach mutual agreement on such terms within such [\*\*\*] day period, shall further negotiate in good faith for a period of [\*\*\*] days an amendment to this Agreement to incorporate such Competing Research Product ("Competing Research Product Amendment"). If (a) the other Party does not provide such written notice within [\*\*\*] days or (b) the Parties fail to reach agreement on the financial terms within the subsequent [\*\*\*] day period or (c) the Parties fail to execute a Competing Research Product Amendment for such Competing Research Product within [\*\*\*] days following mutual agreement on the financial and key terms, then the CRP Initiating Party shall be free to Research, Develop, Manufacture or Commercialize such Competing Research Product, including by entering into any out-license or partnership with a Third Party with respect to such Competing Research Product and otherwise shall have no further obligation to the other Party. Notwithstanding the foregoing, nothing in this Section 10.2.1.1 shall in any way restrict, limit, or prohibit or be deemed to restrict, limit, or prohibit either Party from soliciting, negotiating, facilitating, executing, or undergoing a Change of Control.

88

10.2.1.2. <u>Third Party Interest in Competing Research Product</u>. Notwithstanding <u>Section 10.2.1.1</u> above, and provided that no Joint IP, SGEN IP, SGEN Confidential Information, or other Data generated in connection with activities hereunder (but excluding Data that relates solely to the PIRS Building Block in the applicable Dormant Candidate) is used, PIRS may Research, Develop, Manufacture or Commercialize a Competing Research Product:

(a) immediately with respect to a Dormant Candidate if the Competing Research Product is initiated or requested by a [\*\*\*] the applicable Research Candidate became a Dormant Candidate; or

(b) [\*\*\*] months after the date the applicable Research Candidate became a Dormant Candidate if a [\*\*\*], regardless of whether or not such [\*\*\*] at the end of the applicable Research Term.

10.2.2. In the event that PIRS initiates the Research or Development of a Competing Research Product pursuant to <u>Section 10.2.1.2</u>, then PIRS shall provide written notice to SGEN within [\*\*\*] days of such initiation, identifying the Target pairs of such Competing Research Product. As of the date of SGEN's receipt of such notice, SGEN shall also be permitted to Research, Develop, Manufacture, or Commercialize a Competing Research Product specific for the same Target pairs. Neither Party will have any further obligation to the other under this Agreement in connection with any Competing Research Product permitted under this <u>Section 10.2.2</u>, provided that SGEN uses no PIRS IP or PIRS Confidential Information (unless such PIRS Confidential Information is or becomes excluded pursuant to <u>Section 12.4</u>) and PIRS uses no SGEN IP or SGEN Confidential Information (unless such SGEN Confidential Information is or becomes excluded pursuant to <u>Section 12.4</u>) to Research, Develop, Manufacture or Commercialize such a Competing Research Product.

10.2.3. <u>Dormant Candidate Forbearance</u>. Neither Party shall be permitted to Research, Develop, Manufacture or Commercialize any Dormant Candidate.

10.2.4. <u>Collaboration Product Exclusivity</u>. On a Collaboration Product-by-Collaboration Product basis, during the Term, each Party covenants not to Research, Develop, Manufacture or Commercialize, itself or with any Third Party, any Competing Collaboration Product anywhere in the world except as expressly permitted under this Agreement, provided, however, that, after the [\*\*\*] of an Exclusive Product, [\*\*\*] will be permitted to begin Researching, Developing and Manufacturing Competing Collaboration Products for such Exclusive Product as part of customary lifecycle management. In addition, following the [\*\*\*] of a

89

CoDev Product, [\*\*\*] shall be permitted to begin Researching, Developing and Manufacturing Competing Collaboration Products for such CoDev Product as part of customary lifecycle management.

10.2.5. <u>Multispecific Products</u>. If PIRS or SGEN (whether alone or with a Third Party) wish to Research, Develop, Manufacture or Commercialize a product, which product is not a Compound, Competing Research Product, or Competing Collaboration Product, and if such product binds to and modulates all of the same Therapeutically Relevant Targets as a Compound, but such product also binds to and modulates at least one other Therapeutically Relevant Target, then such Party will be permitted to so Research Develop, Manufacture or Commercialize such product; provided that prior to initiating laboratory work for such product such Party shall offer the other Party a first right to negotiate, in good faith, an amendment to include such product in this Agreement, at terms, including up-front financial terms, to be mutually agreed by the Parties in good faith.

10.3. Effect of Acquisition. Notwithstanding Section 10.2, each Party acknowledges that the other Party (the "Concerned Party") may be acquired or merge with a Third Party or acquire a Third Party during the Term of this Agreement (such transaction, an "Acquisition Transaction", and such Third Party, the "Acquiror" or "Acquiree"). In such event, if the Acquiror or Acquiree (or a Third Party that is an Affiliate of such Acquiror or Acquiree prior to and following the date of such Acquisition Transaction) was Researching, Developing, Manufacturing or Commercializing one or more Competing Research Product(s) or Competing Collaboration Products prior to the closing of such Acquisition Transaction (each an "Acquired Competing Product"), subject to the Concerned Party's compliance with this Section 10.3, such Concerned Party shall be deemed not to be in breach of Section 10.2:

10.3.1. if it Divests to a Third Party or permanently discontinues the Research, Development, Manufacture, and Commercialization of the Acquired Competing Product within [\*\*\*] months after the closing of the Acquisition Transaction;

10.3.2. if the Parties agree to contribute the Acquired Competing Product to the collaboration between the Parties on terms and conditions to be negotiated in good faith and that are mutually acceptable to the Parties, each in its respective sole discretion, with such agreement, if any, to be reflected in an amendment to this Agreement or a separate agreement to be entered into by and between the Parties within [\*\*\*] months after the closing of the Acquisition Transaction; or

10.3.3. if it requires that, the Acquiror (or Acquiree) and its Affiliates existing as of the date of the Acquisition Transaction (excluding the Concerned Party and its Affiliates) continue to Research and Develop (including Manufacture thereof solely for such Development purposes) such Acquired Competing Product without the participation or use of assets (including employees) owned or

90

employed by the Concerned Party prior to the Acquisition Transaction, provided that, in the event the Concerned Party elects to proceed in accordance with this <u>Section 10.3.3</u> no later than [\*\*\*] months following the completion of the first [\*\*\*] for such Product, and in any event and under all circumstances prior to any Commercialization of such Acquired Competing Product anywhere in the world, the Concerned Party shall elect, and shall complete, one of the options set forth in the foregoing <u>Section 10.3.1</u>, and <u>Section 10.3.2</u> above with respect either to the Acquired Competing Product (i.e., if the Concerned Party elects <u>Section 10.3.1</u> or <u>Section 10.3.2</u>) or the Compound corresponding thereto, as applicable. For clarity, any Commercialization of the Acquired Competing Product anywhere in the world (except as expressly contemplated by this <u>Section 10.3</u>) shall be deemed a breach of <u>Section 10.2</u> by the Concerned Party.

10.3.4. For avoidance of doubt, Divestiture of the Acquired Competing Product in accordance with <u>Section 10.3.1</u> shall not constitute Commercialization of the Acquired Competing Product for purposes of <u>Section 10.3.3</u>. Further, if the Parties are unable to agree on the terms under which the Concerned Party may contribute the Acquired Competing Product to the collaboration in accordance with <u>Section 10.3.2</u>, the Concerned Party must still make an election (i.e., <u>Section 10.3.1</u> or <u>Section 10.3.2</u>).

10.3.5. Notwithstanding the foregoing, if a Party is acquired by an Acquiror or merging with an Acquiree having an Acquired Competing Product (i) of a CoDev Product that such Party has entered into a Full Sublicense Agreement with a Third Party, or (ii) if such Party is PIRS, of an Exclusive Product, such Acquiror or Acquiree or its Affiliates may in lieu of Section 10.3.1 to Section 10.3.3 above, elect to continue to Research, Develop, Manufacture and Commercialize such Acquired Competing Product without the participation or use of assets (including employees) owned or employed by such Party prior to the Acquisition Transaction or resulting from this Agreement, and provided that under such circumstances the reporting obligations of SGEN under Sections 3.7.1-3.7.3 shall not apply. Furthermore, if PIRS is acquired by an Acquiror, then such Acquiror shall be permitted to Research, Develop, Manufacture and Commercialize of an Exclusive Product without the participation or use of assets owned or employed by PIRS prior to the Acquisition Transaction or resulting from this Agreement, and provided that under such circumstances of assets owned or employed by PIRS prior to the Acquisition Transaction or resulting from this Agreement of an Exclusive Product without the participation or use of assets owned or employed by PIRS prior to the Acquisition Transaction or resulting from this Agreement, and so as long as such Competing Collaboration Products do not utilize the [\*\*\*].

10.3.6. For purposes of this <u>Section 10.3</u>:

10.3.6.1. The term "**Divest**" or "**Divestiture**" means, with respect to an Acquired Competing Product, the sale, exclusive (even with respect to a Party and its Affiliates) license, or other delegation, assignment or transfer by a

Party or its Affiliates of all of their respective Development and Commercialization rights or obligations with respect to such compound or product to a Third Party without the retention or reservation of any commercialization interest or participation rights (other than solely an economic interest or the right to enforce customary terms and conditions contained in the relevant agreements effectuating such Divestiture, including rights of access and review in connection therewith).

10.3.6.2. With respect to Section 10.3.3 and Section 10.3.5, the acquired or acquiring Party and its Affiliates (including the Acquiror or Acquiree and their respective Affiliates) will adopt reasonable procedures (which include appropriate administrative, physical and technical safeguards, including underlying operating system and network security controls and other firewalls) to prevent the disclosure of (1) all Confidential Information of the other Party, (2) all PIRS IP, SGEN IP and Joint IP, and (3) all other information (including Know-How) with respect to the Research, Development, Manufacture, or Commercialization of Compounds (including any Research Candidate Plans, CoDev Product Plans, and Development Plan Overviews), including any structures of any such item and any Data generated in connection with activities hereunder (collectively, the "Sensitive Information") beyond such acquired or acquiring Party's and its Affiliates' and Sublicensees' or subcontractors' employees, agents or independent contractors who actively work under this Agreement or any Party Supply Agreement and who do not work on any Acquired Competing Program, which procedures will include reasonable restrictions on the scope of any Sensitive Information required to be provided by the other Party. For clarity, the foregoing will not apply to any Sensitive Information that is not treated as Confidential Information hereunder. Pending the election of Section 10.3.1 to Section 10.3.3, or as long as Section 10.3.5 applies, the Non-Concerned Party shall be released from its governance and reporting obligations to the Concerned Party with respect to the Development and Commercialization of the applicable Collaboration Product (other than pursuant to Section 8.2).

## 11. Intellectual Property

### 11.1. Ownership.

11.1.1. <u>Background & Other IP Ownership</u>. Subject to <u>Section 11.1.2</u>, as between the Parties, all Know-How and Intellectual Property Rights Controlled by a Party prior to the Effective Date or developed separate and apart from this Agreement after the Effective Date, shall be deemed owned by the Party Controlling such Know-How and Intellectual Property Rights.

11.1.2. Building Block IP and PIRS Platform Improvement IP Ownership.

*92* 

11.1.2.1. <u>Building Blocks</u>. A Party's Building Blocks, together with the Party's respective Building Block IP (including, for avoidance of doubt, improvements) in-licensed by a Party or generated by employees, agents, or independent contractors of either Party or its Affiliates in the course of performing activities under this Agreement, shall be solely owned by the Party which initially contributed or in-licensed such Building Block, subject to any rights and licenses granted herein. For clarity, the foregoing ownership shall be afforded regardless of whether such respective Building Block IP would otherwise constitute Joint IP under this Agreement. Each Party, for itself and on behalf of its Affiliates, hereby assigns (and to the extent such assignment can only be made in the future hereby agrees to assign), to the other Party all its right, title, and interest in and to the other Party's respective Building Block IP generated by employees, agents, independent contractors or consultants of such Party or its Affiliates in the course of performing activities under this Agreement, and will cooperate, and will cause its and its Affiliates' respective employees, agents, and contractors to cooperate, with the other Party to effectuate and perfect the foregoing ownership, including by promptly executing and recording assignments and other documents consistent with such ownership.

11.1.2.2. <u>PIRS Platform Improvement IP</u>. PIRS Platform Improvement IP shall be solely owned by PIRS. SGEN, for itself and on behalf of its Affiliates, hereby assigns (and to the extent such assignment can only be made in the future hereby agrees to assign), to PIRS all its right, title, and interest in and to any PIRS Platform Improvement IP. SGEN will cooperate, and will cause its and its Affiliates' respective employees, agents, and contractors to cooperate, with PIRS to effectuate and perfect the foregoing ownership, including by promptly executing and recording assignments and other documents consistent with such ownership. For clarity, no right is granted to SGEN under this Agreement with respect to the PIRS Platform Improvement IP.

11.1.3. Foreground IP.

11.1.3.1. <u>SGEN IP Ownership</u>. Except for (i) PIRS Building Block IP, (ii) PIRS Platform IP, (iii) PIRS Platform Improvement IP, and (iv) Joint IP, any invention conceived and reduced to practice, or Know-How generated solely by employees, agents, or independent contractors of SGEN under this Agreement, together with all Intellectual Property Rights therein, shall be owned by SGEN (any such Patent Rights therein, the "SGEN Compound Specific Patents").

93

11.1.3.2. <u>Joint IP</u>. Joint IP shall be owned jointly by the Parties and each Party shall have an equal and undivided right therein.

11.1.3.3. <u>Right to Exploit Joint IP</u>. Subject to and except as otherwise provided in this Agreement, including with respect to the licenses granted to the Parties under <u>Section 2</u> with respect to the Compounds, the non-compete obligation in <u>Section 10.2</u>, and the allocation of ownership of certain rights under <u>Section 11.1</u>, each Party shall have the right to freely sell, assign, license, encumber, and otherwise exploit Joint IP without consent of or notice or accounting to the other Party, including the development and commercialization, alone or with one or more Third Parties, of products that modulate immune cell activity for the treatment of cancer.

11.1.3.4. <u>CoDev Product Compound Specific Patent</u>. Notwithstanding <u>Section 11.1.3.2</u>, for any CoDev Product Compound Specific Patent that is filed prior to the PIRS CoDev Option Exercise Effective Date and that is solely owned by SGEN as of such date, SGEN shall not be obligated to assign half of its interest in such Patent to PIRS.

# 11.2. Patent Prosecution.

11.2.1. <u>General</u>. Except as otherwise set forth in this <u>Section 11.2</u>, each Party will have the sole responsibility, at such Party's sole discretion and sole expense, to prepare, file, prosecute and maintain, in such Party's name, all Patent Rights owned or Controlled by such Party, including without limitation, that PIRS shall have such rights with respect to all Patent Rights within the PIRS Platform IP and PIRS Platform IP.

11.2.2. Joint Patent Filings. Subject to Section 11.2.4 and Section 11.2.5, PIRS and SGEN shall collaborate to prepare the patent application(s) for the Joint Patents, subject to both Parties' review and approval. Such Patents shall be filed jointly in the name of, and shall be owned jointly by, the Parties and each Party shall have an equal and undivided right therein. SGEN shall be responsible for the filing, prosecution and maintenance of such Patents throughout the world. All costs and expenses of filing, prosecuting, and maintaining such Patent Rights shall be borne by SGEN (provided that in the case of any such Patent Covering a CoDev Product, such expense, whether incurred before or after the PIRS CoDev Option Exercise Effective Date, is an Out-of-Pocket Cost for purposes of calculating Reimbursable [\*\*\*] and Shared Costs as applicable). SGEN will provide PIRS copies of all substantive filings and documents related to the prosecution and maintenance of such Patent Rights, and will consider in good faith timely comments from PIRS thereon. If SGEN determines to abandon or not maintain any such Patent Rights,

**94** 

it shall provide PIRS with prior written notice of such determination at least [\*\*\*] days before any loss of rights would occur with respect to such Patent Rights in any applicable patent office or patent granting authority and PIRS shall then have the right to assume the right to prosecute and maintain such Patent Rights at its sole discretion and expense (provided, in the case of any such Patent Covering a CoDev Product, that such expense is an Out-of-Pocket Cost for purposes of calculating Shared Costs). In addition, as of the PIRS CoDev Option Exercise Effective Date any Initial Compound Specific Patent that Covers a CoDev Product shall be filed, prosecuted and maintained in accordance with <u>Section 11.2.4</u> below.

11.2.3. <u>SGEN Compound Specific Patent Filings</u>. Subject to <u>Section 11.2.4</u> and <u>Section 11.2.5</u>, SGEN shall have the sole responsibility, at SGEN's sole discretion and sole expense (provided that, with respect to any SGEN Compound Specific Patent that becomes a CoDev Product Compound Specific Patent, such expense is an Out-of-Pocket Costs for purposes of calculating Reimbursable [\*\*\*] and Shared Costs), to prepare, file, prosecute and maintain, in SGEN's name, all SGEN Compound Specific Patents, except to the extent that such filing contains PIRS Confidential Information, in which case SGEN must obtain the advance written consent of PIRS prior to filing such SGEN Compound Specific Patent. If SGEN determines to abandon or not maintain any SGEN Compound Specific Patent that Covers a Compound, SGEN shall provide PIRS with prior written notice of such determination at least [\*\*\*] days before any loss of rights would occur with respect to such Patent Rights, and PIRS shall have the right to prosecute and maintain such Patent Rights in SGEN's name, and the cost of any such prosecution and maintenance shall be borne by PIRS. For avoidance of doubt, as of the PIRS CoDev Option Exercise Effective Date any SGEN Compound Specific Patent that qualifies as a CoDev Product Compound Specific Patent shall become a CoDev Product Compound Specific Patent and shall be filed, prosecuted and maintained in accordance with <u>Section 11.2.4</u> below.

11.2.4. <u>CoDev Product Compound Specific Patents</u>. Notwithstanding <u>Section 11.2.2</u> and <u>Section 11.2.3</u>, in the event that PIRS exercises a PIRS CoDev Option, as of the PRIS CoDev Option Exercise Effective Date, SGEN shall continue to direct the day-to-day filing, prosecution, and maintenance of the CoDev Product Compound Specific Patents, provided that the Parties shall mutually agree upon the strategy for prosecuting and maintaining such Patent Rights. All costs and expenses of filing, prosecuting, and maintaining such Patent Rights shall be deemed an Out-of-Pocket Cost for purposes of calculating Shared Costs. SGEN shall provide PIRS with the opportunity to review and comment on any and all material prosecution efforts regarding such Patent Rights, and PIRS shall provide SGEN reasonable assistance in such efforts. SGEN may not abandon or not

95

maintain (including, for the United States, failing to maintain a pending continuation or divisional application) any such Patent Rights without the prior consent of PIRS.

11.2.5. <u>Other Joint Patents</u>. To the extent any Joint Patent is not related to a Compound, or Covers an Antibody-Anticalin Protein fusion molecule that is not a Compound, then the Parties shall discuss in good faith the sharing of responsibilities and costs in connection with the filing, prosecution and maintenance of such IP. In the absence of agreement, <u>Section 11.2.2</u> shall apply *mutatis mutandis* to any such Patents.

11.2.6. <u>Building Block Patents</u>. Each Party will have the sole responsibility, at such Party's sole discretion and sole expense, to prepare, file, prosecute, maintain, or abandon, in such Party's name, all Patent Rights within such Party's respective Building Block IP. Each Party will, through the JIPC, consult with the other Party regarding its strategy for the prosecution and maintenance of all such Patent Rights, and shall consider in good faith the other Party's comments regarding the same. Each Party will provide the other copies of all substantive filings and documents related to the prosecution and maintenance of such Patents Rights. Each Party will provide the other sufficient opportunity to review and comment on any prosecution and maintenance activity regarding such Patent Rights. For the avoidance of doubt, each Party shall furnish to the other Party its anticipated filing dates for any such Patents Rights as are relevant to a Compound in a timely matter to reasonably enable coordination between the Parties regarding the same. The Controlling Party will consider in good faith timely comments from the non-Controlling Party thereon.

11.2.7. <u>Reasonable Assistance</u>. Each Party will use reasonable efforts to make available to the other its authorized attorneys, agents, or representatives, or such of its employees as are reasonably necessary to assist the other Party in exercising its rights described under this <u>Section 11.2</u>. Each Party will sign, or will use reasonable efforts to have signed, all legal documents as are reasonably necessary to prosecute and maintain Patents in accordance with this <u>Section 11.2</u>. Each Party shall provide the other Party all reasonable assistance and cooperation in the Patent prosecution efforts described above in this <u>Section 11.2</u>, including providing any necessary powers of attorney, oaths, declarations, assignments, and executing any other required documents or instruments for such prosecution.

11.2.8. <u>No Adverse Action</u>. SGEN shall in good faith seek to avoid any action in the prosecution of the Joint Patents pursuant to this Agreement that would have a material adverse impact on any Patent Rights within the PIRS Building Block IP, the PIRS Platform IP, or the PIRS Platform Improvement IP, and PIRS shall in good faith seek to avoid any action in the prosecution of the Joint Patents pursuant

96

to this Agreement that would have a material adverse impact on any Patent Rights within the SGEN Building Block IP.

11.3. <u>Common Interest Disclosures</u>. With regard to any information or opinions disclosed pursuant to this Agreement by one Party to each other regarding intellectual property and/or technology owned by Third Parties, the Parties agree that they have a common legal interest in determining whether, and to what extent, Third Party intellectual property rights may affect the conduct of a Research Plan, CoDev Product Plan or Development and Commercialization of any CoDev Product, and have a further common legal interest in defending against any actual or prospective Third Party claims based on allegations of misuse or infringement of intellectual property rights relating thereto. Accordingly, the Parties agree that all such information and materials obtained by PIRS and SGEN from each other will be used solely for purposes of the Parties' common legal interests with respect to the conduct of the Agreement. All information and materials will be treated as protected by the attorney-client privilege, the work product privilege, and any other privilege or immunity that may otherwise be applicable. By sharing any such information and materials, neither Party intends to waive or limit any privilege or immunity that may apply to the shared information and materials. Neither Party's prior written consent, nor shall the waiver of privilege or immunity resulting from the conduct of one Party be deemed to apply against any other Party.

### 11.4. Patent Term Extensions.

11.4.1. <u>Generally</u>. The Parties shall cooperate in good faith in order to avoid the loss of any rights that may otherwise be available to the Parties under the U.S. Drug Price Competition and Patent Term Restoration Act of 1984, the Supplementary Certificate of Protection of the Member States of the European Union and other similar measures in any other country.

11.4.2. <u>SGEN</u>. Notwithstanding anything to the contrary in <u>Section 11.4.1</u>, SGEN will have the sole right and responsibility to apply for and obtain any patent term extension, supplementary protection certificates or similar extension of rights for any Joint Patent Covering a Collaboration Product in the SGEN Territory. To the extent necessary, PIRS agrees to execute any authorization or instruments, make any filings, or take such further actions as may be requested by SGEN to implement and obtain any such patent term extension, supplementary protection certificates or similar extension of rights. SGEN will have the sole right but not the obligation to apply for and obtain any patent term extension, supplementary protection certificates or similar extension. SGEN Building Block IP. At SGEN's request, PIRS shall reasonably consider applying for such

an extension with respect to any Patent within the PIRS Building Block IP, PIRS Platform IP or PIRS Platform Improvement IP.

11.4.3. <u>PIRS</u>. Notwithstanding anything to the contrary in <u>Section 11.4.1</u>, PIRS will have the sole right and responsibility to apply for and obtain any patent term extension, supplementary protection certificates or similar extension of rights for any Joint Patent Covering a CoDev Product in the PIRS Territory. To the extent necessary, SGEN agrees to execute any authorization or instruments, make any filings, or take such further actions as may be requested by PIRS to implement and obtain any such patent term extension, supplementary protection certificates or similar extension of rights. PIRS will have the sole right but not the obligation to apply for and obtain any patent term extension, supplementary protection certificates or similar extension of rights, using any PIRS Building Block IP. At PIRS's request, SGEN shall reasonably consider applying for such an extension with respect to any Patent within the SGEN Building Block IP.

11.5. <u>CREATE Act</u>. Neither Party shall invoke the Cooperative Research and Technology Enhancement Act ("**CREATE Act**") in connection with the Prosecution or Maintenance of any PIRS IP, SGEN IP or Joint IP without the prior written consent of the other Party.

# 11.6. Intellectual Property Litigation.

## 11.6.1. Defense.

11.6.1.1. <u>Defense Cooperation</u>. If the Research, Development, Manufacture, or Commercialization, including the use, importation, offer for sale or sale of any Collaboration Product pursuant to this Agreement results in any claim, suit or proceeding alleging patent infringement or trade secret misappropriation against PIRS or SGEN, then such Party shall promptly notify the other Party hereto. The Parties shall reasonably cooperate with each other in connection with any such claim, suit or proceeding and shall keep each other reasonably informed of all material developments in connection with any such claim, suit or proceeding.

11.6.1.2. <u>Compound Defense</u>. If a Third Party asserts that a Patent owned by or licensed to it are infringed by the Research, Development, Manufacture, or Commercialization, including the use, importation, offer for sale or sale of a Research Candidate or Collaboration Product by SGEN or its Affiliates (or by PIRS in the case of a CoDev Product in the PIRS Territory), or that its trade secrets were misappropriated in connection with such activity (any such claim, a "**Third Party IP Claim**"), then (except to the extent such Third Party IP Claim is subject to indemnification under <u>Section 15</u>, in which case <u>Section 15.1</u> or <u>Section 15.2</u>, as applicable, shall govern) (a) SGEN shall

**98** 

have the exclusive right and responsibility to resolve any such Third Party IP Claim made in the SGEN Territory and (b) PIRS shall have the exclusive right and responsibility to resolve any such Third Party IP Claim made in the PIRS Territory with respect to a CoDev Product (the Party resolving such Third Party IP Claim being the "Defending Party"). The Defending Party shall have the right to resolve such Third Party IP Claim in the manner that it chooses, whether by obtaining a license from such Third Party, by defending against such Third Party IP Claim or otherwise, and shall be solely responsible for the defense of any such action, any and all costs incurred in connection with such action (including, without limitation, attorneys' and expert fees) and all liabilities incurred in connection therewith. Notwithstanding the above, the Defending Party shall not enter into any settlement of any such Third Party IP Claim without the prior written consent of the other Party (such Party the "Non-Defending Party") if such settlement would require the Non-Defending Party to be subject to an injunction or to make any monetary payment to the Defending Party or any Third Party, or admit any wrongful conduct by the Non-Defending Party or its Affiliates, or would limit or restrict the claims of or admit any invalidity and/or unenforceability of any of the Patents Controlled by the Non-Defending Party. Subject to Section 8.1.2, and except to the extent the applicable Third Party IP Claim is subject to indemnification under Section 15.1, SGEN shall assume full responsibility for the payment of any award for damages, or any amount due pursuant to any settlement or license entered into by it with a Third Party as a result of any action under this Section 11.6.1.2 for each Exclusive Product. For a CoDev Product, except to the extent the applicable Third Party IP Claim is subject to indemnification under Section 15.1 or Section 15.2 (in which case the Indemnifying Party shall be solely responsible for the following amounts), the payment of any award for damages, or any amount due pursuant to any settlement or license entered into by either Party with a Third Party as a result of any action under this <u>Section 11.6.1.2</u> will be calculated as part of Profits and Losses as set forth in Exhibit 1.189.

11.6.1.3. <u>PIRS Research Term Activities Defense</u>. If a Third Party IP Claim is commenced against PIRS, related to PIRS' conduct of the research program within the scope of the Research Candidate Plan or the discovery of a Research Candidate, in each case in accordance with this Agreement, then, except to the extent the applicable Third Party IP Claim is subject to indemnification under <u>Section 15.1</u>, PIRS shall have the right (but not the obligation) to defend such action, and SGEN shall assist and cooperate with PIRS to the extent necessary in the defense of such suit. PIRS shall have the right to settle the suit or consent to an adverse judgment thereto, in its sole discretion, so long as such settlement or adverse judgment does not adversely

**99** 

affect the rights of SGEN and its Affiliates (including any Patents Controlled by any of them), provided that PIRS may not enter into any settlement or consent that requires the payment of an award for monetary damages or other monetary payment without SGEN's written consent. Except to the extent the applicable Third Party IP Claim is subject to indemnification under Section 15.1, SGEN shall assume full responsibility for the reasonable costs of defending such Third Party IP Claim, payment of any award for damages, or any amount due pursuant to any settlement entered into by it with such Third Party.

