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

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2018

OR

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

Commission File Number 001-33038

ZIOPHARM Oncology, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**84-1475642**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

One First Avenue, Parris Building 34, Navy Yard Plaza
Boston, Massachusetts 02129
(617) 259-1970
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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

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

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

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

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

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

The number of shares of the registrant's common stock, $0.001 par value, outstanding as of October 31, 2018, was 142,379,770 shares.

ZIOPHARM Oncology, Inc.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that are based on our current beliefs and expectations. These forward-looking statements may be accompanied by such words as “anticipate,” “believe,” “estimate,” “expect,” “forecast,” “intend,” “may,” “plan,” “project,” “target,” “will” and other words and terms of similar meaning. Reference is made in particular to forward-looking statements regarding:

- our ability to raise substantial additional capital to fund our planned operations in the near term and to continue as a going concern;
- our estimates regarding expenses, use of cash, timing of future cash needs and capital requirements;
- the development of our product candidates, including statements regarding the timing of initiation, completion and the outcome of clinical studies or trials and related preparatory work and the period during which the results of the trials will become available;
- our ability to advance our product candidates through various stages of development, especially through pivotal safety and efficacy trials;
- the risk that final trial data may not support interim analysis of the viability of our product candidates;
- our expectation regarding the safety and efficacy of our product candidates, the progress and timing of our research and development programs;
- the timing, scope or likelihood of regulatory filings and approvals from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies for our product candidates and for which indications;
- our ability to license additional intellectual property relating to our product candidates from third parties and to comply with our existing license agreements;
- our ability to achieve the results contemplated by our collaboration agreements and the benefits to be derived from relationships with collaborators;
- developments and projections relating to competition from other pharmaceutical and biotechnology companies or our industry;
- our estimates regarding the potential market opportunity for our product candidates;
- the anticipated rate and degree of market acceptance of our product candidates for any indication if approved;
- the anticipated amount, timing and accounting of contract liability (formerly deferred revenue), milestones and other payments under licensing, collaboration or acquisition agreements, research and development costs and other expenses;
- our intellectual property position, including the strength and enforceability of our intellectual property rights;
- our ability to attract and retain qualified employees and key personnel; and
- the impact of government laws and regulations in the United States and foreign countries.

These forward-looking statements involve risks and uncertainties, including those that are described in the “*Risk Factors*” section of this report and elsewhere within this report that could cause actual results to differ materially from those reflected in such statements. You should not place undue reliance on these statements. Forward-looking statements speak only as of the date of this report. We do not undertake any obligation to publicly update any forward-looking statements.

NOTE REGARDING COMPANY REFERENCES

Throughout this Quarterly Report on Form 10-Q, “Ziopharm,” the “Company,” “we,” “us” and “our” refer to ZIOPHARM Oncology, Inc. and its subsidiaries.

NOTE REGARDING TRADEMARKS

All trademarks, trade names and service marks appearing in this Quarterly Report on Form 10-Q are the property of their respective owners.

ZIOPHARM Oncology, Inc.

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Part I - Financial Information

Item 1. Financial Statements

ZIOPHARM Oncology, Inc.

BALANCE SHEETS
(unaudited)

(in thousands, except share and per share data)

	September 30, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 31,728	$ 70,946
Receivables	1,021	19
Prepaid expenses and other current assets	14,412	19,818
Total current assets	47,161	90,783
Property and equipment, net	1,344	1,211
Deposits	128	128
Other non-current assets	18,168	13,484
Total assets	$ 66,801	$ 105,606
LIABILITIES, PREFERRED STOCK AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 1,269	$ 4,417
Accrued expenses	9,377	9,909
Contract liability - current portion	49,513	6,389
Deferred rent - current portion	24	141
Total current liabilities	60,183	20,856
Contract liability, net of current portion	—	35,139
Deferred rent, net of current portion	6	1
Derivative liabilities	2,597	2,424
Total liabilities	62,786	58,420
Commitments and contingencies (Note 6)		
Preferred stock, $0.001 par value, 30,000,000 shares authorized		
Series 1 preferred stock, $1,200 stated value; 250,000 designated; 130,849 and 119,644 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively; liquidation value of $157.0 million and $143.6 million at September 30, 2018 and December 31, 2017, respectively	160,429	143,992
Stockholders' deficit:		
Common stock, $0.001 par value; 250,000,000 shares authorized; 142,379,770 and 142,658,037 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	142	143
Additional paid-in capital	604,653	615,493
Accumulated deficit	(761,209)	(712,442)
Total stockholders' deficit	(156,414)	(96,806)
Total liabilities and stockholders' deficit	$ 66,801	$ 105,606

The accompanying notes are an integral part of the unaudited interim financial statements.

ZIOPHARM Oncology, Inc.

STATEMENTS OF OPERATIONS
(unaudited)

(in thousands, except share and per share data)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2018	2017	2018	2017
Collaboration revenue	$ —	$ 1,598	$ 146	$ 4,792
Operating expenses:				
Research and development	8,263	11,105	25,935	33,903
General and administrative	4,307	3,571	15,355	10,946
Total operating expenses	12,570	14,676	41,290	44,849
Loss from operations	(12,570)	(13,078)	(41,144)	(40,057)
Other income (expense), net	150	175	462	299
Change in fair value of derivative liabilities	(165)	202	46	(1,292)
Net loss	$ (12,585)	$ (12,701)	$ (40,636)	$ (41,050)
Preferred stock dividends	$ (6,074)	$ (4,903)	$ (16,656)	$ (13,939)
Net loss applicable to common stockholders	$ (18,659)	$ (17,604)	$ (57,292)	$ (54,989)
Basic and diluted net loss per share	$ (0.13)	$ (0.13)	$ (0.41)	$ (0.41)
Weighted average common shares outstanding used to compute basic and diluted net loss per share	141,185,404	140,632,297	141,020,025	135,689,364

The accompanying notes are an integral part of the unaudited interim financial statements.

ZIOPHARM Oncology, Inc.

STATEMENTS OF CHANGES IN PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
For the Nine months Ended September 30, 2018
(unaudited)

(in thousands, except share and per share data)

	Series 1 Preferred Stock - Mezzanine		Common Stock		Additional Paid In Capital Common Stock	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance at December 31, 2017	119,644	$143,992	142,658,037	$ 143	$ 615,493	$ (712,442)	$ (96,806)
Adjustment for implementation of ASU No. 2014-09, Revenue from Contracts with Customers	—	—	—	—	—	(8,131)	(8,131)
Stock-based compensation	—	—	—	—	6,850	—	6,850
Exercise of employee stock options	—	—	104,166	—	240	—	240
Cancelled restricted common stock	—	—	(70,867)	—	—	—	—
Repurchase of restricted common stock	—	—	(311,566)	(1)	(1,274)	—	(1,275)
Preferred stock dividends	11,205	16,437	—	—	(16,656)	—	(16,656)
Net loss	—	—	—	—	—	(40,636)	(40,636)
Balance at September 30, 2018	130,849	$160,429	142,379,770	$ 142	$ 604,653	$ (761,209)	$ (156,414)

The accompanying notes are an integral part of the unaudited interim financial statements.

ZIOPHARM Oncology, Inc.

STATEMENTS OF CASH FLOWS
(unaudited)

(in thousands)

	For the Nine Months Ended September 30,	
	2018	2017
Cash flows from operating activities:		
Net loss	$(40,636)	$(41,050)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	412	259
Stock-based compensation	6,850	6,165
Change in fair value of derivative liabilities	(46)	1,292
(Increase) decrease in:		
Receivables	(1,002)	8
Prepaid expenses and other current assets	5,406	(6,660)
Other noncurrent assets	(4,684)	(3)
Increase (decrease) in:		
Accounts payable	(3,148)	1,368
Accrued expenses	(532)	1,002
Contract liabilities	(146)	(4,792)
Deferred rent	(112)	(102)
Net cash used in operating activities	(37,638)	(42,513)
Cash flows from investing activities:		
Purchases of property and equipment	(545)	(461)
Net cash used in investing activities	(545)	(461)
Cash flows from financing activities:		
Proceeds from exercise of stock options	240	99
Repurchase of restricted common stock	(1,275)	(1,042)
Proceeds from issuance of common stock, net	—	47,270
Net cash provided by (used in) financing activities	(1,035)	46,327
Net increase (decrease) in cash, cash equivalents, and restricted cash	(39,218)	3,353
Cash, cash equivalents, and restricted cash, beginning of period	71,335	81,441
Cash, cash equivalents, and restricted cash, end of period	$ 32,117	$ 84,794
Supplementary disclosure of cash flow information:		
Cash paid for interest	$ —	$ —
Cash paid for income taxes	$ —	$ —
Supplementary disclosure of noncash investing and financing activities:		
Payment of Series 1 preferred stock dividends in preferred stock	$ 16,656	$ 13,939

The accompanying notes are an integral part of the unaudited interim financial statements.

ZIOPHARM Oncology, Inc.

NOTES TO FINANCIAL STATEMENTS
(unaudited)

1. Business

Overview

ZIOPHARM Oncology, Inc., which is referred to herein as "Ziopharm," the "Company," or "we", is a biopharmaceutical company seeking to develop, acquire, and commercialize, on its own or with partners, a diverse portfolio of immuno-oncology therapies.

The Company's operations to date have consisted primarily of raising capital and conducting research and development. The Company's fiscal year ends on December 31.

The Company has operated at a loss since its inception in 2003 and has minimal revenues. The Company anticipates that losses will continue for the foreseeable future. At September 30, 2018, the Company's accumulated deficit was approximately $761.2 million. Given its current development plans, the Company anticipates cash resources will be sufficient to fund operations into the second quarter of 2019. The Company's ability to continue operations after its current cash resources are exhausted depends on its ability to obtain additional financing in the near term or to achieve profitable operations, as to which no assurances can be given. Cash requirements may vary materially from those currently planned because of changes in the Company's focus and direction of its research and development programs, competitive and technical advances, patent developments, regulatory changes or other developments. Additional financing will be required to continue operations after the Company exhausts its current cash resources and to continue its long-term plans for clinical trials and new product development.

As of September 30, 2018, the Company had approximately $31.7 million of cash and cash equivalents. Given its development plans, the Company anticipates cash resources will be sufficient to fund its operations into the second quarter of 2019 and the Company has no committed sources of additional capital. Based on the forecast, management determined that there is substantial doubt regarding our ability to continue as a going concern. The forecast of cash resources is forward-looking information that involves risks and uncertainties, and the actual amount of the Company's expenses could vary materially and adversely as a result of a number of factors. The Company has based its estimates on assumptions that may prove to be wrong, and the Company's expenses could prove to be significantly higher than currently anticipated. Management does not know whether additional financing will be available on terms favorable or acceptable to the Company when needed, if at all. If adequate additional funds are not available when required, or if the Company is unsuccessful in entering into partnership agreements for further development of its products, management may need to curtail development efforts.

Basis of Presentation

The accompanying unaudited interim financial statements have been prepared in accordance with the instructions to Form 10-Q pursuant to the rules and regulations of the Securities and Exchange Commission, or the SEC. Certain information and note disclosures required by generally accepted accounting principles in the United States have been condensed or omitted pursuant to such rules and regulations.

It is management's opinion that the accompanying unaudited interim financial statements reflect all adjustments (which are normal and recurring) that are necessary for a fair statement of the results for the interim periods. The unaudited interim financial statements should be read in conjunction with the audited financial statements and the notes thereto for the year ended December 31, 2017, included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2017 filed with the SEC on March 1, 2018, as amended, or the Form 10-K.

The year-end balance sheet data was derived from the audited financial statements but does not include all disclosures required by generally accepted accounting principles in the United States.

The results disclosed in the statements of operations for the three and nine months ended September 30, 2018 are not necessarily indicative of the results to be expected for the full fiscal year.

ZIOPHARM Oncology, Inc.

NOTES TO FINANCIAL STATEMENTS (unaudited)

1. Business – (continued)

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Although the Company regularly assesses these estimates, actual results could differ from those estimates. Changes in estimates are recorded in the period in which they become known.

The Company's most significant estimates and judgments used in the preparation of its financial statements are:

- Clinical trial expenses;
- Collaboration agreements and revenue recognition;
- Fair value measurements of stock based compensation and Series 1 preferred stock; and
- Income taxes

Subsequent Events

The Company evaluated all events and transactions that occurred after the balance sheet date through the date of this filing. Except as disclosed below, the Company did not have any material subsequent events that impacted its financial statements or disclosures.

On October 5, 2018, the Company entered into an exclusive license agreement, or the License Agreement, with Precigen, Inc., or Precigen, a wholly owned subsidiary of Intrexon Corporation, or Intrexon. As between the Company and Precigen, the terms of the License Agreement replace the terms of: (a) that certain Exclusive Channel Partner Agreement by and between the Company and Intrexon, dated January 6, 2011, as amended by the First Amendment to Exclusive Channel Partner Agreement effective September 13, 2011, the Second Amendment to the Exclusive Channel Partner Agreement effective March 27, 2015, and the Third Amendment to Exclusive Channel Partner Agreement effective June 29, 2016, which was subsequently assigned by Intrexon to Precigen; (b) certain rights and obligations pursuant to that certain License and Collaboration Agreement effective March 27, 2015 between the Company, Intrexon and ARES TRADING Trading S.A., or Ares Trading, a subsidiary of Merck KGaA, or Merck, as assigned by Intrexon to Precigen, or the Ares Trading Agreement; (c) that certain License Agreement between the Company, Intrexon and The University of Texas M.D. Anderson Cancer Center, or MD Anderson, with an effective date of January 13, 2015, or the MD Anderson License, which was subsequently assigned by Intrexon and assumed by Precigen effective as of January 1, 2018; and (d) that certain Research and Development Agreement between the Company, Intrexon and MD Anderson with an effective date of August 17, 2015, or the Research and Development Agreement, and any amendments or statements of work thereto.

Pursuant to the terms of the License Agreement, Precigen has granted the Company an exclusive, worldwide, royalty-bearing, sub-licensable license to research, develop and commercialize (i) products utilizing Precigen's RheoSwitch® gene switch, or RTS, for the treatment of cancer, referred to as IL-12 Products, (ii) chimeric antigen receptor, or CAR, products directed to (A) CD19 for the treatment of cancer, referred to as CD19 Products, and (B) a second target, subject to the rights of Merck to pursue such target under the Ares Trading Agreement, and (iii) T-cell receptor, or TCR, products designed for neoantigens for the treatment of cancer. Precigen has also granted the Company an exclusive, worldwide, royalty-bearing, sub-licensable license for certain patents relating to the *Sleeping Beauty* technology to research, develop and commercialize TCR products for both neoantigens and shared antigens for the treatment of cancer, referred to as TCR Products.

The Company will be solely responsible for all aspects of the research, development and commercialization of the exclusively licensed products for the treatment of cancer. The Company is required to use commercially reasonable efforts to develop and commercialize IL-12 Products and CD19 Products and after a two-year period, the TCR Products.

Precigen has also granted the Company an exclusive, worldwide, royalty-bearing, sub-licensable license to research, develop and commercialize products utilizing an additional construct that expresses RTS IL-12 for the treatment of cancer, referred to as Gorilla IL-12 Products.

ZIOPHARM Oncology, Inc.

NOTES TO FINANCIAL STATEMENTS (unaudited)

1. Business – (continued)

Precigen will retain rights to research, develop and commercialize CAR products for all other targets, subject to the rights of Merck to pursue such targets under the Ares Trading Agreement. In addition, Precigen may research, develop and commercialize products for the treatment of cancer outside of the products exclusively licensed to the Company.

In consideration of the licenses and other rights granted by Precigen, the Company will pay Precigen an annual license fee of $100 thousand and has agreed to reimburse Precigen for certain historical costs of the licensed programs up to $1.0 million, payable quarterly.

The Company will make milestone payments totaling up to an additional $52.5 million for each exclusively licensed program upon the initiation of later stage clinical trials and upon the approval of exclusively licensed products in various jurisdictions. In addition, the Company will pay Precigen tiered royalties ranging from low-single digit to high-single digit on the net sales derived from the sales of any approved IL-12 Products and CAR Products. The Company will also pay Precigen royalties ranging from low-single digit to mid-single digit on the net sales derived from the sales of any approved TCR Products, up to a maximum royalty amount of $100.0 million in the aggregate. The Company will also pay Precigen 20% of any sublicensing income received by the Company relating to the licensed products.

The Company is responsible for all development costs associated with each of the licensed products, other than Gorilla IL-12 Products. The Company and Precigen will share the development costs and operating profits for Gorilla IL-12 Products, with the Company responsible for 80% of the development costs and receiving 80% of the operating profits, and Precigen responsible for the remaining 20% of the development costs and receiving 20% of the operating profits.

Precigen will pay the Company royalties ranging from low-single digits to mid-single digits on the net sales derived from the sale of Precigen’s CAR products, up to $100.0 million.

In consideration of the Company entering into the License Agreement, Intrexon has forfeited and returned to the Company all shares of the Company’s Series 1 Preferred Stock held by or payable to Intrexon as of the date of the License Agreement.

In connection with the transaction, the Company incurred approximately $7.0 million of transaction advisory costs with a third-party vendor. Of that amount, approximately $1.0 million was expensed during the three months ended June 30, 2018 and approximately $0.3 million during the three months ended September 30, 2018. The remaining balance of advisory fees is due upon closing of the transaction.

ZIOPHARM Oncology, Inc.

NOTES TO FINANCIAL STATEMENTS (unaudited)

2. Summary of Significant Accounting Policies

The Company's significant accounting policies were identified in the Company's Form 10-K. There have been no material changes in those policies since the filing of its Form 10-K except as noted below with respect to the Company's revenue recognition.

New Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (Topic 842), or ASU 2016-02. The guidance in this ASU supersedes the leasing guidance in *Leases* (Topic 840). Under the new guidance, lessees are required to recognize lease assets and lease liabilities on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance leases or operating leases, with classification affecting the pattern of expense recognition in the statement of operations. The new standard is effective for annual reporting periods beginning after December 15, 2018, including interim reporting periods within each annual reporting period. The Company is currently evaluating the impact of the adoption of this ASU on the financial statements.

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows: Restricted Cash* or ASU 2016-18. The amendments in this update require that amounts generally described as restricted cash and restricted cash equivalents be included within cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 was effective January 1, 2018. As a result of adopting ASU 2016-18, the Company includes its restricted cash balance in the cash and cash equivalents reconciliation of operating, investing and financing activities. The following table provides a reconciliation of cash, cash equivalents, and restricted cash within the statement of financial position that sum to the total of the same such amounts shown in the statement of cash flows.

	September 30,	
	2018	2017
	(in thousands)	
Cash and cash equivalents	$31,728	$84,406
Restricted cash included in prepaid expenses and other current assets	389	—
Restricted cash included in other non-current assets	—	388
Total cash, cash equivalents, and restricted cash shown in the statement of cash flows	$32,117	$84,794

In August 2018, the FASB issued ASU No. 2018-03, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*, or ASU 2018-03. The guidance in this ASU modify the disclosure requirements on fair value measurements in Topic 820, Fair Value Measurement. Under the new guidance, transfers between asset classes and the valuation related to level 3 assets is modified. The new standard is effective for annual reporting periods beginning after December 15, 2019, including interim reporting periods within each annual reporting period. The Company is currently evaluating the impact of the adoption of this ASU on the financial statements.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, or ASU 2018-07. The guidance in this ASU expand the scope of Topic 718 to include sharebased payment transactions for acquiring goods and services from nonemployees. The new standard is effective for annual reporting periods beginning after December 15, 2019, including interim reporting periods within each annual reporting period. The Company is currently evaluating the impact of the adoption of this ASU on the financial statements.

ZIOPHARM Oncology, Inc.

NOTES TO FINANCIAL STATEMENTS (unaudited)

3. Fair Value Measurements

The Company accounts for its financial assets and liabilities using fair value measurements. The authoritative accounting guidance defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles and enhances disclosures about fair value measurements. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The fair value hierarchy is based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value as follows:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Assets and liabilities measured at fair value on a recurring basis as of September 30, 2018 and December 31, 2017 were as follows:

($ in thousands)

		Fair Value Measurements at Reporting Date Using		
Description	Balance as of September 30, 2018	Quoted Prices in Active Markets for Identical Assets/Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	$ 30,305	$ 30,305	$ —	$ —
Liabilities:				
Derivative liabilities	$ (2,597)	$ —	$ —	$ (2,597)

ZIOPHARM Oncology, Inc.

NOTES TO FINANCIAL STATEMENTS (unaudited)

3. Fair Value Measurements - (continued)

($ in thousands)

Description	Balance as of December 31, 2017	Fair Value Measurements at Reporting Date Using: Quoted Prices in Active Markets for Identical Assets/Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	$ 66,156	$ 66,156	$ —	$ —
Liabilities:				
Derivative liabilities	$ (2,424)	$ —	$ —	$ (2,424)

The cash equivalents represent deposits in a short term United States treasury money market mutual fund quoted in an active market and classified as a Level 1 asset.

As discussed further in Notes 6, 7, and 9, the Company issued Intrexon 100,000 shares of the Company's Series 1 preferred stock, a class of preferred stock authorized by the Company's board of directors, in consideration of the parties entering into a Third Amendment to Exclusive Channel Partner Agreement, or the 2016 ECP Amendment, amending the existing Exclusive Channel Partner Agreement, effective January 6, 2011 and as amended to date, which the Company refers to as the Channel Agreement, and an Amendment to Exclusive Channel Collaboration Agreement, or the 2016 GvHD Amendment, amending the existing Exclusive Channel Collaboration Agreement, effective September 28, 2015, which the Company refers to as the GvHD Agreement. The Series 1 preferred stock are financial liabilities that consist of a conversion option and a redemption feature and are classified as a Level 3 asset. There were no transfers between asset classes during the three and nine months ended September 30, 2018.

ZIOPHARM Oncology, Inc.

NOTES TO FINANCIAL STATEMENTS (unaudited)

3. Fair Value Measurements – (continued)

At June 30, 2016, the Company's Series 1 preferred stock was valued using a probability-weighted approach and a Monte Carlo simulation model. Additionally, the monthly dividends issued on the outstanding Series 1 preferred stock are valued using the same probability-weighted approach and a Monte Carlo simulation model. However, there is no adjustment or further revaluation after the initial valuation on the Series 1 preferred stock other than required periodic dividends.

The Company's Level 3 financial liabilities consist of a conversion option and a redemption feature associated with the Company's Series 1 preferred stock issued to Intrexon that have been bifurcated from the Series 1 preferred stock and are accounted for as derivative liabilities at fair value. The preferred stock derivative liabilities were valued using a probability-weighted approach and a Monte Carlo simulation model. The fair value of the embedded derivatives was estimated using the "with" and "without" method where the preferred stock was first valued with all of its features ("with" scenario) and then without derivatives subject to the valuation analysis ("without" scenario). The fair value of the derivatives was then estimated as the difference between the fair value of the preferred stock in the "with" scenario and the preferred stock in the "without" scenario. See Note 6 for additional disclosures on the 2016 ECP Amendment and 2016 GvHD Amendments and Note 9 for additional disclosure on the rights and preferences of the Series 1 preferred stock and valuation methodology.

As discussed in Note 1, in consideration of the Company entering into the License Agreement, Intrexon forfeited and returned to the Company all shares of the Company's Series 1 Preferred Stock held by or payable to Intrexon as of the date of the License Agreement. No shares of Series 1 Preferred Stock are currently outstanding as of the filing date of this Quarterly Report.

4. Net Loss per Share

Basic net loss per share is computed by dividing net loss by the weighted average number of shares of common stock outstanding for the period. The Company's potentially dilutive shares, which include outstanding common stock options, unvested restricted stock and preferred stock, have not been included in the computation of diluted net loss per share for any of the periods presented as the result would be anti-dilutive. Such potentially dilutive shares of common stock at September 30, 2018 and 2017 consisted of the following:

	September 30,	
	2018	2017
Stock options	4,569,468	4,122,335
Unvested restricted stock	1,164,352	1,330,492
Preferred stock	52,583,921	22,398,582
	58,317,741	27,851,409

The Series 1 preferred stock automatically converts into shares of common stock upon the date the first approval in the United States of (i) a Ziopharm Product, as defined in and developed under the Channel Agreement, or (ii) a Product, as defined in and developed under the GvHD Agreement, or (iii) a Product as defined in and developed under the Ares Trading Agreement is publicly announced. Assuming a conversion event date of September 30, 2018, the Series 1 preferred stock would convert into 52,583,921 shares of common stock using the greater of (i) the volume weighted average closing price of the Company's Common Stock as reported by the Nasdaq Stock Market, LLC over the previous 20 trading days ending on the conversion event date or (ii) $1.00 per share. See Note 6 and Note 9 for additional disclosure regarding the 2016 ECP Amendment and 2016 GvHD Amendment, valuation methodology and significant assumptions.

As discussed in Note 1, in consideration of the Company entering into the License Agreement, Intrexon forfeited and returned to the Company all shares of the Company's Series 1 Preferred Stock held by or payable to Intrexon as of the date of the License Agreement. No shares of Series 1 Preferred Stock are currently outstanding as of the filing date of this Quarterly Report.

ZIOPHARM Oncology, Inc.

NOTES TO FINANCIAL STATEMENTS (unaudited)

5. Revenue Recognition

The Company adopted Accounting Standards Codification, or ASC Topic 606, *Revenue from Contracts with Customers*, or ASC 606, using the modified retrospective approach on January 1, 2018. The Company completed its assessment and the implementation resulted in a cumulative effect adjustment to accumulated deficit as of January 1, 2018 of approximately $8.1 million and a corresponding increase to the contract liability (formerly deferred revenue). The adjustment to the Company's financial statements due to the adoption of ASC 606 is related to the Company's Ares Trading Agreement (see Note 6), which was the Company's sole open revenue contract outstanding at January 1, 2018.

The Company primarily generates revenue through collaboration arrangements with strategic partners for the development and commercialization of product candidates. Commencing January 1, 2018, the Company recognizes revenue in accordance with ASC 606. The core principle of ASC 606 is that an entity should recognize revenue to depict the transfer of promised goods and/or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods and/or services. To determine the appropriate amount of revenue to be recognized for arrangements that the Company determines are within the scope of ASC 606, the Company performs the following steps: (i) identify the contract(s) with the customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations in the contract and (v) recognize revenue when (or as) each performance obligation is satisfied.

The Company recognizes collaboration revenue under certain of the Company's license or collaboration agreements that are within the scope of ASC 606. The Company's contracts with customers typically include promises related to licenses to intellectual property, research and development services and options to purchase additional goods and/or services. If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgement to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. Contracts that include an option to acquire additional goods and/or services are evaluated to determine if such option provides a material right to the customer that it would not have received without entering into the contract. If so, the option is accounted for as a separate performance obligation. If not, the option is considered a marketing offer which would be accounted for as a separate contract upon the customer's election.

ZIOPHARM Oncology, Inc.

NOTES TO FINANCIAL STATEMENTS (unaudited)

5. Revenue Recognition – (continued)

The terms of the Company's arrangements with customers typically include the payment of one or more of the following: (i) non-refundable, up-front payment, (ii) development, regulatory and commercial milestone payments, (iii) future options and (iv) royalties on net sales of licensed products. Accordingly, the transaction price is generally comprised of a fixed fee due at contract inception and variable consideration in the form of milestone payments due upon the achievement of specified events and tiered royalties earned when customers recognize net sales of licensed products. The Company measures the transaction price based on the amount of consideration to which it expects to be entitled in exchange for transferring the promised goods and/or services to the customer. The Company utilizes the most likely amount method to estimate the amount of variable consideration, to predict the amount of consideration to which it will be entitled for its one open contract. Amounts of variable consideration are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. At the inception of each arrangement that includes development and regulatory milestone payments, the Company evaluates whether the associated event is considered probable of achievement and estimates the amount to be included in the transaction price using the most likely amount method. Milestone payments that are not within the control of the Company or the licensee, such as those dependent upon receipt of regulatory approval, are not considered to be probable of achievement until the triggering event occurs. At the end of each reporting period, the Company reevaluates the probability of achievement of each milestone and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue and net loss in the period of adjustment. For arrangements that include sales-based royalties, including milestone payments based upon the achievement of a certain level of product sales, the Company recognizes revenue upon the later of: (i) when the related sales occur or (ii) when the performance obligation to which some or all of the payment has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any development, regulatory or commercial milestones or royalty revenue resulting from any of its collaboration arrangements. Consideration that would be received for optional goods and/or services is excluded from the transaction price at contract inception.

The Company allocates the transaction price to each performance obligation identified in the contract on a relative standalone selling price basis. However, certain components of variable consideration are allocated specifically to one or more particular performance obligations in a contact to the extent both of the following criteria are met: (i) the terms of the payment relate specifically to the efforts to satisfy the performance obligation or transfer the distinct good or service and (ii) allocating the variable amount of consideration entirely to the performance obligation or the distinct good or service is consistent with the allocation objective of the standard whereby the amount allocated depicts the amount of consideration to which the entity expects to be entitled in exchange for transferring the promised goods or services. The Company develops assumptions that require judgement to determine the standalone selling price for each performance obligation identified in each contract. The key assumptions utilized in determining the standalone selling price for each performance obligation may include forecasted revenues, development timelines, estimated research and development costs, discount rates, likelihood of exercise and probabilities of technical and regulatory success.

ZIOPHARM Oncology, Inc.

NOTES TO FINANCIAL STATEMENTS (unaudited)

5. Revenue Recognition – (continued)

Revenue is recognized based on the amount of the transaction price that is allocated to each respective performance obligation when or as the performance obligation is satisfied by transferring a promised good and/or service to the customer. For performance obligations that are satisfied over time, the Company recognizes revenue by measuring the progress toward complete satisfaction of the performance obligation using a single method of measuring progress which depicts the performance in transferring control of the associated goods and/or services to the customer. The Company uses input methods to measure the progress toward the complete satisfaction of performance obligations satisfied over time. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue and net loss in the period of adjustment.

As it relates to the Ares Trading Agreement (see Note 6), the Company recognized the upfront payment associated with its one open contract as a contract liability upon receipt of payment as it requires deferral of revenue recognition to a future period until the Company performs its obligations under the arrangement. Amounts expected to be recognized as revenue within the twelve months following the balance sheet date are classified in current liabilities. Amounts not expected to be recognized as revenue within the twelve months following the balance sheet date are classified as contract liabilities, net of current portion. The Company determined that there were three performance obligations; the first performance obligation consists of the license and research development services and the other two performance obligations are material rights as it relates to potential future targets that have not yet been identified. As described above, the transaction price of $57.5 million was allocated to the performance obligations based on their relative standalone selling prices.

There are multiple distinct performance obligations, including material rights; thus, the Company allocates the transaction price to each distinct performance obligation based on its relative standalone selling price. The standalone selling price is generally determined based on the prices charged to customers or using expected cost plus margin. Revenue is recognized by measuring the progress toward complete satisfaction of the performance obligations using an input measure. Furthermore, the Company has not capitalized any contract costs under the guidance in ASC 340-40, *Other Assets and Deferred Costs: Contracts with Customers*.

The Company does not believe that any variable consideration should be included in the transaction price at the date of adoption of ASC 606 on January 1, 2018 or for the period ended September 30, 2018. Such assessment considered the application of the constraint to ensure that estimates of variable consideration would be included in the transaction price only to the extent the Company had a high degree of confidence that revenue would not be reversed in a subsequent reporting period. The Company will re-evaluate the transaction price, including the estimated variable consideration included in the transaction price and all constrained amounts, in each reporting period and as other changes in circumstances occur.

The first performance obligation includes three initial targets, two of which were substantially complete at March 31, 2018. Revenue recognized to date relates to these two targets. There is no remaining contract liability related to these two targets. The third target included in the first performance obligation has not yet been identified; revenue recognition will be deferred until the time that the work on the project begins. No revenue has been recognized related to the material rights, as the option for the material rights has not yet been exercised. The Company has classified the remaining contract liability of $49.5 million as current at September 30, 2018 as all remaining performance obligations are expected to be met in the fourth quarter of 2018, as a result of our License Agreement signed with Precigen subsequent to the balance sheet date (Note 1).

ZIOPHARM Oncology, Inc.

NOTES TO FINANCIAL STATEMENTS (unaudited)

5. Revenue Recognition – (continued)

As a result of adopting ASC 606, the Company recorded an $8.1 million adjustment to the opening balance of accumulated deficit in the first quarter of 2018 as a result of the treatment of the up-front consideration received in July 2015 under ASC 605-25 versus ASC 606. Refer below for a summary of the amount by which each financial statement line item was affected by the impact of the cumulative adjustment:

($ in thousands)	Impact of Topic 606 Adoption on the Balance Sheet as of January 1, 2018		
Description	As reported under Topic 606	Adjustments	Balances without adoption of Topic 606
Contract liability, current portion	$ 622	$ (5,767)	$ 6,389
Contract liability, net of current portion	$ 49,037	$ 13,898	$ 35,139
Accumulated deficit	$ (720,573)	$ (8,131)	$ (712,442)

The amount by which each financial statement line item is affected in the current reporting period by ASC 606 as compared with the guidance that was in effect prior to adoption is disclosed below.

($ in thousands)	Impact of Topic 606 Adoption on the Balance Sheet as of September 30, 2018		
Description	As reported under Topic 606	Adjustments	Balances without adoption of Topic 606
Contract liability, current portion	$ 49,513	$ 12,777	$ 36,736
Accumulated deficit	$ (761,209)	$ 12,777	$ (748,432)

ZIOPHARM Oncology, Inc.

NOTES TO FINANCIAL STATEMENTS (unaudited)

5. Revenue Recognition – (continued)

($ in thousands)	Impact of Topic 606 Adoption on the Statement of Operations for the Three Months Ended September 30, 2018		
Description	As reported under Topic 606	Adjustments	Balances without adoption of Topic 606
Collaboration revenue	$ —	$ (1,597)	$ 1,597
Net loss	$ (12,585)	$ (1,597)	$ (10,988)
Basic and diluted net loss per share	$ (0.13)	$ (0.01)	$ (0.12)

($ in thousands)	Impact of Topic 606 Adoption on the Statement of Operations for the Nine Months Ended September 30, 2018		
Description	As reported under Topic 606	Adjustments	Balances without adoption of Topic 606
Collaboration revenue	$ 146	$ (4,646)	$ 4,792
Net loss	$ (40,636)	$ (4,646)	$ (35,990)
Basic and diluted net loss per share	$ (0.41)	$ (0.04)	$ (0.37)

($ in thousands)	Impact of Topic 606 Adoption on the Statement of Cash Flows for the Nine Months Ended September 30, 2018		
Description	As reported under Topic 606	Adjustments	Balances without adoption of Topic 606
Net loss	$ (40,636)	$ (4,646)	$ (35,990)
Changes in contract liability	$ —	$ 4,792	$ (4,792)

The most significant change above relates to the Company's collaboration revenue, which to date has been exclusively generated from its collaboration arrangement with Ares Trading and Precigen, formerly Intrexon (see Note 6). Under ASC 605, the Company accounted for the up-front payment over the estimated period of performance of the research and development services which was estimated to be 9 years. In connection with the adoption of ASC 606, the Company uses cost-based input method to measure progress because such method best reflects the satisfaction of the performance obligation. In applying the cost-based input method of revenue recognition, the Company uses actual costs incurred relative to the budgeted costs to complete the research programs. These costs consist primarily of internal full-time equivalent effort and third-party contract costs. Revenue is recognized based on actual costs incurred as a percentage of total budgeted costs. As a result, although the performance obligations noted above and identified under ASC 606 were generally consistent with the units of account identified under ASC 605, the timing of the allocation of the transaction price to the identified performance obligations under ASC 606 differed from the allocations of consideration under ASC 605. Accordingly, the transaction price ultimately allocated to each performance obligation under ASC 606 differed from the amounts allocated under ASC 605. The Company has a full valuation allowance so there was no effect on incomes taxes as a result of this change.

ZIOPHARM Oncology, Inc.

NOTES TO FINANCIAL STATEMENTS (unaudited)

6. Commitments and Contingencies

Operating Leases

Prior to December 31, 2012, the Company entered into an operating lease in New York, NY for office space. In accordance with this agreement, the Company entered into a letter of credit in the amount of $388 thousand, naming the Company's landlord as beneficiary. In January 2012, the Company amended the lease agreement, adding additional office space. The collateral for the letter of credit is restricted cash and recorded in other current assets on the balance sheet as of September 30, 2018. The lease for office space in New York, NY expires in October 2018.

On October 17, 2013, the Company entered into a sublease agreement to lease all of its New York office space to a subtenant. The Company remains primarily liable to pay rent on the original lease. The Company recorded a loss on the sublease in the amount of $729 thousand for the year ended December 31, 2013, representing the remaining contractual obligation of $2.3 million, less $1.6 million in payments from its subtenant. Total sublease loss was approximately $31 thousand for each of the three-month periods ending September 30, 2018 and 2017. The Company continues to maintain the $388 thousand letter of credit in respect of the New York office space, which is recorded in other current assets on the balance sheet.

Prior to December 31, 2012, the Company entered into separate operating lease agreements for various spaces in a building in Boston, MA. In June 2012, the Company re-negotiated a master lease for the Company's Boston office space to incorporate all three lease agreements under the same master agreement, which was originally set to expire in August 2016. On December 21, 2015 and April 15, 2016, the Company renewed the sublease for the Company's corporate headquarters in Boston, MA through August 31, 2021. As of September 30, 2018, a security deposit of $128 thousand is included in deposits on the balance sheet.

On January 30, 2018, the Company entered into a lease agreement for office space in Houston, TX at MD Anderson. Under the terms of the Houston lease agreement, the Company leases approximately two hundred and ten square feet and is required to make rental payments at an average monthly rate of approximately $1 thousand through April 2021. Upon signing the lease agreement, the Company expensed approximately $40 thousand for rent expense for the period beginning in May 2015 through December 2017. The $40 thousand for rent expense incurred from May 2015 through December 2017, and all future rent expense incurred in Houston, are being deducted from our prepayment at MD Anderson described in the license agreement section below.

Total rent expense was approximately $145 thousand and $534 thousand for the three and nine months ended September 30, 2018, respectively. Total rent expense was approximately $177 thousand and $545 thousand for the three and nine months ended September 30, 2017, respectively.

The Company records rent expense on a straight-line basis over the term of the lease. Accordingly, the Company has recorded a liability for deferred rent at September 30, 2018 and December 31, 2017 of $30 thousand ($24 thousand as is classified current and $6 thousand as is classified long-term) and $142 thousand ($141 thousand as is classified current and $1 thousand as is classified long-term), respectively, which is recorded in deferred rent on the balance sheets.

ZIOPHARM Oncology, Inc.

NOTES TO FINANCIAL STATEMENTS (unaudited)

6. Commitments and Contingencies – (continued)

License Agreements

Exclusive Channel Partner Agreement with Precigen for the Cancer Programs

On January 6, 2011, the Company entered into the Channel Agreement with Intrexon (which Intrexon subsequently assigned to Precigen), that governs a "channel partnering" arrangement in which the Company uses Precigen's technology to research, develop and commercialize products in which DNA is administered to humans for expression of anti-cancer effectors for treatment or prophylaxis of cancer, which the Company collectively refers to as the Cancer Program. This Channel Agreement established committees comprising representatives of us and Precigen that governed activities related to the Cancer Program in the areas of project establishment, chemistry, manufacturing and controls, clinical and regulatory matters, commercialization efforts and intellectual property.

The Channel Agreement grants the Company a worldwide license to use patents and other intellectual property of Precigen in connection with the research, development, use, importing, manufacture, sale, and offer for sale of products involving DNA administered to humans for expression of anti-cancer effectors for the purpose of treatment or prophylaxis of cancer, which are collectively referred to as the Ziopharm Products. Such license is exclusive with respect to any clinical development, selling, offering for sale or other commercialization of Ziopharm Products, and otherwise is non-exclusive.

Under the Channel Agreement, and subject to certain exceptions, the Company was responsible for, among other things, the performance of the Cancer Program, including the development, commercialization and certain aspects of manufacturing of Ziopharm Products. Precigen is responsible for establishing manufacturing capabilities and facilities for the bulk manufacture of products developed under the Cancer Program, certain other aspects of manufacturing and costs of discovery-stage research with respect to platform improvements and costs of filing, prosecution and maintenance of Precigen's patents.

After the 2016 ECP Amendment, discussed below, and subject to certain expense allocations and other offsets provided in the Channel Agreement, the Company was obligated to pay Precigen on a quarterly basis 20% of net profits derived in that quarter from the sale of Ziopharm Products, calculated on a Ziopharm Product-by-Ziopharm Product basis. The Company likewise agreed to pay Precigen on a quarterly basis 50% of revenue obtained in that quarter from a sublicensor in the event of a sublicensing arrangement. In addition, in partial consideration for each party's execution and delivery of the Channel Agreement, the Company entered into a stock purchase agreement with Precigen.

As discussed further in Note 1, on October 5, 2018, the Company entered into the License Agreement, the terms of which replace the terms of the Channel Agreement.

ZIOPHARM Oncology, Inc.

NOTES TO FINANCIAL STATEMENTS (unaudited)

6. Commitments and Contingencies (Continued)

Amendment of Collaborations with Precigen

On March 27, 2015, the Company, together with Intrexon, (which Intrexon subsequently assigned to Precigen, Inc.), entered into an ECP Amendment, amending the Channel Agreement. The ECP Amendment modified the scope of the parties' collaboration under the Channel Agreement in connection with the Ares Trading Agreement discussed below. Pursuant to the ECP Amendment, the chimeric antigen receptor T-cell products to be developed and commercialized pursuant to the Ares Trading Agreement shall be included within the Precigen/Ziopharm collaboration under the Channel Agreement. The ECP Amendment provided that Precigen will pay us fifty percent of all payments Precigen receives for upfronts, milestones and royalties under the Ares Trading Agreement.

On June 29, 2016, the Company entered into (1) the 2016 ECP Amendment with Precigen, amending the Channel Agreement, and (2) the 2016 GvHD Amendment, amending the GvHD Agreement. The 2016 ECP Amendment reduced the royalty percentage that the Company was able to pay to Precigen under the Channel Agreement on a quarterly basis from 50% to 20% of net profits derived in that quarter from the sale of Ziopharm Products, calculated on a Ziopharm Product-by-Ziopharm Product basis, subject to certain expense allocations and other offsets provided in the Channel Agreement. The 2016 GvHD Amendment reduced the royalty percentage that the Company would pay to Precigen under the GvHD Agreement on a quarterly basis from 50% to 20% of net profits derived in that quarter from the sale of Products (as defined in the GvHD Agreement), subject to certain expense allocations and other offsets provided in the GvHD Agreement. The reductions in the royalty percentages provided by the 2016 ECP Amendment and the 2016 GvHD Amendment do not apply to sublicensing revenue or royalties under the Channel Agreement and GvHD Agreement, nor do they apply to any royalties or other payments made with respect to sublicensing revenue from the existing collaboration with Ares. The Company has announced the decision to stop pursuing the development of engineered cell therapy strategies for targeted treatment of graft-versus-host disease, or GvHD. The Company has reverted the rights under the GvHD Agreement back to Precigen.

