Section 1: 10-Q (FORM 10-Q)

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 June 30, 2019

OR

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

For the transition period from _____ to _____

Commission File Number 001-38128

CHECKPOINT THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**47-2568632**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

2 Gansevoort Street, 9th Floor, New York NY 10014
(Address of principal executive offices and zip code)

(781) 652-4500
(Registrant's telephone number, including area code)

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	CKPT	NASDAQ Capital Market

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definition 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 registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date.

Class of Common Stock	Outstanding Shares as of August 5, 2019
Class A Common Stock, $0.0001 par value	7,000,000
Common Stock, $0.0001 par value	30,995,555

CHECKPOINT THERAPEUTICS, INC.
Form 10-Q
For the Quarter Ended June 30, 2019

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Item 1. Financial Statements.

Checkpoint Therapeutics, Inc.
Condensed Balance Sheets
(in thousands, except share and per share amounts)

	June 30, 2019 (Unaudited)	December 31, 2018
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 13,205	$ 21,995
Prepaid expenses and other assets	967	1,372
Other receivables - related party	1,051	1,532
Total current assets	15,223	24,899
Total Assets	**$ 15,223**	**$ 24,899**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 7,093	$ 12,317
Accounts payable and accrued expenses - related party	921	776
Total current liabilities	8,014	13,093
Total Liabilities	**8,014**	**13,093**
Commitments and Contingencies		
Stockholders' Equity		
Common Stock ($0.0001 par value), 60,000,000 shares authorized		
Class A common shares, 7,000,000 shares issued and outstanding as of June 30, 2019 and December 31, 2018	1	1
Common shares, 29,960,034 and 27,076,154 shares issued and outstanding as of June 30, 2019 and December 31, 2018, respectively	3	3
Common stock issuable, 0 and 960,428 shares as of June 30, 2019 and December 31, 2018, respectively	-	1,748
Additional paid-in capital	113,284	105,451
Accumulated deficit	(106,079)	(95,397)
Total Stockholders’ Equity	7,209	11,806
Total Liabilities and Stockholders’ Equity	**$ 15,223**	**$ 24,899**

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

Checkpoint Therapeutics, Inc.
Condensed Statements of Operations
(in thousands, except share and per share amounts)
(Unaudited)

	For the three months ended June 30,		For the six months ended June 30,	
	2019	**2018**	**2019**	**2018**
Revenue - related party	$ 1,051	$ 127	$ 1,403	$ 470
Operating expenses:				
Research and development	4,120	5,453	8,701	12,385
General and administrative	1,758	1,352	3,461	3,546
Total operating expenses	5,878	6,805	12,162	15,931
Loss from operations	(4,827)	(6,678)	(10,759)	(15,461)
Other income				
Interest income	35	39	77	57
Total other income	35	39	77	57
Net Loss	**$ (4,792)**	**$ (6,639)**	**$ (10,682)**	**$ (15,404)**
Loss per Share:				
Basic and diluted net loss per common share outstanding	$ (0.15)	$ (0.23)	$ (0.33)	$ (0.57)
Basic and diluted weighted average number of common shares outstanding	32,704,590	29,044,962	32,475,465	26,910,116

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

Checkpoint Therapeutics, Inc.
Condensed Statements of Stockholders' Equity
(in thousands, except share amounts)
(Unaudited)

For the Three Months Ended June 30, 2019

	Class A Common Shares		Common Shares		Common Shares Issuable	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balances at March 31, 2019	**7,000,000**	**$ 1**	**28,881,756**	**$ 3**	**$ -**	**$ 108,361**	**$ (101,287)**	**$ 7,078**
Issuance of common shares, net of offering costs - At-the-market offering	-	-	997,957	-	-	4,013	-	4,013
Stock-based compensation expense	-	-	47,652	-	-	813	-	813
Issuance of common shares - Founders Agreement	-	-	24,941	-	-	97	-	97
Exercise of warrants	-	-	7,728	-	-	-	-	-
Net loss	-	-	-	-	-	-	(4,792)	(4,792)
Balances at June 30, 2019	**7,000,000**	**$ 1**	**29,960,034**	**$ 3**	**$ -**	**$ 113,284**	**$ (106,079)**	**$ 7,209**