#### 11.6.2. Enforcement.

11.6.2.1. SGEN Enforcement. SGEN shall have the full and unrestricted right, but not the obligation, to bring and control an appropriate suit or other action against any person or entity under any Joint Patent directly relating to any Collaboration Product in the Field in the SGEN Territory, except as set forth in <u>Section 11.6.2.2</u> ("SGEN Infringement Action"), in its own name and entirely under its own direction and control. In the event that SGEN does not wish to enforce such Patents against such a potential infringer, then SGEN shall deliver prompt written notice thereof to PIRS. In the event that SGEN is unable to initiate or prosecute such SGEN Infringement Action solely in its own name or it is otherwise advisable in order to obtain an effective remedy, PIRS will join, but not control, such SGEN Infringement Action. If SGEN requests so, PIRS shall reasonably cooperate with SGEN in the planning and execution of any SGEN Infringement Action. Notwithstanding the foregoing, if SGEN does not either initiate such an Infringement Action or grant adequate rights and licenses to such Third Party within [\*\*\*] days after SGEN's receipt of a notice of infringement (or sooner if any deadlines require action prior to such [\*\*\*] days) and the infringement relates to the launch or a threat to launch a Biosimilar version of a Collaboration Product, then PIRS will have the second right, but not the obligation, to initiate such Infringement Action. In the case of an Exclusive Product, all monies recovered upon the final judgment or settlement of any such suit or action to enforce such Patents subtracting any costs that the Parties bore in connection with such suit or action shall be divided between the Parties as follows: (a) if SGEN is the enforcing Party, SGEN shall retain [\*\*\*] percent ([\*\*\*]%) and pay [\*\*\*] percent ([\*\*\*]%) to PIRS (in lieu of any royalties or other payments due on such recoveries under the Agreement), and (b) if PIRS is the enforcing Party, PIRS shall retain [\*\*\*] percent ([\*\*\*]%) (in lieu of any royalties or other payments due on such recoveries under the Agreement), and pay [\*\*\*] percent ([\*\*\*]%) to SGEN. In the case of a CoDev Product,

100

all monies recovered upon the final judgment or settlement of any such suit or action to enforce such Patents subtracting any costs that the Parties bore in connection with such suit or action shall be included in the calculation of Profits and Losses as set forth in <u>Exhibit 1.189</u>.

11.6.2.2. PIRS Enforcement. PIRS shall have the full and unrestricted right, but not the obligation, to bring and control an appropriate suit or other action against any person or entity under any Joint Patent or CoDev Product Compound Specific Patent directly relating to a CoDev Product in the Field in the PIRS Territory ("PIRS Infringement Action"), in its own name and entirely under its own direction and control. In the event that PIRS does not wish to enforce such Patents against such a potential infringer, then PIRS shall deliver prompt written notice thereof to SGEN. In the event that PIRS is unable to initiate or prosecute such PIRS Infringement Action solely in its own name or it is otherwise advisable in order to obtain an effective remedy, SGEN will join, but not control, such PIRS Infringement Action. If PIRS requests so, SGEN shall reasonably cooperate with PIRS in the planning and execution of any such action to enforce such Patents. Notwithstanding the foregoing, if PIRS does not either initiate such an Infringement Action or grant adequate rights and licenses to such Third Party within [\*\*\*] days after PIRS's receipt of a notice of infringement (or sooner if any deadlines require action prior to such [\*\*\*] days) and the infringement relates to the launch or a threat to launch a Biosimilar version of a CoDev Product, then SGEN will have the second right, but not the obligation, to initiate such Infringement Action. All monies recovered upon the final judgment or settlement of any such suit or action to enforce such Patents subtracting any costs that the Parties bore in connection with such suit or action shall be included in the calculation of Profits and Losses as set forth in Exhibit 1.189.

## 11.6.2.3. No Other Enforcement Rights.

(a) SGEN shall not have the right to assert or enforce any other Patents owned or Controlled by PIRS under this Agreement, such as the Patent Rights within the PIRS Building Block IP, PIRS Platform IP or PIRS Platform Improvement IP, against a Third Party under any circumstances, and PIRS shall not be under any obligation to enforce such Patent Rights, except that, absent PIRS' reasonable justification, PIRS shall bring an appropriate suit or other action against any person or entity under any Patent Right within the PIRS Building Block IP directly relating to an Exclusive Product at SGEN's request and cost, and using counsel selected by SGEN and reasonably acceptable to

101

PIRS. In addition, with respect to any Exclusive Product Commercialized by SGEN in the SGEN Territory, SGEN will, within [\*\*\*] days after its receipt of written notice (if any) confirming acceptance of a BLA by the FDA for a Biosimilar product (or equivalent acceptance of an application to market a Biosimilar by another Competent Authority), provide PIRS with notice of acceptance of the aBLA, and, to the extent provided by the applicant under 42 USC § 262(1)(2)(A) (or any similar standard under its foreign equivalent applicable law), with a copy of the aBLA and "such other information that describes the process . . . used to manufacture the biological product." PIRS shall then provide SGEN within [\*\*\*] days a list of such Patent Rights within the PIRS Building Block IP that it believes are infringed by the applicant and that PIRS agrees to enforce against the applicant. PIRS also agrees to reasonably cooperate and assist SGEN in complying with its additional obligations under § 262(1) (or foreign equivalent).

(b) PIRS shall not have the right to assert or enforce any other Patents owned or Controlled by SGEN under this Agreement, such as the Patent Rights within the SGEN Building Block IP against a Third Party under any circumstances and PIRS shall not be under any obligation to enforce such Patent Rights.

(c) Other than as set forth herein, upon reasonable request, the Party controlling the Patent Rights set forth in this <u>Section 11.6.2.3</u> shall reasonably consider enforcing or permitting enforcement of such Patent Rights.

11.7. Trademarks.

11.7.1. <u>CoDev Product Trademarks</u>. Unless otherwise set forth in an approved CoDev Product Plan or Global Commercialization Strategy, with respect to the CoDev Products, each Party shall select one or more product trademarks (including backup trademarks) for the CoDev Products for use by such Party in its Respective Territory (including backup trademarks) (the "**Product Trademarks**") in line with the agreed upon Global Branding Strategy. Each Party (or its local Affiliates, as appropriate) shall own and retain all rights to Product Trademarks, together with all goodwill associated therewith, worldwide, and all e-brands, trade dress, service marks, domain names, designs, and Copyrights for a CoDev Product in its respective Territory.

11.7.2. <u>Responsibility</u>.

102

11.7.2.1. SGEN shall be responsible for filing, registering, maintaining, and defending Product Trademarks in the SGEN Territory at SGEN's expense and in its own name. Subject to any Global Branding Strategy, SGEN may, at its own discretion, select for the Product Trademark a trademark which was already filed or registered in SGEN's portfolio. SGEN shall have the right to affix any corporate logo or corporate trade name of its choice on the CoDev Products in the SGEN Territory.

11.7.2.2. PIRS shall be responsible for filing, registering, maintaining, and defending Product Trademarks in the PIRS Territory at PIRS' expense and in its own name. Subject to any Global Branding Strategy, PIRS may, at its own discretion, select for the Product Trademark a trademark which was already filed or registered in PIRS' portfolio. PIRS shall have the right to affix any corporate logo or corporate trade name of its choice on a CoDev Product in the PIRS Territory.

11.7.2.3. If the Parties agree that SGEN will use in its Territory Product Trademarks selected by PIRS for a CoDev Product, SGEN shall file and maintain such Product Trademarks in the SGEN Territory in consultation with PIRS (including, as appropriate, through the JIPC), at SGEN's cost, and shall grant to PIRS an exclusive license with the right to sublicense, to the Product Trademarks in connection with the Development, Manufacturing and Commercialization of a CoDev Products in the PIRS Territory, as applicable.

11.7.2.4. If the Parties agree that PIRS will use in its Territory Product Trademarks selected by SGEN for a CoDev Product, PIRS shall file and maintain such Product Trademarks in the PIRS Territory in consultation with SGEN (including, as appropriate, through the JIPC), at PIRS's cost, and shall grant to SGEN an exclusive license with the right to sublicense, to the Product Trademarks in connection with the Development, Manufacturing and Commercialization of a CoDev Products in the SGEN Territory, as applicable.

11.7.3. <u>Domain Names</u>. The Parties may also separately select domain names including or close to a Product Trademark owned by such Party. Such Party shall be responsible for filing and registering such domain names at such Party's expense and in its own name.

11.7.4. <u>Ownership; Rights</u>. Subject to this <u>Section 11.7</u>, neither Party shall have any interest, title or right in any of the Trademarks used by a Party or other trade dress, logos, trade names and designs. Neither Party shall directly or indirectly seek through judicial or administrative process, to invalidate, oppose or challenge the validity, enforceability or scope of any Trademarks or other trade dress, logos, trade names and designs used by the other Party in connection with any CoDev Products. During the Term of this Agreement and thereafter, the Parties undertake

103

not to take any actions and not to assist in any such actions to acquire any property rights in and to the Trademarks, trade dress, logos, trade names, and designs used in connection with the CoDev Products by the other Party, in particular not to register nor attempt to register in its name any trademark, trade name, trade or designs, identical or similar to the Trademarks, trade dress, logos, trade names, and designs used in connection with the Collaboration Products by the other Party. Subject to the other Party's approval, a Party shall not register nor use directly or indirectly any domain name including a name identical to or similar to the Trademarks or trade names used by the other Party in connection with any CoDev Product.

11.7.5. <u>Approval Right.</u> Any and all use by each Party of the Trademarks or and any trade dress, logos, trade names, and designs used in connection with the CoDev Products by the other Party shall be subject to the other Party's prior express written approval. For avoidance of doubt, SGEN shall not use PIRS' Anticalin® trademark without the advance written permission of PIRS.

11.7.6. <u>Monitoring</u>. Each Party shall maintain vigilance and shall promptly notify the other Party of any infringements or possible infringements of the Trademarks, trade dress, logos, trade names, and designs used in connection with the CoDev Products of which it becomes aware.

11.7.7. <u>Use of Name</u>. The Party in charge of a Clinical Study shall ensure that its name can be freely used and register it. The other Party shall be allowed to make reference to this Clinical Study and to use its registered name solely for the promotion and the commercialization of a CoDev Product in its Territory.

11.7.8. <u>Exclusive Products</u>. SGEN shall be solely responsible for filing, registering, maintaining, and defending Trademarks in the SGEN Territory for Exclusive Products, at SGEN's expense and in its own name.

# 12. Confidentiality

12.1. <u>Confidentiality</u>. Except to the extent expressly authorized by this Agreement or agreed in writing by the Parties, during the Term and for a period of [\*\*\*] years after its termination or expiration, the Parties agree that the Receiving Party shall: (a) keep the Disclosing Party's Confidential Information confidential; (b) not disclose, or permit the disclosure of, the Disclosing Party's Confidential Information; and (c) not use, or permit to be used, the Disclosing Party's Confidential Information for any purpose other than as expressly permitted under the terms of this Agreement; provided that in the case of Confidential Information that constitutes a trade secret pursuant to Chapter I, Article 2 of EU Directive 2016/943 or Article 39 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights ("**ADPIC Treaty**") and has been identified or reasonably understood to be such by the Disclosing Party, the obligations under this Section 12.1 shall apply for so long as such Confidential Information is afforded trade secret protection pursuant to Chapter I, Article 2 EU Directive 2016/943 or Article 39 of the ADPIC Treaty.

12.2. Authorized Disclosure. The Receiving Party shall only be entitled to disclose, on a need to know basis for the purpose of the performance of the Agreement, Confidential Information of the Disclosing Party to its (i) directors, employees, Affiliates, consultants, and advisors, (ii) existing Sublicensees, investors, lenders, underwriters and collaborators, (iii) potential Sublicensees, investors, lenders, underwriters, collaborators or successors in interest solely to the extent necessary for the evaluation of a potential sublicense, collaboration or investment or merger, acquisition or Change of Control, or (iv) Third Party subcontractors (collectively the "Authorized Recipients"); provided that such Authorized Recipients are bound by confidentiality and restricted use obligations or professional standards of confidentiality with respect to such Confidential Information that are at least as stringent as those set forth in this Agreement. The Receiving Party will use diligent efforts to cause its Authorized Recipients to comply with such confidentiality and restricted use obligations. The Receiving Party shall be responsible towards the Disclosing Party for any breach by its Authorized Recipients any such confidentiality and restricted use obligations.

# 12.3. Disclosure to Third Parties.

12.3.1. <u>Right to Disclose</u>. Notwithstanding the foregoing provisions of <u>Section 12.1</u>, the Receiving Party may disclose Confidential Information of the Disclosing Party to the extent (and only to the extent) such disclosure is reasonably necessary:

12.3.1.1. to Competent Authorities (a) to the extent desirable to obtain or maintain Regulatory Approvals for any Product within the Party's respective Territory, and (b) in order to respond to inquiries, requests or investigations relating to Products or this Agreement;

105

12.3.1.2. in connection with filing or prosecuting Patent Rights or trademark rights as permitted under this Agreement;

12.3.1.3. in connection with prosecuting or defending litigation as permitted by this Agreement;

12.3.1.4. to the counterparty of the PIRS Background Agreements, or the SGEN Background Agreements to which such Receiving Party is the contracting Party in order to comply therewith;

12.3.1.5. subject to the provisions of <u>Section 13</u>, in connection with or included in scientific presentations and publications relating to Compounds, including abstracts, posters, journal articles and the like, and posting results of and other information about Clinical Studies to clincialtrials.gov or similar websites; and

12.3.1.6. to the extent necessary in order to enforce its rights under this Agreement.

12.3.2. <u>Disclosure Notice</u>. If a Party deems it reasonably necessary to disclose Confidential Information belonging to the other Party pursuant to this <u>Section 12.3</u>, then the former Party shall, if available, use commercially reasonable effort to obtain a protective order, confidential treatment or other similar measures narrowing the scope of such use and public or other disclosure of such Confidential Information and otherwise take such measures to ensure confidential treatment of such information as is reasonably required. For clarification, any such limited disclosure shall not cause any such information to cease to be Confidential Information.

### 12.4. Excluded Information.

12.4.1. <u>Excluded Information</u>. Notwithstanding <u>Section 12.1</u>, the Confidential Information of the Disclosing Party shall not include information or materials that:

12.4.1.1. at the time of disclosure to, or acquisition by, the Receiving Party or its Affiliates is generally available to the public, or after the time of disclosure or acquisition is generally available to the public through no wrongful act or omission of the Receiving Party or its Authorized Recipients in breach of this Agreement;

12.4.1.2. was in the lawful possession and at the free disposal (not subject to a duty of confidentiality or restricted use obligations) of the Receiving Party prior to disclosure by the Disclosing Party, as evidenced by written records then in the possession of the Receiving Party;

12.4.1.3. is rightfully made available to the Receiving Party by Third Parties not bound by confidentiality or restricted use obligations; or

12.4.1.4. is independently discovered or developed by the Receiving Party without access to or use of the Confidential Information of the Disclosing Party, as evidenced by written records then in the possession of the Receiving Party.

12.5. Legally Required Disclosures. The Receiving Party may disclose Confidential Information of the Disclosing Party in order to comply with the requirements of applicable Law (and only to the extent so required), provided that the Receiving Party shall to the extent possible give reasonable advance written notice of such disclosure to the Disclosing Party and will cooperate with the Disclosing Party in protecting against any such disclosure and/or obtaining a protective order, confidential treatment or other similar measures narrowing the scope of such use and public or other disclosure of such Confidential Information and otherwise taking such measures to ensure confidential treatment of such information as is reasonably required. Any such compelled disclosure will be to the minimum extent permissible as required by applicable Law. For clarification, any such limited disclosure shall not cause any such information to cease to be Confidential Information.

#### 12.6. Terms of this Agreement.

12.6.1. <u>Confidentiality of this Agreement</u>. The Parties agree that the terms of this Agreement will be treated as Confidential Information of both Parties, and thus may be disclosed only as permitted by <u>Section 12.3</u> (other than <u>Section 12.3.1.5</u>) and <u>Section 12.5</u>. Each Party will also be permitted to disclose the terms of this Agreement (including the Exhibits hereto), in each case under appropriate confidentiality provisions (or without such provisions for recipients that are financial or legal advisors under a professional code of conduct giving rise to an expectation of confidentiality and non-use at least as restrictive as those set forth in this Agreement), on a need to know basis, to a Party's (and its Affiliates') existing investors and to any bona fide potential or future permitted acquirer or assignee, investment banker, investor, licensee, Sublicensee, collaborator, underwriter or lender with whom a Party (or its Affiliates) has entered into good faith negotiations regarding a proposed transaction, provided that (a) the disclosing Party agrees to redact information that it reasonably believes is not relevant to the proposed transaction, and (b) the financial terms of this Agreement may be disclosed to any of the foregoing named Persons only after negotiations with such Person have progressed so that such Party reasonably believes that a transaction is reasonably expected to occur.

12.6.2. <u>Securities Filings</u>. If a Party is required by applicable Law to make a disclosure of the terms of this Agreement (including for clarity, the Exhibits and

Schedules hereto) in a filing with or other submission to the United States Securities and Exchange Commission (the "SEC") or any other securities exchange or otherwise to comply with applicable Law, such Party shall provide prompt written notice of the disclosure to the other Party as far in advance of such filing or other disclosure as is reasonably practicable under the circumstance in order to allow the other Party to comment upon or request confidential treatment of its Confidential Information. In the event that no protective order or other remedy is obtained, or the other Party waives compliance with the terms of this Agreement, then such Party will have the right to make such public disclosure at the time and in the manner reasonably determined by its counsel to be required by applicable Law. Notwithstanding anything to the contrary herein, the Party required to make the disclosure shall consider in good faith the comments timely provided by the other Party and shall furnish only that portion of the Confidential Information that the Party is legally required to furnish.

12.7. <u>Agreement Termination</u>. Upon termination of this Agreement, at the Disclosing Party's request, the Receiving Party will return or destroy all documents or other media containing Confidential Information of the Disclosing Party (except for documents or other media containing Joint Know-How or Data that the Receiving Party is permitted to use pursuant to <u>Section 2.6.5</u>), provided however that the Receiving Party may retain one (1) copy for archival and compliance purposes, and as required by applicable Law.

12.8. <u>Remedies</u>. The Parties agree that money damages may not be an adequate remedy if this <u>Section 12</u> is breached and, therefore, either Party may, in addition to any other legal or equitable remedies, seek an injunction or other equitable relief against such breach or threatened breach without the necessity of posting any bond or surety.

108

#### 13. Publications

13.1. Restrictions. Without limiting Section 12 and subject to the other provisions of this Section 13, neither Party shall (a) make any publication or disclosure of Data generated pursuant to a CoDev Product Plan by or on behalf of the other Party without complying with this Section 13, or otherwise obtaining the prior written approval of the other Party or (b) use the name of the other Party in any publicity or advertising without the prior written consent of the other Party. For clarity, PIRS shall not publish any pre-clinical and clinical Data with respect to a Research Candidate or an Exclusive Product without the prior written consent of SGEN. With respect to any publication (including any abstract, poster, presentation or other disclosure) related to a Research Candidate (including any Data generated prior to the [\*\*\*] for such Research Candidate, even if such publication is made after the [\*\*\*]) ("Research Candidate Publication"), SGEN shall promptly inform PIRS of its intention to prepare such a publication and provide draft(s) of such publication as soon as available. The Parties shall discuss in good faith the timing of any Research Candidate Publication in view of the public disclosures at the time related to the Anticalin Protein included in such Research Candidate. With respect to any Research Candidate Publication: (i) PIRS shall have the right to require modifications to such Research Candidate Publication to remove the Confidential Information of PIRS if so requested by PIRS; (ii) SGEN shall not be permitted to publish or otherwise disclose the identity, Target, characterization, performance or other Data associated with the Anticalin Protein included in a Research Candidate (alone or as the fusion protein) until PIRS confirms that appropriate Patent filings have been made for the Anticalin Protein (in particular, any PIRS Building Block IP) commensurate in scope with the proposed disclosure of the Research Candidate Publication, and (iii) in the event that SGEN uses data generated by or on behalf of PIRS in such Research Candidate Publication it shall follow all applicable scientific standards and guidelines regarding authorship and afford the opportunity for all authors to comment on any draft Research Candidate Publication and SGEN shall consider such comments in good faith. SGEN shall have sole decision-making authority with respect to publications (including any abstract, poster, presentation or other disclosure) related to Exclusive Products, provided that PIRS shall have the right to require modifications to any such proposed publication to remove the Confidential Information of PIRS. SGEN will provide to PIRS final copies of all publications (including any abstract, poster, presentation or other disclosure) that SGEN proposes to make with regard to any Research Candidate or Exclusive Product at least [\*\*\*] days prior to the intended date of publication and shall include in all such publications (including any abstract, poster, presentation or other disclosure) an acknowledgement of PIRS and its contributions to the applicable Research Candidate or Exclusive Product.

109

13.2. <u>Scientific Papers</u>, <u>Abstracts and Posters</u>. The provisions below apply to pre-clinical and clinical Data with respect to a CoDev Product. Such pre-clinical and clinical Data with respect to a CoDev Product may be presented at scientific meetings on a regular basis in accordance with the provisions below. The JDC shall discuss attendance at conferences and work in good faith to coordinate messaging and any presentations or posters at such events. For avoidance of doubt, SGEN shall not include any Confidential Information of PIRS in a publication under this <u>Section 13.2</u> without the advance consent of PIRS.

13.2.1. Scientific Papers. Each Party through is Alliance Manager shall provide to the other, prior to submission of a draft of any articles and papers, including primary reports of Data, pooled analyses, theses, dissertations and review papers concerning a CoDev Product, which have been prepared by or on behalf of such Party or under a CoDev Product Plan (each a "Scientific Paper") to be published in medical and scientific journals and similar publications ("Medical Journals"). Commencing with the receipt of such draft Scientific Paper, the receiving Party shall have [\*\*\*] Business Days to notify the sending Party of its observations and suggestions with respect thereto (it being understood that, during such [\*\*\*] Business Day period, no submission for publication thereof shall take place) and the Parties shall discuss these observations and suggestions. The receiving Party shall have the right to require modifications to such Scientific Paper to remove the Confidential Information of the receiving Party if so requested by the receiving Party. The Party proposing to publish such Scientific Paper shall, in good faith, consider the comments made by the other Party, particularly if disclosure may be prejudicial to the other Party's opportunity to obtain any Patent. The other Party may in good faith require that the publication be suspended for a period of time not exceeding [\*\*\*] days if a Patent may be filed using the Data or other Know-How covered in the proposed publication, which period could be extended to an additional [\*\*\*] month period with respect to Data or other Know-How useful to enrich the Patent applications provided that in the event such additional delay is requested, (a) such requesting Party must reasonably demonstrate the need for such extension by providing the other Party with a detailed rationale and explanation therefore along with a reasonably detailed work plan as to how such delay and experiments may improve patentability and (b) the Parties will discuss in good faith the scope and duration of any such extended delay (not to exceed such [\*\*\*] months). Neither Party will publish or present any Confidential Information of the other Party without such other Party's prior written consent. The sending Party shall provide to the receiving Party a copy of each final Scientific Paper published by a Medical Journal within [\*\*\*] Business Days of publication thereof.

110

13.2.2. Abstracts and Posters. If a Party intends to present findings with respect to a CoDev Product at symposia or other meetings of healthcare professionals, or international, national or regional congresses, conferences or meetings organized by a professional society or organization (any such occasion, a "Scientific Meeting"), to the extent permitted by applicable Laws, such Party shall provide to the other, prior to submission or presentation, as the case may be, copies of (a) all abstracts that will be submitted for publication, and (b) all posters that will be presented at such Scientific Meeting, in each case, concerning a CoDev Product, which have been prepared by or on behalf of one of the Parties, for submission or presentation. Commencing with the receipt of any such abstract or poster the receiving Party shall have [\*\*\*] Business Days to inform the sending Party of its observations and suggestions with respect thereto (it being understood that, during such [\*\*\*] Business Day period, no submission or presentation thereof shall take place) and the Parties shall discuss these observations and suggestions. The receiving Party shall have the right to require modifications to such abstract or poster to remove the Confidential Information of the receiving Party if so requested by the receiving Party. The Party proposing to publish such an abstract or make such a presentation shall, in good faith, consider the comments made by the other Party, particularly if disclosure may be prejudicial to the other Party's opportunity to obtain any patent rights. The other Party may in good faith require that the publication of the abstract or presentation be suspended for a period of time not exceeding [\*\*\*] days if a Patent may be filed using the Data or other Know-How covered in the proposed abstract or presentation, which period could be extended to an additional [\*\*\*] month period with respect to Data or other Know-How useful to enrich the patent applications provided that in the event such additional delay is requested, (i) such requesting Party must reasonably demonstrate the need for such extension by providing the other Party with a detailed rationale and explanation therefor along with a reasonably detailed work plan as to how such delay and experiments may improve patentability and (ii) the Parties will discuss in good faith the scope and duration of any such extended delay (not to exceed such [\*\*\*] months). A Party will not publish or present any Confidential Information of the other Party without such other Party's prior written consent. The sending Party shall provide to the receiving Party a copy of each final abstract and final poster published or presented at a Scientific Meeting within [\*\*\*] Business Days of such publication or presentation thereof. The Parties shall use good faith and commercially reasonable efforts to provide the other Party with draft slide presentations in accordance with the foregoing time periods.

13.2.3. <u>Written Materials to be Presented at Scientific Meetings</u>. To the extent permitted by applicable Laws, each Party shall provide to the other, prior to submission or presentation, as the case may be, copies of all written materials

111

(other than abstracts and posters) that will be presented at any Scientific Meetings. Commencing with the receipt of any such written material the receiving Party shall have [\*\*\*] Business Days to inform the sending Party of its observations and suggestions with respect thereto (it being understood that, during such [\*\*\*] Business Day period, no submission or presentation thereof shall take place) and the Parties shall discuss these observations and suggestions. The receiving Party shall have the right to require modifications to such written materials to remove the Confidential Information of the receiving Party if so requested by the receiving Party. The Party proposing to publish such written materials or make such a presentation shall, in good faith, consider the comments made by the other Party, particularly if disclosure may be prejudicial to the other Party's opportunity to obtain any patent rights. The other Party may require that the publication of such written materials or presentation be suspended for a period of time not exceeding [\*\*\*] days if a Patent may be filed using the Data or other Know-How covered in the proposed written materials or presentation, which period could be extended to an additional [\*\*\*] month period with respect to Data or other Know-How useful to enrich the patent applications provided that in the event such additional delay is requested, (a) such requesting Party must reasonably demonstrate the need for such extension by providing the other Party with a detailed rationale and explanation therefor along with a reasonably detailed work plan as to how such delay and experiments may improvement patentability and (b) the Parties will discuss in good faith the scope and duration of any such extended delay (not to exceed such [\*\*\*] months). A Party will not publish or present any Confidential Information of the other Party without such other Party's prior written consent. The sending Party shall provide to the receiving Party a copy of all written materials presented at a Scientific Meeting within [\*\*\*] Business Days of the presentation thereof. The Parties shall use good faith and commercially reasonable efforts to provide the other Party with draft slide presentations in accordance with the foregoing time periods.

112

13.3. <u>Registries</u>. Each Party shall be free to disclose any Clinical Study Data generated by such Party concerning the Collaboration Product in clinical trial registries, in accordance with applicable Laws; <u>provided</u>, <u>however</u>, except to the extent prohibited or otherwise required by applicable Law (and in any event consistent with applicable Law), that the Party proposing to make such disclosure shall have provided the other Party at least [\*\*\*] Business Days prior to such disclosure (to the extent practicable), a detailed description of the proposed disclosure and shall have, in good faith, considered the comments made by the other Party and to delay, upon written request from the other Party, such disclosure by up to [\*\*\*] days (or as long as permitted, if less than [\*\*\*] days) where need to file a patent application.