In consideration for the execution and delivery of the 2016 ECP Amendment and the 2016 GvHD Amendment, the Company agreed to issue to Intrexon 100,000 shares of its Series 1 preferred stock. Each share of Series 1 preferred stock has a stated value of $1,200, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other recapitalization, and certain other rights, preferences, privileges and obligations (see Notes 1 and 9).

As discussed further in Note 1, on October 5, 2018, the Company entered into the License Agreement, the terms of which replace the terms of the Channel Agreement.

Exclusive Channel Collaboration Agreement with Precigen for GvHD

On September 28, 2015, the Company entered into the GvHD Agreement with Intrexon (which Intrexon subsequently assigned to Precigen) whereby the Company would use Precigen's technology directed towards *in vivo* expression of effectors to research, develop and commercialize products for use in the treatment or prevention of GvHD. The GvHD Agreement granted us a worldwide license to use specified patents and other intellectual property of Precigen in connection with the research, development, use, importing, manufacture, sale, and offer for sale of products developed under the GvHD Agreement.

The Company paid Intrexon a technology access fee of $10.0 million in cash in October 2015 and agreed to reimburse Intrexon for all related research and development costs pursuant to the GvHD Agreement. The Company has determined that the rights acquired in the GvHD Agreement represent in-process research and development with no alternative future use. Accordingly, the Company recorded a charge of $10.0 million to research and development expense in September 2015.

As a result of an in-depth review of the Company's research and development portfolio, the determination was made that the pursuit of GvHD as an indication was not a material part of its corporate strategy and therefore have decided to stop pursuing the development of engineered cell therapy strategies, used either separately or in combination, for targeted treatment of GvHD. The Company has reverted the rights under the GvHD program back to Precigen.

ZIOPHARM Oncology, Inc.

NOTES TO FINANCIAL STATEMENTS (unaudited)

6. Commitments and Contingencies (Continued)

License Agreement—The University of Texas MD Anderson Cancer Center

On January 13, 2015, the Company, together with Intrexon (which Intrexon subsequently assigned to Precigen), entered into the MD Anderson License, with MD Anderson. Pursuant to the MD Anderson License, the Company, together with Precigen, hold an exclusive, worldwide license to certain technologies owned and licensed by MD Anderson including technologies relating to novel CAR T-cell therapies, non-viral gene transfer systems, genetic modification and/or propagation of immune cells and other cellular therapy approaches, Natural Killer, or NK Cells, and TCRs, arising from the laboratory of Laurence Cooper, M.D., Ph.D., who became the Company's Chief Executive Officer in May 2015 and was formerly a tenured professor of pediatrics at MD Anderson and is now currently a visiting scientist under that institution's policies, as well as either co-exclusive or non-exclusive licenses under certain related technologies such as gamma delta T cells.

Pursuant to the terms of the MD Anderson License, MD Anderson received consideration consisting of $50.0 million in shares of common stock (or 10,124,561 shares), and $50.0 million in shares of Intrexon's common stock, in each case based on a trailing 20 day volume weighted average of the closing price the Company's and Intrexon's common stock ending on the date prior to the announcement of the entry into the MD Anderson License, collectively referred to as the License Shares. The License Shares were issued to MD Anderson on March 11, 2015, pursuant to the terms of the MD Anderson License.

On January 9, 2015, in order to induce MD Anderson to enter into the MD Anderson License on an accelerated schedule, the Company, together with Intrexon entered into a letter agreement, or the Letter Agreement, pursuant to which MD Anderson received consideration of $7.5 million in shares of common stock (or 1,597,602 shares), and $7.5 million in shares of Intrexon's common stock, in each case based on a trailing 20-day volume-weighted average of the closing price of the Company's and Intrexon's common stock ending on the date prior to the execution of the Letter Agreement, collectively referred to as the Incentive Shares, in the event that the MD Anderson License was entered into on January 14, 2015. The Incentive Shares were issued to MD Anderson on March 11, 2015.

On August 17, 2015, the Company, Precigen and MD Anderson entered into the Research and Development Agreement, to formalize the scope and process for the transfer by MD Anderson, pursuant to the terms of the MD Anderson License, of certain existing research programs and related technology rights, as well as the terms and conditions for future collaborative research and development of new and ongoing research programs.

Pursuant to the Research and Development Agreement, the Company, Precigen and MD Anderson have agreed to form a joint steering committee that will oversee and manage the new and ongoing research programs. As provided under the MD Anderson License, the Company provided funding for research and development activities in support of the research programs under the Research and Development Agreement for a period of three years and in an amount of no less than $15.0 million and no greater than $20.0 million per year. During the nine months ended September 30, 2018, the Company made payments in the aggregate amount of $2.7 million to MD Anderson compared to $9.3 million during the nine months ended September 30, 2017. The decrease in cash paid to MD Anderson during the nine months ended September 30, 2018 as compared to the same period in the prior year is a result of the final quarterly payment being made to MD Anderson in January 2018 and the result of approved expenditures incurred by us being deducted from the January 2018 quarterly payment. As of September 30, 2018, MD Anderson had used $11.4 million in program related expenses and reimbursed the company $3.7 million related to third party passthrough costs to offset of the prepaid balance for the MD Anderson License and the Research and Development Agreement. The net balance of cash resources on hand at MD Anderson available to offset expenses and future costs is $29.6 million, of which $11.5 million is included in other current assets and the remaining $18.1 million is included in non-current assets at September 30, 2018.

ZIOPHARM Oncology, Inc.

NOTES TO FINANCIAL STATEMENTS (unaudited)

6. Commitments and Contingencies (Continued)

The term of the MD Anderson License expires on the last to occur of (a) the expiration of all patents licensed thereunder, or (b) the twentieth anniversary of the date of the MD Anderson License; provided, however, that following the expiration of the term of the MD Anderson License, the Company, together with Precigen, shall then have a fully-paid up, royalty free, perpetual, irrevocable and sublicensable license to use the licensed intellectual property thereunder. After ten years from the date of the MD Anderson License and subject to a 90-day cure period, MD Anderson will have the right to convert the MD Anderson License into a non-exclusive license if the Company and Precigen are not using commercially reasonable efforts to commercialize the licensed intellectual property on a case-by-case basis. After five years from the date of the MD Anderson License and subject to a 180-day cure period, MD Anderson will have the right to terminate the MD Anderson License with respect to specific technology(ies) funded by the government or subject to a third-party contract if the Company and Precigen are not meeting the diligence requirements in such funding agreement or contract, as applicable. MD Anderson may also terminate the agreement with written notice upon material breach by us and Precigen, if such breach has not been cured within 60 days of receiving such notice. In addition, the MD Anderson License will terminate upon the occurrence of certain insolvency events for both the Company and Precigen and may be terminated by the mutual written agreement of the Company, Precigen, and MD Anderson.

The Company determined that the rights acquired in the MD Anderson License represented in process research and development with no alternative future use. Accordingly, the Company recorded a charge of $67.3 million to research and development expense in 2015, representing the fair value of the 11,722,163 shares of its common stock on the date the MD Anderson License was executed.

Ares Trading License and Collaboration Agreement

On March 27, 2015, the Company, together with Intrexon (which Intrexon subsequently assigned to Precigen) and Ares Trading, signed the Ares Trading Agreement, through which the parties established a collaboration for the research and development and commercialization of certain products for the prophylactic, therapeutic, palliative or diagnostic use for cancer in humans.

Under the collaboration, Ares Trading has elected two CAR^+ T-cell targets for which the Company will perform certain research activities that will, in part, be funded by Ares Trading. Once these candidates reach investigational new drug, or IND, stage, the programs will be transferred to Ares Trading for clinical development and commercialization. The Company was expected to perform multiple preclinical development programs, each consisting of the development of one product candidate, pursuant to the agreement.

ZIOPHARM Oncology, Inc.

NOTES TO FINANCIAL STATEMENTS (unaudited)

6. Commitments and Contingencies (Continued)

Precigen is entitled to receive $5.0 million from Ares Trading payable in equal quarterly installments over two years for each identified product candidate, which will be used to fund discovery work. The Company was responsible for costs exceeding the quarterly installments and all other costs of the preclinical research and development. For the three and nine months ended September 30, 2018, the Company has expensed $36 thousand under the Ares Trading Agreement.

Ares Trading paid a non-refundable upfront fee of $115.0 million to Intrexon as consideration for entry into the Ares Trading Agreement. Pursuant to the ECP Amendment, the Company was entitled to receive 50% of the upfront fee, or $57.5 million, which was received from Intrexon in July 2015.

The Ares Trading Agreement provides for up to $60.0 million in development milestone payments, up to $148.0 million in regulatory milestone payments and up to $205.0 million in commercial milestone payments for each product candidate. Development milestone payments are triggered upon initiation of a defined phase of clinical research for a product candidate. Regulatory milestone payments are triggered upon approval to market a product candidate by the U.S. Food and Drug Administration (FDA), or other global regulatory authorities. Commercial milestone payments are triggered when an approved pharmaceutical product reaches certain levels of net sales defined in the license. The Ares Trading Agreement also provides for up to $50.0 million of one-time payments upon the achievement of certain technical milestones evidenced by the initiation of a defined phase of clinical research. All development, regulatory and technical milestones are considered substantive based on the contingent nature of the milestone, specifically reviewing factors such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the milestone as well as the level of effort and investment required. The next potential milestone payment that Precigen could be entitled to receive under the Ares Trading Agreement is a $15.0 million substantive milestone for the initiation of a Phase 1 clinical trial. In addition, to the extent any of the product candidates licensed by Ares Trading are commercialized, Precigen would be entitled to receive royalties ranging from the lower-single digits to the low-teens of net sales derived from the sale of products developed under the agreement.

The term of the Ares Trading Agreement commenced in May 2015 and may be terminated by either party in the event of a material breach as defined in the agreement and may be terminated voluntarily by Ares Trading upon 90 days written notice to the Company.

As discussed further in Note 1, on October 5, 2018, the Company entered into the License Agreement, the terms of which replace certain rights and obligations under the Ares Trading Agreement.

See Note 5 for detail of the accounting for the Ares Trading Agreement.

ZIOPHARM Oncology, Inc.

NOTES TO FINANCIAL STATEMENTS (unaudited)

6. Commitments and Contingencies (Continued)

Patent and Technology License Agreement—The University of Texas MD Anderson Cancer Center and the Texas A&M University System

On August 24, 2004, the Company entered into a patent and technology license agreement with MD Anderson and the Texas A&M University System, which the Company refers to, collectively, as the Licensors. Under this agreement, the Company was granted an exclusive, worldwide license to rights (including rights to U.S. and foreign patent and patent applications and related improvements and know-how) for the manufacture and commercialization of two classes of organic arsenicals (water- and lipid-based) for human and animal use. The class of water-based organic arsenicals includes darinaparsin.

The Company issued to the licensors options to purchase 50,222 shares outside of its stock option plans following the successful completion of certain clinical milestones, of which 37,666 shares have vested. The remaining 12,556 shares vested upon enrollment of the first patient in a multi-center pivotal clinical trial. An expense of $87 thousand was charged to research and development expense for the vesting event which occurred in March 2016. This trial was initiated by Solasia Pharma K.K., or Solasia, on March 28, 2016 and triggered a $1.0 million milestone payment to the Company from Solasia which was received in May 2016. An equivalent of $1.0 million milestone payment was subsequently made to MD Anderson and reported net. The Licensors are entitled to receive certain milestone payments. In addition, the Company may be required to make additional payments to the Licensors (as defined in the MD Anderson License) upon achievement of certain other milestones in varying amounts which, on a cumulative basis could total up to an additional $4.5 million. In addition, the Licensors are entitled to receive single digit percentage royalty payments on sales from a licensed product and will also be entitled to receive a portion of any fees that the Company may receive from a possible sublicense under certain circumstances.

Collaboration Agreement with Solasia Pharma K.K.

On March 7, 2011, the Company entered into a License and Collaboration Agreement with Solasia, or the License and Collaboration Agreement. Pursuant to the License and Collaboration Agreement, the Company granted Solasia an exclusive license to develop and commercialize darinaparsin in both intravenous and oral forms and related organic arsenic molecules, in all indications for human use in a pan-Asian/Pacific territory comprising Japan, China, Hong Kong, Macau, Republic of Korea, Taiwan, Singapore, Australia, New Zealand, Malaysia, Indonesia, Philippines and Thailand.

ZIOPHARM Oncology, Inc.

NOTES TO FINANCIAL STATEMENTS (unaudited)

6. Commitments and Contingencies (Continued)

As consideration for the license, the Company received an upfront payment of $5.0 million to be used exclusively for further clinical development of darinaparsin outside of the pan-Asian/Pacific territory and will be entitled to receive additional payments of up to $32.5 million in development-based milestones and up to $53.5 million in sales-based milestones. The Company will also be entitled to receive double digit royalty payments from Solasia based upon net sales of licensed products in the applicable territories, once commercialized, and a percentage of sublicense revenues generated by Solasia. The $5.0 million upfront payment received in March 2011 was amortized over the period of the research and development effort, which was completed in March 2016.

On July 31, 2014, the Company entered into an amendment and restatement of the License and Collaboration Agreement granting Solasia an exclusive worldwide license to develop and commercialize darinaparsin, and related organoarsenic molecules, in both intravenous and oral forms in all indications for human use. In exchange, the Company will be eligible to receive from Solasia development- and sales-based milestones, a royalty on net sales of darinaparsin, once commercialized, and a percentage of any sublicense revenues generated by Solasia.

Solasia will be responsible for all costs related to the development, manufacturing and commercialization of darinaparsin. The Company's Licensors, as defined in the agreement, will receive a portion of all milestone and royalty payments made by Solasia to us in accordance with the terms of the license agreement with the Licensors.

On March 28, 2016, Solasia initiated a multi-center pivotal clinical trial intended to provide substantial evidence of efficacy necessary to support the filing of an application for a New Drug Application, or NDA, for darinaparsin in certain of the territories assigned to Solasia. The initiation of the trial on March 28, 2016 triggered a $1.0 million milestone payment from Solasia to the Company which was received in May 2016. The Company subsequently made an equivalent payment to MD Anderson as the ultimate licensor of darinaparsin (see above).

License Agreement with Baxter Healthcare S.A.

On November 3, 2006, the Company entered into a definitive Asset Purchase Agreement for indibulin and a License Agreement to proprietary nanosuspension technology with affiliates of Baxter Healthcare S.A. The purchase included the entire indibulin intellectual property portfolio as well as existing drug substance and capsule inventories. The final royalty payment of $250 thousand was paid in November 2017. The terms of the Asset Purchase Agreement included an upfront cash payment and an additional payment for existing inventory. No payments were made during the three and nine months ended September 30, 2018 and 2017.

Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute

On January 10, 2017, the Company announced the signing of a Cooperative Research and Development Agreement, or CRADA, with the National Cancer Institute, or NCI, for the development of adoptive cell transfer, or ACT,-based immunotherapies genetically modified using the *Sleeping Beauty*, or SB, transposon/transposase system to express TCRs for the treatment of solid tumors. The principal goal of the CRADA is to develop and evaluate ACT for patients with advanced cancers using autologous peripheral blood lymphocytes, or PBL, genetically modified using the non-viral SB system to express TCRs that recognize specific immunogenic mutations, or neoantigens, expressed within a patient's cancer. Clinical evaluations of the ability of these SB-engineered PBL to express TCRs reactive against cancer mutations to mediate cancer regression in patients with metastatic disease will be performed. Research conducted under the CRADA will be at the direction of Steven A. Rosenberg, M.D., Ph.D., Chief of the Surgery Branch at the NCI, in collaboration with researchers at the Company and Precigen. The Company's remaining obligation, as of September 30, 2018, for this CRADA is $3.1 million over the next two years, payable in $625 thousand payments on a quarterly basis. During the three and nine months ended September 30, 2018, the Company made payments of $625 thousand and $1.9 million, respectively.

ZIOPHARM Oncology, Inc.

NOTES TO FINANCIAL STATEMENTS (unaudited)

7. Related Party Transactions

Collaborations with Intrexon/ Precigen

On January 6, 2011, the Company entered into the Channel Agreement with Intrexon (which Intrexon subsequently assigned to Precigen), (see Note 6). Randal J. Kirk was a director of the Company until October 5, 2018. Mr. Kirk is the chief executive officer, a director, and the largest stockholder of Intrexon.

On February 3, 2015, Intrexon purchased 1,440,000 shares of common stock in the Company's public offering upon the same terms as others that participated in the offering.

On March 27, 2015, the Company and Precigen entered into a Second Amendment to the Exclusive Channel Partner Agreement amending the Channel Agreement, which is referred to as the ECP Amendment. The ECP Amendment modified the scope of the parties' collaboration under the Channel Agreement in connection with the Ares Trading Agreement, which the Company and Precigen entered into with Ares Trading, on March 27, 2015. The ECP Amendment provided that Precigen will pay to the Company 50% of all payments that Precigen receives for upfronts, milestones and royalties under the Ares Trading Agreement (see Note 6). The Amendment also reduces Precigen's aggregate commitment under a Stock Purchase Agreement that the parties executed in connection with the initial Channel Agreement to purchase the Company's common stock from $50.0 million to $43.5 million, which has been satisfied.

On June 29, 2015, the Company re-purchased 3,711 shares of common stock from Intrexon, at a discount of 5% to the closing price of the Company's common stock on the date of purchase, which represented fractional shares that resulted from Intrexon's special stock dividend of the Company's shares to Intrexon's shareholders, for $34 thousand. On January 8, 2016, the Company re-purchased an additional 168 shares of common stock from Intrexon for $2 thousand at the same terms as the previous share purchase.

On September 28, 2015, the Company entered into the GvHD Agreement with Intrexon (which Intrexon subsequently assigned to Precigen), whereby the Company was granted the right to use Precigen's technology directed towards *in vivo* expression of biologics to research, develop and commercialize products for use in the treatment or prevention of GvHD (see Note 6). The Company paid Precigen a technology access fee of $10.0 million in cash in October 2015 and agreed to reimburse Precigen for all research and development costs under the GvHD Agreement.

ZIOPHARM Oncology, Inc.

NOTES TO FINANCIAL STATEMENTS (unaudited)

7. Related Party Transactions (continued)

On June 29, 2016, the Company entered into the 2016 ECP Amendment, with Intrexon (which Intrexon subsequently assigned to Precigen), amending the Channel Agreement, and the 2016 GvHD Amendment, amending the GvHD Agreement. The 2016 ECP Amendment reduced the royalty percentage that the Company will pay to Precigen under the Channel Agreement on a quarterly basis from 50% to 20% of net profits derived in that quarter from the sale of Ziopharm Products (as defined in the Channel Agreement), calculated on a Ziopharm Product-by-Ziopharm Product basis, subject to certain expense allocations and other offsets provided in the Channel Agreement. The 2016 GvHD Amendment reduced the royalty percentage that the Company would pay to Precigen under the GvHD Agreement on a quarterly basis from 50% to 20% of net profits derived in that quarter from the sale of Products (as defined in the GvHD Agreement), subject to certain expense allocations and other offsets provided in the GvHD Agreement. The reductions in the royalty percentages provided by the 2016 ECP Amendment and the 2016 GvHD Amendment do not apply to sublicensing revenue or royalties under the Channel Agreement and GvHD Agreement, nor do they apply to any royalties or other payments made with respect to sublicensing revenue from the Company's existing collaboration with Merck Serono, the biopharmaceutical business of Merck.

In consideration for the execution and delivery of the 2016 ECP Amendment and the 2016 GvHD Amendment, the Company issued Intrexon 100,000 shares of its Series 1 preferred stock. Each share of the Company's Series 1 preferred stock has a stated value of $1,200, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other recapitalization, and certain other rights, preferences, privileges and obligations (see Note 9). The holders of the shares of Series 1 preferred stock are entitled to receive a monthly dividend, payable in additional shares of Series 1 preferred stock, equal to $12.00 per preferred share held by such holder per month divided by the stated value of the preferred shares, rounded down to the nearest whole share (see Note 9).

During the three months ended September 30, 2018, the Company issued an aggregate of 3,847 shares of Series 1 preferred stock to Intrexon, the holder of all of the outstanding shares of the Company's Series 1 preferred stock, as monthly dividend payments. At September 30, 2018, the Company recorded such shares of Series 1 preferred stock at a fair value of $6.1 million which is a component of temporary equity. During the three months ended September 30, 2018, the Company recorded a loss on the change of the derivative liabilities in the amount of $165 thousand. See Notes 9 and 10 for additional discussion regarding the accounting for and valuation of these derivative financial instruments.

During the three months ended September 30, 2018, and 2017, the Company expensed $2.0 million and $5.6 million, respectively, for services performed by Precigen. During the nine months ended September 30, 2018, and 2017, the Company expensed $6.7 million and $16.8 million, respectively, for services performed by Precigen. As of September 30, 2018, and 2017, the Company recorded $2.9 million and $5.5 million, respectively, in current liabilities on its balance sheet for amounts due to Precigen.

As discussed further in Note 1, on October 5, 2018, the Company entered into the License Agreement, the terms of which replace the terms of the Channel Agreement.

Collaboration with Precigen and MD Anderson

On January 13, 2015, the Company, together with Precigen, entered into the MD Anderson License. Pursuant to the MD Anderson License, the Company and Precigen hold an exclusive, worldwide license to certain technologies owned and licensed by MD Anderson, including technologies relating to novel CAR+ T-cell therapies arising from the laboratory of Laurence Cooper, M.D., Ph.D., who is now the Company's Chief Executive Officer and was formerly a professor of pediatrics at MD Anderson and now currently a visiting scientist under that institution's policies, as well as either co-exclusive or non-exclusive licenses under certain related technologies. In partial consideration for entering into the MD Anderson License, the Company issued MD Anderson an aggregate of 11,722,163 shares of common stock for which the Company incurred a $67.3 million charge recorded in 2015. The Company has determined that the rights acquired in the MD Anderson License represent in-process research and development with no alternative future use. During the three months ending March 31, 2018, the Company made the final quarterly payment of $2.7 million under the Research and Development Agreement, bringing the total aggregate payments to $41.9 million.

ZIOPHARM Oncology, Inc.

NOTES TO FINANCIAL STATEMENTS (unaudited)

8. Stock-Based Compensation

The Company recognized stock-based compensation expense on all employee and non-employee awards as follows:

(in thousands)	For the three months ended September 30, 2018	For the three months ended September 30, 2017	For the nine months ended September 30, 2018	For the nine months ended September 30, 2017
Research and development	$ 552	$ 615	$ 1,765	$ 1,772
General and administrative	928	1,467	5,085	4,393
Stock-based compensation expense	$ 1,480	$ 2,082	$ 6,850	$ 6,165

The Company granted an aggregate of 300,500 and 506,000 stock options during the three and nine months ended September 30, 2018 with a weighted-average grant date fair value of $2.11 and $2.49 per share, respectively. The Company granted an aggregate of 593,500 and 859,000 stock options during the three and nine months ended September 30, 2017 with a weighted-average grant date fair value of $4.29 and $4.34 per share, respectively.

On February 15, 2018, the Company extended the contractual life of 751,667 fully vested stock options held by one officer of the Company by an additional 9 months. Additionally, on March 12, 2018, the Company extended the contractual life of 117,500 fully vested stock options held by a director. These extensions resulted in additional stock-based compensation expense of $481 thousand in the nine months ended September 30, 2018.

On September 18, 2018, the Company extended the contractual life of 92,500 fully vested stock options held by a director of the Company by approximately 9 months and 167,500 fully vested stock options held by another director of the Company by approximately 21 months. These extensions resulted in additional stock-based compensation expense of $117 thousand in the three and nine months ended September 30, 2018. Furthermore, the Company accelerated the vesting of 34,516 shares of restricted stock and recorded an adjustment of ($12) thousand in the three and nine months ended September 30, 2018.

The Company recognizes forefeitures as they occur. For the three months ended September 30, 2018 and 2017, the fair value of stock options was estimated on the date of grant using a Black-Scholes option valuation model with the following assumptions:

	For the three months ended September 30, 2018	2017
Risk-free interest rate	2.82 - 2.98%	1.88 - 2.01%
Expected life in years	6	6
Expected volatility	82.27 - 83.08%	80.82 - 80.95%
Expected dividend yield	0	0

ZIOPHARM Oncology, Inc.

NOTES TO FINANCIAL STATEMENTS (unaudited)

8. Stock-Based Compensation – (continued)

Stock option activity under the Company's stock option plan for the nine months ended September 30, 2018 is as follows:

(in thousands, except share and per share data)	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding, December 31, 2017	3,852,135	$ 5.12		
Granted	506,000	3.50		
Exercised	(104,167)	2.30		
Cancelled	(184,500)	5.77		
Outstanding, September 30, 2018	4,069,468	$ 5.24	6.17	$ 576
Options exercisable, September 30, 2018	2,924,501	$ 5.13	4.98	$ 498
Options exercisable, December 31, 2017	2,925,502	$ 5.12	5.58	$ 1,152
Options available for future grant	5,053,295			

At September 30, 2018, total unrecognized compensation costs related to unvested stock options outstanding amounted to $4.1 million. The cost is expected to be recognized over a weighted-average period of 1.55 years.

In September 2017, the Company issued a stock option award as an inducement grant for the purchase of an aggregate of 500,000 shares of the Company's common stock, outside of the 2012 Plan, at an exercise price of $6.19 per share. The inducement grant is excluded from the option activity table above.

A summary of the status of unvested restricted stock for the nine months ended September 30, 2018 is as follows:

	Number of Shares	Weighted-Average Grant Date Fair Value
Non-vested, December 31, 2017	1,808,559	$ 5.74
Granted	—	—
Vested	(573,340)	7.61
Cancelled	(70,867)	5.07
Non-vested, September 30, 2018	1,164,352	$ 4.85

At September 30, 2018, total unrecognized compensation costs related to unvested restricted stock outstanding amounted to $3.5 million. The cost is expected to be recognized over a weighted-average period of 1.48 years.

ZIOPHARM Oncology, Inc.

NOTES TO FINANCIAL STATEMENTS (unaudited)

9. Preferred Stock

The Company has 30,000,000 shares of preferred stock authorized, of which, 250,000 shares are designated as Series 1 preferred stock.

On June 29, 2016, the Company entered into the 2016 ECP Amendment and 2016 GvHD Amendment with Intrexon (which Intrexon subsequently assigned to Precigen), (see Note 6). In consideration for the execution and delivery of the 2016 ECP Amendment and the 2016 GvHD Amendment, the Company issued to Intrexon 100,000 shares of its newly designated Series 1 preferred stock. Each share of the Company's Series 1 preferred stock has a stated value of $1,200, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other recapitalization.

As discussed in Note 1, in consideration of the Company entering into the License Agreement, Intrexon forfeited and returned to the Company all shares of the Company's Series 1 Preferred Stock held by or payable to Intrexon as of the date of the License Agreement. No shares of Series 1 Preferred Stock are currently outstanding as of the filing date of this Quarterly Report.

The Series 1 preferred stock has the following rights and preferences and certain other rights, preferences, privileges and obligations. See Note 1 for discussion of subsequent transaction regarding Series 1 preferred stock.

Conversion

All shares of Series 1 preferred stock shall automatically convert into shares of common stock upon the public announcement of the first approval in the United States of (i) a Ziopharm Product under the Channel Agreement, (ii) a Product under the GvHD Agreement or (iii) a Product under the Ares Trading Agreement, which the Company refers to as the Conversion Event Date. On the second business day following the Conversion Event Date, each share of Series 1 preferred stock shall convert into a number of shares of common stock equal to the stated value of such Series 1 preferred stock, divided by the greater of (i) the volume weighted average closing price of common stock as reported by The Nasdaq Stock Market, LLC over the 20 trading days ending on the Conversion Event Date or (ii) $1.00 per share; however, without shareholder approval in accordance with the Nasdaq listing rules, the Company will not affect any conversion of the Series 1 preferred stock into shares of common stock in excess of 19.9% of the lesser of (i) the pre-transaction outstanding shares of common stock or (ii) the outstanding shares of common stock at the time of conversion. In addition, without shareholder approval in accordance with the Nasdaq listing rules, the Company will not affect any conversion of the Series 1 preferred stock into common stock to the extent that the number of shares of common stock issued in such conversion would constitute a change of control under the Nasdaq listing rules.

Dividends

The Series 1 preferred stock provides for a monthly dividend, payable in additional shares of Series 1 preferred stock, equal to $12.00 per share, per month divided by the stated value per share, or the PIK Dividend; provided, that if any shares of Series 1 preferred stock are not converted on the Conversion Event Date (discussed below), then the rate of the PIK Dividend on all remaining unconverted shares of Series 1 preferred stock shall automatically increase from $12.00 to $24.00 per share, per month.

Liquidation Preference

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company or a change of control or sale, lease transfer or exclusive license of all or substantially all of the Company's assets prior to the conversion of the Series 1 preferred stock into shares of common stock, then the Series 1 preferred stock will participate in the proceeds of the transaction on a pro rata basis along with common stock, treating the Series 1 preferred stock as if it had been converted into a number of shares of common stock equal to the aggregate stated value of the Series 1 preferred stock, divided by the volume weighted average closing price of common stock over the 20 trading days ending on the public announcement of such voluntary or involuntary liquidation, dissolution or winding up of the Company or change of control or sale, lease transfer or exclusive license of all or substantially all of the Company's assets. Alternatively, the Company may redeem the Series 1 preferred stock at a redemption price equal to the pro rata amount that the Series 1 preferred stock would have received if it had been converted using the same formula.

ZIOPHARM Oncology, Inc.

NOTES TO FINANCIAL STATEMENTS (unaudited)

9. Preferred Stock – (continued)

Voting Rights

The Series 1 preferred stock does not have any voting rights except that the Company may not, without the consent of the holders of a majority of the outstanding shares of the Series 1 preferred stock, voting as a separate class, (i) amend, alter or repeal any provision of its Certificate of Incorporation in a manner that adversely affects the powers, preferences or rights of the Series 1 preferred stock in a manner that is more adverse than the effect on any other class or series of the Company's capital stock; (ii) (A) create, or authorize the creation of, or issue or obligate itself to issue shares of, any additional class or series of the Company's capital stock unless the same ranks junior or pari passu to the Series 1 preferred stock with respect to the distribution of assets on the liquidation, dissolution or winding up of the Company, the payment of dividends and rights of redemption, or (B) reclassify, alter or amend any existing security that is junior or pari passu to the Series 1 preferred stock with respect to the distribution of assets on the liquidation, dissolution or winding up of the Company, the payment of dividends or rights of redemption, if such reclassification, alteration or amendment would render such other security senior to the Series 1 preferred in respect of any such right, preference or privilege; or (iii) enter into any transaction (or series of related transactions) the effect of which would adversely affect the holders of the Series 1 preferred stock in a manner that is more adverse than the effect on any other class or series of capital stock.

Analysis

The Company analyzed the features of the Series 1 preferred stock and determined that the conversion option and the Company's right to redeem the shares at liquidation are embedded derivatives that required bifurcation from the Series 1 preferred stock in accordance with FASB ASC 815, *Derivatives and Hedging*. The embedded derivatives were valued as described below at $0.9 million. Upon issuance of the shares on July 1, 2016, the Company recorded the fair value of the derivatives as a liability and the fair value of the Series 1 preferred stock of $118.2 million as a component of temporary equity. Furthermore, because of the temporary equity classification, the carrying value of the Series 1 preferred stock will not be accreted to redemption value unless or until its redemption becomes probable.

The fair value of the Series 1 preferred stock was estimated using a probability-weighted approach and a Monte Carlo simulation model. The fair value of the embedded derivatives was estimated using the "with" and "without" method where the preferred stock was first valued with all of its features ("with" scenario) and then without derivatives subject to the valuation analysis ("without" scenario). The fair value of the derivatives was then estimated as the difference between the fair value of the preferred stock in the "with" scenario and the preferred stock in the "without" scenario. The model also takes into account, management estimates of clinical success/failure based upon market studies and probability of potential conversion and liquidation events. If these estimates were different, the valuations would change, and that change could be material. Inputs to the models included the following:

Risk-free interest rate	1.04%
Expected dividend rate	0
Expected volatility	70.50%
Preferred stock conversion limit - percentage of outstanding common stock	19.90%
Preferred conversion floor price	$ 1.00

During the three and nine months ended September 30, 2018, the Company issued an aggregate of 3,847 shares and 11,205, shares of Series 1 preferred stock, respectively, to Intrexon, the holder of all of the outstanding shares of its Series 1 preferred stock, as monthly dividend payments. During the three and nine months ended September 30, 2018, the Company recorded such shares of Series 1 preferred stock at a fair value of $6.1 million and $16.7 million, respectively, which is a component of temporary equity. During the three and nine months ended September 30, 2018, the Company recorded a loss of $165 thousand and a gain of $46 thousand, respectively, on the change of the derivative liabilities (see Notes 1 and 10).

ZIOPHARM Oncology, Inc.

NOTES TO FINANCIAL STATEMENTS (unaudited)

10. Derivative Financial Instruments

The Company determined that certain embedded features related to the Series 1 preferred stock are derivative financial instruments.

Fair values of derivative instruments to be classified as derivative liabilities on the balance sheet consist of the following:

($ in thousands) Liability derivates:	Balance Sheet Location	Fair Value
September 30, 2018:		
Derivative liabilities	Liabilities	$ 2,597

The change in the derivative liability for the nine months ended September 30, 2018 consisted of the following:

($ in thousands)	Fair Value
Balance, December 31, 2017	$ 2,424
Dividends	73
Change in fair value	(28)
Balance, March 31, 2018	$ 2,469
Dividends	72
Change in fair value	(183)
Balance, June 30, 2018	$ 2,358
Dividends	74
Change in fair value	165
Balance, September 30, 2018	$ 2,597

The fair value of the Series 1 preferred stock dividends was estimated using a probability-weighted approach and a Monte Carlo simulation model. The fair value of the embedded derivatives was estimated using the “with” and “without” method where the preferred stock was first valued with all of its features (“with” scenario) and then without derivatives subject to the valuation analysis (“without” scenario). The fair value of the derivatives was then estimated as the difference between the fair value of the preferred stock in the “with” scenario and the preferred stock in the “without” scenario. The model also takes into account, management estimates of clinical success/failure based upon market studies and probability of potential conversion and liquidation events. If these estimates were different, the valuations would change, and that change could be material. Inputs to the models included the following:

	September 30, 2018	December 31, 2017
Risk-free interest rate	2.97%	1.92 - 2.12%
Expected dividend rate	0	0
Expected volatility	77.60%	68.7 - 80.4%
Preferred stock conversion limit - percentage of outstanding common stock	19.90%	19.90%
Preferred conversion floor price	$ 1.00	$ 1.00

See Notes 1, 5, and 8 for additional discussion regarding the accounting for and valuation of these derivative financial instruments.

As discussed in Note 1, in consideration of the Company entering into the License Agreement in October 2018, Intrexon has agreed to forfeit and return to the Company all shares of the Company’s Series 1 Preferred Stock held by or payable to Intrexon as of the date of the License Agreement. There are no other shares of Series 1 Preferred Stock outstanding as of the date of this Quarterly Report.

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

Forward Looking Statements

This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements relate to our future plans, objectives, expectations and intentions and may be identified by words such as "may," "will," "should," "expects," "plans," "anticipates," "intends," "targets," "projects," "contemplates," "believes," "seeks," "goals," "estimates," "predicts," "potential" and "continue" or similar words. In particular, statements contained in this Quarterly Report, including but not limited to, statements regarding the costs and timing of our clinical trials and of the development and commercialization of our pipeline products and services; the sufficiency of our cash, investments and cash flows from operations and our expected uses of cash; our ability to finance our operations and business initiatives and obtain funding for such activities; our future results of operations and financial position, business strategy and plan prospects, projected revenue or costs and objectives of management for future research, development or operations, are forward-looking statements. Readers are cautioned that these forward-looking statements are only predictions and are subject to risks, uncertainties, and assumptions that are difficult to predict, including those discussed in Part II, Item 1A. "Risk Factors" section of this Quarterly Report. Therefore, actual results may differ materially and adversely from those expressed in any forward-looking statements. Except as required by law, we undertake no obligation to revise or update any forward-looking statements after the date of such statements.

Overview

We are a biopharmaceutical company focused on discovering, acquiring, developing and commercializing next generation immunotherapy platforms that leverage gene- and cell-based therapies to treat patients with cancer. We are developing two immuno-oncology platform technologies designed to utilize the patient's immune system by employing novel, controlled gene expression and innovative cell engineering technologies to deliver safe, effective, and scalable cell- and viral-based therapies for the treatment of multiple cancer types. Our first platform is Controlled IL-12, which is designed to deliver interleukin 12 or IL-12, a master regulator of the immune system, in a controlled and safe manner to focus the patient's immune system to cancer. Our second platform is referred to as *Sleeping Beauty* and is based on the genetic engineering of immune cells using the *Sleeping Beauty* system to rapidly reprogram T cells outside of the body for subsequent infusion. We believe these two platforms provide or will provide unique and powerful solutions intended to advance the field of immuno-oncology and address the issues associated with (1) treating heterogenous solid tumors and unknown antigens therein through control of IL-12 and (2) providing rapid and cost-effective manufacturing solutions for CAR and TCR-based cell therapies for hematologic malignancies and solid tumors against known antigens.

We are developing a gene therapy that delivers Controlled IL-12 to treat patients with solid tumors including brain and breast cancers. Based on technology licensed from MD Anderson Cancer Center, we are developing CAR T-cell or CAR+ T targeting CD19, and T-cell receptor T-cell, or TCR+ T, therapies. These programs are being advanced in collaboration with MD Anderson and the National Cancer Institute, or NCI.

As of September 30, 2018, we had cash and cash equivalents of approximately $31.7 million. We expect that our existing cash and cash equivalents will be sufficient to fund our current operations into the second quarter of 2019, and we have no committed sources of additional capital at this time. The forecast of cash resources is forward-looking information that involves risks and uncertainties, and the actual amount of our expenses could vary materially and adversely as a result of a number of factors.

We have not generated significant revenue and have incurred significant net losses in each year since our inception. For the nine months ended September 30, 2018, we had a net loss of $40.6 million, and, as of September 30, 2018, we have incurred approximately $761.2 million of accumulated deficit since our inception in 2003. We expect to continue to incur significant operating expenditures and net losses. Further development of our product candidates will likely require substantial increases in our expenses as we:

- continue to undertake clinical trials for product candidates;
- seek regulatory approvals for product candidates;
- work with regulatory authorities to identify and address program-related inquiries;
- implement additional internal systems and infrastructure;
- hire additional personnel; and
- scale-up the formulation and manufacturing of our product candidates.

We continue to seek additional financial resources to fund the further development of our product candidates. If we are unable to obtain sufficient additional capital, one or more of these programs could be delayed, and we may be unable to continue our operations at planned levels and be forced to reduce our operations. Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability.

Recent Developments

New Definitive License Agreement with Precigen, Inc.

We entered into an exclusive license agreement, or the License Agreement, with Precigen, Inc., or Precigen, a wholly-owned subsidiary of Intrexon Corporation, or Intrexon, on October 5, 2018. The terms of the License Agreement replace all existing agreements between us and Precigen, and will provide us with certain exclusive and non-exclusive rights to technology controlled by Precigen. Pursuant to the terms of the License Agreement, Precigen has granted us an exclusive, worldwide, royalty-bearing, sub-licensable license to research, develop and commercialize (i) products utilizing Precigen's RheoSwitch® gene switch for the treatment of cancer, (ii) chimeric antigen receptor, or CAR, products directed to (A) CD19 for the treatment of cancer, referred to as CD19 Products, and (B) a second target, subject to the rights of Merck to pursue such target under the Ares Trading Agreement, and (iii) TCR products designed for neoantigens for the treatment of cancer. Precigen has also granted us an exclusive, worldwide, royalty-bearing, sub-licensable license for certain patents relating to the *Sleeping Beauty* technology to research, develop and commercialize TCR products for both neoantigens and shared antigens for the treatment of cancer.

In consideration of the Company entering into the License Agreement, Intrexon has forfeited and returned to the Company all shares of the Company's Series 1 Preferred Stock held by or payable to Intrexon as of the date of the License Agreement.

Changes to Board of Directors and Management

Scott Tarriff, a member of our board of directors since 2015, was elected to serve as Lead Director of our board of directors, succeeding Sir Murray Brennan, M.D. Sir Dr. Brennan and former U.S. Senator William Wyche Fowler stepped down from our board of directors when their terms expired at our 2018 annual meeting of stockholders. Douglas Pagán, the Chief Financial Officer of Paratek Pharmaceuticals, Inc., Elan Ezickson, the chief operating officer and head of corporate development at Scholar Rock Holding Corporation, and Scott Braunstein, M.D., an operating partner at Aisling Capital, were elected to our board at our 2018 annual meeting of stockholders. Randal J. Kirk resigned from the board, effective October 5, 2018. Dr. Laurence Cooper, our Chief Executive Officer, was appointed to our board, effective October 16, 2018.

On October 16, 2018, we announced that Laurence Cooper, M.D., Ph.D., our Chief Executive Officer, was appointed to our board and that Francois Lebel, M.D., was stepping down as our Executive Vice President, Research and Development and Chief Medical Officer, effective October 26, 2018.