For the Six Months Ended June 30, 2019

	Class A Common Shares		Common Shares		Common Shares Issuable	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balances at December 31, 2018	**7,000,000**	**$ 1**	**27,076,154**	**$ 3**	**$ 1,748**	**$ 105,451**	**$ (95,397)**	**$ 11,806**
Issuance of common shares, net of offering costs - At-the-market offering	-	-	1,088,226	-	-	4,368	-	4,368
Stock-based compensation expense	-	-	760,652	-	-	1,611	-	1,611
Issuance of common shares - Founders Agreement	-	-	987,623	-	(1,748)	1,854	-	106
Exercise of warrants	-	-	47,379	-	-	-	-	-
Net loss	-	-	-	-	-	-	(10,682)	(10,682)
Balances at June 30, 2019	**7,000,000**	**$ 1**	**29,960,034**	**$ 3**	**$ -**	**$ 113,284**	**$ (106,079)**	**$ 7,209**

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

Checkpoint Therapeutics, Inc.
Condensed Statements of Stockholders' Equity
(in thousands, except share amounts)
(Unaudited)

For the Three Months Ended June 30, 2018

	Class A Common Shares		Common Shares		Common Shares Issuable	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balances at March 31, 2018	**7,000,000**	**$ 1**	**25,015,088**	**$ 3**	**$ -**	**$ 96,690**	**$ (67,795)**	**$ 28,899**
Issuance of common shares for cash, net of offering costs	-	-	-	-	-	(28)	-	(28)
Stock-based compensation expense	-	-	91,240	-	-	72	-	72
Exercise of warrants	-	-	1,536	-	-	-	-	-
Net loss	-	-	-	-	-	-	(6,639)	(6,639)
Balances at June 30, 2018	**7,000,000**	**$ 1**	**25,107,864**	**$ 3**	**$ -**	**$ 96,734**	**$ (74,434)**	**$ 22,304**

For the Six Months Ended June 30, 2018

	Class A Common Shares		Common Shares		Common Shares Issuable	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balances at December 31, 2017	**7,000,000**	**$ 1**	**18,512,429**	**$ 2**	**$ 2,296**	**$ 71,772**	**$ (59,030)**	**$ 15,041**
Issuance of common shares for cash, net of offering costs	-	-	5,290,000	1	-	20,816	-	20,817
Stock-based compensation expense	-	-	566,240	-	-	1,209	-	1,209
Issuance of common shares - Founders Agreement	-	-	724,086	-	(2,296)	2,937	-	641
Exercise of warrants	-	-	15,109	-	-	-	-	-
Net loss	-	-	-	-	-	-	(15,404)	(15,404)
Balances at June 30, 2018	**7,000,000**	**$ 1**	**25,107,864**	**$ 3**	**$ -**	**$ 96,734**	**$ (74,434)**	**$ 22,304**

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

Checkpoint Therapeutics, Inc.
Condensed Statements of Cash Flows
(in thousands)
(Unaudited)

	For the six months ended June 30,	
	2019	**2018**
Cash Flows from Operating Activities:		
Net loss	$ (10,682)	$ (15,404)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,611	1,209
Issuance of common shares - Founders Agreement	106	641
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	405	1,329
Other receivables - related party	481	204
Accounts payable and accrued expenses	(5,079)	283
Net cash used in operating activities	(13,158)	(11,738)
Cash Flows from Financing Activities:		
Proceeds from issuance of common stock	-	23,012
Offering costs for the issuance of common stock	-	(2,195)
Proceeds from issuance of common stock – At-the-market offering	4,483	-
Offering costs for the issuance of common stock – At-the-market offering	(115)	-
Net cash provided by financing activities	4,368	20,817
Net (decrease) increase in cash and cash equivalents	(8,790)	9,079
Cash and cash equivalents at beginning of period	21,995	19,225
Cash and cash equivalents at end of period	**$ 13,205**	**$ 28,304**
Supplemental disclosure of noncash investing and financing activities:		
Issuance of common shares - Founders Agreement	$ 1,748	$ 2,296