#### 13.4. Press Releases.

13.4.1. Initial Press Release. The Parties agree to issue the joint press release attached hereto as <u>Exhibit</u> <u>13.4.1</u> on or the day after the Effective Date.

13.4.2. Further Press Releases. Except as provided in Section 12 or this Section 13, neither Party will issue a press release or public announcement relating to this Agreement without the prior written approval of the other Party (such approval not to be unreasonably withheld, conditioned or delayed), except that a Party may (a) once a press release or other public statement is approved in writing by both Parties, make subsequent public disclosure of the information contained in such press release or other written statement without the further approval of the other Party, and (b) issue a press release or public announcement as required by Applicable Law (including a press release corresponding to any securities disclosure, such as pursuant to a Form 8-K), including by the rules or regulations of the United States Securities and Exchange Commission or similar regulatory agency in a country other than the United States or of any stock exchange or listing entity, provided that the Party issuing such press release gives reasonable prior notice (meaning at least [\*\*\*] Business Days if feasible) to the other Party of and the opportunity to comment on the press release or public announcement, and otherwise complies with this Section 13.4.2. In addition, PIRS may issue a press release regarding (x) the exercise of a PIRS CoDev Option, or (y) the payment or receipt of any milestone payments under this Agreement with respect to any Collaboration Product, provided, that (i) such press release does not identify the Target of such Collaboration Product unless otherwise already made public; and (ii) otherwise complies with this Section 13.4.2.

### 13.5. Timeline Extension or Deferral of Disclosures.

13.5.1. Each Party agrees that it will not unreasonably withhold, condition, or delay its consent to requests for extensions of the above timelines in this <u>Section 13</u> in the event that material late breaking Data becomes available.

13.5.1. If either Party believes that any proposed press release or other public statement, or any publication, presentation, or other disclosure would be prejudicial to its opportunity to obtain any Patent, then the affected Party shall notify the publishing Party within the timeframe provided for in this <u>Section</u> <u>13</u> as applicable, or if not applicable, as soon as practicable after receipt of the proposed press release or other public statement, publication, presentation, or other disclosure, in which case the publishing Party shall refrain from making such press release, other public statement, publication, presentation or other disclosure for an additional [\*\*\*] Business Days from the last day of the period otherwise provided for herein to the extent necessary to enable the preparation and filing of any necessary patent applications.

13.6. <u>Failure to Object to Disclosure</u>. If the Party proposing any press release or other public statement, or any publication, presentation, or other disclosure referred to in this <u>Section 13</u> (excluding for the avoidance of doubt any promotional materials) receives no objection from the other Party within the timeframes set forth in the corresponding Section, then, the Party proposing such press release, other public statement, publication, presentation, or other disclosure shall be free to proceed with the same without further reference to or agreement from the other Party; <u>provided</u>, <u>however</u>, that any such press release, other public statement, publication, presentation, or other disclosure shall acknowledge the other Party's contribution to any Data included therein and otherwise comply with this Agreement.

13.7. <u>Copyright Clearance Center</u>. To enable free exchange of copyrighted material between the Parties, each Party agrees that it has or shall (i) obtain and maintain, at its own expense, an Annual Copyright License or equivalent license from the Copyright Clearance Center and (ii) list the other Party as a collaborator in an agreement with the Copyright Clearance Center.

### 14. Representations, Warranties & Covenants

- 14.1. Representations and Warranties of the Parties.
  - 14.1.1. Each Party hereby represents and warrants to the other Party, as of the Effective Date, that:

14.1.1.1. such Party is duly established, validly existing and in good standing under the Laws of the jurisdiction and has full power and authority to enter into this Agreement and to carry out the provisions hereof;

14.1.1.2. all requisite corporate action on the part of such Party, its directors and stockholders required by applicable Law for the authorization, execution and delivery by such Party of this Agreement, and the performance of all obligations of such Party under this Agreement, has been taken;

114

14.1.1.3. this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation, enforceable against it in accordance with the terms hereof; and

14.1.1.4. the execution and delivery of this Agreement by such Party do not, and the performance of this Agreement by such Party will not: (i) conflict with, or result in any violation of or default under, any agreement, instrument or understanding, oral or written, to which it or any Affiliate is a party or by which it or any Affiliate is bound; or (ii) violate any provision of any applicable Law.

#### 14.2. Representations and Warranties of PIRS.

14.2.1. <u>Generally</u>. PIRS hereby represents and warrants to SGEN that, as of the Effective Date:

14.2.1.1. PIRS has the right to grant the rights granted to SGEN under this Agreement, and no rights granted to SGEN pursuant to this Agreement are in violation of any existing agreement between PIRS or any of its Affiliates and any Third Party;

14.2.1.2. None of PIRS or its Affiliates, any Third Party acting by or on behalf of PIRS or any of its Affiliates in connection with the Research, Development or Manufacture of the Anticalin Building Blocks prior to the Effective Date has been debarred or is subject to debarment;

14.2.1.3. PIRS is the owner of or Controls the PIRS Patent Rights listed in <u>Exhibit 14.2.1.3</u> (with an indication as to which Patent Rights are owned and which are controlled) ("**Existing PIRS Patent Rights**"). Each of the Existing PIRS Patent Rights has been filed in good faith, has been prosecuted in accordance with any applicable duty of candor and has been maintained in a manner consistent with standard industry practice, in each case in each applicable jurisdiction in which such PIRS Patent Rights have been filed, and no official final deadlines with respect to prosecution thereof have been missed and all applicable fees due prior to the Effective Date have been paid on or before the due date for payment;

14.2.1.4. All inventors of all the Existing PIRS Patent Rights that are owned by PIRS, have been identified as such in the filings with the relevant patent offices and to PIRS' knowledge, all inventors of all the Existing PIRS Patent Rights that are in-licensed by PIRS have been identified as such in the filings with the relevant patent offices;

14.2.1.5. PIRS does not Control Patent Rights Covering the Compounds other than those listed in Exhibit 14.2.1.3;

14.2.1.6. where applicable, all of PIRS' and its Affiliates' officers, employees, independent contractors, consultants, and agents as of the Effective Date (other than academics or public or academic institutions subject to <u>Section 4.7</u>) performing activities under this Agreement where there is the potential for inventive activity have executed agreements requiring assignment or licensing to PIRS of all inventions Covering a Compound made during the course of and as a result of their association with PIRS or its Affiliate, as applicable, and obligating the individual to maintain as confidential the confidential information of PIRS or its Affiliate, as applicable;

14.2.1.7. where applicable, all of PIRS' and its Affiliates' officers, employees, independent contractors, consultants, and agents engaged after the Effective Date (other than academics or public or academic institutions subject to <u>Section 4.7</u>) performing activities under this Agreement where there is the potential for inventive activity that have not executed agreements with PIRS prior to the Effective Date will execute agreements requiring assignment to PIRS of all inventions Covering a Compound made during the course of and as a result of their association with PIRS or its Affiliate, as applicable, and obligating the individual to maintain as confidential the confidential information of PIRS or its Affiliate, as applicable unless otherwise agreed to by the Parties in writing;

14.2.1.8. There are no agreements (other than the PIRS Background Agreements) to which PIRS or any of its Affiliates is a party under which PIRS or any of its Affiliates obtains or has obtained a license or other right to the PIRS IP from a Third Party that Cover the Compounds in the Field;

14.2.1.9. To PIRS' knowledge, the Existing PIRS Patent Rights are, or, upon issuance, will be, valid and enforceable patents. There is no pending or, to PIRS' knowledge, threatened claim, suit, action, litigation or other proceeding brought by a Third Party against PIRS or any of its Affiliates (a) challenging the validity or enforceability of any of the Existing PIRS Patent Rights, (b) claiming that the making, using, selling, offering for sale or importing of any of the Compounds constitutes infringement of such Third Party's Intellectual Property Right(s), or (c) subjecting any of Existing PIRS Patent Rights to interference, reexamination, reissue, revocation, opposition, appeal or other administrative proceedings;

14.2.1.10. Neither PIRS nor any of its Affiliates has received any communications alleging that it has infringed, misappropriated, or otherwise violated, or that it would infringe, misappropriate, or otherwise violate, through the manufacture, use, import, export, sale, or offer for sale of any of

the Compounds or any portion thereof, any Intellectual Property Rights or Know-How Controlled by any Third Party;

14.2.1.11. To PIRS' knowledge, there is no Third Party intellectual property that would prevent PIRS from generally practicing the PIRS Platform Technology to Manufacture, Develop and Commercialize Anticalin therapeutics generally, which for clarity and without limitation does not include any specific target or particular Anticalin Protein;

14.2.1.12. PIRS has taken reasonable precautions to preserve the confidentiality of the PIRS Know-How required to be transferred to SGEN under this Agreement;

14.2.1.13. PIRS has disclosed or made available to SGEN any material data from studies of the PIRS Building Blocks in its possession, including, subject to Third Party confidentiality obligations, material data related to fusion proteins that include a PIRS Building Block that are relevant to the Research of the Research Candidates;

14.2.1.14. All studies conducted specifically for the PIRS Building Blocks have been conducted by PIRS or any of its (sub)contractors in accordance with applicable Laws by persons with appropriate education, knowledge and experience;

14.2.1.15. The documents containing Data or other PIRS Know-How disclosed or made available to SGEN in the context of the negotiation of this Agreement are true and accurate copies of what they purport to be;

14.2.1.16. PIRS has provided to SGEN a true and complete (though redacted) copy of the PIRS Background, and such PIRS Background Agreements is a valid and binding obligation and is in full force and effect;

14.2.1.17. PIRS is not in breach of the PIRS Background Agreement and has not received any notice of any continuing default, breach or violation under any existing PIRS Background Agreement; and

14.2.1.18. To the knowledge of PIRS, no counterparty to a PIRS Background Agreement is in breach of such Agreement and such counterparty has not been sent or received any notice of any continuing default, breach or violation under any existing PIRS Background Agreement.

### 14.3. Representations and Warranties of SGEN.

14.3.1. <u>Generally</u>. SGEN hereby represents and warrants to PIRS that, as of the Effective Date:

14.3.1.1. SGEN has the right to grant the rights granted to PIRS under this Agreement, and no rights granted to PIRS pursuant to this Agreement are in violation of any existing agreement between SGEN or any of its Affiliates and any Third Party;

14.3.1.2. SGEN is the owner of or Controls the SGEN Know-How required to be transferred to PIRS under this Agreement ("**Existing SGEN Know-How**");

14.3.1.3. All current and former employees and consultants of SGEN who are or have been involved in the conception or reduction to practice of the Existing SGEN Know-How have executed written contracts or are otherwise obligated to assign to SGEN his or her rights to the Existing SGEN Know-How conceived or reduced to practice by such employee and consultant;

14.3.1.4. where applicable, all of SGEN' and its Affiliates' officers, employees, independent contractors, consultants, and agents as of the Effective Date (other than academics or public or academic institutions subject to <u>Section 4.7</u>) performing activities under this Agreement where there is the potential for inventive activity have executed agreements requiring assignment or licensing to SGEN of all inventions Covering a Compound made during the course of and as a result of their association with SGEN or its Affiliate, as applicable, and obligating the individual to maintain as confidential the confidential information of SGEN or its Affiliate, as applicable;

14.3.1.5. where applicable, all of SGEN' and its Affiliates' officers, employees, independent contractors, consultants, and agents engaged after the Effective Date (other than academics or public or academic institutions subject to <u>Section 4.7</u>) performing activities under this Agreement where there is the potential for inventive activity that have not executed agreements with SGEN prior to the Effective Date will execute agreements requiring assignment to SGEN of all inventions Covering a Compound made during the course of and as a result of their association with SGEN or its Affiliate, as applicable, and obligating the individual to maintain as confidential the confidential information of SGEN or its Affiliate, as applicable unless otherwise agreed to by the Parties in writing;

14.3.1.6. To SGEN's knowledge, no Third Party is misappropriating, has misappropriated, or is threatening to misappropriate, the Existing SGEN Know-How. SGEN has not received any written notice from any Third Party asserting or alleging that the Existing SGEN Know-How misappropriates the intellectual property rights or confidential information of such Third Party;

Portions of the exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

118

14.3.1.7. SGEN has taken reasonable precautions to preserve the confidentiality of the Existing SGEN Know-How; and

14.3.1.8. the SGEN Background Agreements (if any) are a valid and binding obligation and are in full force and effect.

14.3.2. <u>Disclaimer</u>. EXCEPT AS EXPRESSLY SET FORTH IN <u>SECTION 14.1</u>, <u>SECTION 14.2</u> AND <u>SECTION 14.3</u> ABOVE, NEITHER PARTY MAKES (AND EACH PARTY EXPRESSLY DISCLAIMS) ANY AND ALL REPRESENTATIONS OR WARRANTIES OF ANY KIND, WHETHER WRITTEN, ORAL, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, INCLUDING ANY EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT OR ANY WARRANTIES THAT MAY ARISE FROM A COURSE OF PERFORMANCE, COURSE OF DEALING OR USAGE OR TRADE, INCLUDING WITH RESPECT TO ANY INTELLECTUAL PROPERTY RIGHTS, TECHNOLOGY OR CONFIDENTIAL INFORMATION OF A PARTY.

14.4. <u>Mutual Covenants</u>. Each Party hereby covenants throughout the Term as set forth below.

14.4.1. <u>Compliance</u>. Each Party will, and will cause its Affiliates and Sublicensees to, conduct the Research Collaboration and the Development, Manufacture, and Commercialization of the Collaboration Products in material compliance with all applicable Laws, including current governmental regulations concerning current good laboratory practices (GLP), good clinical practices (GCP) and good manufacturing practices (GMP).

14.4.2. <u>Non-Debarment</u>. Such Party will not, and will cause its Affiliates and Sublicensees not to, employ or use any contractor or agent that employs any individual or entity (a) that has been debarred by a Competent Authority under applicable Laws or convicted of a crime for which such Person could be so debarred, or (b) that is the subject of a debarment investigation or proceeding of a Competent Authority under applicable Laws, in each case of clauses (a) and (b), in the conduct of such Party's, its Affiliates' and Sublicensees' activities under this Agreement.

14.4.3. <u>No Conflict</u>. Such Party shall not, and shall cause its Affiliates and Sublicensees not to, enter into any agreement or other arrangement with a Third Party that conflicts with the rights granted to the other Party under this Agreement.

14.4.4. Background Agreements.

119

14.4.1. <u>PIRS</u>. During the term of this Agreement, PIRS agrees to comply with the following with respect to each PIRS Background Agreement, but solely to the extent it relates to the Compounds or any rights granted to SGEN hereunder: (i) keep SGEN reasonably informed of any material development pertaining to (including any request or proposal to materially amend or modify a PIRS Background Agreement; (ii) maintain each PIRS Background Agreement in full force and effect; (iii) perform its obligations under each PIRS Background Agreement; (iv) timely pay all license fee, maintenance fee, royalty, milestone, sublicensing revenue or similar payment obligations due pursuant to any PIRS Background Agreement; (v) not terminate any PIRS Background Agreement without the prior written consent of SGEN which consent shall not be unreasonably withheld or delayed; and (vi) not amend, or waive any right under any PIRS Background Agreement that would adversely affect the rights granted to SGEN hereunder, without the prior written consent of SGEN hereunder, without the prior written consent of SGEN hereunder, without the prior written consent shall not be unreasonably withheld or delayed; and (vi) not amend, or waive any right under any PIRS Background Agreement that would adversely affect the rights granted to SGEN hereunder, without the prior written consent of SGEN hereunder, without the prior written consent of SGEN hereunder, without the prior written consent of SGEN hereunder.

14.4.2. <u>SGEN</u>. During the term of this Agreement, SGEN agrees to comply with the following with respect to each SGEN Background Agreement, but solely to the extent such SGEN Background Agreement relates to rights granted hereunder by SGEN with respect to a CoDev Product: (i) keep PIRS reasonably informed of any material development pertaining to (including any request or proposal to materially amend or modify) such SGEN Background Agreement; (ii) maintain each such SGEN Background Agreement in full force and effect; (iii) perform its obligations under each such SGEN Background Agreement; (iv) timely pay all license fee, maintenance fee, royalty, milestone, sublicensing revenue or similar payment obligations due pursuant to any such SGEN Background Agreement; (v) not terminate any such SGEN Background Agreement without the prior written consent of PIRS, which consent shall not be unreasonably withheld or delayed; and (vi) not amend, or waive any right under, any such SGEN Background Agreement that would adversely affect the rights granted to PIRS hereunder for a CoDev Product without the prior written consent of PIRS which consent shall not be unreasonably withheld or delayed.

14.4.5. <u>Licensure</u>. If either Party determines in good faith that the licenses under this Agreement are required to be filed with the Federal Trade Commission ("**FTC**") under the US's Hart-Scott-Rodino Antitrust Improvements Act of 1976 (15 U.S.C. §18a) ("**HSR**") or with equivalent foreign Government Authorities under any similar foreign Law, then each Party will promptly prepare and submit any necessary filings and will use commercially reasonable efforts to obtain such

approvals and the Effective Date shall occur upon all such HSR or other governmental clearances have been obtained. Each Party will be responsible for its own costs; provided that SGEN will pay all filing fee(s) required in the event of an HSR filing or filing for other governmental clearance. Both Parties will use all commercially reasonable efforts to cause the clearance to be obtained as quickly as possible. However, neither Party will be required to adversely affect its legal position (e.g., agree to divestitures or product restrictions) in the interest of expediting such clearance.

121

#### 15. Indemnification & Insurance

15.1. PIRS Indemnity. PIRS shall defend, indemnify and hold harmless SGEN and its Affiliates and their respective directors, officers, agents, representatives, successors, permitted assignees and employees (collectively, the "SGEN Indemnitees") from and against any and all liabilities, losses, costs, damages and expenses, including reasonable attorneys' fees (collectively, "Damages"), incurred as a result of or arising out of any claim, suit, action, demand or other proceeding made or brought by a Third Party (each, a "Third Party **Claim**") against one or more SGEN Indemnitees to the extent resulting from (a) the negligence, recklessness, willful misconduct or intentional wrongful acts or omissions of PIRS or its Affiliates or their respective agents, representatives, consultants or independent contractors, in the performance by or on behalf of PIRS of PIRS' obligations under this Agreement; (b) any breach (or allegation of a breach) by PIRS of any representation, warranty or covenant made by PIRS set forth in Section 14 of this Agreement or any breach or violation of any covenant or agreement of PIRS in or in performance of this Agreement; (c) solely as it pertains to a Third Party Claim for product liability in the PIRS Territory, the Development, Manufacturing, Commercialization, handling, storage, labeling or transfer of any Product to the extent such Damages were incurred with respect to the Research, Development, Manufacture, or Commercialization by or for PIRS or any of its Affiliates or Sublicensees of a CoDev Product in or for the PIRS Territory (including any such activities performed by SGEN pursuant to this Agreement); and (d) any PIRS Background Agreement; except, in any such case, to the extent such Damages arise out of or result from the negligence, recklessness, willful misconduct or intentional wrongful acts or omissions or breach of this Agreement by SGEN or a SGEN Indemnitee or matters for which SGEN is obligated to indemnify PIRS under Section 15.2.

122

15.2. SGEN Indemnity. SGEN shall defend, indemnify and hold harmless PIRS and its Affiliates and their respective directors, officers, agents, representatives, permitted successors, permitted assignees and employees (collectively, the "PIRS Indemnitees") from and against any and all Damages incurred as a result of or arising out of any Third Party Claim made or brought against one or more PIRS Indemnitees to the extent resulting from (a) the negligence, recklessness, willful misconduct or intentional wrongful acts or omissions of SGEN or its Affiliates or their respective agents, representatives, consultants or independent contractors, in the performance by or on behalf of SGEN of SGEN's obligations under this Agreement; (b) any breach (or allegation of a breach) by SGEN of any representation, warranty or covenant made by SGEN set forth in Section 14 of this Agreement or any breach or violation of any covenant or agreement of SGEN in or in performance of this Agreement; (c) solely as it pertains to a Third Party Claim for product liability in the SGEN Territory, the Development, Manufacturing, Commercialization, handling, storage, labeling or transfer of any Collaboration Product to the extent such Damages were incurred with respect to the Research, Development, Manufacture, or Commercialization by or for SGEN or any of its Affiliates or Sublicensees of a CoDev Product in or for the SGEN Territory or for an Exclusive Product anywhere in the world (including any such activities performed by PIRS pursuant to this Agreement); and (d) any SGEN Background Agreement; except, in any such case, to the extent such Damages arise out of or result from the negligence, recklessness, willful misconduct or intentional wrongful acts or omissions or breach of this Agreement by PIRS or a PIRS Indemnitee or matters for which PIRS is obligated to indemnify SGEN under Section 15.1.

#### 15.3. Indemnification and Defense Procedures.

15.3.1. Notice of Claim. All claims for indemnification or defense by a Party as provided herein shall be made solely by the Party seeking indemnification or defense of a Third Party Claim or remedies for any Damages (the "Indemnified Party"). The Indemnified Party shall give written notice of the same to the other Party (the "Indemnifying Party") reasonably promptly after the assertion against the Indemnified Party of any Third Party Claim or fact in respect of which the Indemnified Party intends to base a claim for indemnification hereunder (a "Claim Notice"), provided, however, that failure or delay to provide such Claim Notice shall not affect the Indemnifying Party's indemnification or defense obligations, except to the extent such failure materially and adversely affects the ability to defend such claim. Each Claim Notice must contain a description of the Third Party Claim and the nature and amount of any Damages (to the extent that the nature and amount of such Damages is known at such time). The Indemnified Party shall furnish promptly to the Indemnifying Party copies of all notices, papers, correspondence, communications, and official documents (including court

papers) previously received or sent and thereafter that the Indemnified Party continues to receive or send in respect of any such Third Party Claim.

15.3.2. <u>Assumption of Defense</u>. To the extent permitted by applicable Laws, the Indemnifying Party shall assume the defense and handling of such Third Party Claim, at the Indemnifying Party's sole expense in accordance with <u>Section 15.3.3</u>.

15.3.3. Indemnification Procedure. In assuming the defense of any Third Party Claim, the Indemnifying Party: (a) shall act diligently and in good faith with respect to all matters relating to the defense, settlement or disposition of such Third Party Claim as the defense, settlement or disposition relates to the Indemnified Party; (b) may, at its own cost, appoint as counsel in connection with conducting the defense and handling of such Third Party Claim any law firm or counsel reasonably selected by the Indemnifying Party and reasonably acceptable to the Indemnified Party; (c) keep the Indemnified Party informed of the status of such Third Party Claim; (d) shall have the right to settle the Claim on any terms the Indemnifying Party chooses, subject to prior notification to the Indemnified Party; provided that the Indemnifying Party shall not settle or otherwise resolve any Third Party Claim which could lead to liability or create any financial or other obligation on the part of the Indemnified Party for which the Indemnified Party is not entitled to indemnification hereunder or which admits any wrongdoing or responsibility for the claim on behalf of the Indemnified Party, without prior written consent of the Indemnified Party, which may not be unreasonably withheld or delayed. The Indemnified Party shall reasonably cooperate with the Indemnifying Party in its defense of any Third Party Claim for which the Indemnifying Party has assumed the defense in accordance with this Section 15.3.3, and shall have the right (at its own expense) to be present in person or through counsel at all legal proceedings giving rise to the right of indemnification.

15.3.4. Indemnified Party Right to Participate. If the Indemnifying Party fails to conduct the defense and handling of any Third Party Claim in good faith or if the Third Party Claim seeks non-monetary relief, (a) the Indemnified Party may at the Indemnifying Party's expense, select counsel reasonably acceptable to the Indemnifying Party in connection with conducting the defense and handling of such Third Party Claim and defend against, and consent to the entry of any judgment or enter into any settlement with respect to the Third Party Claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party shall regularly inform the Indemnifying Party of the status of such Claim and consult with the Indemnifying Party but shall have no obligation hereunder to obtain any consent from, the Indemnifying Party in connection therewith, except that the Indemnified Party shall not settle such Third Party Claim without the prior written consent of the Indemnifying Party, which consent

124

shall not be unreasonably withheld or delayed); and (b) the Indemnifying Party shall remain responsible to indemnify the Indemnified Party as provided in this <u>Section 15.3.4</u>. If the Indemnified Party elects to defend or handle such Third Party Claim in accordance with this <u>Section 15.3.4</u>, the Indemnifying Party shall cooperate with the Indemnified Party, at the Indemnified Party's request but at no expense to the Indemnified Party, and shall be entitled to participate in the defense and handling of such Third Party Claim with its own counsel and at its own expense.

15.4. <u>Insurance</u>. During the Term and thereafter for a period of [\*\*\*] years, each Party shall procure and maintain adequate insurance coverage with internationally-reputable company or a program of self-insurance (which shall be of types and amounts sufficient to cover the liabilities hereunder, contingent or otherwise of such Party and its Affiliates). It is understood that such insurances shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this <u>Section 15</u>. Each Party shall provide the other Party with written evidence of such insurance upon request. Each Party shall provide the other Party with written notice at least [\*\*\*] days prior to the cancellation, non-renewal or material change in the insurance coverage.

15.5. DISCLAIMER OF LIABILITY. IN NO EVENT SHALL EITHER PARTY OR ANY OF ITS RESPECTIVE AFFILIATES AND THEIR RESPECTIVE OFFICERS, DIRECTORS AND EMPLOYEES BE LIABLE UNDER THIS AGREEMENT FOR SPECIAL, INDIRECT, PUNITIVE, INCIDENTAL, OR CONSEQUENTIAL DAMAGES SUFFERED BY THE OTHER PARTY UNDER THIS AGREEMENT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE OR OTHERWISE. NOTWITHSTANDING THE FOREGOING, THIS DISCLAIMER DOES NOT APPLY TO LIABILITY OR DAMAGES (A) RESULTING FROM A BREACH OF CONFIDENTIALITY OBLIGATIONS OF A PARTY UNDER <u>SECTION 12</u> OR (B) SUBJECT TO A PARTY'S INDEMNIFICATION OBLIGATIONS PURSUANT TO <u>SECTION 15.1</u>, <u>SECTION 15.2</u> OR <u>SECTION 15.3</u>.

125

# 16. Term & Termination

16.1. <u>Term</u>. The term of this Agreement (the "**Term**") will commence on the Effective Date and will extend, unless this Agreement is terminated earlier in accordance with <u>Section 16.2</u>, (i) with respect to Exclusive Products, on an Exclusive Product-by-Exclusive Product and country-by-country basis, until such time as the Royalty Term for such Exclusive Product expires, or (ii) with respect to CoDev Products, on a CoDev Product-by-CoDev Product basis until the Parties are no longer Commercializing such CoDev Product. Upon the natural expiration (as opposed to termination) of the Royalty Term with respect to an Exclusive Product: (a) the licenses granted by PIRS to SGEN under this Agreement with respect to such Exclusive Product shall become irrevocable, fully paid-up and royalty-free licenses and shall last as long as SGEN intends to Develop or Commercialize the applicable Exclusive Product in such country, and (b) <u>Section 10.2</u> shall no longer apply to the Parties solely with respect to the Development and Commercialization of such Exclusive Product in such country (including the Manufacture thereof solely for such Development and Commercialization purposes).