Clinical Developments

- On November 5, 2018, we announced that a poster with updated survival data for a group of 15 patients who received Ad-RTS-hIL-12 during surgical resection and the 20mg dose of veledimex would be presented at the Annual Meeting and Education Day of the Society for Neuro-Oncology (SNO). Additional data to be presented includes the group of patients who received stereotactic administration of Ad-RTS-hIL-12 and further analysis of the effect of dexamethasone, as data suggests that a lower versus higher dose of steroids improves overall survival.
- Enrollment continues in the Phase 1 expansion clinical trial of our monotherapy trial in patients with recurrent glioblastoma, or rGBM, who have not received bevacizumab for their disease and are not receiving steroids for the four weeks prior to therapy initiation.
- Enrollment continues in our Phase 1 clinical trial to evaluate Ad-RTS-hIL-12 + veledimex in combination with OPDIVO® (nivolumab). The Data and Safety Monitoring Board for the clinical trial has authorized escalation to the second dosing cohort for this clinical trial.
- Under our Collaboration and Research and Development Agreement, the NCI is planning a Phase 1 clinical trial of *Sleeping Beauty*-modified TCRs to treat solid tumors, with enrollment expected to begin in mid-2019. NCI is developing autologous peripheral blood lymphocytes genetically modified with the *Sleeping Beauty* system to express TCRs that recognize specific immunogenic mutations, or neoantigens, expressed within a patient's solid tumor. The submission of the Investigational New Drug, or IND, application to the U.S. Food and Drug Administration, or the FDA, targeted for 2018, is subject to NCI's timeline.
- On October 9, 2018, we announced that we expect to respond to the request for more information by the FDA in the second half of 2019 for our third-generation Phase 1 trial to evaluate CD19-specific CAR-T therapies under our technology referred to as point-of-care. The FDA has placed a clinical hold on the IND for this trial.
- Enrollment continues in the Phase 1 investigator-led trial at MD Anderson to infuse CD19-specific CAR-T cells based on genetic modification with the *Sleeping Beauty* system for patients with B-cell leukemias and lymphomas. This second-generation trial explores T-cell dosing and time to manufacture.

Financial Overview

Overview of Results of Operations

Three and Nine Months Ended September 30, 2018 Compared to Three and Nine Months Ended September 30, 2017

Revenue. Revenue during the three and nine months ended September 30, 2018 and 2017 was as follows:

	Three months ended September 30,				Nine months ended September 30,			
($ in thousands)	2018	2017	Change		2018	2017	Change	
Collaboration revenue	$ —	$ 1,598	$(1,598)	-100%	$ 146	$ 4,792	$(4,646)	-97%

Revenue for the three and nine months ended September 30, 2018 decreased, compared to revenue for the three and nine months ended September 30, 2017 due to the adoption of ASC 606 (Note 5, Revenue Recognition). During the three months ended September 30, 2018, we did not recognize any revenue related to the Ares Trading Agreement. During the nine months ended September 30, 2018, we recognized $146 thousand of revenue related to the Ares Trading Agreement. As of September 30, 2018, the remaining balance of contract liability associated with the upfront payment is $49.5 million, of which the full amount is classified as current. We have classified the remaining contract liability of $49.5 million as current at September 30, 2018 as all remaining performance obligations are expected to be met in the fourth quarter of 2018, as a result of our License Agreement signed with Precigen subsequent to the balance sheet date (see Note 1, Business). During the three months ended September 30, 2017, the Company recognized $1.6 million of revenue related to the Ares Trading Agreement. During the nine months ended September 30, 2017, we recognized $4.8 million of revenue related to the Ares Trading Agreement. As of December 31, 2017, the remaining balance of contract liability (formerly deferred revenue) associated with the upfront payment was $41.5 million, of which $6.4 million is current and $35.1 million is classified as long-term.

Research and development expenses. Research and development expenses during the three and nine months ended September 30, 2018 and 2017 were as follows:

	Three months ended September 30,				Nine months ended September 30,			
($ in thousands)	2018	2017	Change		2018	2017	Change	
Research and development	$8,263	$ 11,105	$(2,842)	-26%	$25,935	$33,903	$(7,968)	-24%

Research and development expenses for the three months ended September 30, 2018 decreased by $2.8 million, as compared to the three months ended September 30, 2017. The decrease in research and development expenses for the three months ended September 30, 2018 is primarily due to decreases of $2.8 million in preclinical cell therapy programs and $0.3 million in GvHD related expenses as we have reverted the rights under the GvHD Agreement back to Precigen. These decreases related to cell therapy and GvHD costs were offset by increases of $0.1 million related our ongoing gene therapy programs and $0.2 million related to stock compensation, salary and employee related expenses, and contracted outside service costs during the three months ended September 30, 2018.

Research and development expenses for the nine months ended September 30, 2018 decreased by $7.9 million, as compared to the nine months ended September 30, 2017. The decrease in research and development expenses for the nine months ended September 30, 2018 is primarily due to decreases of $6.8 million in cell therapy program, $1.5 million in GvHD related expenses, and $0.2 million in gene therapy program spending. These decreases related to program costs were offset by an increase of $0.6 million related to stock compensation, salary and employee related expenses, and contracted outside service costs during the nine months ended September 30, 2018.

Our research and development expense consists primarily of salaries and related expenses for personnel, costs of contract manufacturing services, costs of facilities and equipment, fees paid to professional service providers in conjunction with our clinical trials, fees paid to contract research organizations in conjunction with preclinical animal studies, costs of materials used in research and development, consulting, license and milestone payments and sponsored research fees paid to third parties.

We have not accumulated and tracked our internal historical research and development costs or our personnel and personnel-related costs on a program-by-program basis. Our employee and infrastructure resources are allocated across several projects, and many of our costs are directed to broadly applicable research endeavors. As a result, we cannot state the costs incurred for each of our oncology programs on a program-by-program basis.

For the three months ended September 30, 2018, our clinical stage projects included a Phase 1 trial with Ad-RTS-IL-12 + veledimex in progressive glioblastoma; a Phase 1b/2 trial with Ad-RTS-IL-12 + veledimex in metastatic breast cancer; an investigator-led Phase 1 trial infusing our 2nd generation CD19-specific CAR+ T cells in patients with advanced lymphoid malignancies; an investigator-led Phase 1 trial infusing our CD33-specific CAR+ T therapy for relapsed or refractory acute myeloid leukemia; and a Phase 1 trial of Ad-RTS-hIL-12 with veledimex for the treatment of pediatric brain tumors. The expenses incurred by us to third parties for our Phase 1 trial with Ad-RTS-IL-12 + veledimex in progressive glioblastoma were $0.6 million for the three months ended September 30, 2018, and $5.7 million from the project's inception in June 2015 through September 30, 2018. There were no expenses incurred by us to third parties for our Phase 1b/2 trial with Ad-RTS-IL-12 + veledimex in metastatic breast cancer for the three months ended September 30, 2018, and expenses from the project's inception in April 2015 through September 30, 2018 were $0.8 million. The expenses incurred by us to third parties for our investigator-led Phase 1 trial infusing our 2nd generation CD19-specific CAR+ T cells in patients with advanced lymphoid malignancies were $0.3 million for the three months ended September 30, 2018 and $4.3 million from the project's inception in December 2015 through September 30, 2018. The expenses incurred by us to third parties for our investigator-led Phase 1 trial infusing our CD33-specific CAR+ T therapy for relapsed or refractory acute myeloid leukemia were $0.6 million for the three months ended September 30, 2018 and $3.6 million from the project's inception in September 2017 through September 30, 2018. The expenses incurred by us to third parties for our investigator-led Phase 1 trial of Ad-RTS-hIL-12 with veledimex for the treatment of pediatric brain tumors were $0.1 million for the three months ended September 30, 2018 and $1.6 million from the projects inception in October 2017 through September 30, 2018.

Our future research and development expenses in support of our current and future programs will be subject to numerous uncertainties in timing and cost to completion. We test potential products in numerous preclinical studies for safety, toxicology and efficacy. We may conduct multiple clinical trials for each product. As we obtain results from trials, we may elect to discontinue or delay clinical trials for certain products to focus our resources on more promising products or indications. Completion of clinical trials may take several years or more, and the length of time generally varies substantially according to the type, complexity, novelty and intended use of a product. It is not unusual for preclinical and clinical development of each of these types of products to require the expenditure of substantial resources.

We estimate that clinical trials of the type generally needed to secure new drug approval are typically completed over the following timelines:

Clinical Phase	Estimated Completion Period
Phase 1	1 - 2 years
Phase 2	2 - 3 years
Phase 3	2 - 4 years

The duration and the cost of clinical trials may vary significantly over the life of a project as a result of differences arising during clinical development, including, among others, the following:

- The number of clinical sites included in the trials;
- The length of time required to enroll suitable patents;
- The number of patients that ultimately participate in the trials;
- The duration of patient follow-up to ensure the absence of long-term product-related adverse events; and
- The efficacy and safety profile of the product.

As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our programs or when and to what extent we will receive cash inflows from the commercialization and sale of a product. Our inability to complete our programs in a timely manner or our failure to enter into appropriate collaborative agreements could significantly increase our capital requirements and could adversely impact our liquidity. These uncertainties could force us to seek additional, external sources of financing from time-to-time in order to continue with our product development strategy. Our inability to raise additional capital, or to do so on terms reasonably acceptable to us, would jeopardize the future success of our business.

General and administrative expenses. General and administrative expenses during the three and nine months ended September 30, 2018 and 2017 were as follows:

	Three months ended September 30,				Nine months ended September 30,			
	2018	2017	Change		2018	2017	Change	
($ in thousands)								
General and administrative	$ 4,307	$ 3,571	$736	21%	$15,355	$10,946	$4,409	40%

General and administrative expenses for the three months ended September 30, 2018 increased by $0.7 million, as compared to the three months ended September 30, 2017. The increase for the three months ended September 30, 2018 was primarily due to an increase of $0.7 million in contracted outside service expenses.

General and administrative expenses for the nine months ended September 30, 2018 increased by $4.4 million, as compared to the nine months ended September 30, 2017. The increase for the nine months ended September 30, 2018 was primarily due to an increase of $1.6 million in stock compensation and employee related expenses incurred in the nine months ended September 30, 2018 relating to stock option modifications for a departing officer and director. Additionally, contracted outside service expenses and other operating expense costs increased by $2.8 million in comparison to the nine months ended September 30, 2017.

Other income (expense). Other income (expense) for the three and nine months ended September 30, 2018 and 2017 were as follows:

	Three months ended September 30,				Nine months ended September 30,			
	2018	2017	Change		2018	2017	Change	
($ in thousands)								
Other income (expense), net	$ 150	$ 175	$ (25)	(14%)	$ 462	$ 299	$ 163	55%
Change in derivative value	(165)	202	(367)	(182%)	46	(1,292)	1,338	(104%)
Total	$ (15)	$ 377			$ 508	$ (993)		

The increase in other expense for the three months ended September 30, 2018, compared to the three months ended September 30, 2017, was due primarily to the recording a gain on the change of the derivative liabilities in the amount of $165 thousand for the three months ended September 30, 2018.

The decrease in other expense for the nine months ended September 30, 2018, compared to the nine months ended September 30, 2017, was due primarily to the recording a loss on the change of the derivative liabilities in the amount of $46 thousand for the nine months ended September 30, 2018.

Liquidity and Capital Resources

As of September 30, 2018, we have approximately $31.7 million of cash and cash equivalents. Given our development plans, we anticipate our cash resources will be sufficient to fund our operations into the second quarter of 2019 and we currently have no committed sources of additional capital. The forecast of cash resources is forward-looking information that involves risks and uncertainties, and the actual amount of our expenses could vary materially and adversely as a result of a number of factors. We have based our estimates on assumptions that may prove to be wrong, and our expenses could prove to be significantly higher than we currently anticipate. Management does not know whether additional financing will be on terms favorable or acceptable to us when needed, if at all. If adequate additional funds are not available when required, or if we are unsuccessful in entering into partnership agreements for further development of our products, management may need to curtail development efforts. Based on the forecast, management determined that there is substantial doubt regarding our ability to continue as a going concern. As a result, our independent registered accounting firm has expressed substantial doubt as to our ability to continue as a going concern in their report dated March 1, 2018 included in our Annual Report on the Form 10-K for the fiscal year ended December 31, 2017.

Although all human clinical trials are expensive and difficult to design and implement, we believe that due to complexity, costs associated with clinical trials for synthetic biology immuno-oncology are greater than the corresponding costs associated with clinical trials for small-molecule candidates.

In addition to these factors, our actual cash requirements may vary materially from our current expectations for a number of other factors that may include, but are not limited to, changes in the focus and direction of our development programs, competitive and technical advances, costs associated with the development of our product candidates, our ability to secure partnering arrangements, and the costs of filing, prosecuting, defending and enforcing our intellectual property rights. If we exhaust our capital reserves more quickly than anticipated, regardless of the reason, and we are unable to obtain additional financing on terms acceptable to us or at all, we will be unable to proceed with development of some or all of our product candidates on expected timelines and will be forced to prioritize among them.

We will need to raise substantial additional financing in the near term to support our long-term plans for clinical trials and new product development. Management is currently evaluating different strategies to obtain the required funding for future operations, and these strategies include, but are not limited to, financing our cash needs through the sale of equity and/or debt securities, partnering or other strategic collaborations with other entities for the development of its product candidates and/or debt financings, or through other sources that may be dilutive to existing stockholders. There can be no assurance that we will be able to obtain funding from any of these sources or, if obtained, what the terms of such funding(s) may be, or that any amount that we are able to obtain will be adequate to support our working capital requirements until we achieve profitable operations. We have no current committed sources of additional capital. Recently, capital markets have experienced a period of instability that may severely hinder our ability to raise capital within the time periods needed or on terms we consider acceptable, if at all. If we are unable to raise additional funding when needed, we may not be able to continue development and regulatory approval of our product candidates, or we could be required to delay, scale back or eliminate some or all our research and development programs.

The following table summarizes our net decrease in cash, cash equivalents, and restricted cash for the nine months ended September 30, 2018 and 2017:

($ in thousands)	Nine months ended September 30, 2018	2017
Net cash provided by (used in):		
Operating activities	$(37,638)	$(42,513)
Investing activities	(545)	(461)
Financing activities	(1,035)	46,327
Net increase (decrease) in cash, cash equivalents, and restricted cash	$(39,218)	$ 3,353

Cash flows from operating activities represent the cash receipts and disbursements related to all of our activities other than investing and financing activities. Operating cash flow is derived by adjusting our net loss for:

- Non-cash operating items such as depreciation and amortization, stock-based compensation and common and preferred stock issuances in exchange for license agreements;
- Changes in operating assets and liabilities, which reflect timing differences between the receipt and payment of cash associated with transactions and when they are recognized in results of operations; and
- Changes associated with the fair value of our derivative liabilities.

Net cash used in operating activities for the nine months ended September 30, 2018 was $37.6 million, as compared to net cash used in operating activities of $42.5 million for the nine months ended September 30, 2017. The net cash used in operating activities for the nine months ended September 30, 2018 was primarily due to our net loss of $40.6 million, offset by the change in prepaid and other expenses of $0.7 million, and change in accrued expenses and other liabilities of $3.8 million. The net cash used in operating activities for the nine months ended September 30, 2017 was primarily due to our net loss of $41.1 million, offset by the change in prepaid and other expenses of $6.7 million and change in accrued expenses and other liabilities of $2.5 million.

Net cash used in investing activities was $536 thousand for the nine months ended September 30, 2018 compared to $461 thousand for the nine months ended September 30, 2017. The change was due to an increase in expenses related to the purchase of offsite equipment to support our preclinical trials and CAR programs at MD Anderson.

Net cash used in financing activities was $1.1 million for the nine months ended September 30, 2018 compared to $46.3 million provided by financing activities for the nine months ended September 30, 2017. The $47.3 million decrease in cash provided by financing activities is primarily attributable our May 2017 underwritten offering of common stock.

Operating capital and capital expenditure requirements

We anticipate that losses will continue for the foreseeable future. At September 30, 2018, our accumulated deficit was approximately $761.2 million. Our actual cash requirements may vary materially from those planned because of a number of factors, including:

- Changes in the focus, direction and pace of our development programs;
- Competitive and technical advances;
- Costs associated with the development of our product candidates;
- Our ability to secure partnering arrangements;
- Costs of filing, prosecuting, defending and enforcing any patent claims and any other intellectual property rights, or other developments, and
- Other matters identified under Part II, Item 1A. “Risk Factors.”

Working capital as of September 30, 2018 was ($13.0) million, consisting of $47.2 million in current assets and $60.2 million in current liabilities. Working capital as of December 31, 2017 was $69.9 million, consisting of $90.8 million in current assets and $20.9 million in current liabilities.

Contractual obligations

The following table summarizes our outstanding obligations as of September 30, 2018 and the effect those obligations are expected to have on our liquidity and cash flows in future periods:

($ in thousands)	Total	Less than 1 year	2 - 3 years	4 - 5 years	More than 5 years
Operating leases	$ 2,169	$ 761	$ 1,408	$ —	$ —
Other	10,225	8,500	625	—	—
Total	$12,394	$10,361	$ 2,033	$ —	$ —

Our commitments for operating leases relate to the lease for our corporate headquarters in Boston, Massachusetts, and office space in New York, New York and Houston, Texas. On December 21, 2015 and April 15, 2016, we renewed the sublease for our corporate headquarters in Boston, MA through August 31, 2021. Included in the above table are obligations for the subleased portion of our New York and Houston office space (see Note 6). We expect to receive a total of $28 thousand in the next year from our subtenants in the New York office, which is not reflected in the schedule above.

On January 10, 2017, we announced the signing of a CRADA with the NCI for the development of ACT-based immunotherapies genetically modified using the SB transposon/transposase system for the treatment of solid tumors. Our obligation for the CRADA is reflected above with $2.5 million in the column “Less than 1 Year” and $625 thousand in the column “2 – 3 Years.” Additionally, we have approximately $6.0 million due in advisory fees relected above in the column “Less than 1 Year”.

Off-balance sheet arrangements

During the nine months ended September 30, 2018 and 2017, we did not engage in any off-balance sheet arrangements.

Critical Accounting Policies and Estimates

In our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, our most critical accounting policies and estimates upon which our financial status depends were identified as those relating to clinical trial expenses; collaboration agreements; fair value measurements for stock-based compensation; and income taxes. We reviewed our policies and determined that those policies remain our most critical accounting policies for the nine months ended September 30, 2018. See Note 5, Summary of Significant Accounting Policies, for a discussion of our adoption of ASC 606 relating to revenue recognition.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Our exposure to market risk is limited to our cash. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash. We also seek to maximize income from our investments without assuming significant risk. To achieve our goals, we maintain our cash in interest-bearing bank accounts in global banks, United States treasuries and other government-backed investments, which are subject to minimal interest rate risk.

Effect of Currency Exchange Rates and Exchange Rate Risk Management

We customarily conduct clinical studies outside of the United States, primarily in Western Europe. These business operations are not material at this time, therefore any currency fluctuations will not have a material impact on our financial position, results of operations or cash flows.

Item 4. Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of the end of the period covered by this report. Based on such evaluation, our principal executive officer and principal financial officer have concluded that, as of the end of such period, our disclosure controls and procedures were effective in ensuring 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, on a timely basis, and is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. We implemented internal controls to ensure we adequately evaluated our contracts and account for revenue recognition under the new accounting standard. There were no significant changes to our internal control over financial reporting due to the adoption of the new standard.

Part II - Other Information

Item 1. Legal Proceedings

In the ordinary course of business, we may periodically become subject to legal proceedings and claims arising in connection with ongoing business activities from time to time. The results of litigation and claims cannot be predicted with certainty, and unfavorable resolutions are possible and could materially affect our results of operations, cash flows or financial position. In addition, regardless of the outcome, litigation could have an adverse impact on us because of defense costs, diversion of management attention and resources and other factors.

As of September 30, 2018, based on information readily available, there are no matters that, in the opinion of management, are likely to result in a material adverse effect on our financial position, results of operations or cash flows.

Item 1A. Risk Factors

The following important factors could cause our actual business and financial results to differ materially from those contained in forward-looking statements made in this Quarterly Report on Form 10-Q or elsewhere by management from time to time. The risk factors in this Quarterly Report have been revised to incorporate changes to our risk factors from those included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017. The risk factors set forth below with an asterisk (*) next to the title are new risk factors or risk factors containing changes, which may be material, from the risk factors previously disclosed in Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, as filed with the Securities and Exchange Commission.

RISKS RELATED TO OUR BUSINESS

We will require substantial additional financial resources in order to continue ongoing development of our product candidates and pursue our business objectives; if we are unable to obtain these additional resources when needed, we may be forced to delay or discontinue our planned operations, including clinical testing of our product candidates.

We have not generated significant revenue and have incurred significant net losses in each year since our inception. For the nine months ended September 30, 2018, we had a net loss of $40.6 million, and, as of September 30, 2018, we have incurred approximately $761.2 million of accumulated deficit since our inception in 2003. We expect to continue to incur significant operating expenditures and net losses. Further development of our product candidates will likely require substantial increases in our expenses as we:

- continue to undertake clinical trials for product candidates;
- scale-up the formulation and manufacturing of our product candidates;
- seek regulatory approvals for product candidates;
- work with regulatory authorities to identify and address program-related inquiries;
- implement additional internal systems and infrastructure;
- hire additional personnel;
- begin to advance candidates pursuant to the MD Anderson License; and
- commence providing funding for certain research and development activities of MD Anderson pursuant to the terms of the MD Anderson License.

We continue to seek additional financial resources to fund the further development of our product candidates. If we are unable to obtain sufficient additional capital, one or more of these programs could be placed on hold. Because we are currently devoting a significant portion of our resources to the development of immuno-oncology, further progress with the development of our other candidates may be significantly delayed and may depend on the licensing of those compounds to third parties.

As of September 30, 2018, we have approximately $31.7 million of cash and cash equivalents. Given our current development plans, we anticipate cash resources will be sufficient to fund our operations into the second quarter of 2019, and we have no committed sources of additional capital at this time. The forecast of cash resources is forward-looking information that involves risks and uncertainties, and the actual amount of our expenses could vary materially and adversely as a result of a number of factors. We have based our estimates on assumptions that may prove to be wrong, and our expenses could prove to be significantly higher than we currently anticipate. Management does not know whether additional financing will be on terms favorable or acceptable to us when needed, if at all. If adequate additional funds are not available when required, or if we are unsuccessful in entering into partnership agreements for further development of our product candidates, management may need to curtail its development efforts and planned operations. Based on the forecast, management determined that there is substantial doubt regarding our ability to continue as a going concern. As a result, our independent registered public accounting firm has expressed substantial doubt as to our ability to continue as a going concern in their report dated March 1, 2018 included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017.

We need to raise additional capital to fund our operations. The manner in which we raise any additional funds may affect the value of your investment in our common stock.

Until such time, if ever, as we can generate substantial revenue, we may finance our cash needs through a combination of equity offerings, debt financings and license and collaboration agreements. As of September 30, 2018, we have incurred approximately $761.2 million of accumulated deficit and had approximately $31.7 million of cash and cash equivalents. Given our current development plans, we anticipate that our current cash resources will be sufficient to fund our operations into the second quarter of 2019. However, changes may occur that would consume our existing capital prior to then, including expansion of the scope of, and/or slower than expected progress of, our research and development efforts and changes in governmental regulation. Actual costs may ultimately vary from our current expectations, which could materially impact our use of capital and our forecast of the period of time through which our financial resources will be adequate to support our operations. Also our estimates include the advancement of our immuno-oncology product candidates in the clinic under our License Agreement with Precigen and our increased expenses as we begin to advance candidates pursuant to the MD Anderson License with MD Anderson and commence providing funding for certain research and development activities of MD Anderson pursuant to the terms of the MD Anderson License. We expect that the costs associated with these and any additional product candidates we pursue will increase the level of our overall research and development expenses significantly going forward.

In addition to above factors, our actual cash requirements may vary materially from our current expectations for a number of other factors that may include, but are not limited to, changes in the focus and direction of our development programs, competitive and technical advances, costs associated with the development of our product candidates, our ability to secure partnering arrangements, and costs of filing, prosecuting, defending and enforcing our intellectual property rights. If we exhaust our capital reserves more quickly than anticipated, regardless of the reason, and we are unable to obtain additional financing on terms acceptable to us or at all, we will be unable to proceed with development of some or all of our product candidates on expected timelines and will be forced to prioritize among them.

The unpredictability of the capital markets may severely hinder our ability to raise capital within the time periods needed or on terms we consider acceptable, if at all. Moreover, if we fail to advance one or more of our current product candidates to later-stage clinical trials, successfully commercialize one or more of our product candidates, or acquire new product candidates for development, we may have difficulty attracting investors that might otherwise be a source of additional financing.

Our need for additional capital and limited capital resources may force us to accept financing terms that could be significantly dilutive to existing stockholders. To the extent that we raise additional capital by issuing equity securities, our stockholders may experience dilution. In addition, we may grant future investors rights superior to those of our existing stockholders. If we raise additional funds through collaborations and licensing arrangements, it may be necessary to relinquish some rights to our technologies, product candidates or products, or grant licenses on terms that are not favorable to us. If we raise additional funds by incurring debt, we could incur significant interest expense and become subject to covenants in the related transaction documentation that could affect the manner in which we conduct our business.

Our plans to develop and commercialize non-viral and viral adoptive cellular therapies based on engineered cytokines and CAR T-cell or NK cell therapies as well as TCR therapies can be considered as new approaches to cancer treatment, the successful development of which is subject to significant challenges.

We intend to employ technologies such as the technology licensed from MD Anderson pursuant to the MD Anderson License described above, and from Precigen, pursuant to the License Agreement, to pursue the development and commercialization of non-viral and viral adoptive cellular therapies based on cytokines, T-cells, NK cells, CARs and TCRs, possibly under control of the RTS® and other switch technologies targeting both hematologic and solid tumor malignancies. Because this is a new approach to cancer immunotherapy and cancer treatment generally, developing and commercializing product candidates subjects us to a number of challenges, including:

- obtaining regulatory approval from the FDA and other regulatory authorities that have very limited experience with the commercial development of genetically modified and/or unmodified T-cell and NK-cell therapies for cancer;
- developing and deploying consistent and reliable processes for engineering a patient's and/or donor's T-cells or NK cells *ex vivo* and infusing the T-cells or NK cells back into the patient;
- possibly conditioning patients with chemotherapy in conjunction with delivering each of the potential products, which may increase the risk of adverse side effects of the potential products;
- educating medical personnel regarding the potential side effect profile of each of the potential products, such as the potential adverse side effects related to cytokine release;
- addressing any competing technological and market developments;
- developing processes for the safe administration of these potential products, including long-term follow-up for all patients who receive the potential products;
- sourcing additional clinical and, if approved, commercial supplies for the materials used to manufacture and process the potential products;
- developing a manufacturing process and distribution network with a cost of goods that allows for an attractive return on investment;
- establishing sales and marketing capabilities after obtaining any regulatory approval to gain market acceptance;
- developing therapies for types of cancers beyond those addressed by the current potential products;
- maintaining and defending the intellectual property rights relating to any products we develop;
- and not infringing the intellectual property rights, in particular, the patent rights, of third parties, including competitors, such as those developing T-cell and/or NK-cell therapies.

We cannot be sure that immunotherapy technologies that we intend to develop in partnership with MD Anderson will yield satisfactory products that are safe and effective, scalable, or profitable. Moreover, public perception of therapy safety issues, including adoption of new therapeutics or novel approaches to treatment, may adversely influence the willingness of subjects to participate in clinical trials, or if approved, of physicians to subscribe to the novel treatment mechanics. Physicians, hospitals and third-party payors often are slow to adopt new products, technologies and treatment practices that require additional upfront costs and training. Physicians may not be willing to undergo training to adopt this novel and personalized therapy, may decide the therapy is too complex to adopt without appropriate training and may choose not to administer the therapy. Based on these and other factors, hospitals and payors may decide that the benefits of this new therapy do not or will not outweigh its costs.

We cannot assure you that we will be able to successfully address these challenges, which could prevent us from achieving our research, development and commercialization goals.

Our current product candidates are based on novel technologies and are supported by limited clinical data and we cannot assure you that our current and planned clinical trials will produce data that supports regulatory approval of one or more of these product candidates.

Our License Agreement with Precigen describes the terms of our use of Precigen's Controlled IL-12 platform technology. The immuno-oncology effector platform in which we have acquired rights represents early-stage technology in the field of human oncology biotherapeutics, with Ad-RTS-IL-12 + veledimex having completed trials, in melanoma and breast cancer. We are continuing to pursue intratumoral injection of Ad-RTS-IL-12 + veledimex in brain cancer.

Similarly, our genetically modified and/or non-modified T-cell and/or NK cell product candidates are supported by limited clinical data, all of which has been generated through trials conducted by MD Anderson, not by us. We plan to assume control of the overall clinical and regulatory development of our T-cell and NK-cell product candidates, and any failure to obtain, or delays in obtaining, sponsorship of new INDs, or in filing INDs sponsored by us for these or any other product candidates we determine to advance could negatively affect the timing of our potential future clinical trials. Such an impact on timing could increase research and development costs and could delay or prevent obtaining regulatory approval for our product candidates, either of which could have a material adverse effect on our business. Further, we did not control the design or conduct of the previous trials. It is possible that the FDA will not accept these previous trials as providing adequate support for future clinical trials, whether controlled by us or third parties, for any of one or more reasons, including the safety, purity, and potency of the product candidate, the degree of product characterization, elements of the design or execution of the previous trials or safety concerns, or other trial results. We may also be subject to liabilities arising from any treatment-related injuries or adverse effects in patients enrolled in these previous trials. As a result, we may be subject to unforeseen third-party claims and delays in our potential future clinical trials. We may also be required to repeat in whole or in part clinical trials previously conducted by MD Anderson or other entities, which will be expensive and delay the submission and licensure or other regulatory approvals with respect to any of our product candidates.

In addition, the results of the limited clinical trials conducted to date may not be replicated in future clinical trials. Our Ad-RTS-IL-12 + veledimex and genetically modified and non-modified T-cell and NK-cell product candidates, as well as other product candidates, may fail to show the desired safety and efficacy in clinical development, and we cannot assure you that the results of any future trials will demonstrate the value and efficacy of our product candidates. Moreover, there are a number of regulatory requirements that we must satisfy before we can continue clinical trials of CAR^+ T or other cellular therapy product candidates in the United States. Satisfaction of these requirements will entail substantial time, effort and financial resources. Any time, effort and financial resources we expend on our Ad-RTS-IL-12 + veledimex and genetically modified and non-modified T-cell and NK-cell product candidates and other early-stage product candidate development programs may adversely affect our ability to continue development and commercialization of our immuno-oncology product candidates.

We report interim data on certain of our clinical trials and we cannot assure you that interim data will be predictive of either future interim results or final study results.

As part of our business, we provide updates related to the development of our product candidates, which may include updates related to interim clinical trial data. To date, our clinical trials have involved small patient populations and because of the small sample size, the interim results of these clinical trials may be subject to substantial variability and may not be indicative of either future interim results or final results.

If we cannot compete successfully for market share against other biopharmaceutical companies, we may not achieve sufficient product revenues and our business will suffer.

The biopharmaceutical industry, and the rapidly evolving market for developing genetically engineered T-cells and NK cells in particular, is characterized by intense competition and rapid innovation. Genetically engineering T-cells and NK cells face significant competition in the CAR and TCR technology space from multiple companies and their collaborators. Two such companies have now commercialized autologous CAR+ T-cells against CD19: Novartis and Kite Pharma/Gilead. Additional companies developing autologous CAR+ T targets include Juno Therapeutics/Celgene, bluebird bio, in collaboration with Celgene, Nanjing Legend Biotech and Janssen Biotech, Inc., a subsidiary of Johnson & Johnson, Kite Pharma/Gilead, Bellicum Pharmaceuticals, Juno Therapeutics, Autolus Limited, CARsgen, Mustang Bio and Aurora BioPharma. Cellectis and Allogene Therapeutics are pursuing the development of allogeneic CAR+ T therapies which may compete with our product candidates. In the TCR arena, we face competition from companies targeting shared antigens including Adaptimmune in collaboration with GlaxoSmithKline, Kite Pharma/Gilead, Tmunity and others. Additional competitors are pursuing a vaccine platform to target neoantigens for solid tumors. This includes Advaxis/Amgen, BioNTech, Neon Therapeutics and Gritstone Oncology. Neon has also announced that they are developing a T-cell therapy against neoantigens using a technology which may compete with our product candidates. Other companies are developing non-viral gene therapies including Poseida Therapeutics. We also face competition from non-cell based treatments offered by other companies such as Amgen, AstraZeneca, Bristol-Myers, Incyte, Merck, and Roche.

Several competitors are developing technology which enhances the immune response within the tumor microenvironment, thereby making cold tumors hot. Companies in this area include Nektar Therapeutics, Heat Biologics, and Advantagene as well as others.

Companies that sell marketed drugs for recurrent glioblastoma are Genentech and Roche with Avastin and Arbor Pharmaceuticals. Four companies have product candidates in Phase 3 development for the treatment of glioblastoma. Immunocellular Therapeutics, Tocagen, and DelMar. Other competitors with product candidates currently in Phase 2 clinical trials include Abbvie's Depatus-M (ABT-414) and DNA-2401, a conditionally replicative adenovirus being evaluated in combination with pembrolizumab (KEYTRUDA®) for recurrent glioblastoma by DNATrix and Merck. Duke University is enrolling a randomized Phase 2 study of oncolytic polio/rhinovirus recombinant (PVSRIPO) alone or in combination with lomustine in recurrent WHO Grade IV malignant glioma patients. Also, MedImmune/Astra-Zeneca's durvalumab was evaluated in a Phase 2 trial in patients with rGBM. In addition, OncoSec is advancing IL-12 for the treatment of melanoma and has generated Phase 2 data for ImmunoPulse® IL-12 in combination with pembrolizumab.

Even if we obtain regulatory approval of potential products, we may not be the first to market and that may affect the price or demand for our potential products. Existing or future competing products may provide greater therapeutic convenience or clinical or other benefits for a specific indication than our products, or may offer comparable performance at a lower cost. Additionally, the availability and price of our competitors' products could limit the demand and the price we are able to charge for our potential products. We may not be able to implement our business plan if the acceptance of our potential products is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our potential products, or if physicians switch to other new drug or biologic products or choose to reserve our potential products. Additionally, a competitor could obtain orphan product exclusivity from the FDA with respect to such competitor's product. If such competitor product is determined to be the same product as one of our potential products, that may prevent us from obtaining approval from the FDA for such potential products for the same indication for seven years, except in limited circumstances. If our products fail to capture and maintain market share, we may not achieve sufficient product revenues and our business will suffer.

We compete against fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors have products already approved or in development. In addition, many of these competitors, either alone or together with their collaborative partners, operate larger research and development programs or have substantially greater financial resources than we do, as well as significantly greater experience in:

- developing drugs and biopharmaceuticals;
- undertaking preclinical testing and human clinical trials;
- obtaining FDA and other regulatory approvals of drugs and biopharmaceuticals;
- formulating and manufacturing drugs and biopharmaceuticals; and
- launching, marketing, and selling drugs and biopharmaceuticals.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products.

Any termination of our licenses with Precigen or MD Anderson could result in the loss of significant rights and could harm our ability to develop and commercialize our product candidates.

We are dependent on patents, know-how, and proprietary technology that are licensed from others, particularly MD Anderson and Precigen. Any termination of these licenses could result in the loss of significant rights and could harm our ability to commercialize our product candidates. Disputes may also arise between us and these licensors regarding intellectual property subject to a license agreement, including those relating to:

- the scope of rights granted under the applicable license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes, and the technology and processes of Precigen, MD Anderson and our other licensors, infringe on intellectual property of the licensor that is not subject to the applicable license agreement;
- our right to sublicense patent and other rights to third parties pursuant to our relationships with our licensors and partners;
- whether we and/or Precigen are complying with our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our potential products under the MD Anderson License; and
- the allocation of ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and by us.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements, particularly with MD Anderson and Precigen, on acceptable terms, we may be unable to successfully develop and commercialize the affected potential products. We are generally also subject to all of the same risks with respect to protection of intellectual property that we license as we are for intellectual property that we own. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize potential products under our applicable licenses could suffer. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation, and reexamination proceedings before the United States Patent and Trademark Office, or USPTO, or oppositions and other comparable proceedings in foreign jurisdictions. Recently, due to changes in U.S. law referred to as patent reform, new procedures including inter partes review and post-grant review have been implemented, which adds uncertainty to the possibility of challenge to our or our licensors' patents in the future.

Clinical trials are very expensive, time-consuming, and difficult to design, initiate and implement.

Human clinical trials are very expensive and difficult to design, initiate and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial start-up and process itself is also time-consuming and results are inherently uncertain. We estimate that clinical trials of our product candidates will take at least several years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to delay the start of, abandon or repeat clinical trials. The commencement and completion of clinical trials may be delayed by several factors, including:

- Additional nonclinical data requests by regulatory agencies;
- Unforeseen safety issues;
- Determination of dosing issues;
- Lack of effectiveness during clinical trials;
- Slower than expected rates of patient recruitment and enrollment;
- Inability to monitor patients adequately during or after treatment;
- Inability or unwillingness of medical investigators to follow our clinical protocols; and
- Regulatory determinations to temporarily or permanently cease enrollment for other reasons not related to patient safety.

Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. In addition, we or the FDA may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in our IND submission or in the conduct of these trials. In June 2018, we announced the FDA placed on clinical hold our Phase 1 trial to evaluate CD19-specific CAR-T therapies manufactured under point-of-care and requested additional information in support of the IND submission for the trial. Our business may be materially harmed if we or our partners are unable to adequately address the FDA's requests for this trial in a timely manner.

See also "Risks Related to the Clinical Testing, Regulatory Approval and Manufacturing of our Product Candidates— *Our product candidates are in various stages of clinical trials, which are very expensive and time-consuming. We cannot be certain when we will be able to submit a BLA, to the FDA and any failure or delay in completing clinical trials for our product candidates could harm our business."*

We may not be able to obtain or maintain orphan drug exclusivity for our product candidates.

We have received orphan drug designation for Ad-RTS-IL-12 + veledimex for the treatment of malignant glioma in the United States, and we may be able to receive additional orphan drug designation from the FDA and the European Medicines Agency, or EMA, for our other product candidates. In the United States, orphan designation is available to drugs intended to treat, diagnose or prevent a rare disease or condition that affects fewer than 200,000 people in the United States at the time of application for orphan designation. Orphan designation qualifies the sponsor of the product for a tax credit and marketing incentives. The first sponsor to receive FDA marketing approval for a drug with an orphan designation is entitled to a seven-year exclusive marketing period in the United States for that product for that indication and, typically, a waiver of the prescription drug user fee for its marketing application. However, a drug that the FDA considers to be clinically superior to, or different from, the approved orphan drug, even though for the same indication, may also obtain approval in the United States during the seven-year exclusive marketing period. Orphan drug exclusive marketing rights may also be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug. There is no guarantee that any of our other product candidates will receive orphan drug designation or that, even if such product candidate is granted such status, the product candidate's clinical development and regulatory approval process will not be delayed or will be successful.

We may not be able to commercialize any products, generate significant revenues, or attain profitability.

To date, none of our product candidates have been approved for commercial sale in any country. The process to develop, obtain regulatory approval for, and commercialize potential product candidates is long, complex, and costly. Unless and until we receive approval from the FDA and/or other foreign regulatory authorities for our product candidates, we cannot sell our drugs and will not have product revenues. Even if we obtain regulatory approval for one or more of our product candidates, if we are unable to successfully commercialize our products, we may not be able to generate sufficient revenues to achieve or maintain profitability, or to continue our business without raising significant additional capital, which may not be available. Our failure to achieve or maintain profitability could negatively impact the trading price of our common stock.

Ethical, legal and social concerns about synthetic biologically engineered products could limit or prevent the use of our product candidates.

Our product candidates use an immuno-oncology platform. Public perception about the safety and environmental hazards of, and ethical concerns over, genetically engineered products could influence public acceptance of our product candidates. If we and our collaborators are not able to overcome the ethical, legal and social concerns relating to biological engineering, our product candidates may not be accepted. These concerns could result in increased expenses, regulatory scrutiny, delays or other impediments to the public acceptance and commercialization of our product candidates. Our ability to develop and commercialize products could be limited by public attitudes and governmental regulation.

The subject of genetically modified organisms has received negative publicity, which has aroused public debate. This adverse publicity could lead to greater regulation and trade restrictions on the development and commercialization of genetically altered products. Further, there is a risk that our product candidates could cause adverse health effects or other AEs, which could also lead to negative publicity.

The biological platform that we use may have significantly enhanced characteristics compared to those found in naturally occurring organisms, enzymes or microbes. While we believe we produce biological technologies only for use in a controlled laboratory and industrial environment, the release of such biological technologies into uncontrolled environments could have unintended consequences. Any adverse effect resulting from such a release could have a material adverse effect on our business and financial condition, and we may have exposure to liability for any resulting harm.

We will incur additional expenses in connection with our License Agreement with Precigen.

We expect our overall research and development expenses will continue to increase as we move forward with our research and development efforts in connection with the License Agreement with Precigen. Although all human clinical trials are expensive and difficult to design and implement, we believe that due to complexity, costs associated with clinical trials for immuno-oncology products are greater than the corresponding costs associated with clinical trials for small-molecule candidates. In addition to increased research and development costs, we may need to add headcount to support our efforts in connection with the License Agreement, which would add to our general and administrative expenses going forward.

Although our forecasts for expenses and the sufficiency of our capital resources take into account our plans to develop products in connection with the License Agreement, the actual costs associated therewith may be significantly in excess of forecasted amounts. In addition to the amount and timing of expenses related to the clinical trials, our actual cash requirements may vary materially from our current expectations for a number of other factors that may include, but are not limited to, changes in the focus and direction of our development programs, competitive and technical advances, costs associated with the development of our product candidates and costs of filing, prosecuting, defending and enforcing our intellectual property rights. If we exhaust our capital reserves more quickly than anticipated, regardless of the reason, and we are unable to obtain additional financing on terms acceptable to us or at all, we will be unable to proceed with development of some or all of our product candidates on expected timelines and will be forced to prioritize among them.

The technology on which our License Agreement with Precigen is based relies in part on early stage technology in the field of human oncologic therapeutics.

Our License Agreement with Precigen contemplates our use of Precigen's advanced transgene engineering platform for the controlled and precise cellular production of anti-cancer effectors. The synthetic immuno-oncology effector platform in which we have acquired rights represents early-stage technology in the field of human oncology biotherapeutic, with Ad-RTS-IL-12 + veledimex having completed two Phase 2 studies, in melanoma and breast cancer. We are continuing to pursue intratumoral injection of Ad-RTS-IL-12 + veledimex in brain cancer. Although we may evaluate alternative products targeting key pathways used by cancers to grow and metastasize, we may not be successful in developing and commercializing our existing or any new products for a variety of reasons.