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

Checkpoint Therapeutics, Inc.
Notes to Condensed Financial Statements
(Unaudited)

Note 1 - Organization and Description of Business Operations

Checkpoint Therapeutics, Inc. (the "Company" or "Checkpoint") was incorporated in Delaware on November 10, 2014. Checkpoint is a clinical-stage, immuno-oncology biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for patients with solid tumor cancers. The Company may acquire rights to these technologies by licensing the rights or otherwise acquiring an ownership interest in the technologies, funding their research and development and eventually either out-licensing or bringing the technologies to market. The Company may also enter into collaboration agreements with third and related parties including sponsored research agreements to develop these technologies for liquid tumors while retaining the rights in solid tumors.

The Company is a majority-controlled subsidiary of Fortress Biotech, Inc. ("Fortress").

The Company's common stock is listed on the NASDAQ Capital Market and trades under the symbol "CKPT."

Liquidity and Capital Resources

The Company has incurred substantial operating losses since its inception, and expects to continue to incur significant operating losses for the foreseeable future and may never become profitable. As of June 30, 2019, the Company had an accumulated deficit of $106.1 million.

During the six months ended June 30, 2019, the Company sold a total of 1,088,226 shares of common stock under an At-the-Market Issuance Sales Agreement for aggregate total gross proceeds of approximately $4.5 million at an average selling price of $4.12 per share, resulting in net proceeds of approximately $4.4 million after deducting commissions and other transaction costs.

The Company expects to continue to use the proceeds from previous financing transactions primarily for general corporate purposes, which may include financing the Company's growth, developing new or existing product candidates, and funding capital expenditures, acquisitions and investments. The Company currently anticipates that its cash and cash equivalents balances at June 30, 2019 along with the additional capital raised in the third quarter of 2019 (see Note 6) will be sufficient to fund its anticipated operating cash requirements for at least one year from the date of this Quarterly Report on Form 10-Q.

The Company will be required to expend significant funds in order to advance the development of its product candidates. The Company's estimate as to how long it expects its existing cash to be able to continue to fund its operations is based on assumptions that may prove to be wrong, and it could use its available capital resources sooner than it currently expects. Further, changing circumstances, some of which may be beyond its control, could cause the Company to consume capital faster than it currently anticipates, and it may need to seek additional funds sooner than planned. Accordingly, the Company will be required to obtain further funding through equity offerings, debt financings, collaborations and licensing arrangements or other sources. Further financing may not be available to it on acceptable terms, or at all. The Company's failure to raise capital as and when needed would have a negative impact on its financial condition and its ability to pursue its business strategy and may be forced to curtail or cease operations.

Note 2 - Significant Accounting Policies

Basis of Presentation

The accompanying unaudited interim condensed financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("GAAP") for interim financial information and the instructions to Form 10-Q and Article 10 of Regulation S-X of the Exchange Act. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, the unaudited interim condensed financial statements reflect all adjustments, which include only normal recurring adjustments necessary for the fair statement of the balances and results for the periods presented. They may not include all of the information and footnotes required by GAAP for complete financial statements. Therefore, these financial statements should be read in conjunction with the Company's audited financial statements and notes thereto for the year ended December 31, 2018, which were included in the Company's Form 10-K, and filed with the SEC on March 18, 2019. The results of operations for any interim periods are not necessarily indicative of the results that may be expected for the entire fiscal year or any other interim period.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers all short-term investments with an original maturity of three months or less when purchased to be cash equivalents.

Other Receivables - Related Party

Other receivables consist of amounts due to the Company from TG Therapeutics, Inc. ("TGTX"), a related party, and are recorded at the invoiced amount (see Note 3).

Research and Development Costs

Research and development costs are expensed as incurred. Advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made. Upfront and milestone payments due to third parties that perform research and development services on the Company's behalf will be expensed as services are rendered or when the milestone is achieved.

Research and development costs primarily consist of personnel related expenses, including salaries, benefits, travel, and other related expenses, stock-based compensation, payments made to third parties for license and milestone costs related to in-licensed products and technology, payments made to third party contract research organizations for preclinical and clinical studies, investigative sites for clinical trials, consultants, the cost of acquiring and manufacturing clinical trial materials, costs associated with regulatory filings, laboratory costs and other supplies.