16.2. <u>Termination</u>. Notwithstanding anything in this Agreement or elsewhere to the contrary, subject to <u>Section</u> <u>16.3.4</u> below, this Agreement may be terminated as follows:

16.2.1. <u>Termination for Material Breach</u>. Either Party shall have the right to terminate this Agreement in the event the other Party has materially breached or materially defaulted in the performance of any of its obligations hereunder which breach or default is material in the overall context of the Agreement, and such breach has continued for [\*\*\*] days after written notice thereof was provided to the breaching Party by the non-breaching Party, which clearly describes the material breach and remedies (including, for avoidance of doubt, termination of the Agreement) that the non-breaching Party intends to apply should the breach remain uncured. Any such termination shall become effective at the end of such [\*\*\*] day period if, prior to the expiration of the [\*\*\*] day period, the breaching Party has not cured any such breach or default, provided, that with respect to a breach of such Party's Commercially Reasonable Efforts obligations to Develop or Commercialize a Compound, such cure period shall be extended for a period not to exceed an additional [\*\*\*] days in the event such breaching Party has, within the original [\*\*\*] day period prepared and communicated to the non-breaching Party, a remediation plan reasonably designed to cure such breach or default within a reasonable period of time (which plan is reasonably acceptable to the non-breaching Party) and such breaching Party continues to diligently use Commercially Reasonable Efforts to implement such plan throughout such period. If the allegedly breaching Party disputes the breach and provides written notice of that dispute to the other Party, the matter shall be addressed under the dispute resolution provisions in Section 17.2, and the notifying Party may not terminate this Agreement until it has been finally determined under Section 17.2 that the

126

Agreement was materially breached as described above. In the event the breach is limited to one or more Compounds, the non-breaching Party will have the right to terminate this Agreement solely with respect to the applicable Compound(s).

16.2.2. <u>Termination by Mutual Agreement</u>. This Agreement (as a whole or on a Compound-by-Compound or country-by-country basis) may be terminated by the mutual written consent of the Parties.

16.2.3. <u>Termination by SGEN for Convenience</u>. Beginning twelve (12) months after the Effective Date, SGEN may terminate this Agreement on a Compound-by-Compound basis by providing ninety (90) days' prior written notice to PIRS (unless such SGEN has Initiated a Pivotal Clinical Study for such Compound, in which case such notice period shall be one hundred and eighty (180) days), with such termination being effective upon the end of such ninety (90)-day or one hundred and eighty (180)-day notice period. Notwithstanding the foregoing, during the Research Term for a given SGEN Antibody Target, SGEN may only terminate with respect to all [\*\*\*] Research Candidates that include the same SGEN Antibody Target (i.e., may not terminate with respect to a single Research Candidate). Further notwithstanding the foregoing, SGEN shall not terminate this Agreement prior to the Second Approved SGEN Antibody Target being designated.

16.2.4. <u>CoDev Product Opt-Out</u>. On a CoDev Product-by-CoDev Product basis, PIRS shall have the right to discontinue co-Development and co-Commercialization (including all cost-sharing and other obligations therein) with respect to such CoDev Product ("**CoDev Product Opt-Out**") by providing one [\*\*\*] days' prior written notice to SGEN, with the CoDev Product Opt-Out being effective upon the end of such [\*\*\*]-day notice period.

16.2.5. <u>Termination for Insolvency</u>. Either Party may terminate this Agreement if, at any time, the other Party will file in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for the appointment of a receiver or trustee of the Party or of substantially all of its assets, or if the other Party proposes a written agreement of composition or extension of substantially all of its debts, or if the other Party will be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition will not be dismissed within [\*\*\*] days after the filing thereof, or if the other Party will propose or be a party to any dissolution or liquidation, or if the other Party will make an assignment of substantially all of its assets for the benefit of creditors. Upon the bankruptcy of any Party, the non-bankrupt Party will further be entitled to a complete duplicate of, or complete access to, any such intellectual property, and such, if not already in its possession, will be promptly

127

delivered to the non-bankrupt Party, unless the bankrupt Party elects to continue, and continues, to perform all of its obligations under this Agreement.

# 16.2.6. Termination for Safety.

16.2.6.1. SGEN may terminate this Agreement with respect to a Collaboration Product (other than a CoDev Product) immediately upon written notice to PIRS, that such Collaboration Product demonstrates a Safety Issue in humans.

16.2.6.2. Subject to consultation with the JSC (which shall be expedited by the Parties), PIRS or SGEN may terminate this Agreement with respect to a CoDev Product immediately upon written notice to the other Party, if such CoDev Product demonstrates a Safety Issue in humans.

16.2.6.3. For purposes of this <u>Section 16.2.6</u>, "**Safety Issue**" means instances, in which either the FDA or the EMA require that the Development, Manufacture, or Commercialization of a CoDev Product be stopped.

# 16.2.7. Termination for Patent Challenge.

16.2.7.1. If SGEN (a) disputes, or assists any Third Party to dispute, the validity of any Patent within the PIRS IP, PIRS Platform IP or PIRS Platform Improvement IP Covering a Collaboration Product in a patent re-examination, inter-partes review, post-grant or other patent office proceeding, opposition, litigation, or other court proceeding and (b) within [\*\*\*] days written notice from PIRS, SGEN fails to rescind any and all of such actions, then PIRS may terminate this Agreement upon written notice to SGEN. Notwithstanding the above, nothing in this clause prevents SGEN from taking any of the actions referred to in this clause and provided further that PIRS will not have the right to terminate if SGEN:

(a) asserts invalidity as a defense in any court proceeding brought by PIRS asserting infringement of one of the foregoing Patents;

(b) acquires a Third Party that has an existing challenge, whether in a court or administrative proceeding, against one of the foregoing Patents; or

(c) licenses a product for which PIRS has an existing challenge, whether in a court or administrative proceeding, against one of the foregoing Patents.

16.2.7.2. If PIRS (a) disputes, or assists any Third Party to dispute, the validity of any Patent within the SGEN IP Covering a Collaboration Product in a patent re-examination, inter-partes review, post-grant or other patent office

128

proceeding, opposition, litigation, or other court proceeding and (b) within [\*\*\*] days written notice from SGEN, PIRS fails to rescind any and all of such actions, then SGEN may terminate this Agreement upon written notice to PIRS. Notwithstanding the above, nothing in this clause prevents PIRS from taking any of the actions referred to in this clause and provided further that SGEN will not have the right to terminate if PIRS:

(a) asserts invalidity as a defense in any court proceeding brought by SGEN asserting infringement of one of the foregoing Patents;

(b) acquires a Third Party that has an existing challenge, whether in a court or administrative proceeding, against one of the foregoing Patents; or

(c) licenses a product for which SGEN has an existing challenge, whether in a court or administrative proceeding, against one of the foregoing Patents.

#### 16.3. Effects of Termination.

16.3.1. <u>Effects of Termination</u>. In the event of a termination of this Agreement in its entirety or with respect to one or more Compounds pursuant to (a) <u>Section 16.2.1</u> (Material Breach) by either Party, (b) <u>Section 16.2.2</u> (Mutual Agreement), (c) <u>Section 16.2.5</u> (Insolvency) by either Party, (d) <u>Section 16.2.6</u> (Safety), or (e) <u>Section 16.2.7</u> (Patent Challenge) by either Party, in each case without prejudice to any other remedies of a Party, including the right to claim damages, the following terms shall apply:

16.3.1.1. All Development, Manufacture, and Commercialization of such terminated Compound(s) (and any Research Candidate that includes the same SGEN Building Block as such Compound) by either Party shall immediately cease;

16.3.1.2. Each Party will return to or destroy (and certify such destruction to the other Party), at the other Party's option, all of the other Party's Confidential Information related to the terminated Compound(s), except for Joint Know-How or Data that such Party is permitted to use pursuant to Section 2.6.5 (provided that a Party shall be entitled to retain one (1) copy for archival and compliance purposes, and as required by applicable Law or regulatory requirement);

16.3.1.3. The licenses granted by each Party to the other under, respectively, the PIRS IP and SGEN IP shall immediately terminate; and

129

16.3.1.4. The non-compete set forth in <u>Section 10.2</u> regarding the terminated Compound (including the discontinued Targets pairs therein, except to the extent such Target pairs are contained within a Compound for which this Agreement remains in effect) will no longer apply.

16.3.2. <u>Reversion Rights.</u> In the event that SGEN terminates this Agreement in its entirety or with respect to any given Compound for convenience pursuant to <u>Section 16.2.3</u>, then the following provisions shall apply on a terminated Compound-by-terminated Compound basis:

16.3.2.1. Except as set forth in this <u>Section 16.3.2</u>, SGEN shall immediately cease any Research, Development, Manufacturing or Commercialization of the terminated Compound and any other Research Candidate that includes the same SGEN Building Block as such Compound;

16.3.2.2. At PIRS' request, SGEN will return to PIRS or destroy (and certify such destruction to PIRS), at PIRS' option, all PIRS' Confidential Information and Know-How related to the terminated Compound(s), except for Joint Know-How or Data that SGEN is permitted to use pursuant to <u>Section 2.6.5</u> (provided that SGEN shall be entitled to retain one (1) copy for archival and compliance purposes, and as required by applicable Law or regulatory requirement);

16.3.2.3. All licenses and sublicenses granted by PIRS to SGEN hereunder with respect to the terminated Compound shall terminate, provided however that they will continue solely to enable SGEN to (i) complete sales of Compounds for any purchase orders that were in place prior to the effective date of termination and (ii) sell off any existing inventory of Compounds that PIRS does not purchase pursuant to <u>Section 16.3.2.7</u>; thereafter, SGEN will discontinue Commercialization of the applicable Compound in the applicable countries;

16.3.2.4. On a terminated Compound-by-terminated Compound basis, to the extent requested by PIRS, SGEN shall enter into an agreement whereby SGEN exclusively licenses (such license exclusive solely with respect to the terminated Compound), with the right to sublicense, to PIRS the SGEN IP Covering the SGEN Building Block in such terminated Compound that is necessary or reasonably useful to (and for the sole purpose of) further Develop, Manufacture, and Commercialize such terminated Compound (for clarity, such license grant to PIRS with respect to any SGEN Building Block IP within the SGEN IP shall be exclusive solely with respect to the terminated Compound, and no other right or license shall be granted to PIRS under such SGEN Building Block IP (e.g., to develop and commercialize the applicable SGEN Building Block as a standalone product or as a component of an

unrelated product)), provided that if the terminated Compounds are the [\*\*\*] Research Candidates that include the same SGEN Antibody Target (i.e. such termination occurred prior to [\*\*\*]), then (i) such license shall be with respect to all [\*\*\*] Research Candidates, and (ii):

(a) on a Research Candidate-by-Research Candidate basis, prior to [\*\*\*] for such Research Candidate, PIRS shall provide SGEN written notice of its intent to [\*\*\*] for the Research Candidate and shall pay SGEN the amount [\*\*\*] Dollars (\$[\*\*\*]) within [\*\*\*] days of providing such notice;

(b) upon PIRS's payment of the applicable amount under (a) above for a Research Candidate, such Research Candidate shall become a "**PIRS Collaboration Product**," and the obligations of this Agreement relating to Development of a Collaboration Product that is a Potential CoDev Product shall apply [\*\*\*] with respect to PIRS's further Development of the PIRS Collaboration Product (e.g., PIRS shall (i) provide Development Plan Overviews and updates for such PIRS Collaboration Product to the JDC pursuant to <u>Section 3.3</u>, (ii) comply with the diligence obligations of <u>Section 10.1.2</u> with respect to such PIRS Collaboration Product, and (iii) pay SGEN the [\*\*\*] for such PIRS Collaboration Product);

(c) in addition, for each PIRS Collaboration Product, SGEN shall have—and PIRS hereby grants to SGEN as of the Effective Date—the exclusive option (exercisable at SGEN's sole discretion) to opt into [\*\*\*] global co-Development and co-Commercialization of such PIRS Collaboration Product. For each such exclusive option, the Option Notice procedures of <u>Section 4.4.2.2</u> and [\*\*\*] shall apply *mutatis mutandis*, e.g., (i) PIRS shall issue an Option Notice to SGEN for such PIRS Collaboration Product prior to Initiating the first Pivotal Clinical Study therefor, such Option Notice to include an initial CoDev Product Plan and corresponding Joint Development Budget as well as an accounting of Reimbursable [\*\*\*], and (ii) if SGEN timely exercises such option, [\*\*\*]. Moreover, for each PIRS Collaboration Product, within [\*\*\*] days of the applicable CoDev Option Exercise Effective Date, the Parties shall enter into an agreement for further co-Development and co-Commercialization of such PIRS Collaboration Product on terms and conditions consistent with the terms and conditions of this Agreement for CoDev Products, applied *mutatis mutandis* to such PIRS Collaboration Product as

131

applicable [\*\*\*]. For clarity, the Parties will share [\*\*\*] in the Profits and Losses for such PIRS Collaboration Product; and

(d) in the event that SGEN does not timely exercise an option for a PIRS Collaboration Product, then (i) the reporting obligations in Section 3.7, the obligation to pay the [\*\*\*], and the obligation to pay [\*\*\*] shall apply [\*\*\*] to PIRS's continued Development and Commercialization of such PIRS Collaboration Product, and (ii) on a PIRS Collaboration Product-by-PIRS Collaboration Product and country-by-country basis, PIRS shall pay to SGEN a royalty on Annual Calendar Year Net Sales of such PIRS Collaboration Product in accordance with the [\*\*\*], in each case plus [\*\*\*] percent ([\*\*\*]%), for a period commencing with the First Commercial Sale of such PIRS Collaboration Product and ending with respect to such PIRS Collaboration Product in such country on the later of (a) [\*\*\*] years thereafter in such country; (b) last to expire Regulatory Exclusivity relating to such PIRS Collaboration Product; or (c) expiration of the last to expire Valid Claim within any Patent Rights within the SGEN IP licensed to PIRS pursuant to this Section 16.3.2.4, in each case Covering the import, use, sale or offer for sale (but, for clarity, not the Manufacturing) of such PIRS Collaboration Product in such country of sale, including by 35 U.S.C. § 271(g) or any foreign equivalent. Sections 8.1, 8.2, 8.4 and 8.5 shall apply *mutatis mutandis* to such PIRS Collaboration Product.

16.3.2.5. For avoidance of doubt, <u>Section 16.3.2.4(i)</u> and <u>Section 16.3.2.4(ii)</u> shall not apply to any Compound terminated on or after the [\*\*\*].

16.3.2.6. At the request of PIRS, for any terminated Compound that is an Exclusive Product, the Parties will discuss in good faith the wind-down or continuation of any ongoing Clinical Studies for such Compound being conducted by or on behalf of SGEN at the time of termination; provided that, at PIRS' option, SGEN shall use reasonable efforts to transition such Clinical Study to PIRS or its designated contract research organization (at PIRS' expense, including for any time periods where SGEN must continue to dedicate resources to such Clinical Study after the effective date of the termination). For any terminated Compound that is a CoDev Product, SGEN shall be obligated to continue any Clinical Stud(ies) (including co-funding) Initiated prior to the date of the notice of termination for convenience provided to PIRS under <u>Section 16.2.3</u>, through completion of such Clinical Study (database lock), including any drug supply required for

132

such Clinical Study. The costs associated with such ongoing Clinical Study shall be shared by the Parties as set forth in this Agreement until completion of the applicable Clinical Study.

16.3.2.7. PIRS shall have the right to acquire some or all of the inventory of the terminated Compound, as requested by PIRS, in the possession of SGEN and its Affiliates as of the date of such termination, provided that, if PIRS so acquires any or all such inventory, PIRS shall reimburse SGEN the cost incurred by SGEN for such inventory.

16.3.2.8. SGEN will, subject to PIRS' reasonable assistance, (i) transfer and assign to PIRS or PIRS' designee SGEN's right, title and interest in and to all material governmental or regulatory filings and approvals (including all Regulatory Approvals and pricing approvals, and Regulatory Materials, in all cases, specifically and exclusively relating to the Research, Development, Manufacture, or Commercialization of the terminated Compound), and (ii) use Commercially Reasonable Efforts to transfer to PIRS or PIRS' designee (to the extent not already provided) copies of all material Know-How in SGEN's possession or Control and licensed to PIRS pursuant to Section 16.3.2.4, to the extent specifically related to and required for the Research, Development, Manufacture, or Commercialization of the terminated Compound. In addition, SGEN will appoint PIRS as SGEN's and/or SGEN's Affiliates' agent for all terminated Compound-related matters involving Regulatory Authorities until all Regulatory Approvals and other regulatory filings hereunder have been assigned to PIRS or its designee. In the event of (x) failure to obtain assignment or (y) with respect to regulatory items that would otherwise fall within (i) and (ii) but for such materials not being specifically related to the terminated Compound, but nonetheless which are necessary for the Research, Development, Manufacture, or Commercialization of the terminated Compound above, in each of (x) and (y) SGEN hereby consents and grants to PIRS the right to access and reference (without any further action required on the part of SGEN, whose authorization to file this consent with any Regulatory Authority is hereby granted) any such item with respect to the terminated Compound.

16.3.2.9. If SGEN or its Affiliates have initiated GMP manufacturing of the terminated Compound as of the effective date of termination, and at PIRS' option, SGEN or its Affiliates will use Commercially Reasonable Efforts to supply such Compound (but solely in the form as such terminated Compound was being manufactured by SGEN as of the effective date of termination) to PIRS at SGEN's fully-burdened cost (which shall be calculated following the principles of Commercial Manufacturing Costs under this Agreement) plus

133

[\*\*\*] percent ([\*\*\*]%), until the earlier of (i) successful transition of manufacturing activities to PIRS or its Third Party CMO, and (ii) [\*\*\*] months following the effective date of termination. The Parties will promptly negotiate a supply and related quality agreement to govern the specific terms and conditions of such supply. Furthermore, SGEN shall use Commercially Reasonable Efforts to support a technology transfer for the manufacturing of such terminated Compound from its own manufacturing facility to a new manufacturing facility of Pieris' choice, subject to reimbursement by PIRS of SGEN's reasonable Out-of-Pocket and FTE Cost incurred in connection with such technology transfer activities. If PIRS so requests SGEN will assign to PIRS any Third Party agreements that are specific to the Research, Development, Manufacture, or Commercialization of the terminated Compound, and to which SGEN is a party, subject to any required consents of such Third Party.

16.3.2.10. SGEN will use Commercially Reasonable Efforts, and subject to PIRS' reasonable assistance, to the extent legally permissible (including to the extent permitted under SGEN's obligations to Third Parties on the effective date of termination), to promptly transfer and assign or exclusively license (or, if applicable, will cause its Affiliates to assign) to PIRS all of SGEN's (and such Affiliates') worldwide right, title and interest in and to any registered trademarks or registered internet domain names that are specific to and exclusively used for the terminated Compound (it being understood that the foregoing will not include any trademarks or internet domain names that contain the corporate or business name(s) of SGEN or any of its Affiliates or any other products of SGEN or any of its Affiliates).

16.3.2.11. More generally, SGEN shall use Commercially Reasonable Efforts to ensure a smooth and orderly transition of the terminated Compound in accordance with this <u>Section 16.3.2</u>, including any Development, Manufacturing, or Commercialization activities ongoing at the time of termination to PIRS, pursuant to a termination agreement to be negotiated in good faith by the Parties within [\*\*\*] months following the termination notice. Such agreement shall be consistent with this <u>Section 16.3.2</u>.

16.3.2.12. For avoidance of doubt, the non-compete set forth in <u>Section 10.2</u> will no longer apply to the terminated Compound, including the discontinued Targets pairs therein, except to the extent such Target pairs are contained (i) within a Compound for which this Agreement remains in effect, (ii) within a Research Candidate that PIRS is actively developing or within a PIRS Collaboration Product for which SGEN may exercise an exclusive option.

134

16.3.2.13. In consideration of the rights granted by SGEN to PIRS set forth herein, including the license under Section 16.3.2.4, with respect to each terminated Collaboration Product (i.e., each Compound terminated after [\*\*\*]), PIRS shall pay to SGEN a flat royalty on Net Sales of such terminated Collaboration Product of [\*\*\*] percent ([\*\*\*]%) if the Collaboration Product is terminated prior to the Initiation of the first Phase 1 Clinical Study, [\*\*\*] percent ([\*\*\*]%) if the Collaboration Product is terminated after the Initiation of the first Phase 1 Clinical Study but prior to the Initiation of the first Phase 2 Clinical Study, [\*\*\*] percent ([\*\*\*]%) if the Collaboration Product is terminated after the Initiation of the first Phase 2 Clinical Study but prior to the Initiation of the first Pivotal Clinical Study, and [\*\*\*] percent ([\*\*\*]%) if the Collaboration Product is terminated after the Initiation of the first Pivotal Clinical Study. This royalty shall be payable by PIRS to SGEN on a country-by-country basis with respect to each terminated Collaboration Product for a period commencing with the First Commercial Sale of such Collaboration Product and ending with respect to such Collaboration Product in such country on the later of (a) [\*\*\*] years thereafter in such country; (b) last to expire Regulatory Exclusivity relating to such Collaboration Product; or (c) expiration of the last to expire Valid Claim within any Patent Rights within the SGEN IP licensed to PIRS pursuant to Section 16.3.2.4, in each case, Covering the import, use, sale or offer for sale (but, for clarity, not the Manufacturing) of such Collaboration Product in such country of sale, including by 35 U.S.C. § 271(g) or any foreign equivalent. Sections 8.1, 8.2, 8.4 and 8.5 shall apply mutatis mutandis to such terminated Collaboration Product.

16.3.3. <u>PIRS CoDev Product Opt-Out Termination Consequences</u>. In case PIRS opts-out of a CoDev Product pursuant to <u>Section 16.2.4</u>, then the following consequences shall apply:

16.3.3.1. Except as set forth in this <u>Section 16.3.3</u>, PIRS shall immediately cease any Research, Development, Manufacturing or Commercialization of the discontinued CoDev Product.

16.3.3.2. At SGEN's request, PIRS will return to SGEN or destroy (and certify such destruction to SGEN), at SGEN's option, all SGEN Confidential Information related to the discontinued CoDev Product, except for any such SGEN Confidential Information that PIRS would otherwise be entitled to receive and retain for Exclusive Products, Joint Know-How or Data that PIRS is permitted to use pursuant to <u>Section 2.6.5</u> (provided that PIRS shall be entitled to retain one (1) copy for archival and compliance purposes, and as required by applicable Law or regulatory requirement).

135

16.3.3.3. SGEN shall have the right to acquire some or all of the inventory of the discontinued CoDev Product (to the extent PIRS has any such inventory), as requested by SGEN, in the possession of PIRS and its Affiliates as of the date of such discontinuation, provided that, if SGEN so acquires any or all such inventory, SGEN shall reimburse PIRS the cost incurred by PIRS for such inventory.

16.3.3.4. All licenses and sublicenses granted by SGEN to PIRS with respect to such CoDev Product hereunder shall terminate, provided however that they will continue solely to enable PIRS to (i) complete sales of CoDev Product for any purchase orders that were in place prior to the effective date of PIRS' opt-out and (ii) sell off any existing inventory of CoDev Product that SGEN does not purchase pursuant to <u>Section 16.3.3.3</u>; thereafter, PIRS will discontinue Commercialization of the applicable CoDev Product in the applicable countries.

16.3.3.5. With respect to SGEN's continued Development and Commercialization of the discontinued CoDev Product, the discontinued CoDev Product shall be considered an Exclusive Product for purposes of the license grant under <u>Section 2.1</u>;

16.3.3.6. At the request of SGEN, the Parties will discuss in good faith the wind-down or continuation of any ongoing Clinical Studies for the discontinued CoDev Product currently being conducted by or on behalf of either Party at the time of discontinuation; provided that, at SGEN's option, PIRS shall be obligated to continue (including co-funding) any Clinical Stud(ies) Initiated prior to the date of the notice of opt-out provided to SGEN under <u>Section 16.2.4</u>, through completion of such Clinical Study (database lock), including any drug supply required for such Clinical Study. The costs associated with such ongoing Clinical Study shall be shared by the Parties as set forth in this Agreement until completion of the applicable Clinical Study.

16.3.3.7. PIRS shall, subject to SGEN's reasonable assistance, (i) transfer and assign to SGEN or SGEN's designee PIRS' right, title and interest in and to all material governmental or regulatory filings and approvals (including all Regulatory Approvals and pricing approvals, and Regulatory Materials, in all cases, specifically and exclusively relating to the Research, Development, Manufacture, or Commercialization of the discontinued CoDev Product), and (ii) use Commercially Reasonable Efforts to transfer to SGEN or SGEN's designee (to the extent not already provided) copies of all material Know-How in PIRS' possession and Control to the extent specifically related to and required for the Research, Development, Manufacture, or Commercialization

136

of the discontinued CoDev Product. In addition, PIRS will appoint SGEN as PIRS' and/or PIRS' Affiliates' agent for all discontinued CoDev Product-related matters involving Regulatory Authorities until all Regulatory Approvals and other regulatory filings hereunder have been assigned to SGEN or its designee. In the event of (x) failure to obtain assignment or (y) with respect to regulatory items that would otherwise fall within (i) and (ii) but for such materials not being specifically related to the discontinued CoDev Product, but nonetheless which are necessary for the Research, Development, Manufacture, or Commercialization of the discontinued CoDev Products above, in each of (x) and (y) PIRS hereby consents and grants to SGEN the right to access and reference (without any further action required on the part of PIRS, whose authorization to file this consent with any Regulatory Authority is hereby granted) any such item with respect to all discontinued CoDev Products.

16.3.3.8. If (a) PIRS or its Affiliates have initiated GMP manufacturing of the discontinued CoDev Product pursuant to Section 5.3.2.1 as of the date of the PIRS opt-out notice, and (b) SGEN cannot meet its supply requirements for the discontinued CoDev Product with its own source for the Manufacture of the CoDev Product, then, at SGEN's option, PIRS or its Affiliates will use Commercially Reasonable Efforts to supply such CoDev Product (but solely in the form as such discontinued CoDev Product was being manufactured by PIRS as of the effective date of termination) to SGEN at PIRS' fully-burdened cost (which shall be calculated following the principles of Commercial Manufacturing Costs under this Agreement) plus [\*\*\*] percent ([\*\*\*]%) until the earlier of (i) successful transition of manufacturing activities to SGEN or its Third Party CMO, and (ii) [\*\*\*] months following the effective date of termination. The Parties will promptly negotiate a supply and related quality agreement to govern the specific terms and conditions of such supply. Furthermore, PIRS shall use Commercially Reasonable Efforts to support a technology transfer for the manufacturing of such discontinued CoDev Product from its own manufacturing facility to a new manufacturing facility of SGEN's choice, subject to reimbursement by SGEN of PIRS' reasonable Out-of-Pocket and FTE Cost incurred in connection with such technology transfer activities. If SGEN so requests PIRS will assign to SGEN any Third Party agreements that are specific to the Research, Development, Manufacture, or Commercialization of the discontinued CoDev Product, and to which PIRS is a party, subject to any required consents of such Third Party.

16.3.3.9. PIRS will use Commercially Reasonably Efforts, and subject to SGEN's reasonable assistance, to the extent legally permissible (including to the extent permitted under PIRS' obligations to Third Parties on the effective

date of discontinuation), to promptly transfer and assign or exclusively license (or, if applicable, will cause its Affiliates to assign) to SGEN all of PIRS' (and such Affiliates') worldwide right, title and interest in and to any registered trademarks or registered internet domain names that are specific to and exclusively used for the discontinued CoDev Product (it being understood that the foregoing will not include any trademarks or internet domain names that contain the corporate or business name(s) of PIRS or any of its Affiliates or any other products of PIRS or any of its Affiliates).

16.3.3.10. More generally, PIRS shall use Commercially Reasonable Efforts to ensure a smooth and orderly transition of the discontinued CoDev Product in accordance with this <u>Section 16.3.3</u>, including any Development, Manufacturing, or Commercialization activities ongoing at the time of notice of opt-out to SGEN, pursuant to an opt-out agreement to be negotiated in good faith by the Parties within [\*\*\*] months following the termination notice. Such agreement shall be consistent with this <u>Section 16.3.3</u>.

16.3.3.11. For avoidance of doubt, the discontinued CoDev Product shall be treated as an Exclusive Product for purposes of the non-compete provisions of Section 10.2 and the provisions of Section 10.3.