We will incur additional expenses in connection with our License Agreement with MD Anderson

Pursuant to the MD Anderson License with MD Anderson, we, together with Precigen, obtained an exclusive, worldwide license to certain technologies owned and licensed by MD Anderson including technologies relating to novel CAR+ T cell, NK cell and TCR cell therapies arising from the laboratory of Laurence Cooper, M.D., Ph.D., who was then at MD Anderson, as well as either co-exclusive or non-exclusive licenses under certain related technologies. Pursuant to the MD Anderson License, MD Anderson agreed to transfer to us certain existing research programs described in the MD Anderson License and we, together with Precigen, entered into a research and development agreement with MD Anderson pursuant to which we agreed to provide funding for certain research and development activities of MD Anderson for a period of three years from the date of the MD Anderson License, in an amount between $15.0 and $20.0 million per year. We made the final payment in January 2018. In addition, we also expect to enter into additional collaboration and technology transfer agreements with MD Anderson to accelerate technology and clinical development of these product candidates. We expect to increase the level of our overall research and development expenses significantly going forward as a result of each of these items.

Although our forecasts for expenses and the sufficiency of our capital resources takes into account our plans to develop the technology licensed from MD Anderson and our obligations under the MD Anderson License, the MD Anderson License is still only beginning to be implemented, therefore the actual costs associated therewith may be significantly in excess of forecasted amounts. In addition to the amount and timing of expenses related to our relationship with MD Anderson, our actual cash requirements may vary materially from our current expectations for a number of other factors that may include, but are not limited to, changes in the focus and direction of our development programs, competitive and technical advances, costs associated with the development of our product candidates and costs of filing, prosecuting, defending and enforcing our intellectual property rights. If we exhaust our capital reserves more quickly than anticipated, regardless of the reason, and we are unable to obtain additional financing on terms acceptable to us or at all, we will be unable to proceed with development of some or all of our product candidates on expected timelines and will be forced to prioritize among them.

We may not be able to retain the rights licensed to us and Precigen by M.D. Anderson to technologies relating to CAR, T-cell therapies and other related technologies.

Under the MD Anderson License, we, together with Precigen, received an exclusive, worldwide license to certain technologies owned and licensed by MD Anderson including technologies relating to novel CAR+ T cell, NK cell and TCR cell therapies arising from the laboratory of Laurence Cooper, M.D., Ph.D., who was then at MD Anderson, as well as either co-exclusive or non-exclusive licenses under certain related technologies. When combined with Precigen's technology suite and Ziopharm's clinically tested RTS® interleukin-12 modules, the resulting proprietary methods and technologies may help realize the promise of genetically modified CAR+ T cell and other immune cells by controlling cell expansion and activation in the body, minimizing off-target and unwanted on-target effects and toxicity while maximizing therapeutic efficacy. The term of the MD Anderson License expires on the last to occur of (a) the expiration of all patents licensed thereunder, or (b) the twentieth anniversary of the date of the MD Anderson License; provided, however, that following the expiration of the term, we and Precigen shall then have a fully-paid up, royalty free, perpetual, irrevocable and sublicensable license to use the licensed intellectual property thereunder.

After 10 years from the date of the MD Anderson License and subject to a 90-day cure period, MD Anderson will have the right to convert the MD Anderson License into a non-exclusive license if we and Precigen are not using commercially reasonable efforts to commercialize the licensed intellectual property on a case-by-case basis. After five years from the date of the MD Anderson License and subject to a 180-day cure period, MD Anderson will have the right to terminate the MD Anderson License with respect to specific technology(ies) funded by the government or subject to a third-party contract if we and Precigen are not meeting the diligence requirements in such funding agreement or contract, as applicable. Subject to a 30-day cure period, MD Anderson has the right to terminate the MD Anderson License if we and Precigen fail to timely deliver the shares due in consideration for the MD Anderson License. MD Anderson may also terminate the agreement with written notice upon material breach by us or Precigen, if such breach has not been cured within 60 days of receiving such notice. In addition, the MD Anderson License will terminate upon the occurrence of certain insolvency events for both us or Precigen and may be terminated by the mutual written agreement of us, Precigen and MD Anderson.

There can be no assurance that we will be able to successfully perform under the MD Anderson License and if the MD Anderson License is terminated it may prevent us from achieving our business objectives.

We have a limited operating history upon which to base an investment decision.

We have not demonstrated an ability to perform the functions necessary for the successful commercialization of any product candidates. The successful commercialization of any product candidates will require us to perform a variety of functions, including:

- Continuing to undertake preclinical development and clinical trials;
- Participating in regulatory approval processes;
- Formulating and manufacturing products; and
- Conducting sales and marketing activities.

Our operations have been limited to organizing and staffing our company, acquiring, developing and securing our proprietary product candidates, and undertaking preclinical and clinical trials of our product candidates. These operations provide a limited basis for you to assess our ability to commercialize our product candidates and the advisability of investing in our securities.

Because we currently neither have nor intend to establish internal research capabilities, we are dependent upon pharmaceutical and biotechnology companies and academic and other researchers to sell or license us their product candidates and technology.

Proposing, negotiating, and implementing an economically viable product acquisition or license is a lengthy and complex process. We compete for partnering arrangements and license agreements with pharmaceutical, biopharmaceutical, and biotechnology companies, many of which have significantly more experience than we do and have significantly more financial resources. Our competitors may have stronger relationships with certain third parties including academic research institutions, with whom we are interested in collaborating and may have, therefore, a competitive advantage in entering into partnering arrangements with those third parties. We may not be able to acquire rights to additional product candidates on terms that we find acceptable, or at all.

We expect that any product candidate to which we acquire rights will require significant additional development and other efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All drug product candidates are subject to the risks of failure inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe or effective for approval by regulatory authorities. Even if our product candidates are approved, they may not be economically manufactured or produced, or be successfully commercialized.

We actively evaluate additional product candidates to acquire for development. Such additional product candidates, if any, could significantly increase our capital requirements and place further strain on the time of our existing personnel, which may delay or otherwise adversely affect the development of our existing product candidates. We must manage our development efforts and clinical trials effectively, and hire, train and integrate additional management, administrative, and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing.

We may not be able to successfully manage our growth.

In the future, if we are able to advance our product candidates to the point of, and thereafter through, clinical trials, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide for these capabilities. Any future growth will place a significant strain on our management and on our administrative, operational, and financial resources. Therefore, our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To manage this growth, we must expand our facilities, augment our operational, financial and management systems, and hire and train additional qualified personnel. If we are unable to manage our growth effectively, our business may be harmed.

Our business will subject us to the risk of liability claims associated with the use of hazardous materials and chemicals.

Our contract research and development activities may involve the controlled use of hazardous materials and chemicals. Although we believe that our safety procedures for using, storing, handling and disposing of these materials comply with federal, state and local laws and regulations, we cannot completely eliminate the risk of accidental injury or contamination from these materials. In the event of such an accident, we could be held liable for any resulting damages and any liability could have a materially adverse effect on our business, financial condition, and results of operations. In addition, the federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous or radioactive materials and waste products may require our contractors to incur substantial compliance costs that could materially adversely affect our business, financial condition, and results of operations.

****We rely on key executive officers and scientific and medical advisors, and their knowledge of our business and technical expertise would be difficult to replace.***

We are highly dependent on Dr. Laurence J.N. Cooper, our Chief Executive Officer; Dr. David Mauney, our Executive Vice President and Chief Business Officer and interim Chief Operating Officer; and our principal scientific, regulatory, and medical advisors. Each of Drs. Cooper and Mauney may terminate their employment with us at any time, subject, however, to certain non-compete and non-solicitation covenants. The loss of the technical knowledge and management and industry expertise of each of Drs. Cooper or Mauney, or any of our other key personnel, could result in delays in product development, loss of customers and sales, and diversion of management resources, which could adversely affect our operating results. We do not carry “key person” life insurance policies on any of our officers or key employees.

If we are unable to hire additional qualified personnel, our ability to grow our business may be harmed.

We will need to hire additional qualified personnel with expertise in preclinical and clinical research and testing, government regulation, formulation and manufacturing, and eventually, sales and marketing. We compete for qualified individuals with numerous biopharmaceutical companies, universities, and other research institutions. Competition for such individuals is intense and we cannot be certain that our search for such personnel will be successful. Attracting and retaining qualified personnel will be critical to our success. If we are unable to hire additional qualified personnel, our ability to grow our business may be harmed.

We may incur substantial liabilities and may be required to limit commercialization of our products in response to product liability lawsuits.

The testing and marketing of medical products entail an inherent risk of product liability. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products, if approved. Even a successful defense would require significant financial and management resources. Regardless of the merit or eventual outcome, liability claims may result in:

- Decreased demand for our product candidates;
- Injury to our reputation;
- Withdrawal of clinical trial participants;
- Withdrawal of prior governmental approvals;
- Costs of related litigation;
- Substantial monetary awards to patients;
- Product recalls;
- Loss of revenue; and
- The inability to commercialize our product candidates.

We currently carry clinical trial insurance and product liability insurance. However, an inability to renew our policies or to obtain sufficient insurance at an acceptable cost could prevent or inhibit the commercialization of pharmaceutical products that we develop, alone or with collaborators.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems and those of our current and future contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we are not aware of any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties to manufacture our product candidates and conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

RISKS RELATED TO THE CLINICAL TESTING, REGULATORY APPROVAL AND MANUFACTURING OF OUR PRODUCT CANDIDATES

If we are unable to obtain the necessary U.S. or worldwide regulatory approvals to commercialize any product candidate, our business will suffer.

We may not be able to obtain the approvals necessary to commercialize our product candidates, or any product candidate that we may acquire or develop in the future for commercial sale. We will need FDA approval to commercialize our product candidates in the United States and approvals from regulatory authorities in foreign jurisdictions equivalent to the FDA to commercialize our product candidates in those jurisdictions. In order to obtain FDA approval of any product candidate, we must submit to the FDA a Biologics License Application, or BLA, demonstrating that the product candidate is safe for humans and effective for its intended use. This demonstration requires significant research and animal tests, which are referred to as preclinical studies, as well as human tests, which are referred to as clinical trials. Satisfaction of the FDA's regulatory requirements typically takes many years, depending upon the type, complexity, and novelty of the product candidate, and will require substantial resources for research, development, and testing. We cannot predict whether our research, development, and clinical approaches will result in drugs that the FDA will consider safe for humans and effective for their intended uses. The FDA has substantial discretion in the drug approval process and may require us to conduct additional preclinical and clinical testing or to perform post-marketing studies. The approval process may also be delayed by changes in government regulation, future legislation, or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals may:

- Delay commercialization of, and our ability to derive product revenues from, our product candidates;
- Impose costly procedures on us; and
- Diminish any competitive advantages that we may otherwise enjoy.

Even if we comply with all FDA requests, the FDA may ultimately reject one or more of our BLAs. We cannot be sure that we will ever obtain regulatory approval for any of our product candidates. Failure to obtain FDA approval for our product candidates will severely undermine our business by leaving us without a saleable product, and therefore without any potential revenue source, until another product candidate can be developed. There is no guarantee that we will ever be able to develop or acquire another product candidate or that we will obtain FDA approval if we are able to do so.

In foreign jurisdictions, we similarly must receive approval from applicable regulatory authorities before we can commercialize any drugs. Foreign regulatory approval processes generally include all of the risks associated with the FDA approval procedures described above.

Our product candidates are in various stages of clinical trials, which are very expensive and time-consuming. We cannot be certain when we will be able to submit a BLA to the FDA and any failure or delay in completing clinical trials for our product candidates could harm our business.

Our product candidates are in various stages of development and require extensive clinical testing. Notwithstanding our current clinical trial plans for each of our existing product candidates, we may not be able to commence additional trials or see results from these trials within our anticipated timelines. As such, we cannot predict with any certainty if or when we might submit a BLA for regulatory approval of our product candidates or whether such a BLA will be accepted. Because we do not anticipate generating revenues unless and until we submit one or more BLAs and thereafter obtain requisite FDA approvals, the timing of our BLA submissions and FDA determinations regarding approval thereof, will directly affect if and when we are able to generate revenues.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following any potential marketing approval.

As with many pharmaceutical and biological products, treatment with our product candidates may produce undesirable side effects or adverse reactions or events, including potential adverse side effects related to cytokine release. If our product candidates or similar products or product candidates under development by third parties demonstrate unacceptable AEs, we may be required to halt or delay further clinical development of our product candidates. The FDA or other foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications.

The product-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately or timely recognized or managed by the treating medical staff, particularly outside of the institutions that collaborate with us, as toxicities resulting from our novel technologies may not be normally encountered in the general patient population and by medical personnel. We expect to have to train medical personnel using our product candidates to understand their side effect profiles, both for our planned clinical trials and upon any commercialization of any product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in adverse effects to patients, including death.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, including during any long-term follow-up observation period recommended or required for patients who receive treatment using our products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a risk evaluation and mitigation strategy plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, and/or other elements to assure safe use;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of the foregoing could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved. Furthermore, any of these occurrences may harm our business, financial condition and prospects significantly.

Our cell-based and gene therapy immuno-oncology products rely on the availability of reagents, specialized equipment, and other specialty materials and infrastructure, which may not be available to us on acceptable terms or at all. For some of these reagents, equipment, and materials, we rely or may rely on sole source vendors or a limited number of vendors, which could impair our ability to manufacture and supply our products.

Manufacturing our product candidates will require many reagents, which are substances used in our manufacturing processes to bring about chemical or biological reactions, and other specialty materials and equipment, some of which are manufactured or supplied by small companies with limited resources and experience to support commercial biologics production. We currently depend on a limited number of vendors for certain materials and equipment used in the manufacture of our product candidates. Some of these suppliers may not have the capacity to support commercial products manufactured under current good manufacturing practices by biopharmaceutical firms or may otherwise be ill-equipped to support our needs. We also do not have supply contracts with many of these suppliers and may not be able to obtain supply contracts with them on acceptable terms or at all. Accordingly, we may experience delays in receiving key materials and equipment to support clinical or commercial manufacturing.

For some of these reagents, equipment, infrastructure, and materials, we rely and may in the future rely on sole source vendors or a limited number of vendors. An inability to continue to source product from any of these suppliers, which could be due to regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands, or quality issues, could adversely affect our ability to satisfy demand for our product candidates, which could adversely and materially affect our product sales and operating results or our ability to conduct clinical trials, either of which could significantly harm our business.

As we continue to develop and scale our manufacturing process, we expect that we will need to obtain rights to and supplies of certain materials and equipment to be used as part of that process. We may not be able to obtain rights to such materials on commercially reasonable terms, or at all, and if we are unable to alter our process in a commercially viable manner to avoid the use of such materials or find a suitable substitute, it would have a material adverse effect on our business. Even if we are able to alter our process so as to use other materials or equipment, such a change may lead to a delay in our clinical development and/or commercialization plans. If such a change occurs for product candidate that is already in clinical testing, the change may require us to perform both ex vivo comparability studies and to collect additional data from patients prior to undertaking more advanced clinical trials.

The results of our clinical trials may not support our product candidate claims.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support approval of our product candidates. The FDA normally expects two randomized, well-controlled Phase 3 pivotal trials in support of approval of a BLA. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be certain that the results of later clinical trials will replicate the results of prior clinical trials and preclinical testing. The clinical trial process may fail to demonstrate that our product candidates are safe for humans and effective for the indicated uses. This failure would cause us to abandon a product candidate and may delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay the submission of our BLAs with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues. In addition, our clinical trials involve small patient populations. Because of the small sample size, the results of these clinical trials may not be indicative of future results.

Our synthetic immuno-oncology product candidates are based on a novel technology, which makes it difficult to predict the time and cost of product candidate development and subsequently obtaining regulatory approval. Currently, few gene therapy products have been approved in the United States and Europe.

We are currently focused on developing products in immuno-oncology that employ novel gene expression, control and cell technologies to deliver safe, effective and scalable cell- and viral-based therapies for the treatment of cancer. Due to the novelty of this medical technology, there can be no assurance that any development problems we experience in the future related to our immuno-oncology platform will not cause significant delays or unanticipated costs, or that such development problems can be solved. We may also experience unanticipated problems or delays in expanding our manufacturing capacity or transferring our manufacturing process to commercial partners, which may prevent us from completing our clinical trials or commercializing our immuno-oncology product candidates on a timely or profitable basis, if at all.

In addition, the clinical study requirements of the FDA, the EMA and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates. Currently, two gene therapy products, Glybera and Strimvelis, have received approval from the EMA. UniQure's Glybera, received marketing authorization from the EMA in 2012 but its authorization was withdrawn for sponsor non-renewalas a result of high cost and limited demand. GlaxoSmithKline's Strimvelis was approved by the EMA in May 2016 and in March 2017 dosed its first patient. According to GlaxoSmithKline, delays in Strimvelis's commercialization were due to cross-border European reimbursement. These factors make it difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our product candidates in either the United States or Europe. Approvals by the EMA may not be indicative of what the FDA may require for approval. The FDA approved its first gene therapy, Luxturna, in December 2017.

Regulatory requirements governing gene and cell therapy products have changed frequently and may continue to change in the future. For example, the FDA has established the Office of Tissue and Advanced Therapies within its Center for Biologics Evaluation and Research, or CBER, to consolidate the review of gene therapy and related products, and the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. Gene therapy clinical trials conducted at institutions that receive funding for recombinant DNA research from the U.S. National Institutes of Health, or the NIH, are also subject to potential review by the NIH Office of Biotechnology Activities' Recombinant DNA Advisory Committee, or the RAC. Although the FDA decides whether individual gene therapy protocols may proceed, the RAC review process can impede the initiation of a clinical trial, even if the FDA has reviewed the trial and approved its initiation. Conversely, the FDA can put an IND on clinical hold even if the RAC has provided a favorable review. Also, before a clinical trial can begin at an NIH-funded institution, that institution's institutional review board, or IRB, and its Institutional Biosafety Committee will have to review the proposed clinical trial to assess the safety of the trial. In addition, adverse developments in clinical trials of gene therapy products conducted by others may cause the FDA or other regulatory bodies to change the requirements for approval of any of our product candidates.

These regulatory review committees and advisory groups and the new guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these treatment candidates or lead to significant post-approval limitations or restrictions. As we advance our immuno-oncology product candidates, we will be required to consult with these regulatory and advisory groups, and comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of our product candidates. These additional processes may result in a review and approval process that is longer than we otherwise would have expected for oncology product candidates. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient product revenue to maintain our business.

Because we are dependent upon clinical research institutions and other contractors for clinical testing and for research and development activities, the results of our clinical trials and such research activities are, to a certain extent, beyond our control.

We materially rely upon independent investigators and collaborators, such as universities and medical institutions, to conduct our preclinical and clinical trials under agreements with us. These collaborators are not our employees and we cannot control the amount or timing of resources that they devote to our programs. These investigators may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking such programs ourselves. If outside collaborators fail to devote sufficient time and resources to our drug development programs, or if their performance is substandard, the approval of our FDA applications, if any, and our introduction of new products, if any, will be delayed. These collaborators may also have relationships with other commercial entities, some of whom may compete with us. If our collaborators assist our competitors to our detriment, our competitive position would be harmed.

****Our reliance on third parties to formulate and manufacture our product candidates exposes us to a number of risks that may delay the development, regulatory approval and commercialization of our products or result in higher product costs.***

We do not have experience in drug formulation or manufacturing of drugs or biologics and do not intend to establish our own manufacturing facilities. We lack the resources and expertise to formulate or manufacture our own product candidates. We currently are contracting for the manufacture of our product candidates. We intend to contract with one or more manufacturers to manufacture, supply, store, and distribute drug supplies for our clinical trials. If a product candidate we develop or acquire in the future receives FDA approval, we will rely on one or more third-party contractors to manufacture our products. Our anticipated future reliance on a limited number of third-party manufacturers exposes us to the following risks:

- We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA must approve any replacement contractor. This approval would require new testing and compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA approval, if any.
- Our third-party manufacturers might be unable to formulate and manufacture our products in the volume and of the quality required to meet our clinical needs and commercial needs, if any.
- Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store, and distribute our products.
- Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Administration and corresponding state and foreign agencies to ensure strict compliance with current good manufacturing practices, or cGMP, and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.
- If any third-party manufacturer makes improvements in the manufacturing process for our products, we may not own, or may have to share, the intellectual property rights to the innovation.
- Our third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of drug candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

Each of these risks could delay our clinical trials, the approval, if any, of our product candidates by the FDA or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenues.

Any product candidate for which we obtain marketing approval could be subject to post-marketing restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include, among other things, submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including the requirement to implement a risk evaluation and mitigation strategy, or REMS, which could include requirements for a restricted distribution system. If any of our product candidates receives marketing approval, the accompanying label may limit the approved uses, which could limit sales of the product.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of our approved products. The FDA closely regulates the post-approval marketing and promotion of products to ensure that they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we market our products outside of their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug and Cosmetic Act relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown AEs or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- Litigation involving patients taking our product;
- Restrictions on such products, manufacturers or manufacturing processes;
- Restrictions on the labeling or marketing of a product;
- Restrictions on product distribution or use;
- Requirements to conduct post-marketing studies or clinical trials;
- Warning letters;
- Withdrawal of the products from the market;
- Refusal to approve pending applications or supplements to approved applications that we submit;
- Recall of products;
- Fines, restitution or disgorgement of profits or revenues;
- Suspension or withdrawal of marketing approvals;
- Damage to relationships with existing and potential collaborators;
- Unfavorable press coverage and damage to our reputation;
- Refusal to permit the import or export of our products;
- Product seizure; or
- Injunctions or the imposition of civil or criminal penalties.

Noncompliance with similar EU requirements regarding safety monitoring or pharmacovigilance can also result in significant financial penalties. Similarly, failure to comply with U.S. and foreign regulatory requirements regarding the development of products for pediatric populations and the protection of personal health information can also lead to significant penalties and sanctions.

RISKS RELATED TO OUR ABILITY TO COMMERCIALIZE OUR PRODUCT CANDIDATES

If we are unable either to create sales, marketing and distribution capabilities or enter into agreements with third parties to perform these functions, we will be unable to commercialize our product candidates successfully.

We currently have no marketing, sales, or distribution capabilities. If and when we become reasonably certain that we will be able to commercialize our current or future product candidates, we anticipate allocating resources to the marketing, sales and distribution of our proposed products in North America and in certain other countries; however, we cannot assure that we will be able to market, sell, and distribute our products successfully. Our future success also may depend, in part, on our ability to enter into and maintain collaborative relationships for such capabilities and to encourage the collaborator's strategic interest in the products under development, and such collaborator's ability to successfully market and sell any such products. Although we intend to pursue certain collaborative arrangements regarding the sale and marketing of certain of our product candidates, there are no assurances that we will be able to establish or maintain collaborative arrangements or, if we are able to do so, whether we would be able to conduct our own sales efforts. There can also be no assurance that we will be able to establish or maintain relationships with third-party collaborators or develop in-house sales and distribution capabilities. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful. In addition, there can also be no assurance that we will be able to market and sell our product candidates in the United States or overseas.

If we are not able to partner with a third party and are not successful in recruiting sales and marketing personnel or in building a sales and marketing infrastructure, we will have difficulty commercializing our product candidates, which would harm our business. If we rely on pharmaceutical or biotechnology companies with established distribution systems to market our products, we will need to establish and maintain partnership arrangements, and we may not be able to enter into these arrangements on acceptable terms or at all. To the extent that we enter into co-promotion or other arrangements, any revenues we receive will depend upon the efforts of third parties that may not be successful and that will be only partially in our control.

If we cannot compete successfully for market share against other biopharmaceutical companies, we may not achieve sufficient product revenues and our business will suffer.

The market for our product candidates is characterized by intense competition and rapid technological advances. If a product candidate receives FDA approval, it will compete with a number of existing and future products and therapies developed, manufactured and marketed by others. Existing or future competing products may provide greater therapeutic convenience or clinical or other benefits for a specific indication than our products, or may offer comparable performance at a lower cost. If our products fail to capture and maintain market share, we may not achieve sufficient product revenues and our business will suffer.

We will compete against fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors have products already approved or in development. In addition, many of these competitors, either alone or together with their collaborative partners, operate larger research and development programs or have substantially greater financial resources than we do, as well as significantly greater experience in:

- Developing drugs and biopharmaceuticals;
- Undertaking preclinical testing and human clinical trials;
- Obtaining FDA and other regulatory approvals of drugs and biopharmaceuticals;
- Formulating and manufacturing drugs and biopharmaceuticals; and
- Launching, marketing, and selling drugs and biopharmaceuticals.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products.

If physicians and patients do not accept and use our product candidates, our ability to generate revenue from sales of our products will be materially impaired.

Even if the FDA and/or foreign equivalents thereof approve our product candidates, physicians and patients may not accept and use them. Acceptance and use of our products will depend upon a number of factors including:

- Perceptions by members of the healthcare community, including physicians, about the safety and effectiveness of our drugs;
- Pharmacological benefit and cost-effectiveness of our products relative to competing products;
- Availability of coverage and adequate reimbursement for our products from government or other healthcare payors;
- Effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any; and
- The price at which we sell our products.

Because we expect sales of our current product candidates, if approved, to generate substantially all of our product revenues for the foreseeable future, the failure of a drug to find market acceptance would harm our business and could require us to seek additional financing in order to fund the development of future product candidates.

Our ability to generate product revenues will be diminished if our products do not obtain coverage and adequate reimbursement from payors.

Our ability to commercialize our product candidates, if approved, alone or with collaborators, will depend in part on the extent to which coverage and reimbursement will be available from government and health administration authorities, private health maintenance organizations and health insurers and other third-party payors.

Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Sufficient coverage and adequate reimbursement from third-party payors is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. It is difficult to predict the coverage and reimbursement decisions that will be made by third-party payors for novel gene therapy products such as ours. Even if we obtain coverage for our product candidates, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates.

In addition, the market for our product candidates for which we may receive regulatory approval will depend significantly on access to third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement, which might not include all of the FDA-approved drugs for a particular indication. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that requires us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that approval will be obtained. If we are unable to obtain coverage of and adequate payment levels for our product candidates from third-party payors, physicians may limit how much or under what circumstances they will prescribe or administer our products and patients may decline to purchase them. This in turn could affect our ability to successfully commercialize our products and impact our profitability, results of operations, financial condition, and future success.

In addition, in many foreign countries, particularly the countries of the EU, the pricing of prescription drugs is subject to government control. In some non-U.S. jurisdictions, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. We may face competition for our product candidates from lower-priced products in foreign countries that have placed price controls on pharmaceutical products. In addition, there may be importation of foreign products that compete with our own products, which could negatively impact our profitability.

The market opportunities for our product candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small.

Cancer therapies are sometimes characterized as first line, second line, or third line, and the FDA often approves new therapies initially only for third line use. When cancer is detected early enough, first line therapy is sometimes adequate to cure the cancer or prolong life without a cure. Whenever first line therapy, usually chemotherapy, hormone therapy, surgery, or a combination of these, proves unsuccessful, second line therapy may be administered. Second line therapies often consist of more chemotherapy, radiation, antibody drugs, tumor targeted small molecules, or a combination of these. Third line therapies can include bone marrow transplantation, antibody and small molecule targeted therapies, more invasive forms of surgery, and new technologies. We expect to initially seek approval of our product candidates as a third line therapy for patients who have failed other approved treatments.

Subsequently, for those products that prove to be sufficiently beneficial, if any, we would expect to seek approval as a second line therapy and potentially as a first line therapy, but there is no guarantee that our product candidates, even if approved, would be approved for second line or first line therapy. In addition, we may have to conduct additional clinical trials prior to gaining approval for second line or first line therapy.

Our projections of both the number of people who have the cancers we are targeting, as well as the subset of people with these cancers in a position to receive third line therapy and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these cancers. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. Even if we obtain significant market share for our product candidates, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications, including use as a first or second line therapy.

Our market opportunities may also be limited by competitor treatments that may enter the market. See also "Risks Related to Our Ability to Commercialize Our Product Candidates—*If we cannot compete successfully for market share against other biopharmaceutical companies, we may not achieve sufficient product revenues and our business will suffer*."

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory enactments in recent years that change the healthcare system in ways that could impact our future ability to sell our product candidates profitably.

Furthermore, there have been and continue to be a number of initiatives at the federal and state level that seek to reduce healthcare costs. Most significantly, in March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, which includes measures that significantly change the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA of importance to the pharmaceutical industry are the following:

- An annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- An increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively;
- A new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- An extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- New methodologies by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, and for drugs that are line extensions;
- Expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing both the volume of sales and manufacturers' Medicaid rebate liability;
- Expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- A new requirement to annually report drug samples that certain manufacturers and authorized distributors provide to physicians;
- Expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- A licensure framework for follow-on biologic products;
- A new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- Establishment of a Center for Medicare & Medicaid Innovation at the Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Some of the provisions of the ACA have yet to be implemented, and there have been legal and political challenges to certain aspects of the ACA. Since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA. In December 2017, Congress repealed the tax penalty, effective January 1, 2019, for an individual's failure to maintain ACA-mandated health insurance as part of a tax reform bill. Further, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans and the annual fee imposed on certain health insurance providers based on market share. Additionally, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". More recently, in July 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. Congress may consider other legislation to repeal or replace other elements of the ACA. The ultimate content, timing or effect of any healthcare reform legislation on the U.S. healthcare industry is unclear.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, in August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee on Deficit Reduction did not achieve its targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reductions to several government programs. These reductions include aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013, and, due to subsequent legislative amendments, will stay in effect through 2027 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. As a result, there have been several U.S. Congressional inquiries and proposed and enacted federal and state legislation bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Further, the Trump administration released a "Blueprint", or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services, or HHS, has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2019, and in October 2018, CMS proposed a new rule that would require direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product. While some of these, and other proposed, measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, or the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or if we receive regulatory approval, commercialize our products.

If we fail to comply with federal and state healthcare laws, including fraud and abuse and health information privacy and security laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected.

As a pharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. For example, we could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include, among others:

- The federal Anti-Kickback Statute, which regulates our business activities, including our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities, by prohibiting, among other things, soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, either the referral of an individual or the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- Federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;
- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;
- Requirements to report annually to CMS certain financial arrangements with physicians and teaching hospitals, as defined in the ACA and its implementing regulations, including reporting any "transfer of value" made or distributed to teaching hospitals, prescribers, and other healthcare providers and reporting any ownership and investment interests held by physicians and their immediate family members and applicable group purchasing organizations during the preceding calendar year; and
- State and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government that otherwise restricts certain payments that may be made to healthcare providers and entities; state laws that require drug manufacturers to report information related to payments and other transfer of value to physicians and other healthcare providers and entities; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities, including our consulting agreements with physicians, some of whom receive stock or stock options as compensation for their services, could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has further strengthened these laws. For example, the ACA, among other things, amends the intent requirement of the federal anti-kickback statute and certain criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. Moreover, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

To the extent that any of our product candidates is ultimately sold in a foreign country, we may be subject to similar foreign laws and regulations.

If we or our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, exclusion from participation in United States federal or state health care programs, such as Medicare and Medicaid, disgorgement, individual imprisonment and the curtailment or restructuring of our operations any of which could materially adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management’s attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

Our ability to use net operating loss carryforwards and research tax credits to reduce future tax payments may be limited or restricted.

We have generated significant net operating loss carryforwards, or NOLs, and research and development tax credits, or R&D credits, as a result of our incurrence of losses and our conduct of research activities since inception. We generally are able to carry NOLs and R&D credits forward to reduce our tax liability in future years. However, our ability to utilize the NOLs and R&D credits is subject to the rules of Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, respectively. Those sections generally restrict the use of NOLs and R&D credits after an "ownership change." An ownership change occurs if, among other things, the stockholders (or specified groups of stockholders) who own or have owned, directly or indirectly, 5% or more of a corporation's common stock or are otherwise treated as 5% stockholders under Section 382 of the code and the United States Treasury Department regulations promulgated thereunder increase their aggregate percentage ownership of that corporation's stock by more than 50 percentage points over the lowest percentage of the stock owned by these stockholders over the applicable testing period. In the event of an ownership change, Section 382 imposes an annual limitation on the amount of taxable income a corporation may offset with NOL carry forwards and Section 383 imposes an annual limitation on the amount of tax a corporation may offset with business credit (including the R&D credit) carry forwards. We may have experienced an "ownership change" within the meaning of Section 382 in the past and there can be no assurance that we will not experience additional ownership changes in the future. As a result, our NOLs and business credits (including the R&D credit) may be subject to limitations and we may be required to pay taxes earlier and in larger amounts than would be the case if our NOLs or R&D credits were freely usable.

Our synthetic immuno-oncology product candidates may face competition in the future from biosimilars.

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, provides an abbreviated pathway for the approval of follow-on biological products. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. However, there is a risk that the U.S. Congress could amend the BPCIA to significantly shorten this exclusivity period, potentially creating the opportunity for generic competition sooner than anticipated. Further, this data exclusivity does not prevent another company from developing a product that is highly similar to the original branded product, generating its own data and seeking approval. Data exclusivity only assures that another company cannot rely upon the data within the innovator's application to support the biosimilar product's approval.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

If we or our licensors fail to adequately protect or enforce our intellectual property rights or secure rights to patents of others, the value of our intellectual property rights would diminish and our ability to successfully commercialize our products may be impaired.

Our success, competitive position, and future revenues will depend in part on our ability and the abilities of our licensors to obtain and maintain patent protection for our products, methods, processes and other technologies, to preserve our trade secrets, to prevent third parties from infringing on our proprietary rights, and to operate without infringing the proprietary rights of third parties.

To date, we have exclusive rights to certain U.S. and foreign intellectual property with respect to the Precigen technology, including the existing Precigen product candidates, such as Ad-RTS-IL-12 + veledimex, and with respect to CAR+ T, NK and TCR cell therapies arising from the laboratory of Laurence Cooper, M.D., Ph.D., who was then at MD Anderson. Under our License Agreement with Precigen, Precigen has the right, but not the obligation, to prepare, file, prosecute, and maintain the patents and patent applications licensed to us and shall bear any related costs incurred by it in regards to those actions. Precigen is required to consult with us and keep us reasonably informed of the status of the patents and patent applications licensed to us, and to confer with us and incorporate our comments prior to submitting any related filings and correspondence. Although under the agreement Precigen has agreed to consider in good faith and consult with us regarding any comments we may have regarding these patents and patent applications, we cannot guarantee that our comments will be solicited or followed. Under the MD Anderson License, future filings and applications require the agreement of each of MD Anderson, Precigen and us, and MD Anderson has the right to control the preparation and filing of additional patent applications unless the parties agree that we or Precigen may prosecute the application directly. Although under the agreement MD Anderson has agreed to review and incorporate any reasonable comments that we or Precigen may have regarding these patents and patent applications, we cannot guarantee that our comments will be solicited or followed. Without direct control of the in-licensed patents and patent applications, we are dependent on Precigen or MD Anderson, as applicable, to keep us advised of prosecution, particularly in foreign jurisdictions where prosecution information may not be publicly available. We anticipate that we, Precigen and MD Anderson will file additional patent applications both in the United States and in other countries. However, we cannot predict or guarantee:

- The degree and range of protection any patents will afford us against competitors, including whether third parties will find ways to invalidate or otherwise circumvent our patents;
- If and when patents will be issued;
- Whether or not others will obtain patents claiming subject matter related to or relevant to our product candidates; or
- Whether we will need to initiate litigation or administrative proceedings that may be costly whether we win or lose.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost, in a timely manner, or in all jurisdictions. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties. We may also require the cooperation of our licensors in order to enforce the licensed patent rights, and such cooperation may not be provided. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States and we may fail to seek or obtain patent protection in all major markets. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all.

Changes in patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection. In September 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law, resulting in a number of significant changes to United States patent law. These changes include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In addition, the United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the value of patents, once obtained, and with regard to our ability to obtain patents in the future. As the USPTO continues to implement the Leahy-Smith Act, and as the federal courts have the opportunity to interpret the Leahy-Smith Act, the laws and regulations governing patents, and the rules regarding patent procurement could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Certain technologies utilized in our research and development programs are already in the public domain. Moreover, a number of our competitors have developed technologies, filed patent applications or obtained patents on technologies, compositions and methods of use that are related to our business and may cover or conflict with our owned or licensed patent applications, technologies or product candidates. Such conflicts could limit the scope of the patents that we may be able to obtain or may result in the rejection of claims in our patent applications. Because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, or in some cases not at all, and because publications of discoveries in the scientific literature often lag behind actual discoveries, neither we nor our licensors can be certain that others have not filed or maintained patent applications for technology used by us or covered by our pending patent applications without our being aware of these applications. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned patents or pending patent applications, or that we were the first to file for patent protection of such inventions, nor can we know whether those from whom we license patents were the first to make the inventions claimed or were the first to file. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, our own earlier filed patents and applications or those of Precigen may limit the scope of later patents we obtain or may result in the rejection of claims in our later filed patent applications. If third parties filed patent applications or obtained patents on technologies, compositions and methods of use that are related to our business and that cover or conflict with our owned or licensed patent applications, technologies or product candidates, we may be required to challenge such protection, terminate or modify our programs impacted by such protection or obtain licenses from such third parties, which might not be available on acceptable terms, or at all.

Even if our owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

Our success also depends upon the skills, knowledge, and experience of our scientific and technical personnel, our consultants and advisors, as well as our licensors and contractors. To help protect our proprietary know-how and our inventions for which patents may be unobtainable or difficult to obtain, and to maintain our competitive position, we rely on trade secret protection and confidentiality agreements. To this end, it is our general policy to require our employees, consultants, advisors, and contractors to enter into agreements that prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries, and inventions important to our business. These agreements may not provide adequate protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure or the lawful development by others of such information. Moreover, we may not be able to obtain adequate remedies for any breaches of these agreements. Our trade secrets may also be obtained by third parties by other means, such as breaches of our physical or computer security systems. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets, know-how or other proprietary information is disclosed, the value of our trade secrets, know-how and other proprietary rights would be significantly impaired and our business and competitive position would suffer.

****Third-party claims of intellectual property infringement would require us to spend significant time and money and could prevent us from developing or commercializing our products.***

In order to protect or enforce patent rights, we may initiate patent infringement litigation against third parties. Similarly, we may be sued by others for patent infringement. We also may become subject to proceedings conducted in the United States Patent and Trademark Office, including interference proceedings to determine the priority or derivation of inventions, or post-grant review, inter partes review, or reexamination proceedings reviewing the patentability of our patented claims. In addition, any foreign patents that are granted may become subject to opposition, nullity, or revocation proceedings in foreign jurisdictions having such proceedings. The defense and prosecution, if necessary, of intellectual property actions are costly and divert technical and management personnel away from their normal responsibilities.

Our commercial success depends upon our ability, and the ability of our collaborators, to develop, manufacture, market and sell our product candidates without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. While no such litigation has been brought against us and we have not been held by any court to have infringed a third party's intellectual property rights, we cannot guarantee that our products or use of our products do not infringe third-party patents. It is also possible that we have failed to identify relevant third-party patents or applications. For example, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing, which is referred to as the priority date. Therefore, patent applications covering our products or technology could have been filed by others without our knowledge. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our products or the use of our products.

Our research, development and commercialization activities, as well as any product candidates or products resulting from these activities, may infringe or be claimed to infringe patents or patent applications under which we do not hold licenses or other rights. Patents do not protect its owner from a claim of infringement of another owner's patent. Therefore, our patent position cannot and does not provide any assurance that we are not infringing the patent rights of another.

The patent landscape in the field of synthetic immuno-oncology is particularly complex. We are aware of numerous United States and foreign patents and pending patent applications of third parties that cover compositions, methods of use and methods of manufacture of synthetic immuno-oncology, including biotherapeutics involving the in vivo expression of human IL-12. In addition, there may be patents and patent applications in the field of which we are not aware. The technology we license from Precigen is early-stage technology and we are in the process of designing and developing products using this technology. Although we will seek to avoid pursuing the development of products that may infringe any patent claims that we believe to be valid and enforceable, we may fail to do so. Moreover, given the breadth and number of claims in patents and pending patent applications in the field of synthetic immuno-oncology and the complexities and uncertainties associated with them, third parties may allege that we are infringing upon patent claims even if we do not believe such claims to be valid and enforceable.

If a claim for patent infringement is asserted, there can be no assurance that the resolution of the claim would permit us to continue marketing the relevant product on commercially reasonable terms, if at all. We may not have sufficient resources to bring these actions to a successful conclusion. If we do not successfully defend any infringement actions to which we become a party or are unable to have infringed patents declared invalid or unenforceable, we may have to pay substantial monetary damages, which can be tripled if the infringement is deemed willful, or be required to discontinue or significantly delay commercialization and development of the affected products.

Any legal action against us or our collaborators claiming damages and seeking to enjoin developmental or marketing activities relating to affected products could, in addition to subjecting us to potential liability for damages, require us or our collaborators to obtain licenses to continue to develop, manufacture, or market the affected products. Such a license may not be available to us on commercially reasonable terms, if at all.

An adverse determination in a proceeding involving our owned or licensed intellectual property may allow entry of generic substitutes for our products.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

****If we breach any of the agreements under which we license rights to products or technology from others, we could lose license rights that are material to our business or be subject to claims by our licensors.***

We license rights to products and technology that are important to our business, and we expect to enter into additional licenses in the future. For instance, we have exclusively licensed patents and patent applications under our License Agreement with Precigen as well as under the MD Anderson License. Under these agreements, we are subject to a range of commercialization and development, sublicensing, royalty, patent prosecution and maintenance, insurance and other obligations.

Any failure by us to comply with any of these obligations or any other breach by us of our license agreements could give the licensor the right to terminate the license in whole, terminate the exclusive nature of the license or bring a claim against us for damages. Any such termination or claim could have a material adverse effect on our financial condition, results of operations, liquidity or business. Even if we contest any such termination or claim and are ultimately successful, such dispute could lead to delays in the development or commercialization of potential products and result in time-consuming and expensive litigation or arbitration. On termination we may be required to license to the licensor any related intellectual property that we developed.

In addition, in certain cases, the rights licensed to us are rights of a third party licensed to our licensor. In such instances, if our licensors do not comply with their obligations under such licenses, our rights under our license agreements with our licensor may be adversely affected.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these employees or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims.

In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

OTHER RISKS RELATED TO OUR COMPANY

Our stock price has been, and may continue to be, volatile.