In accordance with Accounting Standards Codification ("ASC") 730-10-25-1, *Research and Development*, costs incurred in obtaining technology licenses are charged to research and development expense if the technology licensed has not reached commercial feasibility and has no alternative future use. Such licenses purchased by the Company require substantial completion of research and development, regulatory and marketing approval efforts in order to reach commercial feasibility and have no alternative future use.

Annual Equity Fee

Under the Founder's Agreement with Checkpoint dated March 17, 2015, and amended and restated on July 11, 2016, Fortress is entitled to an annual equity fee on each anniversary of the Agreement equal to 2.5% of fully diluted outstanding equity, payable in Checkpoint common shares ("Annual Equity Fee"). The Annual Equity Fee was part of the consideration payable for formation of the Company, identification of certain assets, including the license contributed to Checkpoint by Fortress (see Note 4).

The Company records the Annual Equity Fee in connection with the Founders Agreement with Fortress as contingent consideration. Contingent consideration is recorded when probable and reasonably estimable. The Company's future share prices and shares outstanding cannot be estimated prior to the issuance of the Annual Equity Fee due to the nature of its assets and the Company's stage of development. Due to these uncertainties, the Company has concluded that it is unable to reasonably estimate the contingent consideration until shares are actually issued on January 1 of each year.

Pursuant to the Founders Agreement, the Company issued 960,428 shares of common stock to Fortress for the Annual Equity Fee, representing 2.5% of the fully-diluted outstanding equity of Checkpoint on January 1, 2019. Because the issuance of shares on January 1, 2019 occurred prior to the issuance of the December 31, 2018 financial statements, the Company recorded approximately $1.7 million in research and development expense and a credit to Common shares issuable - Founders Agreement during the year ended December 31, 2018.

Stock-Based Compensation Expenses

The Company expenses stock-based compensation over the requisite service period based on the estimated grant-date fair value of the awards and forfeiture rates. The Company accounts for forfeitures as they occur.

The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model. The assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. All stock-based compensation costs are recorded in general and administrative or research and development costs in the Condensed Statements of Operations based upon the underlying individual's role at the Company.

Fair Value Measurement

The Company follows the accounting guidance in ASC 820 for its fair value measurements of financial assets and liabilities measured at fair value on a recurring basis. Under this accounting guidance, fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability.

The accounting guidance requires fair value measurements be classified and disclosed in one of the following three categories:

Level 1: Quoted prices in active markets for identical assets or liabilities.

Level 2: Observable inputs other than Level 1 prices, for similar assets or liabilities that are directly or indirectly observable in the marketplace.

Level 3: Unobservable inputs which are supported by little or no market activity and that are financial instruments whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation.

The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

Revenue from Contracts with Customers

The Company recognizes revenue under ASC 606, Revenue from Contracts with Customers. The core principle of the new revenue standard is that a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The following five steps are applied to achieve that core principle:

- Step 1: Identify the contract with the customer
- Step 2: Identify the performance obligations in the contract
- Step 3: Determine the transaction price
- Step 4: Allocate the transaction price to the performance obligations in the contract
- Step 5: Recognize revenue when the company satisfies a performance obligation

In order to identify the performance obligations in a contract with a customer, a company must assess the promised goods or services in the contract and identify each promised good or service that is distinct. A performance obligation meets ASC 606's definition of a "distinct" good or service (or bundle of goods or services) if both of the following criteria are met:

- The customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer (i.e., the good or service is capable of being distinct).
- The entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract (i.e., the promise to transfer the good or service is distinct within the context of the contract).

If a good or service is not distinct, the good or service is combined with other promised goods or services until a bundle of goods or services is identified that is distinct.

The transaction price is the amount of consideration to which an entity expects to be entitled in exchange for transferring promised goods or services to a customer, excluding amounts collected on behalf of third parties (for example, some sales taxes). The consideration promised in a contract with a customer may include fixed amounts, variable amounts, or both. When determining the transaction price, an entity must consider the effects of all of the following:

- Variable consideration
- Constraining estimates of variable consideration
- The existence of a significant financing component in the contract
- Noncash consideration
- Consideration payable to a customer

Variable consideration is included in the transaction price only 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.