16.3.3.12. In consideration of the rights granted by PIRS to SGEN set forth herein, including the license under <u>Section 2.1</u>, SGEN shall pay to PIRS a flat royalty on Net Sales of each discontinued CoDev Product of [\*\*\*] percent ([\*\*\*]%). This royalty shall be payable by SGEN to PIRS on a country-by-country basis and discontinued CoDev Product-by- discontinued CoDev Product basis for a period commencing with the First Commercial Sale of the relevant discontinued CoDev Product and ending with respect to such discontinued CoDev Product in such country on the later of (a) [\*\*\*] years thereafter in such country; (b) last to expire Regulatory Exclusivity relating to such discontinued CoDev Product; or (c) expiration of the last to expire Valid Claim within the Initial Compound Specific Patent and/or any Patent Rights within the PIRS Building Block IP, in each case, Covering the import, use, sale or offer for sale (but, for clarity, not the Manufacturing) of such discontinued CoDev Product in such country of sale, including by 35 U.S.C. § 271(g) or any foreign equivalent. <u>Sections 8.1, 8.2, and 8.5</u> shall apply to such discontinued CoDev Product. For avoidance of doubt, no milestones shall be due to PIRS in connection with such discontinued CoDev Product. In addition, such discontinued CoDev Product shall be treated as an Exclusive Product for purposes of annual updates pursuant to <u>Section 3.7</u>.

138

16.3.3.13. For avoidance of doubt, following compliance with the provisions of this <u>Section 16.3.3</u> for each discontinued CoDev Product, PIRS shall no longer be required to contribute resources to the Development or Commercialization of the discontinued CoDev Product.

16.3.4. Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement are, and shall otherwise be deemed to be, for all purposes of Section 365(n) of the United States Bankruptcy Code and of any similar or analogous provisions of applicable Laws outside of the United States (the "Bankruptcy Code"), licenses and rights to "intellectual property" as defined under Section 101(35A) of the U.S. Bankruptcy Code. Each Party agrees that the other Party, as licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code. In the event of the commencement of a bankruptcy proceeding by or against a Party under the Bankruptcy Code (the "Insolvent Party"), the other Party shall be entitled to a complete duplicate of (or complete access to, as appropriate) any intellectual property and Know-How licensed to such Party under this Agreement and held by such first Party and its successors and assigns (and all embodiments of such intellectual property and Know-How), provided that, a Party shall not be required to provide any duplicate copies and embodiments of such intellectual property or Know-How to the other Party so long it has already provided such intellectual property and Know-How it is required to provide to under this Agreement, and, if not already in its possession, shall be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon its written request therefore, unless the Insolvent Party continues to perform all of its obligations under this Agreement, or (b) if not delivered or granted under (a) above, following the rejection of this Agreement by or on behalf of the Insolvent Party upon written request therefore by the other Party.

16.3.5. <u>Survival</u>. The termination or expiration of this Agreement shall not affect any payment of any debts or obligations accruing prior to or after such date of termination or expiration. <u>Section 1</u> (to the extent necessary to give effect to the surviving provisions); <u>Section 2.6.5</u> (subject to maintaining confidentiality for any applicable Data of the other Party that is the other Party's Confidential Information pursuant to <u>Section 12</u>); <u>Section 2.6.6</u> (the first sentence); <u>Section 7</u> (with respect to any payments (including milestones and royalties) accrued during the Term as well as with respect to Net Sales accrued following the Term during a permitted sell-off period under <u>Section 16.3.2.3</u> or <u>Section 16.3.2.4</u>); <u>Section 8</u> (with respect to the last Calendar Quarter of the Term or following the Term for any permitted sell-off period under <u>Section 11.2</u> (solely with respect to Patents jointly owned by the Parties pursuant to the terms of this Agreement);

139

<u>Section 11.3</u> (the last three sentences); <u>Section 11.7.4</u>; <u>Section 12</u> (for the period of time set forth in <u>Section 12.1</u>); <u>Section 14.3.2</u>; <u>Section 15</u>; <u>Section 16.1</u> (last sentence solely upon the natural expiration of this Agreement); <u>Section 16.3</u>; and <u>Section 17</u> will survive the expiration or any termination of this Agreement for any reason, in accordance with their respective terms and conditions, and for the respective duration stated therein, and where no duration is stated, will survive indefinitely. In addition, any Section that is referred to in the above listed Sections shall survive solely for the interpretation or enforcement of the latters.

### 17. Miscellaneous

17.1. <u>Restrictions; No Other Licenses</u>. Except as expressly set forth hereunder, neither Party grants to the other Party any rights, licenses, or covenants in or to any Intellectual Property Rights, whether by implication, estoppel, vicariously, indirectly, or otherwise, other than the license rights that are specifically and expressly granted under this Agreement. All rights not specifically and expressly granted by a licensing Party under this Agreement are reserved by such licensing Party and may be used or practiced by such licensing Party for any purpose.

17.2. <u>Dispute Resolution</u>. For any Dispute or CoDev-Related Dispute that is not already subject to Arbitration or Accelerated Arbitration, as applicable, the Alliance Managers will attempt in good faith to resolve such Dispute or CoDev-Related Dispute, failing which either Party may cause such Dispute or CoDev-Related Dispute to be referred to the Senior Executives for resolution. The Senior Executives shall attempt in good faith to resolve such Dispute or CoDev-Related Dispute by unanimous consent. If the Senior Executives cannot resolve such Dispute within [\*\*\*] days of the matter being referred to them, then <u>Section 17.2.1</u> or <u>Section 17.2.2</u> shall apply, as applicable.

17.2.1. <u>Arbitration</u>. In the event a dispute arises (each, a "**Dispute**") that is not a CoDev Dispute, then either Party may submit such Dispute to arbitration for final resolution by arbitration request (the "**Arbitration Request**") under the Rules of Arbitration of the International Chamber of Commerce (the "**Rules**") by three (3) arbitrators appointed in accordance with the said Rules (each such arbitration, an "**Arbitration**"). Each Arbitration will be conducted in English and all foreign language documents shall be submitted in the original language and, if so requested by any arbitrator or Party, shall also be accompanied by a translation into English. The place of arbitration shall be New York, NY. The arbitrators in any Arbitration shall enforce and not modify the terms of this Agreement. The award of the arbitrators shall be final and binding on each Party and its respective successors and assigns. All costs and expenses of any Arbitration, including reasonable attorneys' fees and expenses and the administrative and arbitrator fees and expenses, shall be borne by the Parties as determined by the arbitrators.

17.2.2. Accelerated Arbitration.

140

17.2.2.1. <u>Initiation of Arbitration</u>. Notwithstanding <u>Section 17.2.1</u>, in the event that a Dispute arises regarding a difference of business or technical judgment that is related to the Research, Development, Manufacture or Commercialization of a CoDev Product under this Agreement (a "**CoDev-Related Dispute**"), then this <u>Section 17.2.2</u> shall govern the dispute resolution process with respect to such CoDev-Related Dispute. In the event of a CoDev-Related Dispute, either Party may submit such Dispute to arbitration for final resolution by arbitration request (the "Accelerated Arbitration Request") under the International Chamber of Commerce Expedited Procedure Rules ("Expedited Rules") by a single arbitrator appointed in accordance with said Expedited Rules (each such arbitration, an "Accelerated Arbitration"). The arbitrator appointed shall have at least [\*\*\*] years' experience in the life sciences industry and shall have the requisite background and expertise with respect to the particular issue that is the subject of the CoDev-Related Dispute.

17.2.2.2.Exchange of Proposals. Within [\*\*\*] days of the appointment of the arbitrator, each Party will deliver to the arbitrator and the other Party a detailed written proposal setting forth its proposed terms for the resolution of the dispute at issue (the "**Proposed Terms**") and a memorandum (the "**Support Memorandum**") in support thereof, not exceeding [\*\*\*] pages in length. The Parties will also provide the arbitrator with a copy of this Agreement, as amended through such date. Within [\*\*\*] days after receipt of the other Party's Proposed Terms and Support Memorandum, each Party may submit to the arbitrator (with a copy to the other Party) a response to the other Party's Proposed Terms and Support Memorandum, such response not exceeding [\*\*\*] pages in length. Neither Party may have any other communications (either written or oral) with the arbitrator other than for the sole purpose of engaging the arbitrators or as expressly permitted in this <u>Section 17.2.2.2</u>; provided, that, the arbitrator may, in his or her discretion, convene a hearing to ask questions of the Parties and hear oral argument and discussion regarding each Party's Proposed Terms and Support Memorandum, at which time each Party shall have an agreed upon time to argue and present witnesses in support of its Proposed Terms.

17.2.2.3.<u>Selection of Final Proposal</u>. Within [\*\*\*] days after the arbitrator is appointed, the arbitrator panel shall select one of the two Proposed Terms (without modification) provided by the Parties which most closely reflects a commercially reasonable interpretation of the terms of this Agreement. In making its selection, (i) the arbitrator shall not modify the terms or conditions of either Party's Proposed Terms nor shall the arbitrator combine provisions from both Proposed Terms and (ii) the arbitrator shall consider the terms and

141

conditions of this Agreement, the relative merits of the Proposed Terms, the Support Memorandums and, if applicable, the oral arguments of the Parties.

17.2.2.4. <u>Notification of Decision</u>. The arbitrator shall make its decision known to both Parties as promptly as possible by delivering written notice to both Parties. The Parties shall agree in writing to comply with the Proposed Terms selected by the arbitrator within [\*\*\*] days of receipt of such written decision, which agreement may be made pursuant to an amendment to this Agreement. The decision of the arbitrator shall be final and binding on the Parties, and specific performance may be ordered by any court of competent jurisdiction.

17.2.2.5. <u>Miscellaneous</u>. Each Arbitration will be conducted in English and all foreign language documents shall be submitted in the original language and, if so requested by any arbitrator or Party, shall also be accompanied by a translation into English. The place of arbitration shall be New York, NY. The arbitrators in any Arbitration shall enforce and not modify the terms of this Agreement. The award of the arbitrator shall be final and binding on each Party and its respective successors and assigns. All costs and expenses of any Arbitration, including reasonable attorneys' fees and expenses and the administrative and arbitrator fees and expenses, shall be borne by the Parties as determined by the arbitrator.

17.2.3. <u>Confidentiality</u>. Except to the limited extent necessary to comply with applicable Law, legal process, or a court order or to enforce a final settlement agreement or secure enforcement or vacatur of the arbitrator's award, the Parties agree that the existence, terms and content of any Arbitration, all information and documents disclosed in any Arbitration or evidencing any arbitration results, award, judgment or settlement, or the performance thereof, and any allegations, statements and admissions made or positions taken by either Party in any Arbitration shall be treated and maintained in confidence and are not intended to be used or disclosed for any other purpose or in any other forum.

17.2.4. <u>Communications with Internal Counsel</u>. In the course of the negotiation and implementation of this Agreement and the resolution of any disputes, investigations, administrative or other proceedings relating thereto, each Party will call upon the members of its internal legal department to provide advice to such Party and its directors, employees, and agents on legal matters. Notwithstanding any rights to the contrary under applicable procedural or substantive rules of law, each Party agrees not to request, produce or otherwise use any such communications between members of its legal department and directors, employees or agents in connection with any such disputes, investigations, administrative or other proceedings, to the extent such

142

communications, if they had been exchanged between such Party and external attorneys, would have been covered by legal privilege and not disclosable.

17.3. <u>Governing Law</u>. This Agreement and any dispute arising from the performance or breach hereof will be governed by and construed and enforced in accordance with the Laws of New York, excluding its rules of conflict of laws.

17.4. <u>Assignment</u>. This Agreement will not be assignable by either Party, nor may either Party delegate its obligations or otherwise transfer any licenses granted herein or other rights created by this Agreement, except as expressly permitted hereunder, without the prior written consent of the other Party hereto, which consent will not be unreasonably withheld, conditioned, or delayed. Notwithstanding the foregoing, each Party may assign this Agreement, without the consent of the other Party, to an Affiliate or to its Third Party successor in connection with a merger, consolidation, sale of all or substantially all of the assets to which this Agreement pertains or that portion of its business pertaining to the subject matter of this Agreement, or any Change of Control of such Party; provided that the assignee assumes all of the assigning Party's obligations under this Agreement, subject to this <u>Section 17.4</u>. Any assignment in violation of this provision is void and without effect.

17.5. <u>Acquiror IP</u>. Notwithstanding anything to the contrary in this Agreement, in the event of an acquisition of a Party or its business by an Acquiror after the Effective Date, whether by merger, asset purchase or otherwise, as to any such Acquiror, the non-acquired Party shall not obtain rights, licenses, options or access to any Intellectual Property Rights or Know-How, product candidates or products that are held by the Acquiror or any Affiliate of the Acquiror that becomes an Affiliate of the acquired Party as a result of such acquisition (but excluding the acquired Party itself), that were not generated through any use or access to the Intellectual Property Rights or Know-How of the acquired Party, or that are not licensed by the acquired Party under this Agreement prior to the date of acquisition.

17.6. <u>Binding Agreement</u>. This Agreement, and the terms and conditions hereof, will be binding upon and will inure to the benefit of the Parties and their respective successors, heirs, administrators and permitted assigns.

143

17.7. Force Majeure. Except for payment obligations under this Agreement, no Party will be held liable or responsible to the other Party nor be deemed to be in default under, or in breach of any provision of, this Agreement for failure or delay in fulfilling or performing any obligation of this Agreement when such failure or delay is due to force majeure, and without the fault or negligence of the Party so failing or delaying. For purposes of this Agreement, "force majeure" is defined as causes beyond the control of the Party, including, without limitation, acts of God; Laws of any government; war; civil commotion; destruction of production facilities or materials by fire, flood, earthquake, explosion, or storm; labor disturbances; epidemic; and failure of public utilities or common carriers. In the event of force majeure, PIRS or SGEN, as the case may be, will immediately notify the other Party of such inability and of the period for which such inability is expected to continue. The Party giving such notice will thereupon be excused from such of its obligations under this Agreement as it is thereby disabled from performing for so long as such Party is so disabled, up to a maximum of [\*\*\*] days, after which time the Party will use reasonable efforts to minimize the duration of any force majeure.

17.8. <u>Notices</u>. Any notice or request required or permitted to be given under or in connection with this Agreement will be deemed to have been sufficiently given if in writing and personally delivered or sent by certified mail (return receipt requested), facsimile transmission (receipt verified), email or overnight express courier service (signature required), prepaid, to the Party for which such notice is intended, at the address set forth for such Party below:

### If to PIRS:

Pieris Pharmaceuticals GmbH Lise-Meitner-Strasse 30 85354 Freising, Germany Attention: [\*\*\*]

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

#### If to SGEN:

Seattle Genetics, Inc. 21823 30<sup>th</sup> Drive SE

144

Bothell, WA 98021 Attention: [\*\*\*] Facsimile: [\*\*\*] Email: [\*\*\*]

17.9. or to such other address for such Party as it will have specified by like notice to the other Parties, provided that notices of a change of address will be effective only upon receipt thereof. If delivered personally or by facsimile transmission, the date of delivery will be deemed to be the date on which such notice or request was given. If sent by overnight express courier service, the date of delivery will be deemed to be the next Business Day after such notice or request was deposited with such service. If sent by certified mail, the date of delivery will be deemed to be the third (3rd) day after such notice or request was deposited with the postal service. If sent by email, the date of delivery will be deemed to be the day that the Party giving notice receives electronic confirmation of sending from its email provider.

17.10. <u>Waiver</u>. Neither Party may waive or release any of its rights or interests in this Agreement except in writing. The failure of either Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement will not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition. No waiver by either Party of any condition or term in any one or more instances will be construed as a continuing waiver of such condition or term or of another condition or term.

17.11. <u>Severability</u>. If any provision hereof should be held invalid, illegal, or unenforceable in any jurisdiction, the Parties will negotiate in good faith a valid, legal, and enforceable substitute provision that most nearly reflects the original intent of the Parties and all other provisions hereof will remain in full force and effect in such jurisdiction and will be liberally construed in order to carry out the intentions of the Parties hereto as nearly as may be possible. Such invalidity, illegality or unenforceability will not affect the validity, legality, or enforceability of such provision in any other jurisdiction.

17.12. Entire Agreement. This Agreement, including the schedules and Exhibits hereto together with the Platform Agreement, sets forth all the covenants, promises, agreements, appendices, warranties, representations, conditions, and understandings between the Parties hereto and supersedes and terminates all prior agreements and understandings between the Parties relating to the subject matter hereof, including the Prior CDA. There are no covenants, promises, agreements, warranties, representations, conditions, or understandings, either oral or written, between the Parties relating to the subject matter hereof other than as set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement will be binding upon the Parties hereto unless reduced to writing and signed by the respective authorized officers of the Parties. To the extent of any conflict between the terms of this Agreement and its schedules and Exhibits, or any related agreement, the terms of this Agreement shall govern.

17.13. <u>Independent Contractors</u>. Nothing herein will be construed to create any relationship of employer and employee, agent and principal, partnership, or joint venture between the Parties. Each Party is an independent contractor. Neither Party will assume, either directly or indirectly, any liability of or for the other Party. Neither Party will have the authority to bind or obligate the other Party nor will either Party represent that it has such authority.

17.14. <u>Headings</u>. Headings used herein are for convenience only and will not in any way affect the construction of or be taken into consideration in interpreting this Agreement.

146

17.15. Construction of Agreement. The terms and provisions of this Agreement represent the results of negotiations between the Parties and their representatives, each of which has been represented by counsel of its own choosing, and neither of which has acted under duress or compulsion, whether legal, economic, or otherwise. Accordingly, the terms and provisions of this Agreement will be interpreted and construed in accordance with their usual and customary meanings, and each of the Parties hereto hereby waives the application in connection with the interpretation and construction of this Agreement of any rule of Law to the effect that ambiguous or conflicting terms or provisions contained in this Agreement will be interpreted or construed against the Party whose attorney prepared the executed draft or any earlier draft of this Agreement. The definitions of the terms herein shall apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine and neuter forms. The Parties each acknowledge that they have had the advice of counsel with respect to this Agreement, that this Agreement has been jointly drafted, and that no rule of strict construction shall be applied in the interpretation hereof. Unless the context requires otherwise: (a) the words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation"; (b) any reference to any applicable Law herein shall be construed as referring to such applicable Law as from time to time enacted, repealed or amended; (c) any reference herein to any person shall be construed to include the person's permitted successors and assigns; (d) the words "herein", "hereof" and "hereunder", and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof; (e) all references herein to Articles, Sections, or Exhibits, unless otherwise specifically provided, shall be construed to refer to Articles, Sections, or Exhibits of this Agreement; (f) provisions that require that a Party, the Parties or any Committee hereunder "agree", "consent" or "approve" or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, electronic mail, letter, approved minutes or otherwise (but excluding instant messaging); (g) the term "or" shall be interpreted in the inclusive sense commonly associated with the term "and/or"; and (h) the words "will" and "shall" will have the same meaning in this Agreement. This Agreement has been executed in English, and the English version (which is the only version) of this Agreement shall control.

17.16. <u>Compliance with Applicable Law</u>. Each Party's obligations under this Agreement shall be subject to such Party's compliance with applicable Law applicable to its performance and its other obligations under the Agreement (including any anti-corruption, export control, environmental, hazardous substance, and data privacy and security Laws).

147

17.17. <u>No Third Party Beneficiary</u>. Except with respect the Indemnified Parties under <u>Section 15</u>, Nothing expressed or implied in this Agreement is intended, or shall be construed, to confer upon or give any person other than the Parties and their respective Affiliates, successors and assigns, any rights or remedies under or by reason of this Agreement.

17.18. <u>Counterparts</u>. This Agreement may be signed in counterparts, each and every one of which will be deemed an original, notwithstanding variations in format or file designation which may result from the electronic transmission, storage, and printing of copies of this Agreement from separate computers or printers. Facsimile signatures will be treated as original signatures.

# [Remainder of page intentionally left blank; signature page follows]

IN WITNESS WHEREOF, the Parties have caused this License and Collaboration Agreement to be executed by their duly authorized representatives:

For Pieris Pharmaceuticals, Inc.

By: /s/ Stephen S. Yoder\_

Name: Stephen S. Yoder

Title: President and CEO

For Seattle Genetics, Inc.

By: <u>/s/ Clay B. Siegall, Ph.D.</u>

Name: Clay B. Siegall, Ph.D.

Title: President and CEO

# For Pieris Pharmaceuticals GmbH

By: /s/ Stephen S. Yoder

Name: Stephen S. Yoder

Title: Managing Director

*148* 

# **Exhibit Index**

Exhibit 1.178: PIRS Patent Rights

Exhibit 1.179: Patent Rights within the PIRS Platform Improvement IP

Exhibit 1.180: Patent Rights within the PIRS Platform IP

Exhibit 1.189: CoDev Product Profits and Losses

Exhibit 1.222: SGEN Antibody Target-Dependent T Cell Activation Criteria

Exhibit 1.231: SGEN Patent Rights

Exhibit 4.1.1.2: First Approved SGEN Antibody Target

Exhibit 4.1.1.3(a): Second Approved SGEN Antibody Target

Exhibit 4.1.1.3(b): Third Approved SGEN Antibody Target

Exhibit 4.1.1.5(a): Gatekeeper Identity & Contact Information

Exhibit 4.1.2: Research Candidate Plan for the First Approved SGEN Antibody Target

Exhibit 4.1.2.3(a): Research Candidate Plan for the Second Approved SGEN Antibody Target

Exhibit 4.1.2.3(b) Research Candidate Plan for the Third Approved SGEN Antibody Target

Exhibit 6.2: Global Commercialization Agreement Principles

Exhibit 13.4.1: Joint Press Release

Exhibit 14.2.1.3: Existing PIRS Patent Rights

149

# Exhibit 1.178: PIRS Patent Rights

[\*\*\*]

# Exhibit 1.179: Patent Rights within the PIRS Platform Improvement IP

# Exhibit 1.180: Patent Rights within the PIRS Platform IP

[\*\*\*, 4 pages]

#### **Exhibit 1.189:** CoDev Product Profits and Losses

- 1. Definitions. All capitalized terms in this <u>Exhibit 1.189</u> shall have the same meaning as set forth in this Agreement. In addition, the following capitalized terms or derivatives thereof (verbs, nouns, singular, plural), when used in this Agreement, shall have the following meanings:
  - a. "Advertising" means the advertising and promotion of a CoDev Product in the Territory in accordance with the Global Commercialization Strategy and related budget. Advertising may be through any means, including, without limitation, (a) television and radio advertisements; (b) advertisements appearing in journals, newspapers, magazines, the internet or other media; (c) seminars and conventions; (iv) packaging design; (v) professional education programs; (d) visual aids and other selling materials; (vii) hospital formulary committee presentations; and (e) presentations to state and other governmental formulary committees; provided, that, unless specifically provided for in the Global Commercialization Strategy, Advertising shall exclude sales calling and General Public Relations.
  - b. "Commercialization Costs" means, with respect to a CoDev Product, all actual out-of-pocket and FTE costs incurred by the Parties, or their Affiliates for Commercialization activities in accordance with the relevant Global Commercialization Strategy and related budget, that are not already accounted for under Sales and Marketing Expenses, and excluding Commercial Manufacturing Costs and Infrastructure Construction Costs unless otherwise agreed to by the Parties in writing. The JCC will agree upon the FTE rate (which, for clarity, may be different from the FTE Rate) to be applied in the calculation of Commercialization Costs, which may, as determined by the JCC, comprise a global rate or more than one rate for different regions (e.g., for the United States and outside the United States).
  - c. "**Commercialization Expenses**" means the sum of (a) Sales and Marketing Expenses, and (b) Commercialization Costs.
  - d. "General Public Relations" means any public relations activity (including a press release or image piece) which (a) promotes generally the business of a company or deals in a general manner with the activities of such company in a general pharmaceutical market; and (b) mentions in an incidental manner the fact that such company or its Affiliates markets or sells a CoDev Product or provides other incidental information concerning a CoDev Product.

- e. **"Infrastructure Construction Costs**" means the actual costs (including labor and out-of-pocket costs) incurred by a Party in order to construct the infrastructure of such Party required for the conduct of Commercialization activities under the Global Commercialization Strategy; provided, that Infrastructure Construction Costs shall not include the ongoing costs of maintaining such Party's infrastructure, including the costs attributable to the maintenance of utilities (such as sewage, water and electric systems), that are, in any case, directly attributable or Reasonably Allocable to the conduct by such Party of Commercialization activities.
- "Commercial Manufacturing Costs" means with respect to a CoDev Product Manufactured by or on f. behalf of a Party in accordance with the applicable CoDev Product Plan or the Global Commercialization Strategy and related budgets at any time following the first Regulatory Approval of the applicable CoDev Product, such Party's actual costs (including labor and out-of-pocket costs) of Manufacturing such CoDev Product (for both clinical as well as commercial supply) without any markup, from the date PIRS receives the Option Notice until such CoDev Product is no longer Manufactured. Each Party's Commercial Manufacturing Cost shall be calculated in accordance with the methodology consistently applied for such costs throughout the organization, and shall be the sum of the following components: (a) direct costs, including manufacturing labor and materials directly used in Manufacturing the CoDev Product by such Party or its Affiliates; (b) direct labor costs of nonmanufacturing departments (such as quality) directly attributable or Reasonably Allocable to the CoDev Product; (c) toll process and other charges incurred by such Party for outsourcing the Manufacture of the CoDev Product and the cost of supervising and managing the Third Party manufacturers, and of receipt, incoming inspections, storage, packaging, handling quality control testing and release of the outsourced items, and (d) any other reasonable and customary out-of-pocket costs borne by such Party for the testing, transport, customs clearance, duty, insurance, storage or packaging of the CoDev Product. If a Party elects to Manufacture any such CoDev Product at a Manufacturing facility owned and operated by such Party, then the costs set forth in clauses (a) and (b) above shall be pro-rated based on capacity utilized by such Party in the Manufacture of the CoDev Product, as the case may be, or any intermediate thereof at such facility as compared to the capacity used to manufacture any other product or intermediate. The basis for all allocations under this Section shall be included in any invoice for Commercial Manufacturing Costs and all allocations under this Section shall be based on space occupied or head-count

or other activity-based method. For clarity, unless otherwise agreed by the Parties, the following expenses are not included in Commercial Manufacturing Costs: (a) inventory carrying costs; (b) regulatory affairs costs; (c) idle capacity cost; (d) product liability and/or business interruption insurance expenses; (e) financing charges for plant and equipment; (f) costs of general corporate and regional and divisional office activities; (g) non-standard costs such as abnormal waste or rework, experiments, unallocated production costs; and (h) inventory adjustments such as adjustments to inventory concerning revaluation to new standards, stock conversions, capitalized/amortized production variances, shortages or overages, and damage or obsolescence of regular on-hand inventory.

- g. "Net Income" means, with respect to a CoDev Product, the sum of (i) Net Sales and (ii) any award for damages as set forth in <u>Section 11.6.1.2</u>, minus the sum of (i) Shared Costs (which includes, but is not limited to, Development Costs, Commercial Manufacturing Costs, and Commercialization Expenses, and is subject to Sublicensing Income sharing as set forth in <u>Section 9.1.2</u>), and (ii) any amount due pursuant to any settlement or license entered into by either Party in accordance with <u>Section 11.6.1.2</u>, in each case, incurred in a given Calendar Quarter for that CoDev Product.
  - i. In calculating the Net Income under this Agreement, the following principles shall apply:
    - 1. There shall be no double counting of any costs or expenses or of any revenues, and to the extent a cost or expense has been included in one category or sub-category, it shall not be included in another; similarly, to the extent any revenue has been taken into account in one category or sub-category it shall not be taken into account in another.
    - 2. When allocating costs and expenses under this Agreement, each Party shall utilize the same policies and principles as it utilizes consistently within its group and business units when making internal cost allocations.
    - 3. To the extent an item of income or revenue is received by a Party or a cost or expense is incurred by a Party, and is necessary and Reasonably Allocable to the Commercialization of a CoDev Product and is not otherwise

accounted for in the calculation of Net Income, such Party shall credit such income or revenue and shall be permitted to charge such cost or expense to the Net Income.