The market price for our common stock is volatile and may fluctuate significantly in response to a number of factors, most of which we cannot control, including:

- Price and volume fluctuations in the overall stock market;
- Market conditions or trends in our industry or the economy as a whole;
- Laboratory or clinical trial results;
- Public concern as to the safety of drugs developed by us or others;
- Changes in operating results and performance and stock market valuations of other biopharmaceutical companies generally, or those that develop and commercialize cancer drugs in particular;
- The financial or operational projections we may provide to the public, any changes in these projections or our failure to meet these projections;
- Comments by securities analysts or changes in financial estimates or ratings by any securities analysts who follow our common stock, our failure to meet these estimates or failure of those analysts to initiate or maintain coverage of our common stock;
- The public's response to press releases or other public announcements by us or third parties, including our filings with the Securities Exchange Commission, or the SEC, and announcements of the status of development of our products, announcements of technological innovations or new therapeutic products by us or our competitors, announcements regarding collaborative agreements and other announcements relating to product development, litigation and intellectual property impacting us or our business;
- Government regulation;
- FDA determinations on the approval of a product candidate BLA submission;
- The sustainability of an active trading market for our common stock;
- Future sales of our common stock by our executive officers, directors and significant stockholders;
- Announcements of mergers or acquisition transactions;
- Our inclusion or deletion from certain stock indices;
- Developments in patent or other proprietary rights;
- Changes in reimbursement policies;
- Announcements of medical innovations or new products by our competitors;
- Announcements of changes in our senior management;
- Other events or factors, including those resulting from war, incidents of terrorism, natural disasters or responses to these events; and
- Changes in accounting principles.

In addition, the stock market from time to time experiences significant price and volume fluctuations unrelated to the operating performance of particular companies. The stock markets, and in particular the Nasdaq Capital Market, have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many biopharmaceutical companies. Stock prices of many biopharmaceutical companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies. In the past, stockholders have instituted securities class action litigation following periods of market volatility. If we were involved in securities litigation, we could incur substantial costs and our resources and the attention of management could be diverted from our business.

Anti-takeover provisions in our charter documents and under Delaware law may make an acquisition of us, which may be beneficial to our stockholders, more difficult.

Provisions of our amended and restated certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us, even if doing so would benefit our stockholders. These provisions authorize the issuance of "blank check" preferred stock that could be issued by our board of directors to increase the number of outstanding shares and hinder a takeover attempt, and limit who may call a special meeting of stockholders. In addition, Section 203 of the Delaware General Corporation Law generally prohibits a publicly-held Delaware corporation from engaging in a business combination with a party that owns at least 15% of its common stock unless the business combination is approved by the company's board of directors before the person acquires the 15% ownership stake or later by its board of directors and two-thirds of its stockholders. Section 203 could have the effect of delaying, deferring or preventing a change in control that our stockholders might consider to be in their best interests.

In connection with our January 2011 issuance of shares of common stock to Intrexon in a private placement transaction, our board of directors waived the Section 203 prohibition with respect to a future business combination with Intrexon.

Because we do not expect to pay dividends, you will not realize any income from an investment in our common stock unless and until you sell your shares at profit.

We have never paid dividends on our common stock and we do not anticipate that we will pay any dividends for the foreseeable future. Accordingly, any return on an investment in us will be realized, if at all, only when you sell shares of our common stock.

If securities and/or industry analysts fail to continue publishing research about our business, if they change their recommendations adversely or if our results of operations do not meet their expectations, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. In addition, it is likely that in some future period our operating results will be below the expectations of securities analysts or investors. If one or more of the analysts who cover us downgrade our stock, or if our results of operations do not meet their expectations, our stock price could decline.

****Our principal stockholders, executive officers and directors have substantial control over the company, which may prevent you and other stockholders from influencing significant corporate decisions and may harm the market price of our common stock.***

As of September 30, 2018, our executive officers, directors and holders of five percent or more of our outstanding common stock, beneficially owned, in the aggregate, 20.6% of our outstanding common stock. These stockholders may have interests that conflict with our other stockholders and, if acting together, have the ability to influence the outcome of matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets. Accordingly, this concentration of ownership may harm the market price of our common stock by:

- Delaying, deferring or preventing a change in control;
- Impeding a merger, consolidation, takeover or other business combination involving us; or
- Discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law new legislation that significantly revises the Code. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for NOLs to 80% of current year taxable income and elimination of NOL carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax law. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

The SEC staff issued Staff Accounting Bulletin (SAB 118) to address the application of US GAAP in situations when a registrant does not have the necessary information available, prepared or analyzed in reasonable detail to complete the accounting for certain income tax effects of the Tax Act and allows the registrant to record provisional amounts during the measurement period. We are in the process of analyzing the impact of the various provisions of the Tax Act. We expect to complete our analysis within the measurement period in accordance with SAB 118.

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

Unregistered Sale of Equity Securities and Use of Proceeds

For the three months ended September 30, 2018, we issued an aggregate of 3,847 shares of Series 1 preferred stock to Intrexon Corporation, or Intrexon, the holder of all of the outstanding shares of our Series 1 preferred stock, as dividends, representing monthly dividends due from July 1, 2018 through September 30, 2018. The issuances of the dividend shares were exempt from registration under Section 4(a)(2) of the Securities Act of 1933, as amended.

As discussed in Note 1, *Business*, to our financial statements, in consideration of our entering into the License Agreement, Intrexon forfeited and returned to us all shares of our Series 1 Preferred Stock held by or payable to Intrexon as of the date of the License Agreement.

Issuer Purchases of Equity Securities

None.

Item 3. Defaults upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

The exhibits listed in the Exhibit Index immediately preceding such exhibits are filed as part of this report and such Exhibit Index is incorporated herein by reference.

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant, as filed with the Delaware Secretary of State on April 26, 2006 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, SEC File No. 000-32353, filed April 26, 2006).
3.2	Bylaws of the Registrant, as amended to date (incorporated by reference to Exhibit 3.3 to the Registrant's Current Report on Form 8-K, SEC File No. 000-32353, filed September 19, 2005).
3.3	Amended and Restated Certificate of Designation, Preferences and Rights of Series 1 preferred stock, as filed with the Delaware Secretary of State on July 1, 2016 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K/A, SEC File No. 001-33038, filed July 1, 2016).
10.1*†	Exclusive License Agreement by and between the registrant, Precigen, Inc. and Intrexon Corporation, dated October 5, 2018.
31.1*	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certifications pursuant to 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 Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

** This certification is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.

† Confidential treatment has been requested with respect to certain portions of this agreement.

SIGNATURES

Pursuant to the requirements 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.

ZIOPHARM ONCOLOGY, INC.

By: /s/ Laurence J.N. Cooper
Laurence J.N. Cooper, M.D., Ph.D.
Chief Executive Officer
(Principal Executive Officer)
Dated: November 9, 2018

By: /s/ Kevin G. Lafond
Kevin G. Lafond
Senior Vice President, Chief Accounting
Officer and Treasurer
(Principal Financial and Accounting Officer)
Dated: November 9, 2018

Exhibit 10.1

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

Execution Version

EXCLUSIVE LICENSE AGREEMENT

This **EXCLUSIVE LICENSE AGREEMENT** (the "**Agreement**") is entered into as of October 5, 2018 (the "**Effective Date**") by and between **ZIOPHARM ONCOLOGY, INC.**, a Delaware corporation, with its principal place of business at 1180 Avenue of the Americas, 19th Floor, New York, NY 10036 ("**Ziopharm**"), and **PRECIGEN, INC.**, a Delaware corporation, with its principal place of business at 20358 Seneca Meadows Parkway, Germantown, MD 20876 ("**Precigen**"), a wholly owned subsidiary of Intrexon Corporation, a Virginia corporation, with its principal place of business at 20374 Seneca Meadows Parkway, Germantown, MD 20876 ("**Intrexon**"). Ziopharm and Precigen are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**". Intrexon is a party to: the Recitals; Section 2.2, Section 3.4, Article 13 and Section 14.13 of this Agreement.

RECITALS

WHEREAS, Precigen possesses certain intellectual property related to Licensed Products (as defined below);

WHEREAS, Ziopharm is a biopharmaceutical company focused on development of immuno-oncology products;

WHEREAS, Intrexon and Ziopharm are parties to certain agreements that, by this Agreement, are being terminated and/or amended;

WHEREAS, in consideration of Ziopharm entering into this Agreement, Intrexon has agreed to forfeit, return, contribute and transfer to Ziopharm all shares of Ziopharm's Series 1 Preferred Stock held by or payable to Intrexon as of the date of this Agreement;

WHEREAS, in connection with the termination of the 2011 Stock Purchase Agreement (as defined below), Randal J. Kirk has agreed to resign from Ziopharm's board of directors and all committees thereof effective upon the Effective Date; and

WHEREAS, in connection with the Parties entering into this Agreement, the Parties have agreed to release each other and certain related parties from certain claims that either such Party may have under any prior agreement or arrangement between the Parties.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Agreement, the Parties agree as follows:

ARTICLE 1
DEFINITIONS

1.1 "**2011 Registration Rights Agreement**" means that certain Registration Rights Agreement, by and between Ziopharm and Intrexon, dated as of January 12, 2011.

1.2 "**2011 Stock Purchase Agreement**" means that certain Stock Purchase Agreement, by and between Ziopharm and Intrexon, dated as of January 6, 2011, as amended by that certain Amendment to Stock Purchase Agreement dated February 1, 2011.

1.3 "**2015 MDACC License**" means that certain License Agreement by and among Intrexon, Ziopharm and MDACC with an effective date of January 13, 2015, as amended, and as assigned by Intrexon and assumed by Precigen effective as of January 1, 2018.

1.4 "**2016 Securities Issuance Agreement**" means that certain Securities Issuance Agreement, by and between the Ziopharm and Intrexon, dated as of June 29, 2016.

1.5 "**2018 MDACC License**" means that certain License Agreement by and among Precigen, Ziopharm and MDACC with an effective date of January 8, 2018, as amended.

1.6 "**AAA**" has the meaning set forth in Section 12.2.

1.7 "**AAA Rules**" has the meaning set forth in Section 12.2.

1.8 "**Accessory Material Agents**" means those materials as set forth in a letter agreement dated as of the date hereof by and between the Parties for use in the Field with Licensed Products.

1.9 "**Activator Ligand**" means (i) veledimex and all formulations covered by the Drug Master File, (ii) changes to the subject matter described in (i) made by Ziopharm to advance a Licensed Product ("**Ziopharm Veledimex Alterations**"), and (iii) [***] formulations of veledimex that include [***] solely to the extent such formulations have been generated prior to the Effective Date.

1.10 "**Adenovirus Production Patents**" means Schedules 5 and 6 of the Licensed Intellectual Property in Exhibit B.

1.11 "**Affiliate**" means, with respect to a particular Party or other entity, a person, corporation, partnership, or other entity that controls, is controlled by or is under common control with such Party or other entity. For the purposes of this definition, the word "control" (including, with correlative meaning, the terms "controlled by" or "under common control with") means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by the ownership of fifty percent (50%) or more of the voting stock of such entity, or by contract or otherwise.

1.12 "**Agreed Services**" shall have the meaning set forth in Section 4.5(a).

1.13 "**Assigned Contracts**" shall have the meaning set forth in Section 3.2(a).

1.14 "**Bankrupt Party**" has the meaning set forth in Section 14.2(a).

1.15 "[***] **CAR Products**" means any biological product, process or therapy developed under or arising from the [***] ([***]) CAR Program that is comprised of a CAR that is directed to [***], including all forms, formulations, presentations, doses, administrations and package configurations.

1.16 "[***] **CAR Program**" means a program(s) of Research and Development focused on using CAR cells directed to [***].

1.17 "**Business Day**" means a day other than Saturday, Sunday or any day that banks in New York, New York, USA are required or permitted to be closed.

1.18 "**CAR-T Cap**" shall have the meaning set forth in Section 6.6(c).

1.19 "**CAR-T License**" shall have the meaning set forth in Section 1.91.

1.20 "**CAR-T Products**" means any biological product, process or therapy that is comprised of a CAR-T other than CD19 or [***].

1.21 "**CAR-T Royalty Term**" shall have the meaning set forth in Section 6.6(e).

1.22 "**CD19 CAR Products**" means any biological product, process or therapy developed under or arising from the CD19 CAR Program that is comprised of a CAR that is directed to CD19, including all forms, formulations, presentations, doses, administrations and package configurations. CD19 CAR Products include all product candidates currently under Development by Ziopharm (and Precigen and its Affiliates) as of the Effective Date that contain a CAR that targets CD19.

1.23 "**CD19 CAR Program**" means a program(s) of Research and Development focused on using CAR cells directed to CD19.

1.24 "**Certificate of Designation**" means the Ziopharm's Certificate of Designation, Preferences and Rights of the Series 1 Preferred Stock, dated as of June 29, 2016.

1.25 "**Change of Control**" means, with respect to a Party: (a) the sale of all or substantially all of its assets or all of its assets relating to a Licensed Product; (b) a merger, reorganization or consolidation involving such Party in which the holders of the voting securities of such Party outstanding immediately prior thereto cease to beneficially own at least fifty percent (50%) of the combined voting power of the surviving entity, directly or indirectly, immediately after such merger, reorganization or consolidation; or (c) a transaction in which an entity or individual, or group of entities and/or individuals acting in concert, acquires more than fifty percent (50%) of the voting equity securities of such Party.

1.26 "**Chimeric Antigen Receptor**" or "**CAR**" means [***]. For the avoidance of doubt, [***]. For clarity CARs include CAR-Ts.

1.27 "**Chimeric Antigen Receptor T-Cell**" or "**CAR-T**" means (i) a T-Cell having a Chimeric Antigen Receptor, or (ii) a T-Cell under switch control having a Chimeric Antigen Receptor and any Activator Ligands or antibodies that are administered to control such T-Cells irrespective of whether such Activator Ligands and antibodies are packaged with and/or delivered with such T-cell directed to a Chimeric Antigen Receptor, or (iii) any component sold as a kit, such as a device, delivery system or therapy scheme for (i) or (ii) to modify such T-Cell including one or more polypeptides or nucleic acids encoding a CAR.

1.28 "**Claims**" has the meaning set forth in Section 9.1.

1.29 "**Combination Product**" means: (a) a pharmaceutical product that consists of a Licensed Product (or CAR-T Product, as applicable) and at least one other clinically active ingredient that is not a Licensed Product (or CAR-T Product, as applicable); or (b) any combination of a Licensed Product (or CAR-T Product, as applicable) and another pharmaceutical product that contains at least one other clinically active ingredient that is not a Licensed Product (or CAR-T Product, as applicable), where such products are not formulated together but are sold together as a single product and invoiced as one product. The other clinically active ingredient(s) in clause (a) and the other pharmaceutical product(s) in clause (b) are each referred to as the "**Other Product(s)**".

1.30 "**Commercialization**" means the marketing, promotion, sale and/or distribution of products in the Territory, and all related manufacturing activities not included in the definition of Development. Commercialization shall include commercial activities conducted in preparation for Licensed Product launch. "**Commercialize**" has a correlative meaning.

1.31 "**Commercialization Costs**" means, with respect to (i) the Gorilla IL-12 Products in the HPV Field, or (ii) the Gorilla IL-12 Products in the Field, but outside of the HPV Field the following costs incurred by or on behalf of Ziopharm or its Affiliates that are directly allocable to the Commercialization of such product, in all cases determined in accordance with GAAP consistently and strictly applied: (a) Manufacturing Costs; (b) Sales and Marketing Costs; (c) Distribution Costs; (d) Third Party Payments; (e) trademark and patent prosecution costs; (f) costs of patient assistance and indigent/expanded access programs with respect to such Gorilla IL-12 Product (g) import duties and similar charges for Gorilla IL-12 Products sold, to the extent not recovered as a Manufacturing Cost; (h) amounts written off by reason of uncollectible debts, to the extent consistent with Ziopharm's business practices for its other products; (i) costs of developing Information and data specifically intended for national accounts, managed care organizations and group purchasing organizations with respect to a Gorilla IL-12 Product; (j) costs of conducting advisory board meetings or other consultant programs, other than internal FTE costs, the purpose of which is to obtain advice and feedback related to Commercialization of a Gorilla IL-12 Product and (k) all Regulatory Costs. To the extent that any of the foregoing expenses apply to both the Gorilla IL-12 Product and other Licensed Products, such costs shall be reasonably allocated. Notwithstanding the foregoing, Commercialization Costs shall exclude (i) any Gorilla Development Costs; and (ii) income tax liabilities and corporate overhead costs of Ziopharm.

1.32 "**Commercially Reasonable Efforts**" means, with respect to the efforts and resources to be expended, or considerations to be undertaken by Ziopharm with respect to any objective, activity, or decision to be undertaken hereunder with respect to the Development or Commercialization of an IL-12 Product, CD19 CAR Product or TCR Exclusive Product, the reasonable efforts and resources to accomplish such objective, activity or decision that would be comparable with the efforts and resources that a similarly situated biopharmaceutical company would normally use in the exercise of its reasonable business discretion to accomplish a similar

objective taking into account: (i) expected and actual issues of efficacy, safety and manufacturing, and expected and actual approved labeling, including the discovery of unanticipated toxicity or any material adverse event or condition relating to the safety or efficacy of any such IL-12 Product, CD19 CAR Product or TCR Exclusive Product; (ii) the expected and actual competitiveness of alternative products (including generic or biosimilar products) under development or sold in the marketplace; (iii) adverse changes in the targeted market conditions which affect the market potential of such IL-12 Product, CD19 CAR Product or TCR Exclusive Product; (iv) the expected and actual product profile of such IL-12 Product, CD19 CAR Product or TCR Exclusive Product, taking into account the existence of failed or inconclusive clinical studies; (v) the nature and extent of expected and actual market exclusivity (including patent coverage, regulatory and other exclusivity) of such IL-12 Product, CD19 CAR Product or TCR Exclusive Product; (vi) the likelihood of Regulatory Approval given the regulatory structure involved, including regulatory or data exclusivity; and (vii) changes in clinical or regulatory strategy justified by compliance with the requirements of regulatory feedback from any Regulatory Authority. Commercially Reasonable Efforts shall take into account the stage of Development, product profile and expected Regulatory Approval and commercial success of each IL-12 Product, CD19 CAR Product or TCR Exclusive Product and shall not necessarily require Ziopharm to Develop each type of an IL-12 Product, CD19 CAR Product or TCR Exclusive Product.

1.33 "**Confidential Information**" of a Party means any and all Information of such Party that is disclosed to the other Party under this Agreement, whether in oral, written, graphic, or electronic form. In addition, all Information disclosed by Intrexon pursuant to the Ziopharm Agreement shall be deemed to be Precigen's Confidential Information disclosed hereunder, and all Information disclosed by Ziopharm pursuant to the Ziopharm Agreement shall be deemed to be Ziopharm's Confidential Information disclosed hereunder; provided that any use or disclosure of any Information that is authorized under Section 10.2 shall not be restricted by, or be deemed a violation of, the surviving confidentiality provisions under the Ziopharm Agreement.

1.34 "**Consent**" shall have the meaning set forth in Section 4.5(c).

1.35 "**Construct**" means the RTS switch that controls expression of IL-12 included in Accessory Material Agents.

1.36 "**Control**" means, with respect to any material, Information, or intellectual property right, that a Party (a) owns or (b) has a license (other than a license granted to such Party under this Agreement) to such material, Information, or intellectual property right and, in each case, has the ability to grant to the other Party access, a license, or a sublicense (as applicable) to the foregoing on the terms and conditions set forth in this Agreement without violating the terms of any then-existing agreement or other legally enforceable arrangement with any Third Party.

1.37 "**Cover**" means, with respect to a claim of a Patent and a product, that such claim would be infringed, absent a license, by the manufacture, use, offer for sale, sale or importation of such product (considering claims of patent applications to be issued as then pending). "**Covering**" and "**Covered**" shall have a correlative meaning.

1.38 "**Covering Claim**" has the meaning set forth in Section 6.5(c).

1.39 "**Competing Program**" has the meaning set forth in Section 2.2.

1.40 "**Development**" means all activities that relate to the pre-clinical and clinical development of a product or to (a) obtaining, maintaining or expanding Regulatory Approval of a product, or (b) developing the ability to manufacture clinical and commercial quantities of a product. This includes: (i) preclinical testing, toxicology, and clinical trials; (ii) preparation, submission, review, and development of data or information for the purpose of submission to a Governmental Authority to obtain, maintain or expand Regulatory Approval of a product; and (iii) manufacturing process development and scale-up, bulk production and fill/finish work associated with the supply of a product for preclinical testing and clinical trials, and related quality assurance and technical support activities. "**Develop**" and "**Developed**" have a correlative meaning.

1.41 "**Development Costs**" means the actual costs and expenses, including internal and out-of-pocket costs and expenses, that are incurred by or on behalf of Ziopharm in undertaking the Development of the Gorilla IL-12 Products which costs and expenses are directly attributable to (a) any FTE costs incurred in connection with the performance of such Development activities, which shall be determined in accordance with the FTE Rate multiplied by the number of hours devoted by employees solely to conducting such Development activities, and (b) the actual amounts paid to a Third Party for specific external activities applicable to the Development of the Gorilla IL-12 Products in the Field and/or for obtaining supplies of Gorilla IL-12 Product or any raw materials or intermediates for the conduct of such Development in the Field.

1.42 "**Development Credit**" has the meaning set forth in Section 6.2(a)(ii).

1.43 "**Dispute**" has the meaning set forth in Section 12.1.

1.44 **"Distribution Costs**" means the following out-of-pocket costs incurred by Ziopharm or its Affiliates or for its account that are directly allocable to the distribution of (a) the Gorilla IL-12 Products in the HPV Field, or (b) the Gorilla IL-12 Products in the Field, but outside of the HPV Field determined in accordance with GAAP, consistently and strictly applied: (i) handling and transportation to fulfill orders (but excluding such costs to the extent they are treated as a deduction in the definition of Net Sales); and (ii) customer services, including order entry, billing and adjustments, inquiry and credit and collection with respect to such Gorilla IL-12 Product.

1.45 "**Dollar**" means a U.S. dollar, and "**$**" shall be interpreted accordingly.

1.46 "**EMA**" means the European Medicines Agency or any successor entity.

1.47 "**Exclusive Products**" means (a) TCR Exclusive Products, (b) CD19 CAR Products, (c) [***] CAR Products, and (d) IL-12 Products. For clarity, Exclusive Products include all forms, formulations, presentations, doses, administrations and package configurations thereof.

1.48 "**Exclusive Program**" means, as applicable, (a) the TCR Exclusive Program, (b) the CD19 CAR Program, (c) the [***] CAR Program and (d) the Human IL-12 Program.

1.49 "**Exclusive Royalty-Bearing Products**" means (a) CD19 CAR Products, (b) [***] CAR Products, and (c) Human IL-12 Products.

1.50 "**Executive Officer**" means, with respect to Precigen, its President or CEO, and with respect to Ziopharm, its CEO.

1.51 "**Existing Gorilla IL-12 CRADA**" means that certain Cooperative Research and Development Agreement by and between Precigen and the National Cancer Institute dated February 28, 2018, including all amendments thereto and any research plans thereunder.

1.52 "**Existing TCR CRADA**" means that certain Cooperative Research and Development Agreement by and between Precigen and the National Cancer Institute dated October 6, 2016, including all amendments thereto and any research plans thereunder.

1.53 "**FD&C Act**" means the U.S. Federal Food, Drug and Cosmetic Act, as amended.

1.54 "**FDA**" means the U.S. Food and Drug Administration or any successor entity.

1.55 "**Field**" means (a) use of a Licensed Products (including TCR Products or Gorilla IL-12 Products), for Treatment of cancer in humans, including solid and hematological cancers, and (b) use of TCR Products or Gorilla IL-12 Products, in the HPV Field. Except to the extent permitted under clause (b), the Field shall not include the prophylaxis or amelioration of conditions or symptoms associated with cancer or infectious disease which may result in cancer.

1.56 "**First Commercial Sale**" means, with respect to a product, the first sale on a commercial basis to a Third Party of such product in a given regulatory jurisdiction after Regulatory Approval has been obtained in such jurisdiction for such product.

1.57 "**FTE Rate**" means $[***] per hour.

1.58 "**GAAP**" means the U.S. generally accepted accounting principles, consistently applied.

1.59 "**Gamma Delta T Cells**" means T-Cells expressing gamma delta TCRs.

1.60 "**Gorilla Agreed Budget**" has the meaning set forth in Section 5.2(c).

1.61 "**Gorilla Development Activities"** means those Research and Development activities with respect to the Gorilla IL-12 Products conducted by or on behalf of Ziopharm.

1.62 "**Gorilla Development Budget**" means a detailed budget for all Gorilla Development Costs, which shall be included as a part of the Gorilla Development Plan, and which shall be reviewed by the JDC in accordance with Section 5.3(b)(i). Unless otherwise agreed, the Gorilla Development Budget shall be allocated on a calendar quarterly basis.

1.63 "**Gorilla Development Costs**" means the Development Costs in respect of the Gorilla IL-12 Products in the Field, but not the HPV Field.

1.64 "**Gorilla Development Plan**" means that certain development plan for the conduct of the Gorilla Development Activities as determined by Ziopharm in accordance with this Agreement.

1.65 "**Gorilla IL-12 Construct**" means the specific [***] Construct which expresses RTS IL-12, included in Accessory Material Agents, and any derivatives, modifications or improvements thereto generated as a result of the conduct of the Gorilla IL-12 Program by or on behalf of Ziopharm after the Effective Date.

1.66 "**Gorilla IL-12 Products**" means any biological product, process or therapy Developed under the Gorilla IL-12 Program that is comprised of the Gorilla IL-12 Construct, including all forms, formulations, presentations, doses, administrations and package configurations.

1.67 "**Gorilla IL-12 Program**" means a program(s) of Research and Development dependent on use of the Gorilla IL-12 Construct.

1.68 "**Gorilla Inventions**" has the meaning set forth in Section 7.1(b).

1.69 "**Gorilla Patents**" has the meaning set forth in Section 7.1(b).

1.70 "**Governmental Authority**" means any multi-national, federal, state, local, municipal, provincial or other governmental authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).

1.71 **"HPV Field"** means, the treatment and prevention of human papillomavirus (HPV) infection and/or *in vivo* replication or proliferation solely to the extent the primary reason for such treatment or prevention is to prevent cancer.

1.72 "**Human IL-12 Products**" means any biological product, process or therapy Developed under the Human IL-12 Program, including all forms, formulations, presentations, doses, administrations and package configurations.

1.73 "**Human IL-12 Program**" means a program(s) of Research and Development focused on the use of the human clinical adenovirus to express Constructs.

1.74 "**IL-12 Combination Patent**" means patent family [***] as detailed on Schedule 4 of the Licensed Intellectual Property in Exhibit B.

1.75 "**IL-12 Products**" means the Human IL-12 Products and the Gorilla IL-12 Products.

1.76 "**IL-12 Program**" means, as applicable, the Human IL-12 Program or the Gorilla IL-12 Program.

1.77 "**IND**" means (a) an Investigational New Drug Application as defined in the FD&C Act and applicable regulations promulgated thereunder by the FDA, or (b) the equivalent application to the equivalent agency in any other regulatory jurisdiction, the filing of which is necessary to initiate or conduct clinical testing of a pharmaceutical product in humans in such jurisdiction.

1.78 "**Indemnified Party**" has the meaning set forth in Section 9.3.

1.79 "**Indemnifying Party**" has the meaning set forth in Section 9.3.

1.80 "**Information**" means any data, results, technology, in any tangible or intangible form, including know-how, trade secrets, practices, techniques, methods, processes, inventions, developments, specifications, formulations, formulae, algorithms, technology, test data (including biological and chemical, biochemical, clinical test data and data resulting from non-clinical studies), CMC information, stability data and other study data and procedures.

1.81 "**Initial Technology Transfer**" has the meaning set forth in Section 4.1(a).

1.82 "**Initial Ziopharm Technology Transfer"** has the meaning set forth in Section 4.1(b).

1.83 "**Initiation**" means, with respect to a clinical trial, first dosing of the third subject in such clinical trial.

1.84 "**Joint Development Committee**" or "**JDC**" means the committee formed by the Parties as described in Section 5.3.

1.85 "**Joint Press Release**" has the meaning set forth in Section 10.4(b).

1.86 "**Laws**" means all laws, statutes, rules, regulations, ordinances and other pronouncements having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision, domestic or foreign.

1.87 "**Licensed Intellectual Property**" means the Licensed Know-How and Licensed Patents and any Ziopharm Veledimex Alterations.

1.88 "**Licensed Know-How**" means all Information Controlled by Precigen or its Affiliates as of the Effective Date that (a) is reasonably required or useful to advance Licensed Products and (i) was generated by or on behalf of Precigen or its Affiliates and was actually provided to and/or used by or on behalf of Ziopharm or its Affiliates in connection with a Program as of, or prior to, the Effective Date (as evidenced by such Party's or its Affiliates' contemporaneous records) or (ii) was actually generated by or on behalf of Ziopharm or its Affiliates or (b) is reasonably required to manufacture the Activator Ligand or Accessory Material Agents.

1.89 "**Licensed Patent**" means (a) any patent or patent application listed on Exhibit B, together with all continuations, divisions, continuations-in-part, re-examinations, reissues, substitutions, confirmations, registrations, re-validations, patent term extensions, supplementary

protection certificates, certificates of invention, and applications for certificates of invention, or the like, of any such patents and patent applications, and (b) any patent application filed after the Effective Date solely to the extent that such patent application Covers Licensed Know-How that is both in existence as of the Effective Date and necessary to use the Accessory Material Agents or Activator Ligands in connection with the Research, Development, manufacture or Commercialization of a Licensed Product in the Field.

1.90 "**Licensed Product**" means any Exclusive Product or Non-Exclusive Product and "Licensed Products" collectively means all Exclusive Products and Non-Exclusive Products.

1.91 "**Licensing Income**" means [***].

1.92 "**MAA**" means an application to the appropriate Regulatory Authority for approval to market a Licensed Product (but excluding Pricing Approval) in any particular jurisdiction, including an NDA in the U.S.

1.93 "**Makeup Payment**" has the meaning set forth in Section 6.7.

1.94 "**Manufacturing Costs**" means, with respect to (a) the Gorilla IL-12 Products in the HPV Field, or (b) the Gorilla IL-12 Products in the Field, but outside of the HPV Field, the costs of manufacturing such Gorilla IL-12 Product which Gorilla IL-12 Product is either: (x) supplied to a Party by a Third Party; or (y) manufactured directly by a Party or its Affiliate, in each case to the extent such costs are directly allocable to the Development or Commercialization of such Gorilla IL-12 Product in the Territory, as further described below and in accordance with generally accepted accounting principles in the U.S. (**"US GAAP"**). Manufacturing Costs shall be included in Commercialization Costs on a "cost of sales" basis as such Gorilla IL-12 Product is sold, or Development Costs on a usage basis as clinical supplies are used, as the case may be, in each case via standard costs and reconciliation for variances to standard cost and inventory write-offs. In the event that a Party performs any of its manufacturing and supply obligations through one or more Affiliates, any inter-company amounts or fees paid for any such services for Gorilla IL-12 Product or any intermediate used therein by such Party shall not be included in calculating Manufacturing Costs and only those costs directly incurred by such Affiliate shall be so included.

(i) For costs in **subsection (x)**, Manufacturing Costs means: (1) the amount paid to such a Third Party (excluding any Third Party Payments); plus (2) the relevant manufacturing Party's reasonable direct and identifiable internal costs and out-of-pocket costs, incurred or accrued (including any prepayments) by the manufacturing Party in connection with inventory write-offs, variances, manufacturing process improvements, storage, freight, manufacturing scale-up, manufacturing site qualification, materials, quality assurance and quality control (including testing), supply chain management, capital equipment, similar activities comprising the manufacturing Party's oversight of the manufacturing process of the Third Party, and any value-added tax or similar tax due for amounts paid to such Third Party, but excluding costs otherwise included within Development Costs.

(ii) For costs in **subsection (y)**, Manufacturing Costs means the "standard cost" per unit, including variances to standard costs and inventory write-offs. This

standard cost shall include the cost of materials, labor, and other direct and identifiable variable costs incurred or accrued by the manufacturing Party in connection with the manufacture of a Gorilla IL-12 Product, manufacturing process improvements, storage, freight, manufacturing scale-up, manufacturing site qualification, quality assurance and quality control (including testing), supply chain management, and costs of equipment, plant operations and plant support services necessary to produce a Gorilla IL-12 Product, but excluding costs otherwise included within Development Costs. These costs of plant operations and support services shall include utilities, maintenance, engineering, safety, human resources, finance, plant management and other similar activities, including idle plant capacity reserved specifically for the Gorilla IL-12 Product based on anticipated Gorilla IL-12 Product volumes in the ensuing twelve (12) months. Costs that cannot be identified to a specific activity supporting manufacturing of a Gorilla IL-12 Product, such as charges for corporate overhead or excess capacity not specifically reserved for the Gorilla IL-12 Product as described above, shall be excluded from the determination of Manufacturing Costs.

1.95 "**MDACC Research Agreement**" means certain Research and Development Agreement by and among Intrexon, Ziopharm and The University of Texas M.D. Anderson Cancer Center ("**MDACC**") with an effective date of August 17, 2015, and any amendments or statements of work thereto.

1.96 "**MDACC Sponsored Research Agreement**" means that certain Sponsored Research Agreement by and between Precigen, Ziopharm and MDACC with an effective date of April 9, 2018, and any amendments thereto.

1.97 "**Merck Agreement**" means that certain License and Collaboration Agreement by and among Intrexon, Ziopharm and Ares Trading S.A., a corporation organized and existing under the laws of Switzerland, having offices at Zone Industrielle de L'Ouriettaz, 1170 Aubonne, Switzerland ("**Ares Trading**") effective March 27, 2015, as amended.

1.98 "**NDA**" means a New Drug Application, as defined in the FD&C Act, as amended, and applicable regulations promulgated thereunder by the FDA.

1.99 "**Neo-antigens**" means any [***].

1.100 "**Net Sales**" means, [***].

1.101 "**New Product Marks**" has the meaning set forth in Section 7.9.

1.102 "**NK Cells**" means natural killer cells.

1.103 "**NK Cells and Gamma Delta T Cell Products**" means any pharmaceutical or biological product, process or therapy developed under or arising from the NK Cells and Gamma Delta T Cell Program, including all forms, formulations, presentations, doses, administrations and package configurations.

1.104 "**NK Cells and Gamma Delta T Cell Program**" means a program(s) of Research and Development focused on NK Cells and Gamma Delta T Cells.

1.105 "**Non-Exclusive Products**" means (a) NK Cells and Gamma Delta T Cell Products, and (b) TCR Non-Exclusive Products, in each case as generated or Developed by Ziopharm. For clarity, Non-Exclusive Products include all forms, formulations, presentations, doses, administrations and package configurations thereof.

1.106 "**Obligations**" has the meaning set forth in Section 14.13.

1.107 "**Oncology**" means the treatment or prevention of a human patient who has received a cancer diagnosis.

1.108 "**Operating Profit (or Loss)**" means, with respect to (a) the Gorilla IL-12 Products in the HPV Field, or (b) the Gorilla IL-12 Products in the Field, but outside of the HPV Field all Received Amounts with respect to such Gorilla IL-12 Product during such specified period, less the sum of (a) Commercialization Costs and (b) Development Costs incurred by Ziopharm during such time period. For sake of clarity, Operating Profit (or Loss) shall be determined prior to application of any income taxes, and if such terms are used individually, "**Operating Profit**" shall mean a positive Operating Profit (or Loss), and "**Operating Loss**" shall mean a negative Operating Profit (or Loss).

1.109 "**Original Preferred Shares**" means those certain 100,000 shares of Series 1 Preferred Stock issued to Intrexon on or about July 1, 2016 pursuant to the 2016 Securities Issuance Agreement.

1.110 "**Overpaying Party**" has the meaning set forth in Section 6.7.

1.111 "**Patents**" means (a) pending patent applications, issued patents, utility models and designs; (b) reissues, substitutions, confirmations, registrations, validations, re-examinations, continuations, continued prosecution applications, continuations-in-part, or divisions of or to any of the foregoing; and (c) extensions, renewals or restorations of any of the foregoing by existing or future extension, renewal or restoration mechanisms, including supplementary protection certificates or the equivalent thereof.

1.112 "**Phase 3 Clinical Trial**" means a human clinical trial of a Licensed Product with a defined dose or a set of defined doses of such Licensed Product designed to ascertain efficacy and safety of such Licensed Product for the purpose of enabling the preparation and submission of Regulatory Approval to the competent Regulatory Authorities in a country of the Territory, as further defined in 21 C.F.R. § 312.21(c) for the U.S., as amended from time to time, or the corresponding foreign regulations.

1.113 "**PIK Shares**" means those shares of Series 1 Preferred Stock payable by Ziopharm as a monthly dividend to the holders of Series 1 Preferred Stock pursuant to Article B, Section 1 of the Certificate of Designation.

1.114 "**Potential Claims**" has the meaning set forth in Section 3.4(a).

1.115 "**Precigen Impact Situation**" has the meaning set forth in Section 7.4(a).

1.116 "**Precigen Indemnitees**" has the meaning set forth in Section 9.2.

1.117 "**Preferred Shares**" means the Original Preferred Shares plus all PIK Shares accrued, paid or payable to Intrexon as of the date of this Agreement.

1.118 "**Pricing Approval**" means such governmental approval, agreement, determination or decision establishing prices for a product that can be charged and/or reimbursed in regulatory jurisdictions where the applicable Governmental Authorities approve or determine the price and/or reimbursement of pharmaceutical products.

1.119 "**Product Infringement**" has the meaning set forth in Section 7.5(a).

1.120 "**Program**" means, as applicable, the IL-12 Program, the TCR Program, [***] CAR Program, CD19 CAR Program, and NK Cells and Gamma Delta T Cell Program.

1.121 "**Proposed Terms**" has the meaning set forth in Section 12.2.

1.122 "**Qualified IPO**" has the meaning set forth in Section 14.13.

1.123 "**Received Amounts**" means with respect to (a) the Gorilla IL-12 Products in the HPV Field, or (b) the Gorilla IL-12 Products in the Field, but outside of the HPV Field, all consideration received by Ziopharm and its Affiliates on account thereof, including the sum of (i) worldwide Net Sales of the applicable Gorilla IL-12 Products during the applicable period by Ziopharm and its Affiliates (but not, for clarity, Sublicensees), and (ii) any royalties or other payments received by Ziopharm or its Affiliates based on sales of the relevant Gorilla IL-12 Products by its Sublicensees pursuant to a sublicense granted by Ziopharm or its Affiliates under the Licensed Intellectual Property (excluding, for clarity, any Sublicensing Income).

1.124 "**Regulatory Approval**" means all approvals, including, if applicable, Pricing Approvals reasonably acceptable to the selling Party, that are necessary for the commercial sale of product in the applicable field in a given country or regulatory jurisdiction.

1.125 "**Regulatory Authority**" means, in a particular country or jurisdiction, any applicable Governmental Authority involved in granting Regulatory Approval in such country or jurisdiction.

1.126 "**Regulatory Costs**" means costs incurred to prepare Gorilla IL-12 Product regulatory submissions to obtain and/or maintain Regulatory Approval and to comply with post-Regulatory Approvals requirements of a Regulatory Authority, including FDA user and other fees, reporting and regulatory affairs activities, and recalls and withdrawals for Gorilla IL-12 Products (other than costs for Gorilla IL-12 Products that are deductible from Net Sales or that are included as Development Costs), but excluding internal FTE costs.

1.127 "**Regulatory Exchange Agreement**" has the meaning set forth in Section 4.7.

1.128 "**Regulatory Materials**" means regulatory applications, submissions, notifications, communications, correspondence, registrations, Regulatory Approvals and/or other filings made to, received from or otherwise conducted with a Regulatory Authority in order to Develop, manufacture, market, sell or otherwise Commercialize a Licensed Product in a particular country or jurisdiction.

1.129 "**Releasees**" has the meaning set forth in Section 3.4(a).

1.130 "**Released Claims**" has the meaning set forth in Section 3.4(a).

1.131 "**Reporting Product**" has the meaning set forth in Section 4.6.

1.132 "**Research**" means non-clinical studies of a product conducted before the filing of an IND for such product.

1.133 "**Royalty Term**" has the meaning set forth in Section 6.5(c).

1.134 "**Sales and Marketing Costs**" means, with respect to (a) the Gorilla IL-12 Products in the HPV Field, or (b) the Gorilla IL-12 Products in the Field, but outside of the HPV Field, and to the extent incurred by Ziopharm or its Affiliates, the reasonable internal FTE and out-of-pocket costs that are directly allocable to the sales and marketing of a Gorilla IL-12 Product, including: (i) activities directed to the advertising of a Gorilla IL-12 Product; (ii) costs of advertising, public relations and medical education agencies with respect to a Gorilla IL-12 Product; (iii) speaker programs with respect to a Gorilla IL-12 Product, including the training of such speakers; (iv) developing and providing training packages, promotional literature, samples, promotional materials and other selling materials with respect to a Gorilla IL-12 Product; (v) developing and performing market research with respect to a Gorilla IL-12 Product and developing branding, communications and life cycle management plans; (vi) conducting symposia and opinion leader development activities with respect to a Gorilla IL-12 Product; (vii) developing reimbursement programs with respect to a Gorilla IL-12 Product.

1.135 "**Second ECP Amendment**" has the meaning set forth in Section 1.162.

1.136 "**Series 1 Preferred Stock**" means Ziopharm's Series 1 preferred stock, par value $0.001 per share.

1.137 "**Sleeping Beauty Intellectual Property**" means patent families [***] and [***] as detailed on Schedule 3 of the Licensed Intellectual Property in Exhibit B.

1.138 [***] means [***].

1.139 "**Sublicensee**" means any Third Party granted a sublicense, covenant not to sue, forbearance agreement, co-promotion agreement or other similar arrangement (a "**Sublicense**") by Ziopharm to the rights licensed to Ziopharm under Section 2.1(a) or Section 2.1(b).

1.140 "**Sublicensing Income**" means any [***].

1.141 "**Support Memorandum**" has the meaning set forth in Section 12.2.

1.142 "**Switch Intellectual Property**" means Schedules 1 and 2 of the Licensed Intellectual Property in Exhibit B.

1.143 "**T-Cell**" means a T-lymphocyte, including alpha beta T cells and gamma delta T cells.

1.144 "**TCR**" means T-cell receptor complex.

1.145 "**TCR Exclusive Products**" means any biological product, process or therapy that includes a TCR for a Neo-antigen, including all forms, formulations, presentations, doses, administrations and package configurations.