The transaction price is allocated to each performance obligation on a relative standalone selling price basis. The transaction price allocated to each performance obligation is recognized when that performance obligation is satisfied, at a point in time or over time as appropriate.

Revenue for a sales-based or usage-based royalty promised in exchange for a license of intellectual property is recognized only when (or as) the later of the following events occurs:

a. The subsequent sale or usage occurs.

b. The performance obligation to which some or all of the sales-based or usage-based royalty has been allocated has been satisfied (or partially satisfied).

Incremental contract costs are expensed when incurred when the amortization period of the asset that would have been recognized is one year or less; otherwise, incremental contract costs are recognized as an asset and amortized over time as services are provided to a customer.

Net Loss per Share

Net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Since dividends are declared, paid and set aside among the holders of shares of common stock and Class A common stock pro-rata on an as-if-converted basis, the two-class method of computing net loss per share is not required. Diluted net loss per share does not reflect the effect of shares of common stock to be issued upon the exercise of stock options and warrants, as their inclusion would be anti-dilutive. The following table summarizes potentially dilutive securities outstanding at June 30, 2019 and 2018, that were excluded from the computation of diluted net loss per share, as they would be anti-dilutive:

	June 30,	
	2019	**2018**
Warrants (Note 6)	4,233,593	4,311,446
Stock options (Note 6)	110,000	60,000
Unvested restricted stock (Note 6)	3,512,132	3,036,731
Total	7,855,725	7,408,177

Recently Issued Accounting Standards

In August 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update (“ASU”) 2018-13, “ *Fair Value Measurement (Topic 820), - Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement* ,” which makes a number of changes meant to add, modify or remove certain disclosure requirements associated with the movement amongst or hierarchy associated with Level 1, Level 2 and Level 3 fair value measurements. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted upon issuance of the update. The Company does not expect the adoption of this guidance to have a material impact on its condensed financial statements.

Recently Adopted Accounting Standards

In June 2018, the FASB issued ASU 2018-07, *"Improvements to Nonemployee Share-Based Payment Accounting"*, which simplifies the accounting for share-based payments granted to nonemployees for goods and services. Under the ASU, most of the guidance on such payments to nonemployees would be aligned with the requirements for share-based payments granted to employees. The changes take effect for public companies for fiscal years starting after December 15, 2018, including interim periods within that fiscal year. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606. The Company adopted ASU No. 2018-07 as of January 1, 2019. The adoption of this update did not have a material impact on the Company's condensed financial statements.

In November 2018, the FASB issued ASU No. 2018-18, *"Collaboration Arrangements: Clarifying the Interaction between Topic 808 and Topic 606*". The issuance of ASC 606 raised questions about the interaction between the guidance on collaborative arrangements and revenue recognition. ASU 2018-18 addresses this uncertainty by (1) clarifying that certain transactions between collaborative arrangement participants should be accounted for as revenue under ASC 606 when the collaboration arrangement participant is a customer, (2) adding unit of account guidance to assess whether the collaboration arrangement or a part of the arrangement is with a customer and (3) precluding a company from presenting transactions with collaboration arrangement participants that are not directly related to sales to third parties together with revenue from contracts with customers. The new standard is effective on January 1, 2020 with early adoption permitted. The Company elected to adopt ASU 2018-18 in December 2018. The adoption of this update did not have a material impact on the Company's condensed financial statements.