- 4. All costs and expenses shall be determined, and all calculations shall be made, in accordance with GAAP, as applicable.
- 5. No payments made by a Party under this Agreement, including Net Income Payments, shall be included as Commercialization Expenses of such Party or otherwise deducted by such Party in determining the amount of Net Income due and payable to the other Party under this Agreement.
- h. "Net Sales" as set forth in Section 1.149 of this Agreement shall apply *mutatis mutandis* to each Party with respect to CoDev Products.
- "Sales and Marketing Expenses" means all actual out-of-pocket costs (including, without limitation, i. costs of outsourcing any of the following activities or functions) and direct internal labor costs incurred by a Party that are directly attributable or Reasonably Allocable to activities for the sale, promotion and marketing of a CoDev Product in each Party's Territory in accordance with the Global Commercialization Strategy, which may include: (a) market research on a CoDev Product, (b) marketing, Advertising and promoting of a CoDev Product (including, without limitation, public relations targeted specifically at a CoDev Product, educational expenses, advocate development programs and symposia, trade shows, sales meetings, direct to consumer/patient advertising, agency fees for the development of promotional materials and printing of promotional materials), (c) training and communication materials for a CoDev Product (d) corporate accounts, (e) managed care, (f) sales force training, (g) sales call or other sales force costs applicable to a CoDev Product that are not otherwise covered, (h) product hotlines, (i) reimbursement support, (j) contracting, (k) pricing, (l) conducting patient assistance programs, investigator initiated studies and Phase V studies (that are not included as a Shared Cost) in a Party's Territory for a CoDev Product (including, without limitation, Manufacturing or purchasing costs for a CoDev Product utilized in such patient assistance programs), (m) telemarketing services, (n) medical and product advisory boards, (o) medical science liaisons, (p) medical affairs and (q) market development activities and other similar pre-launch activities. Sales and

156

Marketing Expense shall not include (a) any General Public Relations or any other activities that promote the business of a Party as a whole without specifically referencing a CoDev Product, or (b) the pro-rata share of any expenses set forth in (a)-(q) above that are directed at General Public Relations or any other activities or products of a Party, and not directed at a CoDev Product.

- 2. <u>Net Income Payments</u>. Following the First Commercial Sale of a CoDev Product anywhere in the world, the Parties shall share equally the Net Income attributable to such CoDev Product on a worldwide basis, and make payments to each other in order to effectuate such equal sharing of Net Income on a quarterly basis (such payments, the "Net Income Payments"). The Party's obligation to make Net Income Payments shall begin to accrue on the date of First Commercial Sale of such CoDev Product anywhere in the world, and shall continue for so long as there are sales of such CoDev Product.
- 3. <u>Quarterly Reports</u>. Within [\*\*\*] days following the end of each Calendar Quarter following the date of First Commercial Sale of a CoDev Product anywhere in the world, each Party shall submit to the JSC a written report (the "**Net Income Quarterly Report**") that sets forth, in reasonable detail (i) all Shared Costs (including all Development Costs, Commercial Manufacturing Costs, Commercialization Expenses) incurred or received, as applicable, by it with respect to such CoDev Product over such Calendar Quarter, (ii) the Net Sales applicable to such CoDev Product in its Territory over such Calendar Quarter, and (iii) the calculation of Net Income for such CoDev Product in its Territory.
- 4. <u>Net Income Reconciliation and</u> <u>Payments</u>.
  - a. With respect to each Calendar Quarter, no later than the later of (i) [\*\*\*] days following the end of such Calendar Quarter and (ii) [\*\*\*] days following each Party' receipt of the Net Income Quarterly Report, the Parties shall calculate the reconciliation amount to be paid by each Party (the "**Net Income Reconciliation Report**").
  - b. Within [\*\*\*] days after the Parties' agreement as to the Net Income Reconciliation Report, the Party having achieved the lower Net Income during such Calendar Quarter, shall deliver to the other Party an invoice for [\*\*\*] percent ([\*\*\*]%) of the difference in Net Income of the Parties for such Calendar Quarter, and the other Party shall pay such amount within [\*\*\*] days of receipt of the invoice.

c. Section 8.4 and Section 8.5 shall apply *mutatis mutandis* to a CoDev Product and the Net Income Payments described in this Exhibit 1.189.

158

# Exhibit 1.222: SGEN Antibody Target-Dependent T Cell Activation Criteria

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# Exhibit 1.231: SGEN Patent Rights

160

# Exhibit 4.1.1.1: First Approved SGEN Antibody Target

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# Exhibit 4.1.1.3(a): Second Approved SGEN Antibody Target

# Exhibit 4.1.1.3(b): Third Approved SGEN Antibody Target

# Exhibit 4.1.1.5(a): Gatekeeper Identity and Contact Information

To be mutually agreed by the Parties within [\*\*\*] days of the Effective Date.

164

# Exhibit 4.1.2: Research Candidate Plan for the First Approved SGEN Antibody Target

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### **Exhibit 6.2: Global Commercialization Agreement Principles**

The Global Commercialization Agreement for each CoDev Product shall include:

- Further details regarding the roles and responsibilities of the JCC in the Commercialization of the CoDev Product that are consistent with the principles set forth in this Agreement. For each applicable CoDev Product, the JCC shall be responsible for considering (i) the overall Commercialization strategy including updates to the Global Commercialization Strategy as may be required from time to time; (ii) the Global Branding Strategy (including global positioning, promotional messages, colors and other visual branding elements); (iii) creation, preparation, production, reproduction and filing with the applicable Competent Authorities, of relevant written sales, promotion and advertising materials; (iv) review of the marketing and sales performance of the CoDev Product and decision-making regarding the number of sales representatives required for Commercialization of the CoDev Product in the [\*\*\*].
- [\*\*\*]
- An obligation for each Party to report to the JCC on [\*\*\*] basis the status of such Party's Commercialization efforts against the PIRS Territory Commercialization Plan or the SGEN Territory Commercialization Plan, as applicable.
- With respect to Commercialization of the CoDev Product [\*\*\*], an obligation for [\*\*\*] to meet mutually agreed milestones for establishing, training and qualifying the appropriate number of sales representatives and medical science liaisons prior to Marketing Approval [\*\*\*]. The Parties will schedule [\*\*\*] readiness checks no later than [\*\*\*] and [\*\*\*] prior to anticipated launch respectively. In the event [\*\*\*] is unable to meet such milestones or otherwise does not meet the requirements for Commercialization efforts [\*\*\*] by the timelines set forth in the Global Commercialization Agreement, [\*\*\*], provided, that if [\*\*\*].
- An obligation of each Party to provide not less than a [\*\*\*] (or such other activity or performance metric on which the Parties may agree) in the Party's respective Territory post-Marketing Approval (in the SGEN Territory, on a country-by-country basis). In the event that either Party (each, a "Shortfall Party") fails to provide at least [\*\*\*] percent ([\*\*\*]%) of such Party's quarterly detailing target for [\*\*\*] Calendar Quarters, then the Shortfall Party shall provide to the JCC for its review and approval, within [\*\*\*] days of the end of such period, a plan of action for curing the deficiency in the succeeding Calendar Quarter. [\*\*\*].

- An appropriate mechanism for measuring performance of each Party's sales representatives.
- Provisions detailing that each Party [\*\*\*].
- [\*\*\*].
- [\*\*\*].
- A requirement that, in the event that any Competent Authority issues or requests a recall or takes a similar action in connection with a CoDev Product in a Territory, or in the event either Party determines that an event, incident or circumstance has occurred that may result in the need for a recall or market withdrawal of a CoDev Product in its Territory, the Party notified of such recall or similar action, or the Party that desires such recall or similar action, shall, within twenty-four (24) hours of such request, order or determination, notify the other Party's Alliance Manager and JCC members by telephone or e-mail. Each Party, in consultation with the other Party, shall decide whether to conduct a recall of a CoDev Product in its own Territory and the manner in which any such recall shall be conducted (except in the case of a government mandated recall, when such Party may act without such advance notice but shall notify the other Party as soon as possible). Except as may otherwise be agreed to by the Parties, each Party shall bear the expense of any such recall in its own Territory. Each Party will make available all of its pertinent records that may be reasonably requested by the other Party in order to undertake a recall of a CoDev Product in the other Party's Territory. The Parties' rights and obligations under this <u>Exhibit 6.2</u> shall be subject to the terms of any Party Supply Agreement(s). In the event of a conflict between the provisions of any such Party Supply Agreement and this <u>Exhibit 6.2</u>, the provisions of such Party Supply Agreement shall govern.
- Provisions relating to ex-Territory sales; export monitoring, including provisions providing that:
  - Neither Party (nor any of its Affiliates or Sublicensees) shall engage in any advertising or promotional activities relating to a CoDev Product directed primarily to customers or other buyers or users of such Product located outside its Territory or accept orders for a CoDev Product from or sell a CoDev Product into such other Party's Territory for its own account, and if a Party receives any order for a CoDev Product in the other Party's Territory, it shall refer such orders to the other Party.
  - o Each Party and its Affiliates will use reasonable efforts to monitor and prevent exports of a CoDev Product from its own Territory for

167

Commercialization in the other Party's Territory using methods permitted under applicable Law that are commonly used in the industry for such purpose (if any), and shall promptly inform the other Party of any such exports of a CoDev Product from its Territory, and any actions taken to prevent such exports. Each Party agrees to take reasonable actions requested in writing by the other Party that are consistent with Law to prevent exports of a CoDev Product from its Territory for Commercialization in the other Party's Territory.

### Exhibit 13.4.1: Joint Press Release

# Pieris Pharmaceuticals and Seattle Genetics Announce Multi-Program Immuno-Oncology Collaboration

-Companies to Evaluate Novel Bispecific Immuno-Oncology Agents that Combine Pieris' Anticalin Technology with Select Seattle Genetics Cancer-Targeted Antibodies-

**Boston, MA and Bothell, WA (Marketwired)**—02/XX/2018 – Pieris Pharmaceuticals, Inc. (NASDAQ: PIRS), a clinical-stage biotechnology company advancing novel biotherapeutics through its proprietary Anticalin<sup>®</sup> technology platform for cancer, respiratory and other diseases, and Seattle Genetics, Inc. (NASDAQ: SGEN), a global biotechnology company developing innovative, targeted therapies for cancer, today announced they have entered into a collaboration and license agreement with the goal of developing multiple targeted bispecific immuno-oncology treatments for solid tumors and blood cancers.

The collaboration leverages the expertise and core technologies of both companies to develop novel Antibody-Anticalin fusion proteins. Pieris' proprietary suite of agonistic costimulatory Anticalin proteins, when fused to a tumor-targeting antibody, can activate the immune system preferentially in the tumor microenvironment. Seattle Genetics, through its industry-leading work in the field of antibody-drug conjugates (ADCs), has a substantial portfolio of cancer targets and tumor-specific monoclonal antibodies from which programs will be selected for the collaboration. The bispecific drug candidates in this alliance will be designed to enable the patient's immune cells to specifically attack tumors.

"As the industry leader in ADCs, we bring deep expertise in targeted cancer therapy development to this collaboration with Pieris," said Dennis Benjamin, Ph.D., Senior Vice President of Research at Seattle Genetics. "Pieris' Anticalin technology and Antibody-Anticalin bispecific approach are intended to overcome the limitations of currently available immuno-oncology products. This partnership leverages our cancer targets and tumor-specific antibodies to explore multiple novel bispecific combinations, with the goal of developing targeted therapies that improve outcomes for people with cancer."

Under the terms of the agreement, Seattle Genetics will pay Pieris a \$30 million upfront fee, tiered royalties on net sales up to low double-digits, and up to \$1.2 billion in total success-based payments across three product candidates. The companies will pursue multiple Antibody-Anticalin fusion proteins during the research phase, and Seattle Genetics has the option to select up to three therapeutic programs for further development. Prior to the initiation of a pivotal trial, Pieris may opt into global co-

169

development and US commercialization of the second program and share in global costs and profits on a 50/50 basis. Seattle Genetics will solely develop, fund and commercialize the other two programs.

"Pieris was the first company to bring a tumor-targeted costimulatory bispecific to patients with PRS-343, and we are looking forward to broadening our bispecific pipeline through this alliance. Seattle Genetics is a compelling partner for Pieris with a long-standing commitment to oncology," said Stephen S. Yoder, President and CEO of Pieris. "The collaboration combines the excellent protein engineering and translational capabilities of both companies, utilizing Seattle Genetics' tumor-targeted monoclonal antibodies and Pieris' Anticalin proteins to create novel bispecifics. This is our third significant alliance since January 2017 and is in alignment with our goal to create a respiratory- and oncology-focused commercial company."

### About Anticalin® Therapeutics:

Anticalin® proteins are derived from lipocalins, small human proteins that naturally bind, store and transport a wide spectrum of molecules. Anticalin® proteins feature the typical four-loop variable region and a rigidly conserved beta-barrel backbone of lipocalins, which, together, form a shapeable cup-like binding pocket. Proprietary to Pieris, Anticalin® proteins are a novel class of protein therapeutics validated in the clinic and by partnerships with leading pharmaceutical companies. Anticalin® is a registered trademark of Pieris.

### **About Pieris Pharmaceuticals:**

Pieris is a clinical-stage biotechnology company that discovers and develops Anticalin protein-based drugs to target validated disease pathways in a unique and transformative way. Our pipeline includes immunooncology multi-specifics tailored for the tumor microenvironment, an inhaled Anticalin® protein to treat uncontrolled asthma and a half-life-optimized Anticalin® protein to treat anemia. Proprietary to Pieris, Anticalin proteins are a novel class of therapeutics validated in the clinic and by partnerships with leading pharmaceutical companies. Anticalin® is a registered trademark of Pieris. For more information, visit www.pieris.com.

For more information visit <u>www.pieris.com</u>.

#### **About Seattle Genetics:**

Seattle Genetics is an innovative biotechnology company dedicated to improving the lives of people with cancer through novel antibody-based therapies. The company's industry-leading antibody-drug conjugate (ADC) technology harnesses the targeting ability of antibodies to deliver cell-killing agents directly to cancer cells. Seattle Genetics commercializes ADCETRIS® (brentuximab vedotin) for the treatment of several types of CD30-expressing lymphomas. The company is also advancing a robust pipeline of novel therapies for solid tumors and blood-related cancers designed to address significant unmet medical needs and improve treatment outcomes for patients. More information can be found at <u>www.seattlegenetics.com</u> and follow @SeattleGenetics on Twitter.

170

### Pieris Forward Looking Statements Disclaimer:

This press release contains forward-looking statements as that term is defined in Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Statements in this press release that are not purely historical are forward-looking statements. Such forward-looking statements include, among other things, references to novel technologies and methods; our business and product development plans; the timing and progress of our studies, including the timing of enrollment and dosing of PRS-343 patients and PRS-060 healthy subjects, the enrollment of patients in the PRS-080 multi-dose trial; our liquidity and ability to fund our future operations; our ability to achieve certain milestones and receive future milestone or royalty payments; or market information. Actual results could differ from those projected in any forward-looking statements due to numerous factors. Such factors include, among others, our ability to raise the additional funding we will need to continue to pursue our business and product development plans; the inherent uncertainties associated with developing new products or technologies and operating as a development stage company; our ability to develop, complete clinical trials for, obtain approvals for and commercialize any of our product candidates, including our ability to recruit and enroll patients in our studies; our ability to address the requests of the FDA; competition in the industry in which we operate and market conditions. These forward-looking statements are made as of the date of this press release, and we assume no obligation to update the forward-looking statements, or to update the reasons why actual results could differ from those projected in the forward-looking statements, except as required by law. Investors should consult all of the information set forth herein and should also refer to the risk factor disclosure set forth in the reports and other documents we file with the SEC available at www.sec.gov, including without limitation the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016 and the Company's Quarterly Reports on Form 10-Q.

171

### Seattle Genetics Forward Looking Statements Disclaimer:

Certain of the statements made in this press release are forward looking, such as those, among others, relating to the research, development, and therapeutic and commercial potential of Anticalin-based products. Actual results or developments may differ materially from those projected or implied in these forward-looking statements. Factors that may cause such a difference include the possibility that the referenced product candidates may not be feasible to develop, may not show utility in treating cancer, may not have the desired activity or may be associated with adverse events that limit their use in which case Seattle Genetics may not realize the anticipated benefits from the collaboration. More information about the risks and uncertainties faced by Seattle Genetics is contained under the caption "Risk Factors" included in Exhibit 99.1 to the company's Current Report on Form 8-K filed with the Securities and Exchange Commission in January 31, 2018. Seattle Genetics disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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#### ##END##

172

Exhibit 14.2.1.3: Existing PIRS Patent Rights

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#### NON-EXCLUSIVE ANTICALIN® PLATFORM TECHNOLOGY LICENSE AGREEMENT

THIS NON-EXCLUSIVE ANTICALIN PLATFORM TECHNOLOGY LICENSE AGREEMENT ("Agreement") is made and entered into effective as of February 8, 2018 (the "Effective Date"), by and among PIERIS PHARMACEUTICALS, INC., a Nevada corporation having its principal place of business at 255 State Street, 9th floor, Boston, MA 02109 AND PIERIS PHARMACEUTICALS GMBH, a company organized and existing under the laws of Germany having offices and principal place of business at Lise-Meitner-str. 30, 85354 Freising, Germany (collectively, "Pieris"), and Seattle Genetics, Inc., a Delaware corporation located at 21823 30 th Drive SE, Bothell, WA 98021 ("Licensee"). Pieris and Licensee each may be referred to herein individually as a "Party," or collectively as the "Parties."

#### RECITALS

A . Pieris Controls (defined below) certain intellectual property related to Pieris' Platform Technology (defined below).

**B**. Licensee desires to obtain from Pieris a non-exclusive license (or sublicense, as applicable) under such intellectual property to Research, have Researched, Develop, have Developed, Manufacture, have Manufactured, Commercialize, have Commercialized, the Licensed Products in the Licensed Field and Licensed Territory (as such terms are defined below).

**C.** Pieris is willing to grant such non-exclusive license (or sublicense, as applicable) to Licensee on the terms and conditions set forth herein.

In consideration of the foregoing premises, the mutual promises and covenants set forth in this Agreement, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Pieris and Licensee hereby agree as follows:

#### AGREEMENT

### 1. **DEFINITIONS**

When used in this Agreement, capitalized terms will have the meanings as defined below and throughout the Agreement. Unless the context indicates otherwise, the singular will include the plural and the plural will include the singular.

1.1 "Accounting Standards" means, as applicable, the International Financial Reporting Standards (" IFRS"), the U.S. Generally Accepted Accounting Principles ("U.S. GAAP"), and any other internationally recognized accounting standards that may be adopted by a Party.

**1.2** "Affiliate" means with respect to a Party, any person or entity, which directly or indirectly controls, is controlled by, or is under common control with such Party. Solely as used in this definition, the term "control" means (a) the ownership, directly or indirectly, beneficially or legally, of at least fifty percent (50%) of the outstanding voting securities or capital stock (or such lesser percentage which is the maximum allowed to be owned by a person or entity in a particular jurisdiction)

of such Party or other person or entity, as applicable, or such other comparable ownership interest with respect to any person or entity that is not a corporation; or (b) the power, direct or indirect, whether through ownership of voting securities or partnership or other ownership interests, by contract or otherwise of more than fifty percent (50%), to direct the management and policies of a Party or such other person or entity, as applicable.

**1.3** "Anticalin" or "Anticalin Protein" means, whether in nucleic acid or protein form, (a) any lipocalin mutein isolated from the Anticalin Libraries, or (b) any lipocalin mutein that, in each case, has been derived (either physically, intellectually or by reverse engineering, in one (1) or more steps) from any lipocalin referred to in Section (a) of this definition, in each case, which selectively binds a specific Target. For the sake of this <u>Section 1.3</u>, "mutein" shall mean a protein arising as a result of a mutation or a recombinant DNA procedure.

**1.4** "Anticalin Affinity Maturation" means the process of engineering for an Anticalin Protein to enhance its developability profile, such as altering binding affinity, cross-reactivity, or half-life, and specificity by introducing, e.g., one or more amino acid mutations.

**1.5** "Anticalin Characterization" means the assessment of binding and functional potency and/or the evaluation of the developability profile of Anticalin Proteins and/or fusion proteins that include one or more Anticalin Proteins.

1.6 "Anticalin Expression" means the heterologous expression of an Anticalin Protein in a host cell.

**1.7** "Anticalin Fusion Technology" means the process of fusing or genetically linking (including through the use of different linkers) one or more Anticalin Proteins to an immunoglobulin or fragment thereof to create bispecific fusion proteins.

**1.8** "Anticalin Libraries" means any phage display library based on (a) the [\*\*\*] lipocalin ([\*\*\*]) or (b) the [\*\*\*] lipocalin ([\*\*\*]).

**1.9** "Anticalin Selection" means the process of screening an Anticalin Library with a defined Target through the process of phage display, within a solution, and physically separating the Target bound to Anticalin Proteins from the solution containing non-binding Anticalin Proteins.

1.10 "Arbitration" is defined in <u>Section 10.2.1</u>.

1.11 "Arbitration Request" is defined in <u>Section 10.2.1</u>.

1.12 "Audited Party" shall have the meaning set forth in Section 3.7.

1.13 "Auditing Party" shall have the meaning set forth in Section 3.7.

**1.14** "Biological License Application" or "BLA" means a Biological License Application in the United States as described in Section 351(a) of the United States Public Health Service Act ("PHS Act").

**1.15** "**Biosimilar**" means, with respect to a given Licensed Product in a given country, any biological product on the market in such country that is approved (a) by the applicable Competent Authority in such country under the biosimilarity standard set forth in the United States under 42 U.S.C. §§ 262(i)(2) and (k), or any similar standard under its foreign equivalent applicable Law, on a country-by-country basis where such Licensed Product is marketed, provided that such applicable Law exists and (b) in reliance in whole or in part, on a prior Marketing Approval (or on any safety or efficacy data submitted in support of such prior Marketing Approval) of such Licensed Product. For countries or jurisdictions where no explicit biosimilar regulations exist, "Biosimilar" includes products which have been deemed to be a Biosimilar or otherwise deemed interchangeable by a Competent Authority in the United Sates or European Union. Any product or component thereof (including any Licensed Product or component thereof) licensed, marketed, sold, manufactured, or produced by or on behalf of a Party, its Affiliates or Sublicensees (to the extent such Sublicensee commercializes a Biosimilar in reliance on or access to the Data, Patents, and Know-How licensed under this Agreement) will not constitute a Biosimilar for the purpose of royalty reduction pursuant to <u>Section 3.5.1</u>.

**1.16 "Business Day"** means a day that is not a Saturday, Sunday, or a day on which banking institutions in the United States or Munich, Germany, are authorized by applicable Law to remain closed.

**1.17** "Calendar Quarter" means each three (3) consecutive calendar months ending on each March 31, June 30, September 30 and December 31.

**1.18** "Calendar Year" means the period of time commencing on January 1 and ending on the next December 31.

**1.19** "Clinical Studies" means research studies in humans that are (a) designed in accordance with international ethical and scientific quality standards for designing, conducting, recording, and reporting research studies involving investigational medicinal products for human use and that involve the participation of human subjects, which standards are established through applicable Laws, and (b) designed to generate clinical data and results regarding a biological molecule in support of Marketing Approval, including any translational research studies. Clinical Studies include, but are not limited to, any Phase 1 Clinical Study, Phase 2 Clinical Study, or Pivotal Clinical Study.

**1.20** "**CoDev Product**" means a Licensed Product for which Pieris has exercised a co-Development option pursuant to the Collaboration Agreement.

1.21 "Collaboration Agreement" shall have the meaning set forth in Section 2.1.

**1.22** "**Commercialization**" means any and all activities related to obtaining pricing and reimbursement approval, marketing, promoting, distributing, importing, exporting, offering for sale, having sold, selling, or conducting any other commercial exploitation activities relating to a Licensed Product. For clarity, "**Commercialize**" has a correlative meaning.

**1.23** "Compassionate Use" means the use of a Licensed Product as an investigational drug (prior to Marketing Approval) in accordance with applicable Law outside of a Clinical Study to treat a patient with a serious or life-threatening disease or condition who has no comparable or satisfactory alternative treatment options.

**1.24** "**Competent Authority**" means any regulatory agency, department, bureau, commission, council, or other governmental entity of (a) any country, territory, national, federal, state, provincial, county, city, or other political subdivision government, including the U.S. Food and Drug Administration ("**FDA**"), or (b) any supranational body (including the European Medicines Agency ("**EMA**")), in any applicable jurisdiction in the world, involved in the granting of Marketing Approval.

**1.25** "Control", "Controlled", or "Controlling" means, with respect to a subject item (including any intellectual property, Know-How, or Patent) ("Subject Item"), the possession (whether arising by ownership, pursuant to a license or sublicense or otherwise, other than pursuant to this Agreement) by a Party of the ability of such Party or its Affiliate to grant a license, sublicense or access to the other Party with respect to such Subject Item, as provided in this Agreement, without violating the terms of any agreement with any Third Party (and subject to Section 3.5.2), in existence as of the time such Party or its Affiliates would first be required hereunder to grant the other Party such license, sublicense, or access.

**1.26** "**Cover**", "**Covered**" or "**Covering**" with reference to (a) a Patent, means that, in the absence of a (sub)license under, or ownership of, such Patent, the Research, Development, Manufacture, or Commercialization of a Licensed Product (including the making, using, offering for sale, selling or importing thereof), with respect to a given country, would infringe a Valid Claim of such Patent (or, in the case of a Valid Claim that has not yet issued, would infringe such Valid Claim if it were to issue), or (b) Know-How, means that the Research, Manufacture, Development or Commercialization of a Licensed Product incorporates, embodies or otherwise make use of such Know-How.

**1.27** "**Data**" means any and all non-aggregated and aggregated research, pharmacology, pre-clinical, clinical, commercial, marketing, process development, manufacturing, and other data or information, including investigator brochures and reports (both preliminary and final), statistical analyses, expert opinions and reports, and safety data, in each case generated from, or related to, Clinical Studies or non-clinical studies, research or testing specifically related or directed to a Licensed Product.

**1.28** "Development" m means, with respect to a Licensed Product (and any companion diagnostic therefor), any and all pre-clinical, non-clinical and clinical research and development activities before or after obtaining Marketing Approval for such Licensed Product, and that are reasonably related to or leading to the development, preparation, and submission of data and information to a regulatory authority for the purpose of obtaining, supporting or expanding Marketing Approval or to the appropriate body for obtaining, supporting or expanding pricing approval, including all activities related to pharmacokinetic profiling, design and conduct of Clinical Studies, those Manufacturing related activities that support the Development of the applicable Licensed Product (such as process development, scale up, test method development, formulation development, delivery system development, quality control development, and validation) and CMC activities, medical affairs, regulatory affairs, statistical analysis, report writing, and regulatory filing creation and submission (including the services of outside advisors and consultants in connection therewith).

1.29 "Disclosing Party" is defined in <u>Section 6.1</u>.

**1.30** "Dispute" is defined in <u>Section 10.2.1</u>.

4

**1.31** "**First Commercial Sale**" means the first sale to a Third Party of a Licensed Product by or under the authority of Licensee or its Affiliates or Sublicensees, in a country after receipt of the applicable Marketing Approval, as desirable in such country, from the Competent Authorities in that country. For the avoidance of doubt, Compassionate Use shall not be considered a First Commercial Sale.

**1.32** "GLP Tox Study" means, with respect to a Licensed Product, a study conducted in a species using applicable regulatory good laboratory practices for the purposes of assessing the onset, severity, and duration of toxic effects and their dose dependency with the goal of establishing a safety profile required for a regulatory submission supporting the dosing of human subjects as outlined in appropriate ICH guidance. For the avoidance of doubt, preliminary toxicology studies are not regarded as a GLP Tox Study.

**1.33** "Government Authority" means any applicable government authority, court, tribunal, arbitrator, agency, department, legislative body, commission or other government instrumentality of (a) any country, territory, nation, state, province, county, city or other political subdivision thereof or (b) any supranational body, including any Competent Authority.

1.34 "Indemnitee" means either a Licensee Indemnitee or a Pieris Indemnitee.