1.146 "**TCR Exclusive Program**" means a program(s) of Research and Development focused on Developing TCRs designed for Neo-antigens.

1.147 "**TCR Non-Exclusive Products**" means any biological product, process or therapy that is comprised of a TCR, other than a TCR Exclusive Product, including all forms, formulations, presentations, doses, administrations and package configurations.

1.148 "**TCR Products**" means TCR Non-Exclusive Products and TCR Exclusive Products.

1.149 "**Term**" has the meaning set forth in Section 11.1.

1.150 "**Terminated Products**" has the meaning set forth in Section 11.4(a).

1.151 "**Territory**" means all countries of the world.

1.152 "**Third Party**" means any entity other than Precigen or Ziopharm or an Affiliate of either of them.

1.153 "**Third Party Licenses**" has the meaning set forth in Section 2.1(e).

1.154 "**Third Party Payment**" any payment made by Ziopharm or its Affiliates to any Third Party in respect of any license to any Patent owned or controlled by a Third Party that that is reasonably necessary to practice the subject matter claimed in the Licensed Patents in connection with the Development, manufacture or Commercialization of (a) the Gorilla IL-12 Products in the HPV Field, or (b) the Gorilla IL-12 Products in the Field, but outside of the HPV Field, as applicable.

1.155 "**Trademark**" means any word, name, symbol, color, shape, designation or device or any combination thereof, including any trademark, service mark, trade name, trade dress, brand name, product configuration, domain name, logo, design or business symbol, that functions as an identifier of source, origin or membership, whether or not registered, and all statutory and common law rights therein, and all registrations and applications therefor, together with all goodwill associated with, or symbolized by, any of the foregoing.

1.156 "**Transition Period**" shall have the meaning set forth in Section 4.5(a).

1.157 "**Transition Services**" shall have the meaning set forth in Section 4.5(a).

1.158 "**Treat**" means delivery of a therapy to a human patient who has received a cancer diagnosis for the treatment of that cancer, including the prevention of the reoccurrence of any such cancer. "**Treatment**" has its correlative meaning.

1.159 "**U.S.**" means the United States of America, including all possessions and territories thereof.

1.160 "**Underpaying Party**" has the meaning set forth in Section 6.7.

1.161 "**Valid Claim**" means (a) a claim of an issued, unexpired patent within the Licensed Patents that has not been revoked, disclaimed, abandoned or held invalid or unenforceable by a court or other body of competent jurisdiction in an unappealed or unappealable decision and (b) a claim of any patent application within a Licensed Patent, which claim was pending as of the Effective Date and has an effective priority date that is less than five years prior to the then-current date.

1.162 "**Ziopharm Agreement**" means that certain Exclusive Channel Partner Agreement by and between Intrexon and Ziopharm, dated January 6, 2011, as amended by the First Amendment to Exclusive Channel Partner Agreement effective September 13, 2011; the Second Amendment to the Exclusive Channel Partner Agreement effective March 27, 2015 (the "**Second ECP Amendment**") and the Third Amendment to Exclusive Channel Partner Agreement effective June 29, 2016, as assigned by Intrexon to Precigen.

1.163 "**Ziopharm Gorilla Inventions**" has the meaning set forth in Section 7.1(b).

1.164 "**Ziopharm Gorilla Patents**" has the meaning set forth in Section 7.1(b).

1.165 "**Ziopharm Indemnitees**" has the meaning set forth in Section 9.1.

ARTICLE 2
LICENSES AND EXCLUSIVITY

2.1 License to Ziopharm for Licensed Products.

(a) License to Ziopharm for Exclusive Products. Precigen hereby grants Ziopharm (i) an exclusive (even as to Precigen and its Affiliates except as provided in Section 2.1(c) below), royalty-bearing license, with the right to sublicense through multiple tiers in accordance with Section 2.1(d), under the Licensed Intellectual Property (other than the Switch Intellectual Property and the Adenovirus Production Patents) to research, develop, make, have made, use, sell, have sold, offer for sale and import Exclusive Products in the Field in the Territory, (ii) a non-exclusive license, with the right to sublicense in accordance with Section 2.1(d), under the Switch Intellectual Property to research, develop, make, have made, use, sell, have sold, offer for sale and import Exclusive Products in the Field in the Territory and (iii) a non-exclusive license, with right to sublicense in accordance with Section 2.1(d), under the Adenovirus Production Patents to research, develop, make, have made, use, sell, have sold, offer for sale and import IL-12 Products in the Field in the Territory. For clarity, the foregoing license grant includes the right to make and have made Activator Ligands and Accessory Material Agents for use in connection with Licensed Products in the Field.

(b) License to Ziopharm for Accessory Material Agents and Non-Exclusive Products. Precigen hereby grants Ziopharm (i) a non-exclusive, royalty-bearing license, with the right to sublicense through multiple tiers in accordance with Section 2.1(d),

under the Licensed Intellectual Property to research, develop, make, have made, use, sell, have sold, offer for sale and import Non-exclusive Products in the Field in the Territory and (ii) an exclusive license, with the right to sublicense in accordance with Section 2.1(d), under the Sleeping Beauty Intellectual Property to research, develop, make, have made, use, sell, have sold, offer for sale and import TCR Non-Exclusive Products in the Field in the Territory. For clarity, the foregoing license grant includes the right to make and have made Activator Ligands and Accessory Material Agents for use in connection with Licensed Products in the Field.

(c) Precigen Retained Rights. Notwithstanding the rights granted to Ziopharm in Section 2.1(a) and 2.1(b), Precigen may research, develop, manufacture and commercialize (i) products outside of the Exclusive Products in the Field in the Territory (subject to the grant of the exclusive license under the Sleeping Beauty Intellectual Property with respect to TCR Non-exclusive Products in the Field) and (ii) products outside the Field. Further, Precigen retains the right to practice the Licensed Intellectual Property in the Field in the Territory solely (i) as necessary to support the Gorilla Development Activities to the extent in connection with its activities under the JDC or as specifically agreed pursuant to the Gorilla Development Plan in accordance with the terms of this Agreement and (ii) to perform any Transition Service pursuant to this Agreement.

(d) Sublicenses; Assignments.

(i) Ziopharm may grant sublicenses through multiple tiers, under any or all of the rights granted in Section 2.1(a) and Section 2.1(b) to its Affiliates.

(ii) Ziopharm may grant sublicenses through multiple tiers, under any or all of the rights granted in Section 2.1(a) and Section 2.1(b) (other than the Switch Intellectual Property), to Third Parties upon written notice to Precigen solely to the extent reasonably necessary for contract manufacturing activities or Commercialization of Licensed Products with respect to any Licensed Product developed by or on behalf of Ziopharm or its Affiliates. Notwithstanding the foregoing, the Switch Intellectual Property may be sublicensed under this Section 2.1(d)(ii) solely to the extent such is for use in conjunction with a specific Licensed Product.

(iii) In addition, solely with respect to any Exclusive Product or any TCR Non-Exclusive Product, Ziopharm shall also have the right to grant sublicenses through multiple tiers under any or all of the rights granted in Section 2.1(a) and Section 2.1(b) (other than the Switch Intellectual Property) to Third Parties upon written notice to Precigen in connection with any Research, Development or Commercialization collaboration of such Exclusive Product or TCR Non-Exclusive Products. Notwithstanding the foregoing, the Switch Intellectual Property may be sublicensed under this Section 2.1(d)(iii) solely to the extent such is for use in conjunction with a specific Exclusive Product or specific TCR Non-Exclusive Product.

(iv) Except as set forth above, Ziopharm shall not have the right to sublicense any or all of the rights granted under this Agreement to Third Parties to Research, Develop, manufacture or Commercialize products of Third Parties without Precigen’s prior written consent.

(v) Each agreement in which Ziopharm grants a sublicense shall be consistent with the relevant terms and conditions of this Agreement. Ziopharm shall remain responsible for the compliance of its Sublicensees with the terms and conditions of this Agreement.

(vi) In addition to the foregoing, Ziopharm shall have the right to [***].

(e) Third Party Licenses. All Licensed Intellectual Property licensed to Precigen from a Third Party and sublicensed to Ziopharm under this Agreement are subject to and subordinate to the terms of the applicable license agreements with Third Parties set forth on Exhibit F (the "**Third Party Licenses**"). Each Party will fully comply with the terms of any such Third Party License, and Ziopharm shall remain solely responsible for the payment of any royalty, milestone, and other payment obligations, if any, due to Third Parties in connection with exercise of the licenses granted to Ziopharm under this Agreement. Ziopharm shall make all such payments timely in accordance with the terms of the applicable Third Party license. Precigen covenants not to, without the prior written consent of Ziopharm, amend any Third Party License in such a manner that would diminish the rights granted to Ziopharm under this Agreement, materially change any obligations under such Third Party License that would impact Ziopharm hereunder or increase any payment obligation of Ziopharm pursuant to such Third Party License.

2.2 Exclusivity. Each of Precigen and Intrexon hereby covenants that, during the Term, neither it nor its Affiliates will (a) grant or offer any license or other rights to a Third Party, or otherwise discuss or negotiate with any Third Party the terms of any such license or rights, or (b) conduct any activities, whether independently or with or for the benefit of a Third Party, in each case of (a) and (b) with respect to the use of any Licensed Intellectual Property to research, develop, manufacture or commercialize any Exclusive Product in the Field or with respect to the use of any Sleeping Beauty Intellectual Property as Covered by [***] and [***] to research, develop, manufacture or commercialize any TCR Product in the Field. In addition, (i) for a period of three (3) years following the Effective Date, Precigen shall not, either itself or through an Affiliate or Sublicensee, research, develop, manufacture or commercialize any biological product, process or therapy that is comprised of a regulatable switch that controls expression of IL-12 that is expressed by any viral vector for Oncology, and (ii) for a period of three (3) years following the Effective Date research, develop, manufacture or commercialize one or more TCRs designed for Neo-antigens for Oncology (each, a "**Competing Program**"). Notwithstanding the foregoing, the foregoing limitation with respect to any Competing Program shall not apply to a Third Party that acquires Precigen or its Affiliates if at the time of the acquisition the Acquired Party had an ongoing Competing Program, provided that none of the intellectual property of Precigen is thereafter used for, or incorporated into, the Competing Program.

2.3 Development Responsibilities. Ziopharm will have the exclusive right to conduct, and be solely responsible for all aspects of, the Research, Development and manufacture of Licensed Products and setting the regulatory strategy for seeking Regulatory Approvals (including any Pricing Approvals) for Licensed Products in the Field in the Territory.

2.4 Regulatory Responsibilities. Ziopharm shall have the exclusive right to prepare and shall own all Regulatory Materials (including all INDs, BLAs, NDAs, MAAs and Regulatory Approvals) for each Licensed Product in the Field in the Territory. Precigen shall not submit any Regulatory Materials for Licensed Products in the Field in the Territory without the prior written consent of Ziopharm. Except as expressly requested by Ziopharm in writing, Precigen shall not communicate with respect to the Licensed Products in the Field with any Regulatory Authority, unless so required to comply with applicable Laws, in which case Precigen shall promptly notify Ziopharm of such requirement under applicable Laws and, to the extent practicable and permitted under applicable Laws, shall submit any proposed communication to Ziopharm for prior approval or, if not practicable or permitted, shall provide Ziopharm with a copy or summary thereof as soon as reasonably practicable thereafter.

2.5 Commercialization Responsibilities. Ziopharm will have the exclusive right to conduct, and be solely responsible for all aspects of, the Commercialization of Licensed Products in the Field in the Territory, including: (a) developing and executing a commercial launch and pre-launch plan, (b) negotiating with applicable Governmental Authorities regarding the price and reimbursement status of Licensed Products; (c) marketing and promotion; (d) booking sales and distribution and performance of related services; (e) handling all aspects of order processing, invoicing and collection, inventory and receivables; (f) providing customer support, including handling medical queries, and performing other related functions; (g) conforming its practices and procedures to applicable Laws relating to the marketing, detailing and promotion of Licensed Products in the Territory; and (h) manufacturing of Licensed Products for commercial use.

2.6 Diligence.

(a) Development and Commercialization.

(i) As of the Effective Date, Ziopharm shall use Commercially Reasonable Efforts to (A) Develop, including seeking Regulatory Approval for CD19 CAR Products and IL-12 Products in the Field (other than the HPV Field) in the Territory and (B) to Commercialize each CD19 CAR Product and IL-12 Product for which it has obtained Regulatory Approval in the Field (other than the HPV Field) in the Territory.

(ii) Starting as of the second (2nd) anniversary of the Effective Date, Ziopharm shall use Commercially Reasonable Efforts to (A) Develop, including seeking Regulatory Approval for TCR Exclusive Products in the Field in the Territory (other than the HPV Field) and (B) to Commercialize each TCR Exclusive Product for which it has obtained Regulatory Approval in the Field (other than the HPV Field) in the Territory.

(b) No Other Obligation to Develop or Commercialize. Notwithstanding anything contained in this Agreement to the contrary, except as expressly set forth in Section 2.6(a), Ziopharm shall have no obligation to further Develop or Commercialize Licensed Products and shall not be liable to Precigen or its Affiliates for any failure to do so.

2.7 No Implied Licenses. Except as explicitly set forth in this Agreement, neither Party shall be deemed by estoppel or implication to have granted the other Party any license or other right to any intellectual property of such Party. Precigen specifically reserves all rights not expressly granted to Ziopharm under this Agreement.

ARTICLE 3
EXISTING AGREEMENTS

3.1 Termination of Ziopharm Agreement. The Parties hereby agree to terminate the Ziopharm Agreement. All rights and licenses granted by Intrexon to Ziopharm under the Ziopharm Agreement and all rights and licenses granted by Ziopharm to Intrexon, such rights and licenses assigned by Intrexon to Precigen, under the Ziopharm Agreement shall terminate. For clarity, the Parties acknowledge and agree that the provisions of Section 10.4 of the Ziopharm Agreement shall not apply to this termination of the Ziopharm Agreement by mutual written consent. Any provisions of the Second ECP Amendment that survive termination of the Ziopharm Agreement as a result of Section 5.3 of the Second ECP Amendment shall terminate upon the earlier of termination of the Merck Agreement and the provision of Merck's consent to the transfer of all of Ziopharm's obligations and right, title and interest in the Merck Agreement to Precigen as set forth in Section 3.3. Section 6.1 of the Second ECP Amendment shall not survive termination of the Ziopharm Agreement. In the event of any conflict between the surviving terms of the Ziopharm Agreement and the terms of this Agreement, the terms of this Agreement shall control, except with respect to any Section, including but not limited to Sections 3.3 and 6.1 of the Second ECP Amendment as related to the Merck Agreement until such termination of the Merck Agreement. Notwithstanding, anything to the contrary, Ziopharm as a condition of entering this Agreement remains obligated to pay all outstanding invoices generated under the Ziopharm Agreement incurred through the Effective Date of this Agreement.

3.2 Assignment of Assigned Contracts.

(a) MDACC Research Agreement and 2015 MDACC License.

(i) Precigen, on behalf of itself and its Affiliates (including Intrexon), hereby agrees to use diligent good faith efforts to amend the MDACC Research Agreement or otherwise make such arrangements as are reasonably necessary to ensure that the full benefit of all future contractual rights under the MDACC Research Agreement vest in Ziopharm and Precigen shall secure future rights for Ziopharm equivalent to those it would enjoy from having the MDACC Research Agreement assigned to it as of the Effective Date.

(ii) Precigen, on behalf of itself and its Affiliates (including Intrexon), hereby agrees to use diligent good faith efforts to assign to Ziopharm the future right, title and interest in new patents that would otherwise be licensed to Precigen under the 2015 MDACC License after the Effective Date and to make such arrangements as are reasonably necessary to ensure that the full benefit of the future contractual rights under the 2015 MDACC License vest in Ziopharm.

(iii) Notwithstanding the above, Precigen shall retain rights to all intellectual property and materials received through the MDACC Research Agreement and 2015 MDACC License prior to the Effective Date, such right being licensed herein as part of the Licensed Intellectual Property.

(iv) Additionally, prior to the amendment of the MDACC Research Agreement and 2015 MDACC License, Precigen, on behalf of itself and its Affiliates (including Intrexon), hereby agrees, within five (5) Business Days after the Effective Date, to notify MDACC of this Agreement and request that (x) MDACC, on a going forward basis, provide to Ziopharm and not Precigen or its Affiliates information related to Exclusive Programs that is required to be provided to Precigen or Intrexon under either the MDACC Research Agreement or the 2015 MDACC License, and (y) MDACC permit Precigen (or Intrexon) to appoint employees of Ziopharm (rather than Precigen or Intrexon) to any joint steering committee under the MDACC Research Agreement and 2015 MDACC License. Upon the assent by MDACC to such request, Precigen shall appoint two individuals designated by Ziopharm to any such joint steering committee.

(b) Assigned Contracts.

(i) Precigen, on behalf of itself and its Affiliates (including Intrexon), hereby agrees to use diligent good faith efforts to assign to Ziopharm all of its right, title and interest in, the 2018 MDACC License, the Existing TCR CRADA and the MDACC Sponsored Research Agreement (collectively, the "**Assigned Contracts**"). The Assigned Contracts shall automatically be amended to include any additional contracts that the Parties agree to assign to Ziopharm as part of the Transition Services. Precigen shall not unreasonably withhold consent to assign to Ziopharm any contract that relates to the Licensed Products in the Field in the Territory. Without limiting the generality of the foregoing, until such date as the Existing TCR CRADA is assigned to Ziopharm, Precigen, on behalf of itself and its Affiliates (including Intrexon), shall (a) promptly provide Ziopharm with all information provided by NCI with respect to any option granted under the TCR Existing CRADA and (b) solely at the request of Ziopharm, elect to exercise an option under the Existing TCR CRADA and allow Ziopharm full control to negotiate the terms of the resulting license agreement directly with NCI.

(ii) If despite Precigen's diligent good faith efforts it is not able to assign any Assigned Contract, then Precigen and Ziopharm shall make such arrangements as are reasonably necessary to ensure that the full benefit of the contractual rights under such agreement vest in Ziopharm and Precigen shall secure rights for Ziopharm equivalent to those it would enjoy from having such agreement assigned to it. Without limiting the generality of the foregoing, Precigen shall amend the Existing Gorilla IL-12 CRADA to remove all provisions relating to the Gorilla IL-12 Construct or shall terminate the Existing Gorilla IL-12 CRADA as it relates to the Gorilla IL-12 Construct.

(iii) Additionally, prior to the amendment of the Assigned Contracts, Precigen, on behalf of itself and its Affiliates, hereby agrees, within five (5) Business Days after the Effective Date, to notify MDACC and NCI of the existence of this Agreement and request that (x) MDACC and NCI, as applicable, on a going forward basis, provide to Ziopharm and not Precigen or its Affiliates information related to the Assigned Contracts that is required to be provided to Precigen or its Affialites under either any such Assigned Contract, and (y) MDACC and NCI, as applicable, permit Precigen (or Intrexon) to appoint employees of Ziopharm (rather

than Precigen or Intrexon) to any joint steering committee under any such Assigned Contract. Upon the assent by NCI and MDACC to such request, Precigen shall appoint two individuals designated by Ziopharm to any such joint steering committee.

3.3 Relinquishment of Rights and Obligations under Merck Agreement. Precigen, on behalf of itself and its Affiliates (including Intrexon), hereby agrees to use diligent good faith efforts to obtain Ares Trading's consent to the transfer of all of Ziopharm's obligations and right, title and interest in the Merck Agreement to Intrexon or its' Affiliate. As between the Parties, from and after the Effective Date, Precigen agrees to perform all obligations of Ziopharm under the Merck Agreement (other than the obligation of exclusivity set forth in Section 2.5 of the Merck Agreement), and, other than the obligation of exclusivity set forth in Section 2.5 of the Merck Agreement, Ziopharm shall not be responsible for any obligations under the Merck Agreement. For clarity, Section 6.7 addresses Ziopharm's sole ongoing payment obligation related to the payments owed to Ares Trading by Intrexon under Section 4.5(e) of the Merck Agreement. Nothing in this Agreement shall prohibit, and Ziopharm shall have the right to negotiate a separate agreement with Ares Trading regarding obtaining rights to any intellectual property rights owned or controlled by Ares Trading relating to [***]. Promptly following the Effective Date, the Parties shall cooperate in good faith, on Precigen's request and at Precigen's cost, to transfer all activities and rights related to CD33 under the Merck Agreement to Precigen, including the Existing Viral CD33 Trial, as set forth in Article 4.

3.4 Mutual Release and Covenant Not to Sue.

(a) The Parties, on behalf of themselves, their predecessors, successors, direct and indirect parent companies, direct and indirect subsidiary companies, companies under common control with any of the foregoing, affiliates and assigns, and its and their past, present, and future officers, directors, shareholders, interest holders, members, partners, attorneys, agents, employees, insurers, managers, representatives, assigns and successors in interest, and all persons acting by, through, under or in concert with them, and each of them, hereby release and discharge the other Parties, together with their predecessors, successors, direct and indirect parent companies, direct and indirect subsidiary companies, companies under common control with any of the foregoing, affiliates and assigns and its and their past, present, and future officers, directors, shareholders, interest holders, members, partners, attorneys, agents, employees, managers, representatives, assigns and successors in interest, and all persons acting by, through, under or in concert with them, and each of them (the Parties' "**Releasees**", as applicable), from all known and unknown charges, complaints, claims, grievances, liabilities, obligations, promises, agreements, controversies, damages, actions, causes of action, suits, rights, demands, costs, losses, debts, penalties, fees, wages, medical costs, pain and suffering, mental anguish, emotional distress, expenses (including attorneys' fees and costs actually incurred) and punitive damages, of any nature whatsoever, known or unknown, which either Party has, or may have had, against the other Party, whether or not apparent or yet to be discovered, or which may hereafter develop ("**Potential Claims**"), for any acts or omissions, prior to the Effective Date, related to or arising from the Ziopharm Agreement, including but not limited to the Second ECP Amendment, the Merck Agreement, the MDAAC Research Agreement, and each other agreement between Ziopharm and either Precigen or Intrexon, except for any Potential Claims arising from any provisions that survive the termination of the Ziopharm Agreement and the Second ECP Amendment in accordance with Section 3.1 of this Agreement (the "**Released**

Claims"). For avoidance of doubt, the Released Claims shall not include any Potential Claims: (a) for acts or omissions that occur on or after the Effective Date; (b) related to or arising from any provisions that survive the termination of the Ziopharm Agreement and the Second ECP Amendment in accordance with Section 3.1 of this Agreement; or (c) related to or arising from any rights or obligations set forth in this Agreement.

(b) Each Party agrees and hereby covenants that it will not, directly or indirectly, on its own behalf or acting on behalf of or through any other person or entity, initiate or maintain any lawsuit, arbitration or other proceeding, whether legal or equitable, against any other Party or its Releasees, arising from or related to the Released Claims.

ARTICLE 4
TECHNOLOGY AND INVENTORY TRANSFER; REGULATORY

4.1 Transfer of Licensed Know-How; Ongoing Transfers.

(a) Initial Precigen Transfer to Ziopharm. At the request of Ziopharm, provided that such request is made within forty-five (45) days after the Effective Date and provided further that such information is not already in the possession of Ziopharm, Precigen shall reasonably provide Ziopharm with (i) complete and accurate copies of all Licensed Know-How in writing and existence as of the Effective Date and (ii) any Accessory Material Agents and/or Activator Ligands, in each case, that is in Precigen's possession and Control and that Ziopharm determines (in its reasonable discretion) will be reasonably necessary or useful for Ziopharm to practice the licenses granted to Ziopharm in Section 2.1(a) and 2.1(b), including any Accessory Material Agents set forth in the letter agreement referenced in Section 1.8, but excluding any manufacturing-related Licensed Know-How to the extent the transfer of the same requires the consent of a Third Party, which transfer shall be performed under Section 4.1(c) (the "**Initial Technology Transfer**"). Precigen shall reasonably cooperate with Ziopharm in good faith to identify any Licensed Know-How that would be necessary or useful for the Development and Commercialization of Licensed Products hereunder or the practice of the licenses granted to Ziopharm pursuant to Sections 2.1(a) and 2.1(b) and to allocate any Accessory Material Agents and/or Activator Ligands for use, as between the Parties.

(b) Initial Ziopharm Transfer to Precigen. At the request of Precigen, provided that such request is made within forty-five (45) days after the Effective Date and provided further that such information is not already in the possession of Precigen, Ziopharm shall reasonably provide Precigen with (i) complete and accurate copies of all material Information in writing and existence as of the Effective Date and (ii) any Accessory Material Agents and/or Activator Ligands, in each case, that is in Ziopharm's possession and Control (including that which is in MDACC's possession that Ziopharm can, without payment or undue effort, cause to be provided to Precigen) and that Precigen determines (in its reasonable discretion) will be reasonably necessary or useful for Precigen to practice its retained rights under the Licensed Intellectual Property, but excluding any manufacturing-related Information to the extent the transfer of the same requires the consent of a Third Party, which transfer shall be performed under Section 4.1(d) and excluding any Information that is not related to the Licensed Products (the "**Initial Ziopharm Technology Transfer**"). Ziopharm shall reasonably cooperate with Precigen in good faith to identify any Information described in this Section 4.1(b) that

would be necessary or useful the practice of Precigen's retained rights under the Licensed Intellectual Property and to allocate any Accessory Material Agents and/or Activator Ligands for use, as between the Parties.

(c) Manufacture Technology Transfer to Ziopharm. Notwithstanding, but without limiting Section 4.1(a) or 4.5(c), Ziopharm acknowledges that the transfer of certain Licensed Know-How is related to the manufacture of Licensed Products, Activator Ligand, and Accessory Material Agents, including manufacturing and controls information and biologic manufacturing and process development technology, and such technology or Information may be subject to the consent of one or more Third Party contract manufactures. Precigen shall use commercially reasonable efforts to obtain any such consents required for the transfer of any such manufacturing related Information and, upon obtaining such consent, to transfer such manufacturing-related Licensed Know-How to Ziopharm to enable Ziopharm to manufacture Licensed Products, Activator Ligand and Accessory Material Agents. Ziopharm shall reasonably cooperate with Precigen in connection with such consent and transfer.

(d) Manufacture Technology Transfer to Precigen. Notwithstanding, but without limiting Section 4.1(b) or 4.5(c), Precigen acknowledges that the transfer of certain Information described in Section 4.1(b) is related to the CD33 trial and Accessory Material Agents, including manufacturing and controls information and biologic manufacturing and process development technology, and such technology or Information may be subject to the consent of one or more Third Party contract manufactures. Ziopharm shall use commercially reasonable efforts to obtain any such consents required for the transfer of any such manufacturing related Information and, upon obtaining such consent, to transfer such manufacturing-related Information to Precigen to enable Precigen to advance CD33 and Accessory Material Agents. Precigen shall reasonably cooperate with Ziopharm in connection with such consent and transfer.

4.2 Technology Transfer Costs. Other than as may be agreed as a Transition Service hereunder, each Party requesting transfer under Section 4.1 shall reimburse the other Party's out-of-pocket expenses and FTE costs incurred to perform any technology transfer, including any amounts paid in consideration for manufacturing support following such technology transfer. Each Party shall invoice the other Party on a monthly basis for the foregoing costs incurred by, and shall pay the amount invoiced within thirty (30) days after the date of any such invoice.

4.3 IL-12 Product Supply.

(a) Inventory Transfer. On Ziopharm's reasonable request following the Effective Date, Precigen shall transfer to Ziopharm or its designee some or all of its inventory of IL-12 Products (including all final product, drug substance, intermediates, works-in-process, formulation materials, reference standards, drug product clinical reserve samples, packaged retention samples, and the like) that is then in the possession or Control of Precigen or its Affiliates or sublicensees and in quantities reasonably requested by Ziopharm; provided that Ziopharm shall pay Precigen a price equal to Precigen's historical cost plus [***] percent ([***]%) for any such transferred IL-12 Product.

4.4 Assumption of Supply. On Ziopharm's reasonable request, Precigen shall, and shall cause its Affiliates and sublicensees to, reasonably cooperate with Ziopharm to facilitate orderly transition of the manufacture of IL-12 Products to Ziopharm or its designee, including by assigning or amending as appropriate, upon request of Ziopharm, any agreements or arrangements with Third Party contract manufacturers to Ziopharm or, to the extent any such Third Party agreement or arrangement is not assignable to Ziopharm, reasonably cooperating with Ziopharm to facilitate the entry by Ziopharm into a contract directly with such contract manufacturer(s).

4.5 Transition Services.

(a) Transition Services. Precigen agrees to provide or cause to be provided to Ziopharm the services listed on Exhibit C (the "**Agreed Services**"). Without limiting the foregoing, for a period of thirty (30) days following the Effective Date, Ziopharm shall have an opportunity to identify additional activities that Precigen was performing with respect to the Licensed Product or the Development thereof as of the Effective Date that it would like Precigen to continue to perform under this Agreement for a specified period to enable the smooth transition of activities in relation to the Licensed Products to Ziopharm. Upon identification of such activities by Ziopharm, Precigen shall reasonably determine whether it can continue to provide such services and, upon Precigen's consent (which shall not be unreasonably withheld), the Parties shall include such activities as Agreed Services hereunder and shall update Exhibit C to reflect the same. In no event shall any Agreed Services continue for a period longer than one (1) year without the prior written consent of Precigen, which consent may be withheld at Precigen's sole discretion. Without limiting the foregoing, for a period of one (1) year from the Effective Date (or such later date agreed by the Parties in writing) (the "**Transition Period**"), Ziopharm may request that Precigen provide or continue to perform additional services related to any Licensed Product other than the Agreed Services, including, as applicable, the (i) transition to Ziopharm or its designee some or all of any clinical or non-clinical trials for a Licensed Products in the Field and the activities related to or supporting such trials, (ii) the continued conduct of any non-clinical or clinical trials for any Licensed Product in the Field, for a reasonable period of time requested by Ziopharm, (iii) ongoing services related to the manufacturing of Licensed Products or (iv) the termination or wind-down of non-clinical or clinical trials; in each case as requested by Ziopharm, (the "**Additional Services**" and together with the Agreed Services, the "**Transition Services**"). The Parties will negotiate terms for the provision of such Additional Services, provided that, for clarity, Precigen will not be obligated to provide any Additional Services unless Precigen consents to do so, which consent may be withheld at Precigen's sole discretion. Precigen agrees that is shall perform all Transition Services in the same or substantially similar manner, in all material respects, in which Precigen generally performs or has performed similar services for its own product development business, provided that, unless otherwise agreed in writing (including as may be agreed and forth on Exhibit C for a specific Transition Service), Precigen's obligations to perform any Transition Services shall not extend beyond the Transition Period.

(b) Service Fees; Invoicing. Any and all service fees charged by Precigen, either directly, through its Affiliates or through Third Party contractors shall (i) with respect to the Agreed Services, be set forth in Exhibit C and (ii) with respect to the Additional Services, be agreed by the Parties in writing. Unless otherwise agreed by the Parties in writing, or as set forth

on Exhibit C with respect to payment for specific Agreed Services, Precigen will aggregate and invoice in a single invoice each month all of its service fees for any Transition Services that are payable by Ziopharm for the Transition Services performed in such month. Precigen's service fees will be invoiced monthly, in arrears, and Ziopharm shall pay all undisputed invoices within thirty (30) days of the date of receipt of such invoice.

(c) Third Party Consents. Without limiting Section 4.3(a) , Precigen shall use commercially reasonable efforts to obtain any waivers, permits, consents or similar approvals from any Third Parties or Governmental Authorities that are reasonably necessary for Precigen to perform or Ziopharm to receive the Transition Services, as applicable (each a "**Consent**"). Ziopharm shall be solely responsible for the costs paid to any Third Party or Governmental Authority in respect of obtaining any such Consent; provided, however, that Precigen shall notify Ziopharm in advance of any known costs associated with obtaining such Consents and obtain Ziopharm's written approval of such consent fee prior to Precigen agreeing to pay such fee and prior to Ziopharm being liable for any such fee. If, after thirty (30) days using its commercially reasonable efforts, or such longer period as may be requested by Ziopharm, Precigen is unable to obtain any Consent, the Parties shall work together in good faith to agree upon a commercially reasonable alternative arrangement in respect of such Transition Service for which a Consent is required but has not been obtained to the maximum extent possible and shall then perform any such alternative as a Transition Service hereunder.

(d) Third Party Contracts. Precigen shall, to the extent reasonably possible utilize any Third Party contracts on behalf of Ziopharm in the performance of the Transition Services, and Ziopharm agrees to comply with the terms of any Third Party contract to the extent relevant to the receipt of a Transition Service, provided that Ziopharm has received prior written notification of the terms of such Third Party contract, and provided, further, that, following receipt of notification of such terms, Ziopharm may opt to not receive the relevant Transition Service rather than comply with such terms. Where a Third Party contract is required in order for the provision of the Transition Services and such Third Party contract expires or is terminated by the relevant Third Party, then Precigen shall use all reasonable efforts to perform the relevant Transition Services itself or to provide a substitute of similar (but no lower) quality and reputation, with the costs of retaining such substitute borne solely by Precigen, unless otherwise agreed.

(e) Intellectual Property. Ownership of all inventions and intellectual property developed by or on behalf of Precigen in the performance of transition services shall be determined in accordance with Section 7.1(c).

(f) Early Termination. Prior to the expiration of the Transition Period and subject to any limitations set forth on Exhibit C with respect to specific Transition Services, Ziopharm may elect to terminate Precigen's provision of certain of the Transition Services by delivering written notice of such election to Precigen. Such termination of the applicable Transition Services will be effective no earlier than thirty (30) calendar days following Precigen's receipt of such notice, unless Precigen consents to a shorter period. Upon any termination or reduction of any Transition Service and subject to any rights or obligations that have accrued prior to termination, neither Party shall have any further obligation to the other Party in respect of the Transition Services that have been terminated.

4.6 Regulatory or Third Party Action or Inspection. Each Party shall immediately notify the other Party as promptly as reasonably possible following becoming aware of any Regulatory Authority inspections relating to (a) in the case of Precigen, any of its products that utilizes or incorporates any technology that is also used or incorporated in any Licensed Product, and (b) in the case of Ziopharm, a Licensed Product that, in either case of (a) or (b) is reasonably likely to have an impact on the other Party (each of (a) and (b), a "**Reporting Product**" of such Party). To the extent permitted by applicable Law, each Party shall have the right to be present at any such inspections and shall have the opportunity to provide, review and comment on any responses that may be required, in each case, to the extent applicable to such Party's Reporting Product(s). In the event a Party does not receive prior notice of any such inspection, the Party shall notify the other Party as soon as practicable after such inspection and shall provide the other Party with copies of all materials, correspondence, statements, forms and records received or generated pursuant to any such inspection to the extent permitted by applicable Law and to the extent related to such other Party's Reporting Product(s). In addition to such obligations with respect to Regulatory Authority inspections, each Party shall immediately notify the other Party of any material Information it receives regarding any threatened or pending action or communication by or from any Regulatory Authority that is reasonably likely to materially and adversely affect the regulatory status of any Reporting Product(s) of such other Party; provided, that such Party is permitted to disclosure such material Information, including under applicable Law..

4.7 Rights of Reference. Within sixty (60) days following the Effective Date, the Parties will negotiate in good faith and agree in writing to a separate agreement setting forth the terms pursuant to which each Party would grant to the other Party the right to reference and use the Drug Master Files (DMFs) or other regulatory filings of such Party (the "**Regulatory Exchange Agreement**"). The Parties acknowledge that the Regulatory Exchange Agreement shall be subject to the agreement of the Parties in all respects, including with respect to the permitted scope of such reference and use rights, including with respect to specific products, development stages, fields of use, specific entities or persons and territories.

ARTICLE 5
GORILLA IL-12 PROGRAM; JOINT DEVELOPMENT COMMITTEE

5.1 General; Performance Standards. Subject to the terms and conditions of this Agreement, Ziopharm shall be responsible for the Development of the Gorilla IL-12 Products pursuant to and in accordance with the Gorilla Development Plan. As set forth in additional detail herein, Ziopharm shall be responsible for 80% of the Gorilla Development Costs and Precigen shall be responsible for 20% of the Gorilla Development Costs (which, for clarity are only with respect to the Gorilla IL-12 Products for use in the Field but not the HPV Field) and the Parties shall share in the Operating Profit (or Loss) for Gorilla IL-12 Products in accordance with Section 6.2(a) and 6.2(b), as applicable.

5.2 Gorilla IL-12 Product-Development.

(a) Responsibility; Historical Efforts. Ziopharm shall have the exclusive right to Develop the Gorilla IL-12 Product(s) in Field, in accordance with the Gorilla Development Plan, as may be amended from time to time. In recognition of Precigen's historical

efforts with respect to the research and development of Gorilla IL-12 Products, Ziopharm shall reimburse Precigen for certain costs incurred by or on behalf of Precigen or its Affiliates as set forth in Section 6.2(d).

(b) Gorilla Development Plan. Within sixty (60) days following the Effective Date, the Parties shall prepare the initial Gorilla Development Plan for review by the JDC, which shall include all activities with respect to the Development of the Gorilla IL-12 Products through [***]. In preparation of such meeting, Precigen shall provide Ziopharm with all Information in Precigen's possession or Control reasonably related to the Development of the Gorilla IL-12 Products. Following agreement on the initial Gorilla Development Plan, from time-to-time, but at least in connection with the submission of a new Gorilla Development Budget in accordance with Section 5.2(c), Ziopharm shall prepare updates to the Gorilla Development Plan and shall submit such updates to the JDC for review and comment. Once agreed, the initial Development Plan shall be attached to this Agreement as Exhibit A.

(c) Gorilla Development Budget. The initial Gorilla Development Budget covering all Gorilla Development Activities set forth in the initial Gorilla Development Plan shall be provided by Ziopharm to the JDC for review and comment along with the initial Gorilla Development Plan. The Parties (through the JDC) shall, subject to the remainder of this Section agree on such initial Gorilla Development Budget. No later than October 1 of each calendar year following the initial calendar year during the Term, Ziopharm shall submit an updated Gorilla Development Budget to Precigen (through the JDC) for review and approval. Notwithstanding the foregoing, if the JDC cannot agree on the initial Gorilla Development Budget or any updated Gorilla Development Budget, then the matter will be referred for resolution in accordance with Section 5.3(e), provided further that if the Executive Officers cannot agree on the Gorilla Development Budget, then the JDC shall identify that portion of the budget on which there is agreement for cost sharing (such portion, the "**Gorilla Agreed Budget**"). For the avoidance of doubt, Ziopharm shall have no final decision making authority with respect to the amounts set forth in any Gorilla Agreed Budget, which must be agreed by the JDC, provided further that any Gorilla Development Costs incurred by or on behalf of Ziopharm that are in excess of the Gorilla Agreed Budget shall be subject to off-set against amounts otherwise owed to Precigen in accordance with Section 6.2(b).

(d) Development Costs. Except as set forth in Section 6.2(b), Ziopharm shall bear all Gorilla Development Costs and all cost of any Development of any Gorilla IL-12 Products in the HPV Field.

5.3 Joint Development Committee.

(a) Formation; Composition. Within 20 days after the Effective Date, the parties shall establish a Joint Development Committee composed of two (2) representatives of each Party, each of whom shall have appropriate technical credentials, experience, knowledge, and authority within such party's organization to make the decisions required of the JDC. Each Party may change its representatives to the JDC from time to time in its sole discretion, effective upon written notice to the other party of such change. The JDC will be chaired by Ziopharm, which shall designate one of its JDC representatives as chairperson.

(b) Responsibilities and Authority. The JDC's overall responsibility shall be to oversee the conduct of the Gorilla IL-12 Program and Development of the Gorilla IL-12 Products and to encourage and facilitate ongoing cooperation and communication between the Parties. In particular, the JDC shall:

(i) periodically review and provide comments to the Gorilla Development Plans and Gorilla Development Budgets, including, in the event that the Parties do not agree on the initial or updated Gorilla Development Budget(s) agreeing on the Gorilla Agreed Budget, as set forth in Section 5.2(c);

(ii) discuss the protocol for the first phase 1 trial for any Gorilla IL-12 Product hereunder including, without limitation, the endpoint and goals of such trial, which shall be set forth in the Gorilla Development Plan;

(iii) monitor the progress of Gorilla Development Activities, and review and discuss the results thereof;

(iv) discuss and attempt to address scientific or technical issues arising in the course of the Gorilla Development Activities; and

(v) perform such other duties as are specifically delegated to the JDC in this Agreement or otherwise agreed by the Parties.

(c) Meetings. The JDC shall meet as deemed necessary by the members of the JDC. The JDC may meet in person or by means of telecommunication (telephone, video, or web conferences). The location of in-person JDC meetings will be mutually agreed by the Parties in good faith. Each party shall be responsible for all of its own expenses of participating in JDC meetings.

(d) Minutes. Ziopharm shall be responsible for preparing definitive minutes of each JDC meeting. The chairperson shall circulate a draft of the minutes of each meeting to all members of the JDC for comments within 30 days after such meeting. Such minutes shall provide a description, in reasonable detail, of the discussions at the meeting and shall document all actions and determinations approved by the JDC at such meeting. Without limiting the generality of the foregoing, any amendment or update to the Gorilla Development Plan that is approved at a JDC meeting (including the Gorilla Development Budget therein and, if applicable the Gorilla Agreed Budget), and any pre-clinical or clinical study protocol or any amendment thereto that is approved at a JDC meeting shall be attached to the minutes of such meeting. The Parties shall promptly discuss any comments on such minutes and finalize the minutes no later than the date of the next JDC meeting.

(e) Decision-Making. Subject to Section 5.2(c) and Section 5.3(f) the decisions of the JDC shall be made by unanimous vote, with each party's representatives on the JDC collectively having one vote. No vote of the JDC may be taken unless at least one of each party's representatives is present for the vote. Each party shall be responsible for ensuring that, at all times, its representatives on the JDC act reasonably and in good faith in carrying out their respective responsibilities hereunder.

(f) JDC Dispute Resolution. If the JDC cannot reach consensus with regard to any matter within its authority within ten (10) Business Days after such matter has been brought to the JDC's attention, then such matter shall be referred to the Chief Executive Officer of Precigen and the Chief Executive Officer of Ziopharm, who shall each designate a member of their Party's Board of Directors, after which the Parties' Chief Executive Officers and the appointed members from the Parties' respective Board of Directors shall promptly meet and attempt in good faith to resolve such issue within 30 days from the date upon which such matter is referred to them. In the event that the parties respective executives are unable to resolve such issue within thirty (30) days of the issue being referred to them, then, subject to Section 5.2(c), and 5.3(g), Ziopharm's representatives on the JDC shall have the final decision making authority.

(g) Limitation on Authority. The JDC shall have only such rights, powers and authority as are expressly delegated to it under this Agreement and the JDC shall not be a substitute for the rights of the Parties hereunder. Notwithstanding any other provision of this Agreement to the contrary, the JDC shall not have any right, power or authority:

(h) to determine any issue in a manner that would conflict with the express terms and conditions of this Agreement; or

(i) to modify or amend the terms and conditions of this Agreement.

ARTICLE 6
COMPENSATION

6.1 Annual Licensing Payments. Within five (5) Business Days after the Effective Date and each anniversary of the Effective Date during the Term, Ziopharm shall pay to Precigen an annual license payment of one hundred thousand Dollars ($100,000).

6.2 Gorilla IL-12 Products.

(a) Profit and Loss Share in Field (but not the HPV Field).

(i) Profit Share for Gorilla IL-12 Products in Field but outside of the HPV Field. Subject to Section 6.2(a)(ii), the Parties shall share all Operating Profits and all Operating Losses with respect to the Development and Commercialization of each Gorilla IL-12 Product in the Field (but not in the HPV Field, which is addressed in Section 6.2(b)) on the basis of twenty percent (20%) to Precigen and eighty percent (80%) to Ziopharm, provided that Ziopharm shall be entitled to deduct from any amount owed to Precigen under this Section 6.2(a)(i) any amount of Development Credit accrued by Ziopharm (as described in Section 6.2(a)(ii)).

(ii) Development Credit. The Parties agree that Precigen's obligation to bear twenty percent (20%) of all Operating Losses in respect of the Gorilla IL-12 Program shall not require Precigen to make payments in respect of Gorilla Development Costs in excess of twenty percent (20%) of the amounts set forth in any agreed Gorilla Development Budget, or, if the Parties cannot agree on the Gorilla Development Budget, the Gorilla Agreed Budget. However, in the event that the Gorilla Development Costs exceed such agreed amounts, Ziopharm shall be entitled to deduct from any payment of Precigen's share of any Operating

Profits pursuant to Section 6.2(a)(i) an amount equal to [***] percent ([***]%) of the difference between the amount set forth in the agreed Gorilla Development Budget or, if applicable, the Gorilla Agreed Budget and the Gorilla Development Costs actually incurred (such amounts the "**Development Credit**"). For clarity, Ziopharm may carry over any Development Credits that accrue in any calendar quarter to any subsequent calendar quarter.

(b) Profit Share for Gorilla IL-12 Products in HPV Field. Precigen will have the right commencing on the Effective Date to receive from Ziopharm fifty percent (50%) of all Operating Profits (if any) with respect to the Commercialization of each Gorilla IL-12 Product in the HPV Field. For the avoidance of doubt, with respect to any calendar quarter for which Ziopharm reports an Operating Loss with respect to Gorilla IL-12 Products in the HPV Field, Ziopharm will bear all of such Operating Losses.

(c) Profit Share Payments. Any amounts owed by Precigen pursuant to Section 6.2(a)(i) or Section 6.2(b) shall be payable in accordance with Section 6.5(g).

(d) Historical Costs. In consideration for historical costs incurred by or on behalf of Precigen and its Affiliates associated with historical development efforts directed to Gorilla IL-12 Products, Ziopharm shall pay to Precigen a total of one million dollars ($1,000,000) to cover historical expenses including out of pocket expenses and internal FTE costs, payable in calendar quarterly installments, as follows: within fifteen (15) days following each of (i) December 31, 2018, (ii) March 31, 2019, (iii) June 30, 2019 and (iv) September 30, 2019, Precigen shall issue an invoice to Ziopharm for two hundred and fifty thousand dollars ($250,000), which Ziopharm shall pay the undisputed amounts set forth on each invoice within thirty (30) days following Ziopharm's receipt thereof. Precigen shall provide Ziopharm with documented evidence of such historical expenses thirty (30) days prior to the first required payment hereunder.

6.3 Development Milestone Payments. On an Exclusive Program-by-Exclusive Program basis, Ziopharm shall notify Precigen within thirty (30) days after the first achievement by Ziopharm or its Affiliates of the following development milestone events for each Exclusive Program. Thereafter, Precigen shall invoice Ziopharm for the corresponding milestone payment, and Ziopharm shall pay each such invoice within thirty (30) days after receipt thereof. No milestone payments shall be due pursuant to this Section 6.2 as a result of achievement of any milestone event by a Sublicensee.

Development Milestone Event	Milestone Payment
Initiation of the first [***] Clinical Trial	[***] Dollars ($[***])
First Regulatory Approval in [***]	[***] Dollars ($[***])
First Regulatory Approval by [***]	[***] Dollars ($[***])
First Regulatory Approval in [***]	[***] Dollars ($[***])
Total	**Fifty-two million five hundred thousand Dollars ($52,500,000)**

Each milestone payment is payable one time only for each Exclusive Program, regardless of the number of times the corresponding event is achieved by an Exclusive Product in each Exclusive Program and regardless of the number of Exclusive Products in each Exclusive Program to achieve such event. Under no circumstances shall Ziopharm be obligated to pay Precigen more than fifty-two million five hundred thousand Dollars ($52,500,000) pursuant to this Section 6.2 for each Exclusive Program or more than [***] Dollars ($[***]) in total for all four Exclusive Programs under this Agreement.

6.4 Sublicensing Income. Ziopharm shall pay to Precigen twenty percent (20%) of all Sublicensing Income received by Ziopharm from each Sublicensee in accordance with Section 6.5(g).

6.5 Ziopharm Royalties on Licensed Products.

(a) Exclusive Royalty-Bearing Products. Subject to Section 6.5(d) and Section 6.5(e) on an Exclusive Royalty-Bearing Product-by-Exclusive Royalty-Bearing Product basis, Ziopharm shall pay to Precigen royalties on aggregate annual Net Sales of all Exclusive Royalty-Bearing Products sold by Ziopharm or its Affiliates in the Field in the Territory during the applicable Royalty Term, as calculated by multiplying the applicable royalty rate by the corresponding amount of incremental Net Sales of each Exclusive Royalty-Bearing Product in the Field in the Territory in each calendar year.

Royalty Tier	Annual Net Sales of each Exclusive Royalty-Bearing Product in the Territory	Royalty Rate
1	For that portion of annual aggregate Net Sales of each Exclusive Royalty-Bearing Product less than or equal to [***] Dollars ($[***])	[***]%
2	For that portion of annual aggregate Net Sales of Exclusive Royalty-Bearing Product greater than [***] Dollars ($[***]) and less than or equal to [***] Dollars ($[***])	[***]%
3	For that portion of annual aggregate Net Sales of Exclusive Royalty-Bearing Product greater than [***] Dollars ($[***])	[***]%

For example, if aggregate annual Net Sales of a particular Exclusive Royalty-Bearing Product in the Field in the Territory is $1.3 billion in a particular calendar year and aggregate annual Net Sales of a different Exclusive Royalty-Bearing Product in the Field in the Territory is $200 million in the same calendar year, then royalties payable by Ziopharm equal ([***]% of $[***])

+ ([***]% of $[***]) + ([***]% of $[***]) + ([***]% of $[***]) = $[***]. For clarity, Net Sales of an Exclusive Royalty-Bearing Product in all indications shall be grouped together for the purpose of determining royalties owed under this Section 6.5(a).

(b) Non-Exclusive Products and TCR Products. Subject to Section 6.5(d) and Section 6.5(e), on a Licensed Product-by-Licensed Product basis, Ziopharm shall pay to Precigen royalties on aggregate annual Net Sales of all Non-Exclusive Products and TCR Products sold by Ziopharm or its Affiliates in the Field in the Territory during the applicable Royalty Term, as calculated by multiplying the applicable royalty rate by the corresponding amount of incremental Net Sales of each Non-Exclusive Product and TCR Product in the Field in the Territory in each calendar year.

Royalty Tier	Annual Net Sales of each Non-Exclusive Product and TCR Product in the Territory	Royalty Rate
1	For that portion of annual aggregate Net Sales of each Non-Exclusive Product and TCR Product less than or equal to [***] Dollars ($[***])	[***]%
2	For that portion of annual aggregate Net Sales of each Non-Exclusive Product and TCR Product greater than [***] Dollars ($[***]) and less than or equal to [***] Dollars ($[***])	[***]%
3	For that portion of annual aggregate Net Sales of each Non-Exclusive Product and TCR Product greater than [***] Dollars ($[***])	[***]%

For example, if aggregate annual Net Sales of a particular Non-Exclusive Product or TCR Product in the Field in the Territory is $1.3 billion in a particular calendar year and annual Net Sales of a different Non-Exclusive Product or TCR Product in the Field in the Territory is $200 million in the same calendar year, then royalties payable by Ziopharm equal ([***]% of $[***]) + ([***]% of $[***]) + ([***]% of $[***]) + ([***]% of $[***]) = $[***]. For clarity, Net Sales of a particular Non-Exclusive Product or Net Sales of a particular TCR Product, as applicable, in all indications shall be grouped together for the purpose of determining royalties owed under this Section 6.5(b).

(c) Royalty Term. Ziopharm shall pay royalties under this Section 6.5, on a country-by-country and Licensed Product-by-Licensed Product basis, on Net Sales during the period of time beginning on the First Commercial Sale of such Licensed Product in such country and continuing until the later of: (i) the expiration or abandonment of the last-to-expire Valid Claim in such country Covering such Licensed Product (a "**Covering Claim**" in such country for such Licensed Product) and (ii) twelve (12) years after the First Commercial Sale of such Licensed Product in such country (the "**Royalty Term**").

(d) TCR Product Royalty Cap. The total payments owed by Ziopharm under Section 6.5(b) as a result of Net Sales of TCR Products combined shall not exceed one hundred million Dollars ($100,000,000).

(e) Covering Claim Reduction. The royalty rates set forth in Section 6.5(a) and Section 6.5(b) applicable to the Net Sales of any Licensed Product in any country will be reduced by [***] percent ([***]%) during any period of the Royalty Term when there exists no Covering Claim for such Licensed Product in such country and there is no Regulatory Exclusivity for such Licensed Product in such country.

(f) Reserved

(g) Reports and Payments. Within [***] ([***]) days after the end of each calendar quarter during the Royalty Term, Ziopharm shall (i) deliver to Precigen a statement, on a country-by-country and Licensed Product-by-Licensed Product basis, of the amount of Sublicensing Income received during such calendar quarter and gross sales and Net Sales of Licensed Products during the applicable calendar quarter and a calculation of the amount of royalty payment due on such sales for such calendar quarter; and (ii) pay all royalty payments, Sublicensing Income payments and Makeup Payments due to Precigen for such calendar quarter. In addition, with respect to any payments owed on account of Gorilla IL-12 Products, along with the royalty report, Ziopharm shall provide Precigen with a reasonably detailed statement of its Development Costs and a reasonably detailed statement of its Commercialization Costs (or in each case an estimate of any portions thereof where actuals are not known as of such time) for each Gorilla IL-12 Product as well as the a summary of the total Received Amounts allocable to such Gorilla IL-12 Product in such calendar quarter and the total amount owed to or payable by Precigen on account thereof, including whether any Development Credits were generated during such quarter or applied to amounts payable in such calendar quarter and whether any remaining Development Credits exist. Any net payment owed from Ziopharm to Precigen in respect of Operating Profits shall be paid within [***] ([***]) days following the delivery of the profit sharing report (i.e. within [***] ([***]) days after the end of the calendar quarter). The undisputed portion of any net payment owed from Precigen to Ziopharm in respect of Operating Loss shall be paid within [***] ([***]) days following the delivery of the profit sharing report.

6.6 Precigen Licensing Income and Royalties on CAR-T Products.

(a) Precigen Licensing Income. Subject to Section 6.6(c) and Section 6.6(d), in the event Precigen grants a CAR-T License to one or more licensees, Precigen shall pay to Ziopharm [***] percent ([***]%) of all Licensing Income received by Precigen from such licensee in accordance with Section 6.6(f).

(b) CAR-T Royalties. Subject to Section 6.6(c) and Section 6.6(d), Precigen shall pay to Ziopharm a [***] percent ([***]%) royalty on Net Sales of all CAR-T Products sold by Precigen or its Affiliates for use in Oncology in the Territory during the applicable CAR-T Royalty Term.

(c) CAR-T Cap. Subject to Section 6.6(d), the total payments owed by Precigen under Section 6.6(a) and Section 6.6(b) combined shall not exceed one hundred million Dollars ($100,000,000) (the "**CAR-T Cap**").

(d) CAR-T Royalty Reduction and CAR-T Cap Reduction. In the event Precigen or its Affiliates are obligated to [***], then the royalty rate pursuant to Section 6.6(a) shall be reduced to [***] percent ([***]%) and the CAR-T Cap shall be reduced to [***] Dollars ($[***]).

(e) CAR-T Royalty Term. Precigen shall pay royalties under this Section 6.6, on a country-by-country and CAR-T Product-by-CAR-T Product basis, on Net Sales during the period of time beginning on the First Commercial Sale of such CAR-T Product in such country and continuing until the later of: (i) the expiration or abandonment of the last-to-expire Valid Claim in such country Covering such CAR-T Product and (ii) twelve (12) years after the First Commercial Sale of such CAR-T Product in such country (the "**CAR-T Royalty Term**").

(f) Reports and Payments. Within [***] ([***]) days after the end of each calendar quarter during the Royalty Term or during the term of any CAR-T License, Precigen shall (i) deliver to Ziopharm a statement, on a country-by-country and CAR-T Product-by-CAR-T Product basis, of the amount of Licensing Income received during such calendar quarter and gross sales and Net Sales of CAR-T Products during the applicable calendar quarter and a calculation of the amount of royalty payment due on such sales for such calendar quarter; and (ii) pay all royalty payments, Licensing Income payments and Makeup Payments due to Ziopharm for such calendar quarter.

6.7 Payments under Merck Agreement. Ziopharm shall remain responsible for all payments owed to Merck under Section 4.5(e) of the Merck Agreement as a result of Ziopharm's, its Affiliates' or Sublicensees' exploitation of CAR-T Products. Precigen shall remain responsible for all payments owed to Merck under Section 4.5(e) of the Merck Agreement as a result of Precigen's, its Affiliates or licensees' exploitation of CAR-T Products. Notwithstanding the foregoing, in the event that one Party (the "**Overpaying Party**") pays more than fifty percent (50%) of the One-Time Intrexon Program Option Fee (as defined under the Merck Agreement), then the other Party (the "**Underpaying Party**") shall pay the Overpaying Party [***] percent ([***]%) of all Net Sales of Licensed Products (in the case of Ziopharm as the Underpaying Party) or CAR-T Products (in the case of Precigen as the Underpaying Party), as applicable, (such makeup payments, the "**Makeup Payments**") until the total of the payments towards the One-Time Intrexon Program Option Fee made by the Underpaying Party pursuant to the Merck Agreement plus the Makeup Payments equals fifty percent (50%) of the One-Time Intrexon Program Option Fee.

6.8 Foreign Exchange. The rate of exchange to be used in computing the amount of currency equivalent in Dollars of Net Sales invoiced in other currencies shall be the applicable spot exchange rate sourced from Reuters/Bloomberg, or such other source agreed to by both Parties.

6.9 Manner and Place of Payment. All payments owed under this Agreement shall be made by wire transfer in immediately available funds to a bank and account designated in writing by the Party receiving the payment.

6.10 Records; Audits. Ziopharm and its Affiliates will maintain complete and accurate records in reasonably sufficient detail to permit Precigen to confirm the accuracy of (a) the calculation of Operating Profits (or Loss) under Section 6.2 (including any Development Credits accrued with respect thereto), (b) the Sublicensing Income payments under Section 6.4, (c) the calculation of royalty payments under Section 6.5 and (d) the calculation of any Makeup Payments under Section 6.7. Precigen and its Affiliates will maintain complete and accurate records in reasonably sufficient detail to permit Ziopharm to confirm the accuracy of (i) the calculation of Development Costs or Operating Profits (or Loss) under Section 6.2, (ii) the Licensing Income payments under Section 6.6(a), (iii) the calculation of royalty payments under Section 6.6(b) and (iv) the calculation of any Makeup Payments under Section 6.7. Upon reasonable prior notice, such records shall be available during regular business hours for a period of three (3) years from the end of the calendar year to which they pertain for examination, not more often than once each calendar year, by an independent certified public accountant selected by the auditing Party and reasonably acceptable to the audited Party, for the sole purpose of verifying the accuracy of the financial reports furnished by the other Party pursuant to this Agreement. Any such auditor shall enter into a confidentiality agreement with the audited Party and shall not disclose the audited Party's Confidential Information, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by the audited Party or the amount of payments due by one Party to the other Party under this Agreement. Any amounts shown to be owed but unpaid shall be paid, and any amounts showed to be overpaid will be refunded, within forty-five (45) days from the accountant's report. The auditing Party shall bear the full cost of such audit unless such audit discloses an underpayment or overcharge by the audited Party of more than [***] percent ([***]%) of the amount due, in which case the audited Party shall bear the full cost of such audit.

6.11 Taxes.

(a) Taxes on Income. Each Party shall be solely responsible for the payment of all taxes imposed on its share of income arising directly or indirectly from the efforts of the Parties under this Agreement.

(b) Tax Cooperation. The Parties agree to cooperate with one another and use reasonable efforts to reduce or eliminate tax withholding or similar obligations in respect of annual licensing payments, royalties, milestone payments, licensing income payments and other payments made by either Party under this Agreement. To the extent either Party is required to deduct and withhold taxes on any payment to the other Party, the paying Party shall pay the amounts of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to the other Party an official tax certificate or other evidence of such withholding sufficient to enable the other Party to claim such payment of taxes. The other Party shall provide the paying Party any tax forms that may be reasonably necessary in order for the paying Party not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. Each Party shall provide the other with reasonable assistance to enable the recovery, as permitted by applicable Laws, of withholding taxes, value added taxes, or similar obligations

resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or value added tax. To the extent any such amounts are so deducted or withheld, and paid over to the appropriate Governmental Authority, such amounts shall be treated for all purposes under this Agreement as having been paid to the person to whom such amounts would otherwise have been paid.

ARTICLE 7
INTELLECTUAL PROPERTY MATTERS

7.1 Ownership of Inventions.

(a) Activities by Ziopharm. Unless provided for otherwise herein, Ziopharm shall own all Information and inventions, whether or not patentable, made in the course of Ziopharm's Research, Development, manufacture and Commercialization of Licensed Products after the Effective Date.

(b) Gorilla IL-12 Program Inventions. All Information and inventions, whether or not patentable, made in the course of Ziopharm's performance of activities under the Gorilla Development Plan, including all intellectual property rights therein (collectively, "**Gorilla Inventions**") and all Patents claiming Gorilla Inventions ("**Gorilla Patents**") shall be solely and exclusively owned by Ziopharm, if made (i) solely by employees, agents, or independent contractors of Ziopharm or (ii) (A) solely by employees, agents, or independent contractors of Precigen or (B) jointly by employees, agents or independent contractors of each Party (in each case of (A) and (B), with Precigen's involvement being limited to participation at JDC meetings) (such Gorilla Inventions under (i) and (ii), the "**Ziopharm Gorilla Inventions**" and such Gorilla Patents under (i) and (ii), the "**Ziopharm Gorilla Patents**"). Precigen hereby assigns to Ziopharm any and all right, title and interest it may have in any Ziopharm Gorilla Inventions, and agrees to take such further actions reasonably requested by Ziopharm to evidence such assignment. Precigen will require all of its employees, consultants agents and contractors, and will cause its Affiliates and subcontractors to require all of their employees, consultants agents and contractors to assign all Ziopharm Gorilla Inventions that are conceived, generated or otherwise made by such employees, consultants agents and contractors to it, respectively, for further assignment according to the ownership principles described in this Section 7.1(b).

(c) Transition Services Inventions. Any Information and inventions, whether or not patentable that Precigen or its Affiliates may solely or jointly conceive, develop or reduce to practice, or cause to be conceived, developed or reduced to practice, in the performance of the Transition Services (including the use or manufacture thereof), including any and all intellectual property rights (including moral rights) inherent therein and appurtenant thereto, (collectively, "**Service Inventions**"), shall be solely and exclusively owned by Precigen. Precigen hereby grants to Ziopharm under any all right, title and interest it may have in any Service Inventions to Ziopharm solely for practice of any or all of the rights granted to Ziopharm in Section 2.1(a) and Section 2.1(b). Precigen will ensure that all individuals providing Transition Services have or will prior to providing any Transition Service enter into an inventions assignment agreement whereby, to the fullest extent permitted under applicable Law, all such Service Inventions are assigned to Precigen.

(d) Ziopharm Veledimex Alterations. Precigen shall own all Ziopharm Veledimex Alterations, whether or not patentable, made in the course of Ziopharm's Research, Development, manufacture and Commercialization of Licensed Products after the Effective Date. Ziopharm hereby assigns to Precigen any and all right, title and interest it may have in any Ziopharm Veledimex Alterations, and agrees to take such further actions reasonably requested by Precigen to evidence such assignment. Ziopharm will require all of its employees, consultants agents and contractors, and will cause its Affiliates and subcontractors to require all of their employees, consultants agents and contractors to assign all Ziopharm Veledimex Alterations that are conceived, generated or otherwise made by such employees, consultants agents and contractors to it, respectively, for further assignment according to the ownership principles described in this Section 7.1(d). For clarity, any Ziopharm Veledimex Alterations are part of the Licensed Intellectual Property and are within the scope of the license to Ziopharm set forth in Section 2.1.

7.2 Inventorship Procedure. Inventorship shall be determined in accordance with U.S. patent laws. All such determinations shall be documented to ensure that any divisional or continuation patent applications reflect appropriate inventorship.

7.3 Disclosure of Inventions. Precigen shall promptly disclose to Ziopharm all Service Inventions.

7.4 Prosecution of Licensed Patents.

(a) Generally. Subject to Section 7.4(b), as between the Parties, Precigen shall have the right, but not the obligation, to prepare, file, prosecute and maintain the Licensed Patents in the Territory. As between the Parties, Precigen shall bear all costs incurred by Precigen in connection with the preparation, filing, prosecution or maintenance of any Licensed Patent. Precigen shall consult with Ziopharm and keep Ziopharm reasonably informed of the status of the Licensed Patents and shall promptly provide Ziopharm with copies of all material correspondence received from any patent authority in connection therewith to the extent not publicly available. In addition, Precigen shall timely provide Ziopharm with drafts of all proposed filings and correspondence to any patent authority with respect to the Licensed Patents in the Field for Ziopharm's review and comment prior to the submission of such proposed filings and correspondence. Precigen shall confer with Ziopharm and incorporate Ziopharm's comments prior to submitting such filings and correspondence, provided, that Ziopharm's comments do not require Precigen to take any action in connection with the Licensed Patents that could reasonably be expected to adversely affect Precigen's or its Affiliate's Development or Commercialization of (i) products (other than Licensed Products) claimed by such Licensed Patent inside or outside the Field in the Territory or (ii) Licensed Products claimed by such Licensed Patent outside the Field in the Territory (a "**Precigen Impact Situation**"). If in either Party's opinion, a Precigen Impact Situation could arise, such Party will promptly notify the other Party and the Parties shall discuss in good faith. Precigen shall have final decision authority with respect to whether or not to incorporate such comments.

(b) New Patent Applications. Notwithstanding Section 7.4(a), if after consultation with Ziopharm, Precigen agrees that a new patent application (including, with respect to Sleeping Beauty Intellectual Property, a divisional application) should be filed based

on the Licensed Know-How, such patent applications shall be deemed Licensed Patents subject to further prosecution and maintenance in accordance with Section 7.4(a). Precigen shall reasonably consult with Ziopharm regarding the drafting and filing of such new patent applications and shall reasonably consider any comments provided by Ziopharm related thereto. For the avoidance of doubt, Precigen shall have authority with respect to such new patent applications (or divisional application) filing, prosecution and maintenance decisions in accordance with Section 7.4(a).

(c) Abandonment. If Precigen decides anywhere in the Territory to abandon any Licensed Patent, Ziopharm may assume Precigen's rights and responsibilities under this Section 7.4 with respect to such Licensed Patent, and in connection with assuming such rights and responsibilities, Ziopharm may apply for any extension (including a supplementary protection certificate or equivalent thereof) and Ziopharm will thereafter be responsible for the prosecution and maintenance of such Licensed Patent in the Territory.

(d) Cooperation. Each Party shall provide the other Party all reasonable assistance and cooperation, at the other Party's request and expense, in the patent prosecution efforts provide above in this Section 7.4, including providing any necessary powers of attorney, executing any other required documents or instruments for such prosecution, and making its personnel with appropriate scientific expertise available to assist in such efforts.

7.5 Enforcement of Licensed Patents.

(a) Notification. If either Party becomes aware of (i) any existing or threatened infringement of the Licensed Patents in the Field in the Territory (including the filing of an ANDA under Section 505(j) of the FD&C Act or an application under Section 505(b)(2) of the FD&C Act naming a Licensed Product as a reference listed drug and including a certification under Section 505(j)(2)(A)(vii)(IV) or 505(b)(2)(A)(IV), respectively), or (ii) a declaratory judgment action against any Licensed Patent in the Territory in connection with any infringement described in clause (i) (each of (i) and (ii), a "**Patent Infringement**"), it shall promptly notify the other Party in writing to that effect, and the Parties will consult with each other regarding any actions to be taken with respect to such Patent Infringement.

(b) Enforcement Rights. For any Patent Infringement, each Party shall share with the other Party all Information available to it regarding such actual or alleged infringement. With respect to any Patent Infringement with a product that competes with an Exclusive Product in the Field (a "**Product Infringement**"), Ziopharm shall have the first right, but not the obligation, to bring an appropriate suit or take other action against any person or entity engaged in, or to defend against, such Product Infringement, at Ziopharm's cost and expense. Ziopharm shall not settle any such suit or action in any manner that would reasonably be expected to (i) create a Precigen Impact Situation anywhere in the Territory, (ii) require Precigen to incur any liability or (iii) require Precigen to make any payments, in each case without the prior written consent of Precigen. If Ziopharm does not, within one hundred eighty (180) days after its receipt or delivery of notice under Section 7.5(a), commence a suit to enforce the Licensed Patents against such Product Infringement, take other action to terminate such Product Infringement or initiate a defense against such Product Infringement, Precigen shall have the right, but not the obligation, to commence such a suit or take such an action or defend against such Product

Infringement in the Territory at its own cost and expense. In such event, Ziopharm shall take appropriate actions in order to enable Precigen to commence a suit or take the actions set forth in the preceding sentence. Precigen shall not settle any such suit or action in any manner that would reasonably be expected to adversely affect Ziopharm's Development or Commercialization of Exclusive Products in the Field in the Territory or the scope of Ziopharm's license under Section 2.1(a) or Section 2.1(b) anywhere in the Territory without the prior written consent of Ziopharm.

(c) Collaboration. Each Party shall provide to the enforcing Party reasonable assistance in such enforcement, at such enforcing Party's request and expense, including joining such action as a party plaintiff if required by applicable Laws to pursue such action. The enforcing Party shall keep the other Party regularly informed of the status and progress of such enforcement efforts and shall reasonably consider the other Party's comments on any such efforts. The non-enforcing Party shall be entitled to separate representation in such matter by counsel of its own choice and at its own expense, but such Party shall at all times cooperate fully with the enforcing Party.

(d) Expenses and Recoveries. The Party bringing or defending a claim, suit or action under Section 7.5(b) shall be solely responsible for any expenses incurred by such Party as a result of such claim, suit or action. If such Party recovers monetary damages in such claim, suit or action, such recovery shall be allocated first to the reimbursement of any expenses incurred by the Parties in such litigation, and any remaining amounts shall be allocated as follows: (i) if Ziopharm is the enforcing or defending Party, the remaining amounts will be retained by Ziopharm, except that all such amounts shall be attributable to lost sales of Licensed Products shall be included in Net Sales subject to the royalty payment by Ziopharm to Precigen pursuant to Section 6.5(a) or Section 6.5(b), as applicable, and (ii) if Precigen is the enforcing or defending Party, Precigen shall retain all amounts.

7.6 Orange Book Listing. Upon a Party's receipt of a notice of allowance (or equivalent) of an applicable Licensed Patent, Precigen shall promptly provide Ziopharm with all information reasonably required by Ziopharm to list such Licensed Patent in the Orange Book maintained by the FDA or similar or equivalent patent listing source, if any, in other countries in the Territory. Ziopharm shall have the sole right to determine which Licensed Patent or other Patent shall be included in the Orange Book for Licensed Products.

7.7 Patent Term Extensions. Precigen will cooperate with Ziopharm, at Ziopharm's request, in seeking and obtaining patent term extensions (including any pediatric exclusivity extensions as may be available) or supplemental protection certificates or their equivalents in any country with respect to any Exclusive Royalty-Bearing Products. If elections with respect to obtaining such patent term extensions are to be made, Ziopharm shall have the sole right to make such elections.

7.8 Personnel Obligations. Prior to beginning work under this Agreement relating to any Development of a Licensed Product, or conducting any Gorilla Development Activities or Transition Services, each employee, agent or independent contractor of both Parties and their Affiliates shall be bound by invention assignment obligations that are consistent with the obligations of each Party in this Article 7, including: (a) promptly reporting any invention,

discovery, process or other intellectual property right; (b) assigning to each Party, as applicable, all of his or her right, title and interest in and to any invention, discovery, process or other intellectual property right; (c) cooperating in the preparation, filing, prosecution, maintenance and enforcement of any Patent; (d) performing all acts and signing, executing, acknowledging and delivering any and all documents required for effecting the obligations and purposes of this Agreement; and (e) complying with obligations of confidentiality and non-use consistent with those contained in this Agreement.

7.9 Trademarks.

(a) Existing Trademarks. Within thirty (30) days of the Effective Date, the Parties shall enter into a trademark license agreement pursuant to which Precigen shall grant to Ziopharm a non-exclusive license under the Trademarks Controlled by Precigen and its Affiliates as of the Effective Date and set forth on Exhibit G hereto, that relate to the Licensed Intellectual Property or Licensed Products solely to promote, market, sell, offer for sale, import and distribute Licensed Products in the Field in the Territory in accordance with the terms of this Agreement. Ziopharm further agrees that in connection with the Commercialization of any Licensed Products hereunder that incorporate the Switch Intellectual Property, that the origins of any such technology will be properly attributed to Precigen, and Precision hereby grants Ziopharm to make such attributions under any appropriate Trademarks of Precigen. The Parties shall discuss in good faith any Trademark usage describing such Switch Intellectual Property in connection with the Commercialization of any Licensed Products hereunder prior to the use thereof.

(b) New Product Marks. Ziopharm and its Affiliates and Sublicensees shall have the right to brand the Licensed Products in the Territory using any Trademarks it determines appropriate for the Licensed Products, which may vary by country or within a country (the "**New Product Marks**"), provided that Ziopharm shall not, and shall ensure that its Affiliates and Sublicensees will not, make any use of the trademarks or house marks of Precigen (including Precigen's corporate name) or any trademark confusingly similar thereto. As between the Parties, Ziopharm shall own all rights in the New Product Marks and shall register and maintain, in its discretion and at its own cost and expense, the New Product Marks in the countries and regions in the Territory that it determines to be appropriate. Ziopharm shall have the sole right, in its discretion and at its expense, to defend and enforce the New Product Marks. Notwithstanding the foregoing, Ziopharm shall not rebrand any portion of the Licensed Intellectual Property that is the subject of a Trademark Controlled by Precigen or its Affiliates as of the Effective Date and set forth on Exhibit G hereto.

ARTICLE 8
REPRESENTATIONS AND WARRANTIES

8.1 Mutual Representations and Warranties. Each Party hereby represents and warrants to the other Party as follows:

(a) Corporate Existence. As of the Effective Date, it is a company or corporation duly organized, validly existing, and in good standing under the Laws of the jurisdiction in which it is incorporated.

(b) Corporate Power, Authority and Binding Agreement. As of the Effective Date, (i) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and (iii) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms.

(c) No Conflicts. It has not entered into any agreement with any Third Party that is in conflict with the rights granted to any other Party under this Agreement, and has not taken and shall not take any action that would in any way prevent it from granting the rights granted to any other Party under this Agreement, or that would otherwise materially conflict with or adversely affect any other Party's rights under this Agreement.

8.2 Additional Representations and Warranties of Precigen. Precigen represents and warrants and, as applicable, covenants to Ziopharm as follows, as of the Effective Date:

(a) Title; Encumbrances. Precigen has the full and legal rights and authority to license to Ziopharm the Licensed Intellectual Property free and clear from any mortgages, pledges, liens, security interests, conditional and installment sale agreements, encumbrances, charges or claims of any kind;

(b) Notice of Infringement. Precigen has not received any written notice or threat from any Third Party asserting or alleging that any Research, manufacture or Development of Licensed Products by Precigen prior to the Effective Date infringed or would infringe the intellectual property rights of such Third Party;

(c) Notice of Misappropriation. Precigen has not received any written notice or threat from any Third Party asserting or alleging that any Research, manufacture or Development of Licensed Products by Precigen prior to the Effective Date misappropriated the intellectual property rights of such Third Party;

(d) Intellectual Property Rights. The Licensed Patents on Exhibit B, includes all intellectual property rights Controlled by Precigen and its Affiliates that are reasonably necessary for the Development and Commercialization of the Human IL-12 Program, Gorilla IL-12 Program (including [***]) and CD-19 Program in the current state that exists as of the Effective Date by Ziopharm in accordance with the terms of this Agreement;

(e) Third Party Infringement. To Precigen's knowledge, no Third Party is infringing or has infringed any Licensed Patents or has misappropriated any Licensed Know-How;

(f) No Proceeding. There are no pending, and to Precigen's knowledge, no threatened, adverse actions, suits or proceedings (including interferences, reissues, reexaminations, cancellations, oppositions, nullity actions, invalidation actions or post-grant reviews) against Precigen or its Affiliates involving the Licensed Intellectual Property or Licensed Products; and

(g) Gorilla Program. The presentation provided by Precigen to Ziopharm, dated September 18, 2018, represents pre-clinical data of the Gorilla IL-12 Construct.

8.3 Mutual Covenants.

(a) No Debarment. In the course of the Research and Development by under the Gorilla Development Plan or the Research and Development by Ziopharm of Licensed Products, neither Party shall use any employee or consultant who has been debarred by any Regulatory Authority or, to such Party's knowledge, is the subject of debarment proceedings by a Regulatory Authority. Each Party shall notify the other Party promptly upon becoming aware that any of its employees or consultants has been debarred or is the subject of debarment proceedings by any Regulatory Authority.

(b) Compliance. Each Party and its Affiliates shall comply in all material respects with all applicable Laws in the Research, Development and Commercialization of Licensed Products and performance of its obligations under this Agreement, including, to the extent applicable to such Party and its activities hereunder, the statutes, regulations and written directives of the FDA, the EMA and any Regulatory Authority having jurisdiction in the Territory, the FD&C Act, the Prescription Drug Marketing Act, the Federal Health Care Programs Anti-Kickback Law, 42 U.S.C. 1320a-7b(b), the statutes, regulations and written directives of Medicare, Medicaid and all other health care programs, as defined in 42 U.S.C. § 1320a-7b(f), and the Foreign Corrupt Practices Act of 1977, each as may be amended from time to time.

(c) No Conflicts. Each Party shall not enter into any agreement with any Third Party that is in conflict with the rights, licenses and obligations under this Agreement, and has not taken and shall not take any action that would in any way prevent it from granting the rights granted to the other Party under this Agreement.

8.4 Disclaimer. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, ARE MADE OR GIVEN BY OR ON BEHALF OF A PARTY, AND ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

ARTICLE 9
INDEMNIFICATION

9.1 Indemnification by Precigen. Precigen shall defend, indemnify, and hold Ziopharm and its Affiliates and their respective officers, directors, employees, and agents (the "**Ziopharm Indemnitees**") harmless from and against any and all damages or other amounts payable to a Third Party claimant, as well as any reasonable attorneys' fees and costs of litigation incurred by such Ziopharm Indemnitees, resulting from any claims, suits, proceedings or causes of action brought by such Third Party (collectively, "**Claims**") against such Ziopharm

Indemnitee to the extent arising from or based on (a) the Research or Development of the Gorilla IL-12 Products by or on behalf of Precigen or its Affiliates prior to the Effective Date, (b) the Merck Agreement (other than a breach by Ziopharm of any of its obligations under the Merck Agreement), (c) the breach of any of Precigen's obligations, representations or warranties under this Agreement, or (d) the willful misconduct or negligent acts of Precigen, its Affiliates, or the officers, directors, employees, or agents of Precigen or its Affiliates. The foregoing indemnity obligation shall not apply to the extent that (i) the Ziopharm Indemnitees fail to comply with the indemnification procedures set forth in Section 9.3 and Precigen's defense of the relevant Claims is prejudiced by such failure, or (ii) any Claim arises from or is based on any activity set forth in Section 9.2(c) or 9.2(d) for which Ziopharm is obligated to indemnify the Precigen Indemnitees under Section 9.2.

9.2 Indemnification by Ziopharm. Ziopharm shall defend, indemnify, and hold Precigen, Intrexon and their Affiliates and their respective officers, directors, employees, and agents (the "**Precigen Indemnitees**") harmless from and against damages or other amounts payable to a Third Party claimant, as well as any reasonable attorneys' fees and costs of litigation incurred by such Precigen Indemnitees, resulting from any Claims against such Precigen Indemnitee to the extent arising from or based on (a) the Development or Commercialization of Licensed Products by or on behalf of Ziopharm or its Affiliates or Sublicensees (other than by Precigen), (b) Ziopharm's breach of any of its obligations under the Merck Agreement, (c) the breach of any of Ziopharm's obligations, representations or warranties under this Agreement, (d) the willful misconduct or negligent acts of Ziopharm, its Affiliates, or the officers, directors, employees, or agents of Ziopharm or its Affiliates, or (e) Ziopharm's breach of any Assigned Contracts or the MDACC Research Agreement or 2015 MDACC License, each as amended pursuant to the Agreement. The foregoing indemnity obligation shall not apply to the extent that (i) the Precigen Indemnitees fail to comply with the indemnification procedures set forth in Section 9.3 and Ziopharm's defense of the relevant Claims is prejudiced by such failure, or (ii) any Claim arises from or is based on any activity set forth in Section 9.1(c) or 9.1(d) for which Precigen is obligated to indemnify the Ziopharm Indemnitees under Section 9.1.

9.3 Indemnification Procedures. The Party claiming indemnity under this Section 9.3 (the "**Indemnified Party**") shall give written notice to the Party from whom indemnity is being sought (the "**Indemnifying Party**") promptly after learning of such Claim. The Indemnified Party shall provide the Indemnifying Party with reasonable assistance, at the Indemnifying Party's expense, in connection with the defense of the Claim for which indemnity is being sought. The Indemnified Party may participate in and monitor such defense with counsel of its own choosing at its sole expense; provided, however, the Indemnifying Party shall have the right to assume and conduct the defense of the Claim with counsel of its choice. The Indemnifying Party shall not settle any Claim without the prior written consent of the Indemnified Party, not to be unreasonably withheld, unless the settlement involves only the payment of money. So long as the Indemnifying Party is actively defending the Claim in good faith, the Indemnified Party shall not settle or compromise any such Claim without the prior written consent of the Indemnifying Party. If the Indemnifying Party does not assume and conduct the defense of the Claim as provided above, (a) the Indemnified Party may defend against, consent to the entry of any judgment, or enter into any settlement with respect to such Claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith), and (b) the Indemnifying Party shall remain responsible to indemnify the Indemnified Party as provided in this Section 9.3.

9.4 Limitation of Liability. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 9.4 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 9.1 OR 9.2 OR DAMAGES AVAILABLE FOR BREACH OF ARTICLE 10.

9.5 Insurance. Each Party shall procure and maintain insurance, including product liability insurance, consistent with normal business practices of prudent companies similarly situated at all times during which any Licensed Product is being clinically tested in human subjects or commercially distributed or sold by such Party and for the three (3) year period thereafter. It is understood that such insurance shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this Section 9.5. 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 thirty (30) days prior to the cancellation or non-renewal of such insurance.

ARTICLE 10
CONFIDENTIALITY

10.1 Confidentiality. Each Party agrees that, during the Term and for a period of ten (10) years thereafter, it shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement (which includes the exercise of any rights or the performance of any obligations hereunder) any Confidential Information furnished to it by the other Party pursuant to this Agreement, except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties; provided, however, that any Confidential Information that is considered a "trade secret" shall remain subject to the confidentiality provisions herein for so long as such Confidential Information maintains its "trade secret" status. The foregoing confidentiality and non-use obligations shall not apply to any portion of the other Party's Confidential Information that the receiving Party can demonstrate by competent written proof:

(a) was already known to the receiving Party or its Affiliate, other than under an obligation of confidentiality, at the time of disclosure by the other Party;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;

(d) was disclosed to the receiving Party or its Affiliate by a Third Party who has a legal right to make such disclosure and who did not obtain such information directly or indirectly from the other Party; or

(e) was independently discovered or developed by the receiving Party or its Affiliate without access to or aid, application or use of the other Party's Confidential Information, as evidenced by a contemporaneous writing.

10.2 Authorized Disclosure. Notwithstanding the obligations set forth in Section 10.1, a Party may disclose the other Party's Confidential Information and the terms of this Agreement to the extent such disclosure is reasonable necessary in the following instances:

(a) filing, prosecuting, or maintaining Patents as permitted by this Agreement;

(b) prosecuting or defending litigation as permitted by this Agreement;

(c) disclosure to its and its Affiliates' employees, agents, consultants and contractors, on a need-to-know basis for the sole purpose of performing its obligations or exercising its rights under this Agreement; provided that in each case, the disclosees are bound by written obligations of confidentiality and non-use consistent with those contained in this Agreement; or

(d) disclosure to potential and actual: investors, acquirors (of part or all of the shares and/or assets of a Party or an Affiliate), collaborators, licensors, licensees and sublicensees and other financial or commercial partners, solely for the purpose of evaluating or carrying out an actual or potential investment, acquisition, collaboration, license or sublicense; provided that in each case, the discloses are bound by written obligations of confidentiality and non-use consistent with those contained in this Agreement (provided that the term of such obligations may be shorter); or

(e) to comply with applicable Laws, including regulations promulgated by applicable security exchanges, court order, administrative subpoena or order; provided that the Party subject to such Laws shall promptly notify the other Party of such required disclosure and shall use reasonable efforts to obtain, or to assist the other Party in obtaining, a protective order preventing or limiting the required disclosure.