**1.35** "IND" or "IND/IMPD" means (a) an Investigational New Drug Application as defined in the FD&C Act and applicable regulations promulgated thereunder by the FDA, (b) the Investigational Medicinal Product Dossier in the applicable European territories, or (c) the equivalent application to the applicable Competent Authority in any other regulatory jurisdiction, and any amendments to the foregoing (a), (b) or (c), in each case, the filing of which is necessary to initiate or conduct clinical testing of an investigational drug or biological product in humans in such jurisdiction.

**1.36** "Know-How" means any and all ideas, concepts, designs, technical information, techniques, Data, database rights, discoveries, inventions, practices, methods, procedures, processes, methods, algorithm, knowledge, skill, experience, test data and any other information or technology, whether in written, electronic, graphic or any other form, including pharmaceutical, chemical, biological and biochemical compositions, formulations, assays, APIs, molecules, samples, cell lines, journals and laboratory notebooks.

**1.37** "Law" means any applicable national, supranational, federal, state, local or foreign law, statute, ordinance, principle of common law, or any rule, regulation, standard, judgment, order, writ, injunction, decree, arbitration award, agency requirement, license or permit of any applicable Government Authority, including any rules, regulations, guidelines, directives or other requirements of applicable Government Authorities, including good clinical practices, good laboratory practices and good manufacturing practices, as well as all anti-bribery or anti-corruption laws, as applicable.

**1.38** "Licensee Indemnitees" is defined in <u>Section 8.2</u>.

**1.39** "Licensed Field" means, with respect to the Licensed Products, any therapeutic, palliative, prophylactic and diagnostic use for any disease or condition.

**1.40** "Licensed Product" means any product that includes at least one Anticalin Protein and is licensed to Licensee under the Collaboration Agreement, including any fusion protein that includes one or more Anticalin Proteins.

**1.41** "Licensed Territory" or "Territory" means, on a Licensed Product-by-Licensed Product basis, the territory licensed to the Licensee under the Collaboration Agreement.

**1.42** "**Manufacture**" means, with respect to a Licensed Product, all activities related to the manufacture of the Licensed Products, including, but not limited to, manufacturing supplies for Development or Commercialization, packaging, in-process and finished product testing, release of product or any component or ingredient thereof, quality assurance and quality control activities related to manufacturing and release of product, ongoing stability tests, storage, shipment, import and export as needed, improvement of production, improvement of manufacturing processes, and regulatory activities related to any of the foregoing. For clarity, "Manufacturing" has a correlative meaning.

**1.43** "MAA" means a Marketing Authorization Application, in relation to any Licensed Product, filed or to be filed with the EMA (or equivalent national agency), for authorization to place a medicinal product on the market in the European Union (or any other territory).

**1.44** "Marketing Approval" means all approvals, licenses, registrations or authorizations of the Competent Authorities in a country, necessary for the commercial marketing and sale of the Licensed Product in such country, including (a) the approval of a MAA or a BLA, and (b) a determination or decision establishing prices for a Licensed Product that can be charged or reimbursed in regulatory jurisdictions where the applicable Competent Authorities approve or determine the price or reimbursement of pharmaceutical products.

**1.45** "Losses" is defined in <u>Section 8.1</u>.

**1.46** "Net Sales" means, in the case of sales by or for the benefit of Licensee, its Affiliates, and its Sublicensees (in each case, "Seller") in the Territory to a Third Party, the gross amount invoiced by Seller with respect to a Licensed Product, less the following deductions solely to the extent such deduction: (i) is reasonable and customary, (ii) is included in the gross invoiced sales price for the Licensed Product or otherwise directly paid, allowed, accrued, or incurred by the Seller with respect to the sale of such Licensed Product (iii) is applicable and in accordance with standard allocation procedures, (iv) has not already been deducted or excluded, (v) is incurred in the ordinary course of business in type and amount consistent with good industry practice, and (vi) is determined in accordance with, and as recorded in revenues under, applicable Accounting Standards ("Permitted Deductions"):

**1.46.1** trade, cash, promotional and quantity discounts and allowances for Licensed Products; price reductions (retroactive or otherwise) including promotional or similar discounts or rebates and discounts or rebates imposed by or otherwise paid to Government Authorities, managed care organizations or other Third Parties;

**1.46.2** any tax, tariff, duty (including custom duty) or other governmental charge (such as excise, sales or use taxes or value added tax), levied on the sale, transportation or delivery of such Licensed Products that are paid to Seller and remitted to a government agency by Seller,

6

but excluding any taxes or other charges measured by or imposed on Seller's income or any franchise taxes, branch profits taxes, or similar tax;

**1.46.3** customary freight, insurance, packing costs and other transportation charges added to the sales price that are incurred in delivering the Licensed Product;

**1.46.4** amounts repaid or credits taken by reason of rejections, defects, or returns of the Licensed Products or because of retroactive price reductions, or due to recalls or rebates required by applicable Laws;

**1.46.5** any fees for services provided by wholesalers and warehousing chains related to the distribution of such Licensed Products and the portion of administrative fees paid during the relevant time period to group purchasing organizations, pharmaceutical benefit managers and/or Medicare Prescription Drug Plans relating specifically to such Licensed Products but only to the extent that such fees are deducted from Net Sales in arriving at the financial information publicly reported in Seller's external financial statements included in its periodic filings with the Securities and Exchange Commission;

**1.46.6** the portion of the annual fee on prescription drug manufacturers imposed by the Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (as amended) (the "**Fee**") that is attributable to the Net Sales of Licensed Products for the Calendar Quarter which as of the Effective Date is determined by multiplying the total Fee times a fraction where the numerator is the "branded prescription drug sales" (as defined in Treas. Reg. § 51.2(d)) ("**Government Sales**") of Licensed Product by the "controlled group" (as defined in Treas. Reg. § 51.2(e)(3)) for the Calendar Quarter and the denominator is the total of all Government Sales for all for all products sold by such "controlled group" for the Calendar Quarter; and

**1.46.7** any other deductions from gross sales of a similar nature to arrive at net sales for the applicable Licensed Product as reported in Seller's Form 10-K and Form 10-Q documents filed with the Securities and Exchange Commission to the extent they are in accordance with GAAP and consistently applied.

For the avoidance of doubt, if a single item falls into more than one of the categories set forth above, such item may not be deducted more than once.

"**Net Sales**" shall not include any consideration received with respect to a sale, use or other disposition of any Licensed Product in a country for purposes of conducting Clinical Studies in the course of Development of the Licensed Product in accordance with this Agreement or as samples (reasonable in number), for Compassionate Use, or for other charitable, promotional, pre-clinical, clinical, regulatory or governmental purposes, in each case to the extent such Licensed Product is sold at or below cost. Notwithstanding the foregoing, the amounts invoiced by Seller, its Affiliates, or their Sublicensees for the sale of Licensed Products among Seller, its Affiliates or their respective Sublicensees for resale shall not be included in the computation of Net Sales hereunder (except where such Affiliates or Sublicensees are the end users) and Net Sales shall be the gross invoice or contract price charged to the Third Party customer for that Licensed Product in an arms' length transaction, less the Permitted Deductions. Net Sales calculations shall be determined in accordance

7

with Accounting Standards consistently applied throughout the organization and across all products of the entity whose sales of Licensed Products are giving rise to Net Sales. In the case of any sale or other transfer for value, such as barter or counter-trade, of a Licensed Product, or part thereof, other than in an arm's length transaction exclusively for cash, Net Sales shall be calculated as above on the value of the non-cash consideration received or the fair market price (if higher) of such Licensed Product in the country of sale or transfer, as determined in accordance with Accounting Standards consistently applied (as contemplated above).

In the case where a Licensed Product is sold as part of a Combination Product in a country in the Territory, Net Sales for the Licensed Product included in such Combination Product in such country shall be calculated as follows:

(i) if the Licensed Product is sold separately in such country and the other active ingredient or ingredients in the Combination Product are sold separately in such country, Net Sales for the Licensed Product shall be calculated by multiplying actual Net Sales of such Combination Product in such country by the fraction A/(A+B), where A is the invoice price of the Licensed Product when sold separately in such country and B is the total invoice price of the other active ingredients in the Combination Product when sold separately in such country;

(ii) if the Licensed Product is sold separately in such country but the other active ingredient or ingredients in the Combination Product are not sold separately in such country, Net Sales for the Licensed Product shall be calculated by multiplying actual Net Sales of such Combination Product in such country by the fraction A/D, where A is the invoice price of the Licensed Product when sold separately in such country and D is the invoice price of the Combination Product in such country;

(iii) if the Licensed Product is not sold separately in such country but the other active ingredient or ingredients in the Combination Product are sold separately in such country, Net Sales for the Licensed Product shall be calculated by multiplying actual Net Sales of such Combination Product by the fraction 1 - (B/D), where B is the invoice price of the other active ingredient or ingredients in the Combination Product in such country; notwithstanding the foregoing, if the other active ingredient or ingredients in the Combination Product are being sold by (a) Seller, then Net Sales for the Licensed Product shall be calculated by multiplying actual Net Sales of such Combination Product shall be calculated by multiplying actual Net Sales of such Combination Product shall be calculated by multiplying actual Net Sales of such Combination Product shall be calculated by multiplying actual Net Sales of such Combination Product, and (b) a Third Party, where E is the number of other active ingredients in the Combination Product, and (b) a Third Party, where such Third Party and Seller have a written agreement on how actual Net Sales of such Combination Product shall be split between Seller and such Third Party, then Net Sales for the Licensed Product shall be the proportion of Net Sales of the Combination Product Seller actually receives under such written agreement with such Third Party; or

8

(iv) if neither the Licensed Product nor the other active ingredient or ingredients in the Combination Product are sold separately in such country, the Parties shall determine Net Sales for the Licensed Product in such Combination Product by mutual agreement based on the relative contribution of the Licensed Product and each other active ingredient to the Combination Product, and shall take into account in good faith any applicable allocations and calculations that may have been made for the same period in other countries.

For purposes of this definition, "**Combination Product**" means a product that includes at least one active ingredient other than a Licensed Product, when a single sale or reimbursement price is set for such Combination Product.

**1.47** "**Patents**" means any and all patent rights and all right, title and interest in all patent applications and patents that issue from them, all letters patent or equivalent rights and applications in each case to the extent the same has not been held, by a court of competent jurisdiction, to be invalid or unenforceable in a decision from which no appeal can be taken or from which no appeal was taken within the time permitted for appeal. Patents include any extension, registration, confirmation, reissue, continuation, supplementary protection certificate, divisional, continuation-in-part, re-examination or renewal thereof or foreign counterparts of any of the foregoing.

**1.48** "**Phase 1 Clinical Study**" means a clinical study of a product in human subjects which provides for the first introduction into humans of a product, conducted in healthy volunteers or patients to obtain information on product safety, tolerability, pharmacological activity or pharmacokinetics, as described in 21 C.F.R. § 312.21(a) (or the non-United States equivalent thereof).

**1.49** "**Phase 1 Clinical Study Expansion Cohort**" means the expansion of a Phase 1 Clinical Study to include additional patient(s) following the selection of a dose during the dose escalation part of the Phase 1 Clinical Study (such as a maximum tolerated dose).

**1.50** "Phase 2 Clinical Study", "Phase 2a Clinical Study" or "Phase 2b Clinical Study" means a clinical study of a product that is prospectively designed to establish the safety, dose ranging and efficacy of a product as further defined in 21 C.F.R. § 312.21(b) (or the non -United States equivalent thereof).

**1.51** "**Pivotal Clinical Study**" means a clinical study of a product that is designed to generate statistically significant evidence of the efficacy of a product for a particular indication or use (as well as additional safety information) and that is intended to form the primary scientific support for filing a BLA to obtain Marketing Approval to market the product, (or any MAA for the non-United States equivalent thereof).

**1.52** "Pieris Indemnitees" is defined in <u>Section 8.1</u>.

**1.53** "Platform Improvement IP" means any and all Patents or Know-How created, invented, or generated by or on behalf of employees, agents, or independent contractors of either Party or their Affiliates (whether alone or jointly) in the course of performing activities pursuant to this Agreement that constitutes an improvement, modification, or enhancement to, or derivative of, the Platform IP, including all Intellectual Property Rights therein.

**1.54** "**Platform IP**" means (a) the Know-How Controlled by Pieris that is necessary or useful for the practice of the Platform Technology, and (b) those Patents Controlled by Pieris directed to the Platform Technology as set forth in <u>Exhibit A</u>.

1.55 "Platform Patent" means all Patents within the Platform IP and Platform Improvement IP.

**1.56** "**Platform Technology**" means Anticalin Libraries, Anticalin Selection, Anticalin Expression, Anticalin Characterization, Anticalin Fusion Technology, and Anticalin Affinity Maturation methods, all to the extent Controlled by Pieris.

**1.57** "**Regulatory Exclusivity**" means any exclusive marketing rights or data exclusivity rights conferred by any applicable Competent Authority, other than an issued and unexpired Patent, including any regulatory data protection exclusivity and/or any other exclusivity afforded by restrictions which prevent the granting by a Competent Authority of regulatory approval to market for any indication a Biosimilar.

**1.58** "**Research**" or "**Researching**" means activities related to the design, discovery, generation, identification, profiling, characterization, production, process development, cell line development, pre-clinical development or non-clinical or pre-clinical studies of a Licensed Product.

1.59 "Royalties" is defined in <u>Section 3.4</u>.

**1.60** "Royalty Term" means, on a country-by-country basis and a Licensed Product-by- Licensed Product basis, the period commencing on the First Commercial Sale of the Licensed Product in a country and ending with respect to such Licensed Product in such country on the later of (a) ten (10) years thereafter in such country of sale; (b) last to expire Regulatory Exclusivity relating to such Licensed Product in such country of sale; or (c) expiration of the last to expire Valid Claim of any Platform Patent, in each case Covering the import, use, sale or offer for sale (but, for clarity, not the Manufacturing) of such Licensed Product in such country of sale, including by 35 U.S.C. § 271(g) or any foreign equivalent.

**1.61** "**Rules**" is defined in <u>Section 10.2.1</u>.

**1.62** "Sublicensee" is defined in <u>Section 2.2</u>.

**1.63** "Target" means the biological target of a pharmacologically active drug compound.

**1.64** "Term" is defined in <u>Section 7.1</u>.

**1.65** "Third Party" means any party other than Pieris, Licensee, or their respective Affiliates.

**1.66** "Third Party Claims" is defined in <u>Section 8.1</u>.

1.67 "Third Party License" is defined in <u>Section 3.5.2</u>.

10

**1.68** "[\*\*\*] License" means that certain [\*\*\*], which was extended by an amended and renewed agreement, signed on [\*\*\*] and further extended by an amended and renewed agreement signed on [\*\*\*] as may be amended.

**1.69 "Valid Claim"** means (a) a claim of an issued and unexpired Patent, which claim has not been revoked or held invalid or unenforceable by a final court without the possibility of appeal or other government agency of competent jurisdiction by a final determination without the possibility of appeal or has not been held (through a final determination without the possibility of appeal) or admitted to be invalid or unenforceable through re-examination or disclaimer, reissue, opposition procedure, nullity suit or otherwise by a final determination without the possibility of appeal or (b) a claim of a pending Patent application that has not been abandoned, finally rejected or expired without the possibility of appeal or refiling; provided, however, that Valid Claim will exclude any such pending claim in an application that has not been granted within [\*\*\*] years following the earliest priority filing date for such application, excluding, however, any pending Patent that does not have a reasonable bona fide basis for patentability (such reasonable bona fide basis to be determined by an outside counsel selected in good faith by the Parties, in the event that the Parties disagree as to whether there is a reasonable bona fide basis for patent that would prevent a Party from enforcing or continuing to enforce such Patent. To the extent that any Patent is issued, restored, or otherwise deemed valid and enforceable, then it once again shall be considered a Valid Claim as from the date of such issuance, restoration, or determination.

#### 1.70 "Withholding Taxes" is defined in <u>Section 3.6.4</u>.

#### 2. LICENSE GRANT

**2.1 Grant.** Subject to the terms and conditions of this Agreement, Pieris hereby grants to Licensee a nonexclusive, non-transferrable (other than in accordance with <u>Section 10</u>), royalty-bearing license (or sublicense) during the Term under the Platform IP and the Platform Improvement IP, to Research, have Researched, Develop, have Developed, Manufacture, have Manufactured, Commercialize, have Commercialized, the Licensed Products in the Licensed Field and Licensed Territory pursuant to and consistent with that certain separate written agreement entitled License and Collaboration Agreement between Pieris and Licensee with an Effective Date of February 08, 2018 (such agreement, the "**Collaboration Agreement**"). For avoidance of doubt, to the extent that the Collaboration Agreement does not provide the right to Commercialize a Licensed Product, then the Licensee also shall not have a license to Commercialize such Licensed Product under this Agreement.

**2.2** Sublicenses. Licensee shall have the right to grant sublicenses (through multiple tiers) under the rights granted in <u>Section 2.1</u> (a) to its Affiliates and (b) to Third Parties, in each of (a) and (b) solely to the extent of, and consistent with, Licensee's right to grant sublicenses under any Patent rights as set forth in the Collaboration Agreement. Each such sublicense granted pursuant to this <u>Section 2.2</u> shall be pursuant to a binding written agreement and shall be consistent with the terms and conditions of this Agreement (including imposing obligations on Sublicensee consistent with those of Licensee under <u>Section 2.3</u>, <u>Section 3.7</u> and <u>Section 6</u>) and the Collaboration Agreement (each such Affiliate or Third Party to which such sublicense is granted, a "**Sublicensee**"). Licensee shall remain responsible for the performance of its Sublicensees such that any act or omission by or on behalf of a Sublicensee that would be a breach of this Agreement if undertaken by Licensee, shall be deemed a

11

breach of this Agreement by Licensee, except in the case of a Full Sublicense by Licensee as set forth in <u>Section 9.3.2</u> of the Collaboration Agreement. In the event of a material default by any Sublicensee under a sublicense, Licensee will promptly notify Pieris and take such action as necessary to remedy such default.

**2.3** No Other License. Licensee understands and agrees that no license under any Patent or Know-How other than Platform Patents and Platform Know-How, is or shall be deemed to have been granted under this Agreement, either expressly or by implication. Licensee shall not practice under the Platform Patents or Platform Know-How outside of the scope of the license granted pursuant to <u>Section 2.1</u> of this Agreement.

### 3. PAYMENTS

**3.1** License Fee. In partial consideration of the rights granted hereunder with respect to the Research of up to [\*\*\*] Licensed Products and the Development, Manufacture and Commercialization of up to [\*\*\*] Licensed Products, Licensee shall pay to Pieris a non-creditable, non-refundable upfront fee in the amount of [\*\*\*] Dollars (\$[\*\*\*]) [\*\*\*] days following receipt of the corresponding invoice from Pieris after the Effective Date.

**3.2** Additional License Fee. In the event that Licensee exercises an option to Develop, Manufacture and Commercialize up to [\*\*\*] additional Licensed Products under the Collaboration Agreement, in partial consideration thereof, Licensee shall pay to Pieris a non-creditable, non-refundable upfront fee in the amount of [\*\*\*] Dollars ([\*\*\*]) [\*\*\*] days following receipt of the corresponding invoice from Pieris after the effective date for each such option under the Collaboration Agreement. For clarity, in the event that Licensee exercises the option described in this Section 3.2 with respect to [\*\*\*] Licensed Products, then a total of [\*\*\*] Dollars ([\*\*\*]) shall have been paid to Pieris pursuant to this Section 3.2.

**3.3** Milestone Payments. Licensee will pay to Pieris the following milestone payments upon the first achievement of the corresponding milestone event set forth in the table below by or on behalf of Licensee, its Affiliates and Sublicensees, on a Licensed Product-by-Licensed Product basis:

Milestone Event	Milestone Payment
Initiation of GLP Tox Study	[***] Dollars (\$[***])
Initiation of Phase 1 Clinical Study	[***] Dollars (\$[***])
Initiation of Phase 2a Clinical Study or Initiation of Phase 1 Clinical Study Expansion Cohorts (whichever comes first)	[***] Dollars (\$[***])
Initiation of Pivotal Clinical Study	[***] Dollars (\$[***])
Marketing Approval in [***]	[***] Dollars (\$[***])

<u>Milestone Payment Terms</u>. Each such milestone payment shall be paid within [\*\*\*] days of achievement of such milestone event by Licensee or its Sublicensee. For any Licensed Product, once a milestone is reached, the amounts under all prior milestones shall be due, if not yet paid (for example, if a Pivotal Clinical Study is initiated and the Phase 2a Clinical Study or Phase

1 Clinical Study Expansion Cohorts milestone has not yet been paid, it shall become due and payable at the same time as the Pivotal Clinical Study milestone). Notwithstanding the foregoing, if a Licensed Product becomes designated as a CoDev Product under the Collaboration Agreement, Pieris shall refund to Licensee all of the milestone payments received from Licensee for such Licensed Product under this <u>Section 3.3</u> within [\*\*\*] days of such Licensed Product becoming a CoDev Product under the Collaboration Agreement, and no further development and regulatory milestone payments shall be due from Licensee for such Licensed Product that has become a CoDev Product under the Collaboration Agreement. For the avoidance of doubt, the upfront fee described in <u>Section 3.1</u> and the additional upfront fee described in <u>Section 3.2</u> shall not be refunded to Licensee under this <u>Section 3.3</u> or otherwise, neither in whole nor in part.

**3.4** Royalties. Within [\*\*\*] days after the end of each Calendar Quarter following the First Commercial Sale of a Licensed Product, Licensee shall make royalty payments to Pieris on a Calendar Quarter and Licensed Product-by-Licensed Product basis, based on the Net Sales of the applicable Licensed Product by Licensee and its Sublicensees at a rate of [\*\*\*] percent ([\*\*\*]%) (the "Royalties"). Royalties shall be payable by Licensee until the expiry of the Royalty Term. Notwithstanding the foregoing, for any Licensee Product that has becomes a CoDev Product under the Collaboration Agreement, no royalties shall be due from Licensee to Pieris on Net Sales of such Licensed Product.

#### 3.5 Adjustments.

**3.5.1** <u>Biosimilar Drug Competition</u>. Notwithstanding the foregoing, subject to <u>Section 3.5.3</u>, if in any Calendar Quarter total sales of any Biosimilar(s) of a Licensed Product in any country reaches more than [\*\*\*] percent ([\*\*\*]%) in units of the total sales of the applicable Licensed Product and the Biosimilar(s) in such country, then the Royalties payable to Pieris for such Licensed Product in such country shall be reduced by [\*\*\*] percent ([\*\*\*]%) of the amount otherwise payable hereunder. Notwithstanding the foregoing, in the event of Biosimilar sales that are later enjoined by a court or otherwise halted (such as on the basis of Patent or Regulatory Exclusivity), then subsequent royalties shall be restored to the level otherwise contemplated under this Agreement.

**3.5.2** <u>Third Party Licenses</u>. If it is necessary for Licensee to license one or more Patents from one or more Third Parties in order to Develop, Manufacture (other than manufacturing processes), or Commercialize the Anticalin Protein of any Licensed Product (but excluding Patents owned or Controlled by a Third Party service provider selected by Licensee, such as a contract manufacturing organization, and Patents related to any aspect or use of the antibody portion of the Licensed Product), whether directly or through any Affiliate or Sublicensee of Licensee, in the Territory, then Licensee may negotiate and obtain a license under such Patent(s) (each such Third Party license referred to herein as a "**Third Party License**"). If any royalty payments are due to a Third Party pursuant to a Third Party License or in the context of proceedings brought by any Third Party alleging that one or more Patent(s) of such Third Party is infringed by the Development, Manufacture, Commercialization or use of the Anticalin Protein of any Licensed Product in the Field under this Agreement, then subject to <u>Section 3.5.3</u> Licensee may deduct [\*\*\*] percent ([\*\*\*]%) of such payment(s) from the Royalties associated to such

13

Licensed Product otherwise payable under <u>Section 3.4</u>, but in no event shall Royalties be reduced by greater than [\*\*\*] percent ([\*\*\*]%) under this <u>Section 3.5.2</u>. For avoidance of doubt, this <u>Section 3.5.2</u> does not limit either Party's right to obtain any Third Party License as it may deem necessary or useful.

**3.5.3** <u>Maximum Deduction</u>. Notwithstanding anything to the contrary herein, under no circumstances shall the combined effect of all reductions to the Royalties permitted under <u>Section 3.5.1</u> and <u>Section 3.5.2</u>, on a country-by-country and Licensed Product-by-Licensed Product basis, reduce the effective Royalties payable by Licensee to Pieris under this Agreement for any Calendar Quarter below [\*\*\*] percent ([\*\*\*]%) of the Royalties that would otherwise be payable pursuant to <u>Section 3.4</u>, as applicable, for such Licensed Product in such country.

#### 3.6 Payment Terms.

**3.6.1** <u>Generally.</u> All payments made by Licensee under this Agreement shall be made in immediately available funds by wire transfer to such bank and account as may be designated from time to time by Pieris. Except as otherwise set forth herein, all other payments due under this Agreement will be paid within [\*\*\*] days following receipt of an invoice requesting such payment. All invoices provided to Licensee hereunder shall include Pieris' bank details, the contact name for issue resolution, and will be marked for the attention of the Alliance Manager (as defined in the Collaboration Agreement).

**3.6.2** Sales Payment Reports and Royalty Payments. After the First Commercial Sale by the Seller of a Licensed Product requiring the payments due to Pieris pursuant to Section 3.4 and ending, on a Licensed Product-by-Licensed Product basis, following the last to expire Royalty Term with respect to such Licensed Product, Licensee shall send to Pieris within [\*\*\*] days after the end of each Calendar Quarter (a) a written report which shall state, for the previous Calendar Quarter, on a country-by-country and Licensed Product-by-Licensed Product basis, the description of each Licensed Product sold, the corresponding amount of gross sales of Licensed Products, an itemized calculation of Net Sales showing deductions provided for in the definition of Net Sales and the calculation of any milestones fees and Royalties due, including any reductions made in accordance with this Agreement, as well as the exchange rate for such country, and (b) payment (in Dollars) all royalty payments due to Pieris hereunder for such Calendar Quarter.

**3.6.3** <u>Interest.</u> Interest shall accrue on any late payment of fees owed to Pieris and not made on the date such payment is due, at an annual interest rate equal to [\*\*\*] percent ([\*\*\*]%) above LIBOR per annum or the maximum applicable legal rate, if less, calculated on the total number of days such payment is delinquent.

**3.6.4** Taxes and Withholding. All payments under this Agreement shall be made without any deduction or withholding for or on account of any tax, except as set forth in this Section 3.6.4, the Parties agree to cooperate with one another and use reasonable efforts to minimize under applicable Law obligations for any and all income or other taxes required by applicable Law to be withheld or deducted from any of the royalty and other payments made by or on behalf of a Party hereunder ("Withholding Taxes"). The Licensee shall, if required by applicable Law, deduct from any amounts that it is required to pay to Pieris an amount equal to

14

such Withholding Taxes. Such Withholding Taxes shall be paid to the proper taxing authority for Pieris's account and, if available, evidence of such payment shall be secured and sent to Pieris within [\*\*\*] days of such payment. The Licensee shall, at Pieris's sole cost and expense, as mutually agreed by the Parties, do all such lawful acts and things and sign all such lawful deeds and documents as Pieris may reasonably request to enable the Licensee to avail itself of any applicable legal provision or any double taxation treaties with the goal of paying the sums due to Pieris hereunder without deducting any Withholding Taxes.

**3.6.5** <u>Conversions</u>. With respect to amounts required to be converted into another currency for calculation of the Net Sales amount and the Royalty payments, such amount shall be converted using a rate of exchange which corresponds to the rate used by Licensee for conversion between the relative currencies for its reporting period in its books and records that are maintained in accordance with Accounting Standards, as applicable, for its external reporting.