Notwithstanding the foregoing, if a Party is required to make a disclosure of the other Party's Confidential Information pursuant to Section 10.2(e), such Party shall notify the other Party of such required disclosure as far in advance as reasonably practicable (and in no event less than fifteen (15) Business Days prior to the anticipated date of disclosure) to provide the non-disclosing Party opportunity to review and comment upon the disclosure.

10.3 Technical Publication. Neither party may publish peer reviewed manuscripts, or provide other forms of public disclosure including abstracts and presentations, of results of studies carried out under the Gorilla Development Plan, or pertaining to an Exclusive Royalty-Bearing Products, without the prior written consent of the other Party. Precigen or Ziopharm will submit the manuscript of any proposed publication to respective parties at least sixty (60) calendar days before publication, and Precigen or Ziopharm shall have the right to review and

comment upon the publication in order to protect either Party's Confidential Information. Upon either Party's request, publication may be delayed up to sixty (60) additional calendar days to enable Precigen or Ziopharm to secure adequate intellectual property protection of either Party's Confidential Information that would otherwise be affected by the publication. Upon request, Confidential Information shall be removed from the publication unless (i) inclusion of such information is required to satisfy disclosure or reporting obligations, or (ii) such information does not relate only to Exclusive Royalty-Bearing Products and does not relate to Accessory Material Agents.

10.4 Publicity; Terms of Agreement.

(a) The Parties agree that the material terms of this Agreement are the Confidential Information of both Parties, subject to the special authorized disclosure provisions set forth in this Section 10.4 or Section 10.2. In addition, a Party may disclose such terms to the extent reasonably necessary to be disclosed to any bona fide potential or actual investor, acquiror or merger partner for the sole purpose of evaluating an actual or potential investment, acquisition or merger; provided that in connection with such disclosure, such Party shall inform each disclosee of the confidential nature of such Confidential Information and ensure that each such disclosee is contractually obligated to treat such Confidential Information as confidential.

(b) On or as promptly as possible following the Effective Date, the Parties agree to issue a joint press release substantially in a form agreed by the Parties as set forth in Exhibit D (the "**Joint Press Release**"). Except for the Joint Press Release and the talking points agreed by the parties for use in connection with investor relations, earning calls and the like, neither Party shall make any public announcements concerning the material terms of this Agreement without the other Party's prior written consent. Each such press release shall contain appropriate references to the other Party if so requested. A Party commenting on such a proposed press release shall provide its comments, if any, within three (3) Business Days after receiving the press release for review. Neither Party shall be required to seek the permission of the other Party to repeat any information that has already been publicly disclosed by such Party, or by the other Party, in accordance with this Section 10.4(b), provided such information remains accurate as of such time.

(c) The Parties acknowledge that either or both Parties may be obligated to file under applicable Laws a copy of this Agreement with the U.S. Securities and Exchange Commission or other Governmental Authorities. Each Party shall be entitled to make such a required filing, provided that it requests confidential treatment of the commercial terms and sensitive technical terms hereof and thereof to the extent such confidential treatment is reasonably available to such Party. In the event of any such filing, each Party will provide the other Party with a copy of this Agreement marked to show provisions for which such Party intends to seek confidential treatment and shall reasonably consider and incorporate the other Party's reasonable comments thereon to the extent consistent with the legal requirements, with respect to the filing Party, governing disclosure of material agreements and material information that must be publicly filed.

ARTICLE 11
TERM AND TERMINATION

11.1 Term. This Agreement shall become effective on the Effective Date and, unless earlier terminated pursuant to this Article 11 shall remain in effect on a Licensed Product-by-Licensed Product and country-by-country basis, until the expiration of the Royalty Term of such Licensed Product in such country (the "**Term**"). Upon the expiration of the Royalty Term for a Licensed Product in a particular country, the licenses granted by Precigen to Ziopharm under Section 2.1(a), Section 2.1(b) and Section 7.9(a) with respect to such Licensed Product and related Trademarks and such country shall become fully-paid, royalty free and irrevocable.

11.2 Unilateral Termination by Ziopharm. Ziopharm may terminate this Agreement, on a country-by-country or Program-by-Program basis or in its entirety, for any or no reason upon ninety (90) days' written notice to Precigen.

11.3 Termination by Either Party for Breach.

(a) Breach. Subject to Section 11.3(b), each Party shall have the right to terminate this Agreement upon written notice to the other Party if such other Party materially breaches its obligations under this Agreement and, after receiving written notice from the non-breaching Party identifying such material breach in reasonable detail, fails to cure such material breach within sixty (60) days from the date of such notice; provided that if such breach is not reasonably capable of cure within such sixty (60)-day period, the breaching Party may submit a reasonable cure plan prior to the end of such sixty (60)-day period, in which case the other Party shall not have the right to terminate this Agreement for so long as the breaching Party is using Commercially Reasonable Efforts to implement such cure plan.

(b) Disputed Breach. If the alleged breaching Party disputes in good faith the existence or materiality of a breach specified in a notice provided by the other Party in accordance with Section 11.3(a), and such alleged breaching Party provides the other Party notice of such dispute within such sixty (60)-day period, then the non-breaching Party shall not have the right to terminate this Agreement under Section 11.3(a) unless and until the arbitrators, in accordance with Section 12.2, has determined that the alleged breaching Party has materially breached the Agreement and that such Party fails to cure such breach within sixty (60) days following such arbitrators' decision. During the pendency of such dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder. Except with respect to breaches of payment obligations, the Parties agree that a breach with respect to a Licensed Product shall not itself be deemed to be a breach with respect to other Licensed Products and any termination of this Agreement shall be limited to the Licensed Product or Licensed Products for which a Party breached its obligations hereunder. Nothing in this Section 11.3 shall limit a Party's ability to seek remedies available under this Agreement in law or equity.

11.4 Effect of Termination. Upon any termination (but not expiration) of this Agreement, with respect to one or more countries, one or more Programs, or in its entirety, all licenses granted to Ziopharm under this Agreement shall terminate for the applicable terminated

countries or applicable Programs (or, if this Agreement is terminated in its entirety, for the Territory), and the following shall apply:

(a) Assignment and License of Exclusive Product Patents. Unless the termination was by Ziopharm pursuant to Section 11.3, Ziopharm shall assign to Precigen all of Ziopharm's right, title, and interest in and to any Patents owned by Ziopharm to the extent solely and exclusively Covering the Exclusive Products for use in the Field. In the event Ziopharm owns or Controls Patents that Cover the Exclusive Products for use in the Field and other compounds technologies or uses for the Exclusive Products outside of the Field, then Ziopharm shall not assign such Patents to Precigen, but shall, and hereby does, grant to Precigen an exclusive, irrevocable, royalty-free license to use such Patents solely to Develop and Commercialize such Exclusive Products for use in the Field in the form that such Exclusive Products exist as of the effective date of termination (such Exclusive Products, the "**Terminated Products**"). The assignments and licenses granted to Precigen pursuant to this Section 11.4(a) are subject to Precigen paying Ziopharm royalties on the Net Sales (as such term is modified to apply to sales by Precigen, its Affiliates and sublicensees) of all Terminated Products in the Field at a rate of [***] percent ([***]%), provided that once the cumulative royalties for all Terminated Products paid by Precigen pursuant to this Section 11.4(a) equal [***] percent ([***]%) of Ziopharm's reasonable documented costs and expenses incurred in the Research, Development, manufacture and Commercialization of Terminated Products during the Term up to the termination date with respect to such Terminated Products. Such royalty payments pursuant to this Section 11.4(a) shall be paid on a Terminated Product-by-Terminated Product and country-by-country basis from the First Commercial Sale of such Terminated Product in such country until the later of (i) the expiration of the last to expire Valid Claim (as such term is modified to apply to the Patents assigned or licensed to Precigen) in such country that Covers such Terminated Product (or any intermediate or component thereof) and (ii) twelve (12) years after the First Commercial Sale of such Terminated Product in such country. Provided such Termination is not due to breach by Ziopharm under this Agreement.

(b) Negotiation Right. In addition, Ziopharm shall negotiate in good faith with Precigen, and shall assist Precigen in any good faith negotiations with applicable Third Parties, to permit Precigen the opportunity to obtain license to any Patents owned by Ziopharm or Third Parties Covering the Exclusive Products but that was not assigned or licensed to Precigen pursuant to Section 11.4(a), in which case the Parties may enter into a separate agreement or an amendment to this Agreement to reflect any such agreed terms.

11.5 Survival. Termination or expiration of this Agreement shall not affect any rights or obligations of the Parties under this Agreement that have accrued prior to the date of termination or expiration. Notwithstanding anything to the contrary, the following provisions shall survive any expiration or termination of this Agreement: Articles 1 (to the extent definitions are used in the following sections or portions thereof), 9, 10, 12, and 14 (other than Section 14.5) and individual Sections: 2.7, 3.2 (solely with respect to any rights that have accrued prior to expiration or termination), 3.3 (with respect to Ziopharm's responsibility under the Merck Agreement), 3.4, 4.5(b) (with respect to Transition Services properly performed prior to the effective date of termination or expiration), 6.2 (solely to the extent required to make final reconciliations on Operating Profits (or Losses) incurred prior to expiration or termination), 6.4 (solely with respect to Sublicensing Income received prior to the effective date of termination or

expiration), 6.5 (solely to the extent required to make final reconciliations on Net Sales of Exclusive Royalty-Bearing Products achieved prior to expiration or termination), 6.7 (solely to the extent required to make final reconciliations of amounts owed prior to the effective date of termination or expiration), 6.8-6.11 (solely as applicable to payments made following termination or expiration), 7.1, 7.2, 8.4, 11.1, 11.4 and 11.5. If this Agreement is terminated with respect to a given Licensed Product, but not in its entirety, then following such termination the foregoing provisions of this Agreement shall remain in effect with respect to the Licensed Product(s) for which the termination is applicable (to the extent they would survive and apply in the event the Agreement expires or is terminated in its entirety) and all provisions not surviving in accordance with the foregoing shall terminate with respect to the relevant Licensed Product for which the termination applies, as applicable, upon the effective date of termination thereof.

ARTICLE 12
DISPUTE RESOLUTION

12.1 Disputes. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation. In the event of any disputes, controversies or differences which may arise between the Parties out of or in relation to or in connection with this Agreement (other than disputes arising from the JDC), including, without limitation, any alleged failure to perform, or breach, of this Agreement, or any issue relating to the interpretation or application of this Agreement (each, a "**Dispute**"), then upon the request of either Party by written notice, the Parties agree to meet and discuss in good faith a possible resolution thereof, which good faith efforts shall include at least one in-person meeting between the Executive Officers of each Party. If the matter is not resolved within thirty (30) days following the written request for discussions, either Party may then invoke the provisions of Section 12.2. For the avoidance of doubt, any disputes, controversies or differences arising from the JDC pursuant to Article 5 shall be resolved solely in accordance with Article 5.

12.2 Arbitration. Any Dispute that is not resolved pursuant to Section 12.1 shall, subject to Section 12.10, be shall resolved by binding arbitration administered by the American Arbitration Association ("**AAA**") (or its successor entity) in accordance with the then current Commercial Rules of the American Arbitration Association including the Procedures for Large, Complex Commercial Disputes (including the Optional Rules for Emergency Measures of Protection) (the "**AAA Rules**"), except as modified in this Agreement, which AAA Rules are deemed to be incorporated by reference into this clause. The decision rendered in any such arbitration will be final, binding and unappealable. The arbitration shall be conducted by a panel of three (3) arbitrators appointed in accordance with the AAA Rules, none of whom shall be a current or former employee or director, or a then-current stockholder, of either Party, their respective Affiliates or any Sublicensee. The place of arbitration shall be New York, New York, U.S., and all proceedings and communications shall be in English. It is the intention of the Parties that discovery, although permitted as described herein, will be limited except in exceptional circumstances. The arbitrators will permit such limited discovery necessary for an understanding of any legitimate issue raised in the arbitration, including the production of documents. No later than thirty (30) days after selection of the arbitrators, the Parties and their representatives shall hold a preliminary meeting with the arbitrators, to mutually agree upon and thereafter follow procedures seeking to assure that the arbitration will be concluded within six (6) months from such meeting. Failing any such mutual agreement, the arbitrators will design and the Parties shall follow procedures to such effect.

12.3 Governing Law. This Agreement shall be governed by and construed under the substantive laws of the State of New York, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction.

12.4 Award. Any award to be paid by one Party to the other Party as determined by the arbitrator(s) as set forth above under Section 12.2 shall be promptly paid in United States dollars free of any tax, deduction or offset; and any costs, fees or taxes incident to enforcing the award shall, to the maximum extent permitted by law, be charged against the losing Party. Each Party agrees to abide by the award rendered in any arbitration conducted pursuant to this Section 12.4, and agrees that, subject to the United States Federal Arbitration Act, 9 U.S.C. §§ 1-16, judgment may be entered upon the final award in any United States District Court located in New York and that other courts may award full faith and credit to such judgment in order to enforce such award. The award shall include interest from the date of any damages incurred for breach of the Agreement, and from the date of the award until paid in full, at a rate fixed by the arbitrator(s). With respect to money damages, nothing contained herein shall be construed to permit the arbitrator(s) or any court or any other forum to award consequential, incidental, special, punitive or exemplary damages. By entering into this agreement to arbitrate, the Parties expressly waive any claim for consequential, incidental, special, punitive or exemplary damages. The only damages recoverable under this Agreement are direct compensatory damages.

12.5 Costs. Each Party shall bear its own legal fees. The arbitrator(s) shall assess his or her costs, fees and expenses against the Party losing the arbitration.

12.6 Injunctive Relief. Nothing in this Article 12 will preclude either Party from seeking equitable relief or interim or provisional relief from a court of competent jurisdiction, including a temporary restraining order, preliminary injunction or other interim equitable relief, concerning a dispute either prior to or during any arbitration if necessary to protect the interests of such Party or to preserve the status quo pending the arbitration proceeding. For the avoidance of doubt, nothing in this Section 12.6 shall otherwise limit a breaching Party's opportunity to cure a material breach as permitted in accordance with Section 11.3.

12.7 Confidentiality. The arbitration proceeding shall be confidential and the arbitrator(s) shall issue appropriate protective orders to safeguard each Party's Confidential Information. Except as required by law, no Party shall make (or instruct the arbitrator(s) to make) any public announcement with respect to the proceedings or decision of the arbitrator(s) without prior written consent of the other Party. The existence of any dispute submitted to arbitration, and the award, shall be kept in confidence by the Parties and the arbitrator(s), except as required in connection with the enforcement of such award or as otherwise required by applicable law.

12.8 Survivability. Any duty to arbitrate under this Agreement shall remain in effect and be enforceable after termination of this Agreement for any reason.

12.9 Jurisdiction. For the purposes of this Article 12, the Parties acknowledge their diversity and agree to accept the jurisdiction of any United States District Court located in New York for the purposes of enforcing or appealing any awards entered pursuant to this Article 12 and for enforcing the agreements reflected in this Article 12 and agree not to commence any action, suit or proceeding related thereto except in such courts.

12.10 Patent and Trademark Disputes. Notwithstanding any other provisions of this Article 12, any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any Licensed Patents shall be submitted to a court of competent jurisdiction in the country in which such Patent was filed or granted.

ARTICLE 13
SHARE FORFEITURE AND AGREEMENT TERMINATIONS

13.1 Series 1 Preferred Forfeiture. Subject to the terms and conditions of this Agreement, Intrexon and its Affiliates are forfeiting, returning, contributing and transferring unto Ziopharm and Ziopharm is accepting from Intrexon, all of the Preferred Shares held by Intrexon and its Affiliates as of the Effective Date. Intrexon and its Affiliates agree to, and hereby do, forfeit, return, contribute, transfer and, as necessary, assign to Ziopharm all of Intrexon's and its Affiliates right, title and interest to and in the Preferred Shares held by Intrexon and its Affiliates as of the date hereof (including any right to receive PIK Shares as of the date hereof or in the future, whether or not accrued or payable as of the date hereof) without any payment of cash or additional consideration by Ziopharm.

13.2 Forfeiture Closing. The closing of the forfeiture, return, contribution and transfer of the Preferred Shares pursuant to Section 13.1 shall occur simultaneously with the execution and delivery of this Agreement. Concurrently with the execution of this Agreement, Intrexon shall deliver to Ziopharm an Assignment by the Parties this Agreement. Concurrently with the execution of this Agreement, Intrexon shall deliver to Ziopharm an Assignment Separate from Certificate for the Preferred Shares in the form attached to this Agreement as Exhibit E executed by Intrexon in favor of Ziopharm. Ziopharm shall instruct its transfer agent to immediately cancel the Preferred Shares on Ziopharm's books and the Preferred Shares shall be automatically and immediately cancelled and retired.

13.3 Representations and Warranties. Intrexon hereby represents and warrants as follows:

(a) Intrexon is the legal and beneficial owner of the Preferred Shares with good and valid title thereto, free and clear of all security interests, liens, pledges or encumbrances other than restrictions imposed by the Certificate of Designation or upon transfer under applicable federal and/or state securities law. As of the date hereof, Intrexon and its Affiliates beneficially own 130,849 shares of Series 1 Preferred Stock and 210 shares of Series 1 Preferred Stock have accrued and are currently payable to Intrexon and its Affiliates as PIK Shares.

(b) Intrexon has the requisite power and authority to enter into and perform this Agreement and to forfeit, return, contribute, transfer and deliver the Preferred Shares in the manner provided in this Agreement. The execution, delivery and performance of this Agreement

by Intrexon and the consummation by it of the transactions contemplated hereby have been duly authorized by all necessary corporate action, and no further consent or authorization of Intrexon or its board of directors, stockholders or other governing body is required. When executed and delivered by Intrexon, this Agreement shall constitute a valid and binding obligation of Intrexon, enforceable against Intrexon in accordance with its terms, except as such enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium, liquidation, conservatorship, receivership or similar laws relating to, or affecting generally the enforcement of, creditor's rights and remedies or by other equitable principles of general application.

(c) The execution, delivery and performance of this Agreement by Intrexon and the consummation by Intrexon of the transactions contemplated hereby do not and will not (i) violate any provision of Intrexon's charter or organizational documents (ii) conflict with, or constitute a default (or an event which with notice or lapse of time or both would become a default) under, or give to others any rights of termination, amendment, acceleration or cancellation of, any agreement, mortgage, deed of trust, indenture, note, bond, license, lease agreement, instrument or obligation to which Intrexon is a party or by which Intrexon's properties or assets are bound, or (iii) result in a violation of any federal, state, local or foreign statute, rule, regulation, order, judgment or decree (including federal and state securities laws and regulations) applicable to Intrexon or by which any property or asset of Intrexon are bound or affected, except, in all cases, other than violations (with respect to federal and state securities laws) above, for such conflicts, defaults, terminations, amendments, acceleration, cancellations and violations as would not, individually or in the aggregate, materially and adversely affect Intrexon's ability to perform its obligations under this Agreement.

13.4 Termination of Purchase Agreement. Effective immediately, Ziopharm and Intrexon hereby terminate the 2011 Stock Purchase Agreement and acknowledge and agree that the 2011 Stock Purchase Agreement shall have no further force or effect and that all of the benefits, rights, obligations and liabilities of the parties thereunder shall immediately cease and terminate.

13.5 Termination of Registration Rights Agreement. Effective immediately, Ziopharm and Intrexon hereby terminate the 2011 Registration Rights Agreement and acknowledge and agree that the 2011 Registration Rights Agreement shall have no further force or effect and that all of the benefits, rights, obligations and liabilities of the parties thereunder shall immediately cease and terminate.

13.6 Termination of Securities Issuance Agreement. Effective immediately, Ziopharm and Intrexon hereby terminate the 2016 Securities Purchase Agreement and acknowledge and agree that the 2016 Securities Purchase Agreement shall have no further force or effect and that all of the benefits, rights, obligations and liabilities of the parties thereunder shall immediately cease and terminate.

13.7 Conditions. The obligations of Ziopharm under this Agreement are subject to (i) the delivery by Intrexon of an Assignment Separate from Certificate for the Preferred Shares in the form attached to this Agreement as Exhibit E and (ii) the delivery by Randal J. Kirk of written notice to Ziopharm of his resignation from Ziopharm's board of directors effective as of the Effective Date.

ARTICLE 14
MISCELLANEOUS

14.1 Entire Agreement; Amendment. This Agreement, including the Exhibits hereto, and the Related Agreements sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes, as of the Effective Date, all prior and contemporaneous agreements and understandings between the Parties with respect to the subject matter hereof. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth in this Agreement or the Related Agreements. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

14.2 Rights in Bankruptcy.

(a) To the extent permitted under applicable Law, all rights and licenses granted under or pursuant to this Agreement by one Party to the other are, for all purposes of Title 11 of the United States Code ("**Title 11**"), licenses of rights to "intellectual property" as defined in Title 11, and, in the event that a case under Title 11 is commenced by or against either Party (the "**Bankrupt Party**"), the other Party shall have all of the rights set forth in Section 365(n) of Title 11 to the maximum extent permitted thereby. All rights of the Parties under this Section 14.2 and under Section 365(n) of Title 11 are in addition to and not in substitution of any and all other rights, powers, and remedies that each party may have under this Agreement, Title 11, and any other applicable Laws. The non-Bankrupt Party shall have the right to perform the obligations of the Bankrupt Party hereunder with respect to such intellectual property, but neither such provision nor such performance by the non-Bankrupt Party shall release the Bankrupt Party from any such obligation or liability for failing to perform it.

(b) The Parties agree that they intend the foregoing non-Bankrupt Party rights to extend to the maximum extent permitted by law and any provisions of applicable contracts with Third Parties, including for purposes of Title 11, (i) the right of access to any intellectual property (including all embodiments thereof) of the Bankrupt Party or any Third Party with whom the Bankrupt Party contracts to perform an obligation of the Bankrupt Party under this Agreement, and, in the case of the Third Party, which is necessary for the Development, Regulatory Approval and manufacture of Licensed Products and (ii) the right to contract directly with any Third Party described in (i) in this sentence to complete the contracted work.

(c) Any intellectual property provided pursuant to the provisions of this Section 14.2 shall be subject to the licenses set forth elsewhere in this Agreement and the payment obligations of this Agreement, which shall be deemed to be royalties for purposes of Title 11.

14.3 Force Majeure. Both Parties shall be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by force majeure and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting force majeure

continues and the nonperforming Party takes reasonable efforts to remove the condition. For purposes of this Agreement, force majeure shall include conditions beyond the control of the Parties, including an act of God, war, civil commotion, terrorist act, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe, and failure of plant or machinery (provided that such failure could not have been prevented by the exercise of skill, diligence, and prudence that would be reasonably and ordinarily expected from a skilled and experienced person engaged in the same type of undertaking under the same or similar circumstances). Notwithstanding the foregoing, a Party shall not be excused from making payments owed hereunder because of a force majeure affecting such Party. If a force majeure persists for more than ninety (90) days, then the Parties will discuss in good faith the modification of the Parties' obligations under this Agreement in order to mitigate the delays caused by such force majeure.

14.4 Notices. Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement, and shall be addressed to the appropriate Party at the address specified below or such other address as may be specified by such Party in writing in accordance with this Section 14.4, and shall be deemed to have been given for all purposes (a) when received, if hand-delivered or sent by confirmed facsimile or a reputable courier service, or (b) five (5) Business Days after mailing, if mailed by first class certified or registered airmail, postage prepaid, return receipt requested.

If to Precigen:

20358 Seneca Meadows Parkways
Germantown, MD 20876
Attn: President

With a copies to (which shall not constitute notice):

Intrexon Corporation
20374 Seneca Meadows Parkway
Germantown, MD 20876
Attn: Chief Legal Officer

Hogan Lovells US LLP
100 International Drive, Suite 2000
Baltimore, MD 21202
Attn: Asher M. Rubin and William I. Intner

If to Ziopharm:

ZIOPHARM Oncology, Inc.
One First Avenue, Parris Building #34
Navy Yard Plaza, Boston, MA 02129
Attn: General Counsel
Fax: 617-241-2855

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

Cooley LLP
One Freedom Square
Reston Town Center
11951 Freedom Drive
Reston, VA 20190-5656 USA
Attn: Kenneth J. Krisko
Fax: 703-456-8100

14.5 No Strict Construction; Headings. This Agreement has been prepared jointly by the Parties and shall not be strictly construed against either Party. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision. The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section. Except where the context otherwise requires, the use of any gender shall be applicable to all genders, and the word "or" is used in the inclusive sense (and/or). The term "including" as used herein means including, without limiting the generality of any description preceding such term.

14.6 Assignment. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other, which consent shall not be unreasonably withheld or delayed, except that a Party may make such an assignment or transfer without the other Party's consent (a) to its Affiliates, (b) to a Third Party in connection with the transfer or sale of all or substantially all of the business or assets of such Party to which this Agreement relates, whether by merger, consolidation, divesture, restructure, sale of stock, sale of assets or otherwise or (c) to a Third Party in connection with the transfer or sale of all or substantially all of the business or assets of such Party relating to a Licensed Product, whether by merger, consolidation, divesture, restructure, sale of stock, sale of assets or otherwise. Any successor or assignee of rights and/or obligations permitted hereunder shall, in writing to the other Party, expressly assume performance of such rights and/or obligations. Any permitted assignment shall be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section 14.6 shall be null, void and of no legal effect.

14.7 Performance by Affiliates. Each Party may discharge any obligations and exercise any right hereunder through any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

14.8 Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

14.9 Severability. If any one or more of the provisions of this Agreement is held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

14.10 No Waiver. Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written and signed waiver relating to a particular matter for a particular period of time.

14.11 Independent Contractors. Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give either Party the power or authority to act for, bind, or commit the other Party in any way. Nothing herein shall be construed to create the relationship of partners, principal and agent, or joint-venture partners between the Parties.

14.12 Counterparts. This Agreement may be executed in one (1) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

14.13 Intrexon Guarantee. Intrexon hereby unconditionally guarantees and undertakes to Ziopharm that Precigen will duly and punctually observe and perform all the undertakings, covenants and obligations of Precigen under this Agreement and under any agreements between the Parties (or any of them) which are expressly supplemental to this Agreement or which this Agreement requires to be executed (the "**Obligations**") to the intent that if Precigen (or any assignee or successor in interest thereto) shall fail for whatever reason so to observe and perform any Obligations, Intrexon shall be liable to perform the same in all respects as if Intrexon was the party principally bound thereby in place of Precigen on demand from Ziopharm, provided that Intrexon shall be deemed to have any defenses or excuses for nonperformance that Precigen would have had to such Obligations. The liability of Intrexon under this Agreement shall be as primary obligor as regards Ziopharm and not merely as surety and no modification, variation or addition to any of the Obligations, no time or other indulgence given by Ziopharm to Precigen nor any neglect, failure or forbearance on the part of Ziopharm to enforce the performance or observance of any of the Obligations shall in any way release, lessen or affect the liability of Intrexon. This is a continuing guarantee and Intrexon's undertakings under this Agreement shall remain in full force and effect until the earlier of (a) a Qualified IPO of Precigen, (b) a Qualified Change of Control, (c) a Qualified Private Financing, and (d) final performance in full of the Obligations. In addition, until the earlier of (i) the termination of this guarantee or (ii) the end of the Term, Intrexon will not divest, restructure, reorganize or reclassify Precigen with any intent in whole or in part to avoid, reduce or eliminate its obligations under this Agreement. As used herein, "**Qualified IPO**" means an initial public offering of shares of Precigen's common stock through which Precigen raises at least [***] dollars ($[***]) and lists Precigen's common stock for sale in the public market; "**Qualified Change of Control**" means a transaction or series of transactions through which Intrexon controls less than fifty percent (50%) of the equity of Precigen provided that Precigen or its parent entity following such transaction or transactions has

a market cap of at least [***] dollars ($[***]), and "**Qualified Private Financing**" means a transaction or series of transactions involving the sale of shares of Precigen's stock (common or preferred) to Third Parties through which Precigen raises at least [***] dollars ($[***]).

{Signature page follows}

IN WITNESS WHEREOF, the Parties have executed this Exclusive License Agreement by their duly authorized officers as of the Effective Date.

ZIOPHARM ONCOLOGY, INC.

By: /s/ Laurence J.N. Cooper

Name: Laurence J.N. Cooper

Title: Chief Executive Officer

PRECIGEN, INC.

By: /s/ Donald P. Lehr

Name: Donald P. Lehr

Title: Director

SOLELY FOR THE PURPOSES OF THE RECITALS, SECTION 2.2, SECTION 3.4, ARTICLE 13 AND SECTION 14.13:

INTREXON CORPORATION

By: /s/ Donald P. Lehr

Name: Donald P. Lehr

Title: Chief Legal Officer

LIST OF EXHIBITS:

Exhibit A: Gorilla Development Plan
Exhibit B: Licensed Patents
- Schedule 1: [***] Patent and Patent Applications
- Schedule 2: [***] Gene Switch- Patents and Patent Applications
- Schedule 3: [***] Patents and Patent Applications
- Schedule 4: [***] Patents and Patent Applications
- Schedule 5: [***] Patents and Patent Applications
- Schedule 6: [***]

Exhibit C: Transition Services
Exhibit D: Joint Press Release
Exhibit E: Form of Assignment Separate from Certificate for the Preferred Shares
Exhibit F: Third Party Licenses
Exhibit G: Common Law and Registered Trademarks Related to this Agreement

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

EXHIBIT A
INITIAL GORILLA DEVELOPMENT PLAN

[*TO BE ATTACHED 60 DAYS FOLLOWING EFFECTIVE DATE*]

EXHIBIT B
LICENSED PATENTS

Schedule 1

[***]Patents and Patent Applications

INTREXON DOCKET NO	TITLE	PRIORITY DATE	COUNTRY	SERIAL NO	FILE DATE	PATENT NO	ISSUE DATE	GENERAL DESCRIPTION
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Schedule 2

[***] Patents and Patent Applications

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Schedule 3

[***] Patents and Patent Applications

INTREXON DOCKET NO	TITLE	PRIORITY DATE	COUNTRY	SERIAL NO	FILE DATE	PATENT NO	ISSUE DATE	GENERAL DESCRIPTION
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Schedule 4

[***] Patents and Patent Applications

INTREXON DOCKET NO	TITLE	PRIORITY DATE	COUNTRY	SERIAL NO	FILE DATE	PATENT NO	ISSUE DATE	GENERAL DESCRIPTION
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Schedule 5

[***] Patents and Patent Applications

INTREXON DOCKET NO	TITLE	PRIORITY DATE	COUNTRY	SERIAL NO	FILE DATE	PATENT NO	ISSUE DATE	GENERAL DESCRIPTION
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Schedule 6

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EXHIBIT C
TRANSITION SERVICES – AGREED SERVICES
[SEE ATTACHED]

[*11 PAGES REDACTED***]**

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EXHIBIT D
FORM OF PRESS RELEASE
[SEE ATTACHED]

Ziopharm and Precigen Redefine Relationships,
Announce New License Agreement

Ziopharm to Host Conference Call Today at 8 a.m.

BOSTON and GERMANTOWN, MD, October 9, 2018 – Ziopharm Oncology, Inc. (Nasdaq: ZIOP) and Precigen, Inc., a wholly-owned subsidiary of Intrexon Corporation (Nasdaq: XON), today announced a new definitive license agreement to replace all existing agreements between the companies that will provide Ziopharm with certain exclusive and non-exclusive rights to technology controlled by Precigen, Inc.

Through the new agreement, Ziopharm will primarily focus its resources on developing its Controlled IL-12 and *Sleeping Beauty* (SB) T-cell receptor (TCR) platform technologies which have the capability to treat solid tumors, while Intrexon further establishes Precigen as a therapeutics company concentrating on immuno-oncology, autoimmune and infectious disease therapies. Both companies will be better positioned to independently focus on their respective platforms and markets with full developmental and financial controls.

With this exclusive license, Ziopharm now has full developmental control and exclusivity utilizing *Sleeping Beauty* for TCRs targeted towards neoantigens and public antigens. The existing Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute related to SB-generated T cells expressing TCRs to target neoantigens buried within solid tumors will be transferred to Ziopharm, and Ziopharm will maintain this exclusive relationship with the NCI for this program. Ziopharm will build on its IL-12 platform utilizing Precigen's RheoSwitch® gene switch with both the existing human adenovirus program and now with rights to pursue next-generation viral technologies. Using the SB system, Ziopharm will continue to advance its CD19-specific chimeric antigen receptor (CAR) program, while retaining rights to a second, unnamed CAR target. Precigen gains exclusive rights for all other CAR-T therapies, including CD33-specific CAR-T therapies, subject to the agreement with Merck KGaA.

"This is a new day for Ziopharm, as we have the power and flexibility to advance IL-12 and *Sleeping Beauty*-generated TCRs ," said Ziopharm Chief Executive Officer Laurence Cooper, M.D., Ph.D. "We now have focused the company on the two platforms to drive the most shareholder value and transitioned a significant portion of our CAR-T program to Precigen. The ability of both Ziopharm and Precigen to autonomously execute their respective operating plans on their independent platforms, while sharing in future economics, enables both parties to undertake more efficient 'divide and conquer' drug-development plans to the benefit of all constituents."

In partial consideration for the termination of the former agreements, in addition to the grant of the revised limited exclusive license, the companies agree that Ziopharm will retire all outstanding shares of its Series 1 Preferred Stock held by Intrexon, including any accrued dividends, valued at approximately $156.9 million, as of Sept. 30, 2018. Additionally, the companies have terminated Intrexon's contractual right to a seat on Ziopharm's board. Randal J. Kirk, Chairman and Chief Executive Officer of Intrexon, who has served as a director on the board of Ziopharm since 2011, has stepped down from that position, effective immediately, and Ziopharm plans to fill all vacant seats in the near term.

"In 2011 with Ziopharm, we entered into our first exclusive collaboration and therewith granted a field that was far broader than any other. Today's announcement is about seeing Ziopharm's tighter focus and about our desire to invest in Precigen. We believe that Ziopharm will succeed under the license to develop and bring to market important new cancer therapeutics, and we look forward to enjoying benefits from these while we continue our investments in Precigen," commented Mr. Kirk.

Ziopharm will receive a low single digit, capped royalty on Precigen products in the field of point-of-care (P-O-C) CAR T-cell therapies. Precigen will receive milestone payments on late-stage regulatory events as well as commercial royalties in the low to high single-digit range for certain CAR and IL-12 targets that Ziopharm develops. Precigen will receive capped commercial royalties in low- to mid-single digits for the TCR products that Ziopharm develops. Further details on the terms of the transaction will be available within SEC filings respectively filed by Intrexon and Ziopharm.

Ziopharm Clinical Programs Update

Ziopharm today updated guidance on the timing of its response to the request for more information from the U.S. Food and Drug Administration (FDA) regarding the clinical hold placed on the investigational new drug (IND) application for its third-generation Phase 1 trial to evaluate CD19-specific CAR-T therapies under P-O-C technology. Ziopharm expects to respond to the FDA's request for information in the second half of 2019.

Ziopharm also affirmed its guidance on the planned Phase 1 trial to evaluate SB-modified TCRs to treat solid tumors. As disclosed in Ziopharm's second quarter business update, the IND application for this Phase 1 trial, which is being led by and conducted at the National Cancer Institute, remains on track to be submitted in the fourth quarter of 2018 followed by enrollment of patients beginning in 2019, pending regulatory clearance.

Conference Call and Slide Webcast

Ziopharm will host a webcast and conference call today, October 9, at 8 a.m. ET. The call can be accessed by dialing 1-844-309-0618 (U.S. and Canada) or 1-661-378-9465 (international). The passcode for the conference call is 9789556. To access the slides and live webcast or the subsequent archived recording, visit the "Investors Events and Presentations" section of the Ziopharm website at www.ziopharm.com. The webcast will be recorded and available for replay on the Company's website for two weeks.

About Ziopharm Oncology, Inc.

Ziopharm Oncology is a Boston-based biotechnology company focused on the development of next-generation immunotherapies utilizing gene- and cell-based therapies to treat patients with cancer. Ziopharm is focused on the development of two platform technologies designed to deliver safe,

effective and scalable cell- and viral-based therapies for the treatment of multiple cancer types: Controlled IL-12 and *Sleeping Beauty* for genetically modifying cells. These programs are being advanced in collaboration with MD Anderson Cancer Center and the National Cancer Institute.

About Precigen: Advancing Medicine with Precision™

Founded in 2017, Precigen is a dedicated discovery and clinical stage biopharmaceutical company advancing the next generation of gene and cellular therapies using precision technology to target the most urgent and intractable diseases in oncology, autoimmune disorders, and emerging specialty therapy areas. Our technologies enable us to find innovative solutions for affordable biotherapeutics in a controlled manner. Precigen operates as an innovation engine progressing a preclinical and clinical pipeline of well-differentiated unique therapies toward clinical proof-of-confidence and commercialization. Precigen was founded as a wholly-owned subsidiary of Intrexon Corporation (Nasdaq: XON) and leverages Intrexon's proprietary technology platforms to advance human health. Learn more about Precigen at www.precigentherapeutics.com.

About Intrexon Corporation

Intrexon Corporation (Nasdaq: XON) is Powering the Bioindustrial Revolution with Better DNA™ to create biologically-based products that improve the quality of life and the health of the planet. Intrexon's integrated technology suite provides its partners across diverse markets with industrial-scale design and development of complex biological systems delivering unprecedented control, quality, function, and performance of living cells. We call our synthetic biology approach Better DNA®, and we invite you to discover more at www.dna.com or follow us on Twitter at @Intrexon, on Facebook, and LinkedIn.

Trademarks

Intrexon, RheoSwitch, Powering the Bioindustrial Revolution with Better DNA, and Better DNA are trademarks of Intrexon and/or its affiliates. Other names may be trademarks of their respective owners.

Forward-Looking Statements Disclaimer

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts, and in some cases can be identified by terms such as "may," "will," "could," "expects," "plans," "anticipates," and "believes." These statements include, but are not limited to, statements regarding Ziopharm's and Intrexon's goals, expectations, financial or other projections, intentions or beliefs, including statements regarding Ziopharm's and Intrexon's business and strategic plans; the expected benefits of the strategic transaction, such as creating shareholder value, growth potential, market profile, enhanced competitive position and flexibility; the progress and timing of the development of Ziopharm's research and development programs, including the expected timing for its response to the U.S. FDA and of the filing of its IND applications; the timing for the initiation and readouts of Ziopharm's upcoming clinical trials; expected additions to Ziopharm's board of directors; and statements regarding future performance. Although Ziopharm's and Intrexon's management teams believe that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Ziopharm and Intrexon, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include

among other things, the uncertainties inherent in research and development, future clinical data and analysis, including whether any of Ziopharm's and Intrexon' product candidates will advance further in the preclinical research or clinical trial process, including receiving clearance from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies to conduct clinical trials and whether and when, if at all, they will receive final approval from the U.S. FDA or equivalent foreign regulatory agencies and for which indication; the strength and enforceability of Ziopharm's and Intrexon's intellectual property rights; Ziopharm's ability to attract qualified board candidates; competition from other pharmaceutical and biotechnology companies as well as risk factors discussed or identified in the public filings with the Securities and Exchange Commission made by Ziopharm and Intrexon, including those risks and uncertainties listed in Ziopharm's and Intrexon's annual reports on Form 10-K for the year ended December 31, 2017 and subsequent Quarterly Reports on Form 10-Q filed by Ziopharm and Intrexon with the Securities and Exchange Commission. We are providing this information as of October [X], 2018, and neither Ziopharm nor Intrexon undertake any obligation to update or revise the information contained in this press release whether as a result of new information, future events or any other reason.

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Vice President, Communications
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EXHIBIT E
FORM OF ASSIGNMENT SEPARATE FROM CERTIFICATE FOR THE PREFERRED SHARES

[SEE ATTACHED]

ASSIGNMENT SEPARATE FROM CERTIFICATE

Pursuant to that certain Exclusive License Agreement by and among the undersigned ("***Transferor***"), ZIOPHARM Oncology, Inc. (the "***Company***") and Precigen, Inc., dated October 5, 2018, Transferor hereby irrevocably assigns and transfers to the Company 131,059 shares of Series 1 Preferred Stock of the Company standing in Transferor's name on the Company's books and does hereby irrevocably constitute and appoint both the Company's Secretary and American Stock Transfer & Trust Company, LLC, or either of them, to transfer said stock on the books of the Company with full power of substitution in the premises.

Dated: October 5, 2018

INTREXON CORPORATION

By: _____
Name:
Title:

EXHIBIT F
THIRD PARTY LICENSES

- Exclusive License Agreement by and between the University of Pittsburgh – Of the commonwealth System of Higher Education and Intrexon Corporation, effective as of February 1, 2008, as amended August 29, 2008, April 3, 2009 and October 25, 2012.

EXHIBIT G

COMMON LAW AND REGISTERED TRADEMARKS RELATED TO THIS AGREEMENT

Adenoverse™

Intrexon®

RheoSwitch®

RheoSwitch Therapeutic System®

RTS®

EXHIBIT 31.1

CERTIFICATION

I, Laurence J.N. Cooper, certify that:

1. I have reviewed this quarterly report on Form 10-Q of ZIOPHARM Oncology, 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.

Date: November 9, 2018

/s/ Laurence J.N. Cooper

Laurence J.N. Cooper, M.D., Ph.D.
Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION

I, Kevin G. Lafond, certify that:

1. I have reviewed this quarterly report on Form 10-Q of ZIOPHARM Oncology, 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.

Date: November 9, 2018

/s/ Kevin G. Lafond

Kevin G. Lafond
Senior Vice President, Chief Accounting Officer and Treasurer
(Principal Financial and Accounting Officer)

EXHIBIT 32.1

CERTIFICATION

In connection with the Quarterly Report on Form 10-Q of ZIOPHARM Oncology, Inc. (the "Company") for the quarter ended September 30, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we Laurence J.N. Cooper, the Principal Executive Officer of the Company and Kevin G. Lafond, the Principal Financial and Accounting Officer of the Company, hereby certify, pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to our knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and

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

Dated: November 9, 2018

/s/ Laurence J.N. Cooper
Laurence J.N. Cooper, M.D., Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Dated: November 9, 2018

/s/ Kevin G. Lafond
Kevin G. Lafond
Senior Vice President, Chief Accounting Officer and Treasurer
(Principal Financial and Accounting Officer)