**3.7 Records Retention**. Licensee shall keep complete, true and accurate books of account and records for the purpose of determining the amounts payable under this Agreement. Such books and records shall be kept at the principal place of business of Licensee, as the case may be, for at least [\*\*\*] years (or such longer period as required by applicable Law) following the end of the Calendar Year to which they pertain. Each Party (the "Audited Party") shall make such account and records available, on reasonable notice sent by the other Party (the "Auditing Party"), for inspection during normal business hours, with not less than [\*\*\*] Business Days' advance written notice, by an independent certified public accounting firm nominated by such and reasonably acceptable for the Audited Party, for the purpose of verifying the accuracy of any statement or report given by the Audited Party and to verify the accuracy of the payments due hereunder for any Calendar Year. Such auditor shall advise the Parties simultaneously promptly upon its completion of its audit whether or not the payments due hereunder have been accurately recorded, calculated and reported, and, if not, then the amount of such discrepancy. A Party's financial records with respect to a given period of time shall only be subject to one (1) audit per Calendar Year except in the case of willful misconduct or fraud. The Auditing Party's right to perform an audit pertaining to any Calendar Year shall expire [\*\*\*] years after the end of such Calendar Year. The auditor shall be required to keep confidential all information learnt during any such inspection, and to disclose to the Auditing Party only such details as may be necessary to report the accuracy of the Audited Party's statement or report. The Auditing Party shall be responsible for the auditor's costs, unless the auditor certifies that there was a variation or error of underpayment or overpayment exceeding [\*\*\*] percent ([\*\*\*]%) of the amount stated for any period covered by the inspection, in which case all reasonable costs relating to the inspection for such period shall be borne by the Audited Party. If such accounting firm correctly identifies a discrepancy made during such period, any unpaid amounts or overpaid amounts that are discovered shall be paid/refunded promptly but in any event within [\*\*\*] days of the date of delivery of such accounting firm's written report so correctly concluding, or as otherwise agreed upon by the Parties.

#### 4. PATENT PROSECUTION, MAINTENANCE AND ENFORCEMENT

As between the Parties, Pieris shall be solely responsible, at its sole discretion and expense, for the prosecution, defense, and maintenance of Platform Patents. Licensee shall not be permitted to enforce the Platform Patents without the written consent of Pieris, which may be withheld for any reason. Notwithstanding the foregoing, Pieris shall in good faith consider bringing an appropriate suit

15

or other action against a Third Party under the Platform Patents relating to a Licensed Product at Licensee's request and cost, and using counsel selected by Licensee and reasonably acceptable to Pieris.

### 5. REPRESENTATION AND WARRANTIES; COVENANTS

**5.1 Mutual Representations and Warranties.** Each Party hereby represents and warrants to the other Party, as of the Effective Date, that:

**5.1.1** such Party is duly established, validly existing and in good standing under the Laws of the jurisdiction and has full power and authority to enter into this Agreement and to carry out the provisions hereof;

**5.1.2** all requisite corporate action on the part of such Party, its directors and stockholders required by applicable Law for the authorization, execution and delivery by such Party of this Agreement, and the performance of all obligations of such Party under this Agreement, has been taken;

**5.1.3** this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation, enforceable against it in accordance with the terms hereof; and

**5.1.4** the execution and delivery of this Agreement by such Party do not, and the performance of this Agreement by such Party will not: (i) conflict with, or result in any violation of or default under, any agreement, instrument or understanding, oral or written, to which it or any Affiliate is a party or by which it or any Affiliate is bound; or (ii) violate any provision of any applicable Law.

**5.2** Further Representations by Pieris. Pieris hereby represents and warrants that it has not entered into any agreement with any Third Party that is in conflict with the rights granted to Licensee under this Agreement and covenants that during the Term it shall not enter into any agreement with a Third Party that would materially conflict with the rights granted to Licensee under this Agreement.

**5.3 DISCLAIMER OF WARRANTIES.** EXCEPT AS EXPRESSLY SET FORTH IN SECTIONS 5.1 AND 5.2 ABOVE AND THOSE SET FORTH IN THE COLLABORATION AGREEMENT, NEITHER PARTY MAKES (AND EACH PARTY HEREBY DISCLAIMS) ANY AND ALL REPRESENTATIONS AND WARRANTIES OF ANY KIND, WHETHER WRITTEN, ORAL, EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, INCLUDING ANY EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NONINFRINGEMENT OR ANY WARRANTIES THAT MAY ARISE FROM A COURSE OF PERFORMANCE, COURSE OF DEALING OR USAGE OR TRADE, INCLUDING WITH RESPECT TO ANY INTELLECTUAL PROPERTY RIGHTS, TECHNOLOGY OR CONFIDENTIAL INFORMATION OF A PARTY.

### 6. CONFIDENTIALITY; PUBLICITY

16

**6.1** Neither Party shall disclose any of the terms of this Agreement (including the financial terms) to any Third Party without the prior written consent of the other Party; provided, however, that each Party shall be free to disclose the terms of this Agreement (a) to the extent that a Party reasonably believes it is required to do so by securities or other applicable laws, regulations, or rules (including the regulations or rules of any relevant stock exchange), (b) pursuant to a legal proceeding or order of a court or governmental agency, (c) to actual or prospective Sublicensees, (d) to [\*\*\*] (in the case of Pieris), (e) to its accountants, attorneys and other professional advisors, (f) to its Affiliates or (g) in connection with a financing, merger, consolidation, acquisition or a permitted assignment of this Agreement, provided that in the case of any disclosure under (c), (d), (e), (f) or (g) above, the recipient(s) are obligated and do so undertake to keep such terms of this Agreement confidential to the same extent as said Party, and provided that in the case of disclosure under clause (a) the disclosing Party will use reasonable efforts to obtain confidential treatment for portions of this Agreement as available, consult with the other Party, and permit the other Party to participate, to the extent practicable, in seeking a protective order or other confidential treatment and in the case of disclosure under clause (b) the Disclosing Party will use reasonable efforts to secure confidential treatment of such terms of this Agreement as are required to be disclosed.

**6.2 Publicity**. Neither Party shall issue any press release or other publicity material or make any public representation that refers to the terms, including, without limitation, the financial terms, of this Agreement without the prior written consent of the other Party.

#### 7. TERM AND TERMINATION

7.1 Term. This Agreement will commence on the Effective Date and remain in full force and effect until the expiration of all of Licensee's payment obligations under this Agreement (the "Term"), unless earlier terminated in accordance with this Article 7. Following the natural expiration of the Term, the license granted to Licensee shall be fully paid up, irrevocable, and royalty-free. In addition, on a Licensed Product-by-Licensed Product and country-by-country basis, this Agreement shall terminate upon termination of the Collaboration Agreement.

**7.2** Termination for Material Breach. Either Party shall have the right to terminate this Agreement in the event the other Party has materially breached or materially defaulted in the performance of any of its payment obligations hereunder which breach or default is material in the overall context of the Agreement, and such breach has continued for [\*\*\*] days after written notice thereof was provided to the breaching Party by the non-breaching Party which clearly describes the material breach and remedies (including, for avoidance of doubt, termination of the Agreement) that the non-breaching Party intends to apply should the breach remain uncured. Any such termination shall become effective at the end of such [\*\*\*] day period if, prior to the expiration of the [\*\*\*] day period, the breaching Party has not cured any such breach or default. If the allegedly breaching Party disputes the breach and provides written notice of that dispute to the other Party, the matter shall be addressed under the dispute resolution provisions in Section 10.2 and the notifying Party may not terminate this Agreement until it has been finally determined under Section 10.2 that the Agreement was materially breached as described above. In the event the breach is limited to one or more Licensed Product(s), the non-breaching Party will have the right to terminate this Agreement solely with respect to the applicable Licensed Product(s).

17

**7.3** Termination for Patent Challenge. If Licensee (a) disputes, or assists any Third Party to dispute, the validity of any Platform Patent Covering a Licensed Product in a patent re-examination, inter-partes review, post-grant or other patent office proceeding, opposition, litigation, or other court proceeding and (b) within [\*\*\*] days written notice from Pieris, Licensee fails to rescind any and all of such actions, then Pieris may terminate this Agreement upon written notice to Licensee. Notwithstanding the above, nothing in this clause prevents Licensee from taking any of the actions referred to in this clause and provided further that Pieris will not have the right to terminate if Licensee:

**7.3.1** asserts invalidity as a defense in any court proceeding brought by Pieris asserting infringement of one of the foregoing Patents;

**7.3.2** acquires a Third Party that has an existing challenge, whether in a court or administrative proceeding, against one of the foregoing Patents; or

**7.3.3** licenses a product for which Pieris has an existing challenge, whether in a court or administrative proceeding, against one of the foregoing Patents.

**7.4** Effect of Termination. Expiration or termination of this Agreement will not relieve the Parties of any obligation accruing prior to such expiration or termination, including Licensee's obligations to pay all fees and royalties that shall have accrued hereunder prior to the effective date of expiration or termination. Termination of this Agreement shall result in the termination of the licenses granted to Licensee, and all such rights shall immediately revert to Pieris in full and Licensee shall thereafter discontinue all use of the Pieris Platform Technology, including the Research, Development, Manufacture or Commercialization of any Licensed Product. The provisions of Sections 1 (to the extent necessary to give effect to the surviving provisions), 3.6 (for any final payments), 3.7 (for any final reports), 5.3, 6, 7, 8, 9 and 10 will survive any termination or expiration of this Agreement.

## 8. INDEMNIFICATION AND INSURANCE

**8.1 Indemnification by Licensee.** Licensee will indemnify Pieris, its Affiliates, and their respective directors, officers, employees and agents (collectively, the "**Pieris Indemnitees**"), and defend and hold each of them harmless, from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees and expenses) (collectively, "**Losses**") in connection with any and all liability suits, investigations, claims or demands by Third Parties (collectively, "**Third Party Claims**") arising out of (a) a Licensee Indemnitee's negligence or willful misconduct; or (b) Licensee's breach (or allegation of a breach) of any obligation, representation, warranty or covenant in this Agreement, except to the extent that such Losses arise out of or result from (i) the negligence or willful misconduct of a Pieris Indemnitee, or (ii) Pieris's breach of any obligation, representation, warranty or covenant in this Agreement.

**8.2** Indemnification by Pieris. Pieris will indemnify Licensee and its Sublicensees, and their respective directors, officers, employees and agents (collectively, the "Licensee Indemnitees"), and defend and hold each of them harmless, from and against any and all Losses in connection with any and all Third Party Claims to the extent arising from or occurring as a result of or in connection with (a) a Pieris Indemnitee's negligence or willful misconduct or (b) Pieris's breach (or allegation of a breach) of any obligation, representation, warranty or covenant in this Agreement, except to the extent that such Losses arise out of or result from (i) the negligence or willful misconduct of a Licensee

18

Indemnitee, or (ii) Licensee's breach of any obligation, representation, warranty or covenant in this Agreement.

**8.3 Indemnification Procedure.** To be eligible to be indemnified as described in this <u>Section 8</u>, each of the Indemnitees seeking to be indemnified shall provide the indemnifying Party with prompt notice of any claim (with a description of the claim and the nature and amount of any such loss) giving rise to the indemnification obligation pursuant to <u>Section 8.1</u> or <u>Section 8.2</u>, as the case may be, and the ability to defend such claim (with the reasonable cooperation of the Indemnitee(s)). Each Indemnitee shall have the right to retain its own counsel, at its own expense, if representation by the counsel of the indemnifying Party would be inappropriate due to actual or potential differing interests between such Indemnitee(s) and the indemnifying Party. Neither the Indemnitee(s) nor the indemnifying Party shall settle or consent to the entry of any judgment with respect to any claim for losses for which indemnification is sought without the prior written consent of the other (not to be unreasonably withheld or delayed).

**8.4 Insurance.** Licensee will, and will cause its Sublicensees to, have and maintain such types and amounts of liability insurance (including product liability coverage) as is normal and customary in the industry generally for a party similarly situated, and will upon Pieris's request provide Pieris with a copy of such policies of insurance in that regard, along with any amendments and revisions thereto.

### 9. LIMITATION OF LIABILITY

IN NO EVENT WILL EITHER PARTY OR ANY OF ITS RESPECTIVE AFFILIATES AND THEIR RESPECTIVE OFFICERS, DIRECTORS AND EMPLOYEES BE LIABLE TO THE OTHER PARTY FOR SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES SUFFERED BY THE OTHER PARTY UNDER THIS AGREEMENT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE OR OTHERWISE AND WHETHER OR NOT SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, THIS DISCLAIMER DOES NOT APPLY TO LIABILITY OR DAMAGES (A) RESULTING FROM A BREACH OF CONFIDENTIALITY OBLIGATIONS OF A PARTY UNDER <u>SECTION 6</u> OR (B) SUBJECT TO A PARTY'S INDEMNIFICATION OBLIGATIONS PURSUANT TO <u>SECTION 8.1</u> OR <u>SECTION 8.2</u>.

#### 10. MISCELLANEOUS

**10.1 Restrictions; No Other Licenses.** Except as expressly set forth hereunder, neither Party grants to the other Party any rights, licenses or covenants in or to any Patents or Know-How, whether by implication, estoppel, vicariously, indirectly or otherwise, other than the license rights that are specifically and expressly granted under this Agreement. All rights not specifically and expressly granted by a licensing party under this Agreement are reserved by such licensing party and may be used or practiced by such licensing party for any purpose.

#### 10.2 Dispute Resolution

**10.2.1** <u>Arbitration</u>. In the event a dispute arises under this Agreement (each, a " **Dispute**"), the Parties will attempt in good faith to resolve such Dispute, failing which either

Party may cause such Dispute to be referred to the Senior Executives (as defined in the Collaboration Agreement) for resolution. The Senior Executives shall attempt in good faith to resolve such Dispute by unanimous consent. If the Senior Executives cannot resolve such Dispute within [\*\*\*] days of the matter being referred to them, then either Party may submit such Dispute to arbitration for final resolution in accordance with (a) or (b) below, as applicable.

(a) <u>General Arbitration</u>. Either Party may submit a Dispute that is not specifically related to a CoDev Product to arbitration for final resolution by arbitration request (the "Arbitration Request") under the Rules of Arbitration of the International Chamber of Commerce (the "Rules") by three (3) arbitrators appointed in accordance with the said Rules (each such arbitration, an "Arbitration"). Each Arbitration will be conducted in English and all foreign language documents shall be submitted in the original language and, if so requested by any arbitrator or Party, shall also be accompanied by a translation into English. The place of arbitration shall be New York, NY. The arbitrators in any Arbitration shall enforce and not modify the terms of this Agreement. The award of the arbitrators shall be final and binding on each Party and its respective successors and assigns. All costs and expenses of any Arbitration, including reasonable attorneys' fees and expenses and the administrative and arbitrator fees and expenses, shall be borne by the Parties as determined by the arbitrators.

(b) <u>Accelerated Arbitration</u>. In the event that a Dispute specifically relating to a CoDev Product arises (a "**CoDev-Related Dispute**"), then the dispute resolution process with respect to such CoDev-Related Dispute shall be as follows:

(i) Either Party may submit such Dispute to arbitration for final resolution by arbitration request (the "Accelerated Arbitration Request") under the International Chamber of Commerce Expedited Procedure Rules ("Expedited Rules") by a single arbitrator appointed in accordance with said Expedited Rules (each such arbitration, an "Accelerated Arbitration"). The arbitrator appointed shall have at least [\*\*\*] years' experience in the life sciences industry and shall have the requisite background and expertise with respect to the particular issue that is the subject of the CoDev-Related Dispute;

(ii) Within [\*\*\*] days of the appointment of the arbitrator, each Party will deliver to the arbitrator and the other Party a detailed written proposal setting forth its proposed terms for the resolution of the dispute at issue (the "**Proposed Terms**") and a memorandum (the "**Support Memorandum**") in support thereof, not exceeding [\*\*\*] pages in length. The Parties will also provide the arbitrator with a copy of this Agreement, as amended through such date. Within [\*\*\*] days after receipt of the other Party's Proposed Terms and Support Memorandum, each Party may submit to the arbitrator (with a copy to the other Party) a response to the other Party's Proposed Terms and Support Memorandum, such response not exceeding [\*\*\*] pages in length. Neither Party may have any other communications (either written or oral) with the arbitrator other than for the sole purpose of engaging the arbitrators or as expressly permitted in this <u>Section (b)</u>; provided, however, that the arbitrator

20

may, in his or her discretion, convene a hearing to ask questions of the Parties and hear oral argument and discussion regarding each Party's Proposed Terms and Support Memorandum, at which time each Party shall have an agreed upon time to argue and present witnesses in support of its Proposed Terms;

(iii) Within [\*\*\*] days after the arbitrator is appointed, the arbitrator panel shall select one of the two Proposed Terms (without modification) provided by the Parties which most closely reflects a commercially reasonable interpretation of the terms of this Agreement. In making its selection, (i) the arbitrator shall not modify the terms or conditions of either Party's Proposed Terms nor shall the arbitrator combine provisions from both Proposed Terms and (ii) the arbitrator shall consider the terms and conditions of this Agreement, the relative merits of the Proposed Terms, the Support Memorandums and, if applicable, the oral arguments of the Parties;

(iv) The arbitrator shall make its decision known to both Parties as promptly as possible by delivering written notice to both Parties. The Parties shall agree in writing to comply with the Proposed Terms selected by the arbitrator within [\*\*\*] days of receipt of such written decision, which agreement may be made pursuant to an amendment to this Agreement. The decision of the arbitrator shall be final and binding on the Parties, and specific performance may be ordered by any court of competent jurisdiction; and

(v) Each Arbitration will be conducted in English and all foreign language documents shall be submitted in the original language and, if so requested by any arbitrator or Party, shall also be accompanied by a translation into English. The place of arbitration shall be New York, NY. The arbitrators in any Arbitration shall enforce and not modify the terms of this Agreement. The award of the arbitrator shall be final and binding on each Party and its respective successors and assigns. All costs and expenses of any Arbitration, including reasonable attorneys' fees and expenses and the administrative and arbitrator fees and expenses, shall be borne by the Parties as determined by the arbitrator.

**10.2.2** <u>Confidentiality</u>. Except to the limited extent necessary to comply with applicable Law, legal process, or a court order or to enforce a final settlement agreement or secure enforcement or vacatur of the arbitrators' award, the Parties agree that the existence, terms and content of any Arbitration, all information and documents disclosed in any Arbitration or evidencing any arbitration results, award, judgment or settlement, or the performance thereof, and any allegations, statements and admissions made or positions taken by either Party in any Arbitration shall be treated and maintained in confidence and are not intended to be used or disclosed for any other purpose or in any other forum.

**10.2.3** <u>Communications with Internal Counsel</u>. In the course of the negotiation and implementation of this Agreement and the resolution of any disputes, investigations, administrative or other proceedings relating thereto, each Party will call upon the members of its internal legal department to provide advice to such Party and its directors, employees and agents on legal matters.

Notwithstanding any rights to the contrary under applicable procedural or substantive rules of law, each Party agrees not to request, produce or otherwise use any such communications between members of its legal department and directors, employees or agents in connection with any such disputes, investigations, administrative or other proceedings, to the extent such communications, if they had been exchanged between such Party and external attorneys, would have been covered by legal privilege and not disclosable.

**10.3** Governing Law. This Agreement and any dispute arising from the performance or breach hereof will be governed by and construed and enforced in accordance with the Laws of the State of New York, excluding its rules of conflict of laws.

**10.4 Assignment.** This Agreement will not be assignable by either Party, nor may either Party delegate its obligations or otherwise transfer any licenses granted herein or other rights created by this Agreement, except as expressly permitted hereunder, without the prior written consent of the other Party hereto, which consent will not be unreasonably withheld, conditioned or delayed. Notwithstanding the foregoing, each Party may assign this Agreement, without the consent of the other Party, to an Affiliate or to its Third Party successor in connection with a merger, consolidation, sale of all or substantially all of the assets to which this Agreement pertains or that portion of its business pertaining to the subject matter of this Agreement (including in all cases, the Collaboration Agreement), or any Change of Control of such Party; provided that the assignee assumes all of the assigning Party's obligations under this Agreement, subject to this Section 10.4. Any assignment in violation of this provision is void and without effect.

**10.5** Trade names and Trademarks . Except as otherwise provided herein, no right, express or implied, is granted to a Party by this Agreement to use in any manner the name of the other Party or its Affiliates or any other trade name, trademark or logo of the other Party or its Affiliates.

**10.6 Binding Agreement.** This Agreement, and the terms and conditions hereof, will be binding upon and will inure to the benefit of the Parties and their respective successors, heirs, administrators and permitted assigns.

**10.7** Force Majeure. Except for payment obligations under this Agreement, no Party will be held liable or responsible to the other Party nor be deemed to be in default under, or in breach of any provision of, this Agreement for failure or delay in fulfilling or performing any obligation of this Agreement when such failure or delay is due to force majeure, and without the fault or negligence of the Party so failing or delaying. For purposes of this Agreement, "force majeure" is defined as causes beyond the control of the Party, including, without limitation, acts of God; Laws of any government; war; civil commotion; destruction of production facilities or materials by fire, flood, earthquake, explosion or storm; labor disturbances; epidemic; and failure of public utilities or common carriers. In the event of force majeure, Pieris or Licensee, as the case may be, will immediately notify the other Party of such inability and of the period for which such inability is expected to continue. The Party giving such notice will thereupon be excused from such of its obligations under this Agreement as it is thereby disabled from performing for so long as such Party is so disabled, up to a maximum of [\*\*\*] days, after which time the Party not affected by the force majeure may terminate this Agreement. To the extent possible, each Party will use reasonable efforts to minimize the duration of any force majeure.

22

**10.8** Notices. Any notice or request required or permitted to be given under or in connection with this Agreement will be deemed to have been sufficiently given if in writing and personally delivered or sent by certified mail (return receipt requested), facsimile transmission (receipt verified), email or overnight express courier service (signature required), prepaid, to the Party for which such notice is intended, at the address set forth for such Party below:

If to Pieris: Pieris Pharmaceuticals GmbH Lise-Meitner-Strasse 30 85354 Freising, Germany Attention: [\*\*\*]

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

If to Licensee: Seattle Genetics, Inc. 21823 30<sup>th</sup> Drive SE Bothell, WA 98021 Attention: [\*\*\*] Facsimile: [\*\*\*] Email: [\*\*\*]

or to such other address for such Party as it will have specified by like notice to the other Parties, provided that notices of a change of address will be effective only upon receipt thereof. If delivered personally or by facsimile transmission, the date of delivery will be deemed to be the date on which such notice or request was given. If sent by overnight express courier service, the date of delivery will be deemed to be the next Business Day after such notice or request was deposited with such service. If sent by certified mail, the date of delivery will be deemed to be the third (3rd) day after such notice or request was deposited with the postal service. If sent by email, the date of delivery will be deemed to be the day that the Party giving notice receives electronic confirmation of sending from its email provider.

**10.9** Waiver. Neither Party may waive or release any of its rights or interests in this Agreement except in writing. The failure of either Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement will not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition. No waiver by either Party of any condition or term in any one or more instances will be construed as a continuing waiver of such condition or term or of another condition or term.

**10.10** Severability. If any provision hereof should be held invalid, illegal or unenforceable in any jurisdiction, the Parties will negotiate in good faith a valid, legal and enforceable substitute

23

provision that most nearly reflects the original intent of the Parties and all other provisions hereof will remain in full force and effect in such jurisdiction and will be liberally construed in order to carry out the intentions of the Parties hereto as nearly as may be possible. Such invalidity, illegality or unenforceability will not affect the validity, legality or enforceability of such provision in any other jurisdiction.

**10.11** Entire Agreement. This Agreement, including the schedules and exhibits hereto, and the Collaboration Agreement set forth all the covenants, promises, agreements, appendices, warranties, representations, conditions and understandings between the Parties hereto and supersedes and terminates all prior agreements and understandings between the Parties relating to the subject matter hereof. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties relating to the subject matter hereof other than as set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement will be binding upon the Parties hereto unless reduced to writing and signed by the respective authorized officers of the Parties. To the extent of any conflict between the terms of this Agreement and its schedules and exhibits, the terms of this Agreement shall govern. In the event of any conflict between the terms of this Agreement and the terms of the Collaboration Agreement, the terms of the Collaboration Agreement shall govern.

**10.12** Independent Contractors. Nothing herein will be construed to create any relationship of employer and employee, agent and principal, partnership or joint venture between the Parties. Each Party is an independent contractor. Neither Party will assume, either directly or indirectly, any liability of or for the other Party. Neither Party will have the authority to bind or obligate the other Party nor will either Party represent that it has such authority.

**10.13 Headings.** Headings used herein are for convenience only and will not in any way affect the construction of or be taken into consideration in interpreting this Agreement.

Construction of Agreement. The terms and provisions of this Agreement represent the results of 10.14 negotiations between the Parties and their representatives, each of which has been represented by counsel of its own choosing, and neither of which has acted under duress or compulsion, whether legal, economic or otherwise. Accordingly, the terms and provisions of this Agreement will be interpreted and construed in accordance with their usual and customary meanings, and each of the Parties hereto hereby waives the application in connection with the interpretation and construction of this Agreement of any rule of Law to the effect that ambiguous or conflicting terms or provisions contained in this Agreement will be interpreted or construed against the Party whose attorney prepared the executed draft or any earlier draft of this Agreement. The definitions of the terms herein shall apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine and neuter forms. The Parties each acknowledge that they have had the advice of counsel with respect to this Agreement, that this Agreement has been jointly drafted, and that no rule of strict construction shall be applied in the interpretation hereof. Unless the context requires otherwise: (a) the words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation"; (b) any reference to any applicable Law herein shall be construed as referring to such applicable Law as from time to time enacted, repealed or amended; (c) any reference herein to any person shall be construed to include the person's permitted successors and assigns; (d) the words "herein", "hereof" and "hereunder", and

24

words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof; (e) all references herein to Articles, Sections, or Exhibits, unless otherwise specifically provided, shall be construed to refer to Articles, Sections or Exhibits of this Agreement; (f) provisions that require that a Party, the Parties or any Committee hereunder "agree", "consent" or "approve" or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, electronic mail, letter, approved minutes or otherwise (but excluding instant messaging); (g) the term "or" shall be interpreted in the inclusive sense commonly associated with the term "and/or" and (h) the words "will" and "shall" will have the same meaning in this Agreement. This Agreement has been executed in English, and the English version (which is the only version) of this Agreement shall control.

**10.15** Compliance with Applicable Law. Each Party's obligations under this Agreement shall be subject to such Party's compliance with applicable Law applicable to its performance and its other obligations under the Agreement (including any anti-corruption, export control, environmental, hazardous substance, and data privacy and security Laws).

**10.16** No Third Party Beneficiary. Nothing expressed or implied in this Agreement is intended, or shall be construed, to confer upon or give any person other than the Parties and their respective Affiliates, successors and assigns, any rights or remedies under or by reason of this Agreement.

**10.17 Counterparts.** This Agreement may be signed in counterparts, each and every one of which will be deemed an original, notwithstanding variations in format or file designation which may result from the electronic transmission, storage and printing of copies of this Agreement from separate computers or printers. Facsimile signatures will be treated as original signatures.

# [Remainder of page intentionally left blank. Signature page follows.]

25

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

By: <u>/s/ Stephen S. Yoder</u>

Name: Stephen Yoder

Title: President and CEO

By: <u>/s/ Clay B. Siegall, Ph.D.</u>

For Seattle Genetics, Inc.

Name: Clay B. Siegall, Ph.D.

Title: President and CEO

For Pieris Pharmaceuticals GmbH

By: /s/ Stephen S. Yoder

Name: Stephen Yoder Title: Managing Director

26

# Exhibit A

## **Platform Patents**

[\*\*\*, 4 pages]

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

I, Stephen S. Yoder, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Pieris Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

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

Dated: May 10, 2018

/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: May 10, 2018

/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 ended March 31, 2018 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

Dated: May 10, 2018

/s/ Stephen S. Yoder

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

#### **CERTIFICATIONS UNDER SECTION 906**

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

(i) the accompanying Quarterly Report on Form 10-Q of the Company for the fiscal quarter ended March 31, 2018 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

Dated: May 10, 2018

/s/ Allan Reine

Allan Reine Title: Chief Financial Officer (principal financial officer)