Note 3 - License Agreements

Dana-Farber Cancer Institute

In March 2015, the Company entered into an exclusive license agreement with Dana-Farber Cancer Institute ("Dana Farber") to develop a portfolio of fully human immuno-oncology targeted antibodies. Under the terms of the agreement, the Company paid Dana-Farber an up-front licensing fee of $1.0 million and, on May 11, 2015, granted Dana-Farber 500,000 shares, valued at $32,500 or $0.065 per share. The agreement included an anti-dilution clause that maintained Dana-Farber's ownership at 5% until such time that the Company raised $10 million in cash in exchange for common shares. Pursuant to this provision, on September 30, 2015, the Company granted to Dana-Farber an additional 136,830 shares of common stock valued at approximately $0.6 million and the anti-dilution clause thereafter expired. Dana-Farber is eligible to receive payments of up to an aggregate of approximately $21.5 million for each licensed product upon the Company's successful achievement of certain clinical development, regulatory and first commercial sale milestones. In addition, Dana-Farber is eligible to receive up to an aggregate of $60.0 million upon the Company's successful achievement of certain sales milestones based on aggregate net sales, in addition to royalty payments based on a tiered low to mid-single digit percentage of net sales. Following the second anniversary of the effective date of the license agreement, Dana-Farber receives an annual license maintenance fee of $50,000, which is creditable against milestone payments or royalties due to Dana-Farber. The portfolio of antibodies licensed from Dana-Farber include antibodies targeting PD-L1, GITR and CAIX.

In September 2018 the Company expensed a non-refundable milestone payment of $1.0 million upon the twelfth patient dosed in a Phase 1 clinical study of its anti-PD-LI antibody, cosibelimab (formerly referred to as CK-301).

In connection with the license agreement with Dana-Farber, in March 2015 the Company entered into a collaboration agreement with TGTX, which was amended and restated in June 2019, to develop and commercialize the anti-PD-L1 and anti-GITR antibody research programs in the field of hematological malignancies, while the Company retains the right to develop and commercialize these antibodies in the field of solid tumors. Michael Weiss, Chairman of the Board of Directors of Checkpoint and Fortress' Executive Vice Chairman, Strategic Development, is also the Executive Chairman, President and Chief Executive Officer and a stockholder of TGTX. Under the terms of the original collaboration agreement, TGTX paid the Company $0.5 million, representing an upfront licensing fee. Upon the signing of the amended and restated collaboration agreement in June 2019, TGTX owed the Company an additional $1.0 million upfront licensing fee. The Company is eligible to receive substantive potential milestone payments for the anti-PD-L1 program of up to an aggregate of approximately $28.6 million upon TGTX's successful achievement of certain clinical development, regulatory and first commercial sale milestones. This is comprised of up to approximately $9.4 million upon TGTX's successful completion of clinical development milestones, and up to approximately $19.2 million upon regulatory filings and first commercial sales in specified territories. The Company is also eligible to receive substantive potential milestone payments for the anti-GITR antibody program of up to an aggregate of approximately $21.5 million upon TGTX's successful achievement of certain clinical development, regulatory and first commercial sale milestones. This is comprised of up to approximately $7.0 million upon TGTX's successful completion of clinical development milestones, and up to approximately $14.5 million upon first commercial sales in specified territories. In addition, the Company is eligible to receive up to an aggregate of $60.0 million upon TGTX's successful achievement of certain sales milestones based on aggregate net sales for both programs, in addition to royalty payments based on a tiered low double-digit percentage of net sales. Following the second anniversary of the effective date of the agreement, the Company receives an annual license maintenance fee, which is creditable against milestone payments or royalties due to the Company. TGTX also pays the Company for its out-of-pocket costs of material used by TGTX for their development activities. For the three months ended June 30, 2019 and 2018, the Company recognized approximately $1.0 million and $0, respectively, in revenue from its collaboration agreement with TGTX in the Condensed Statements of Operations. For the six months ended June 30, 2019 and 2018, the Company recognized approximately $1.4 million and $44,000, respectively, in revenue from its collaboration agreement with TGTX in the Condensed Statements of Operations.

Adimab, LLC

In October 2015, Fortress entered into a collaboration agreement with Adimab to discover and optimize antibodies using their proprietary core technology platform. Under this agreement, Adimab optimized cosibelimab (formerly referred to as CK-301), the Company's anti-PD-L1 antibody which it originally licensed from Dana-Farber. In January 2019, Fortress transferred the rights to the optimized antibody to the Company, and Checkpoint entered into a collaboration agreement directly with Adimab on the same day. Under the terms of the agreement, Adimab is eligible to receive payments up to an aggregate of approximately $7.1 million upon the Company's successful achievement of certain clinical development and regulatory milestones, of which $4.8 million are due upon various filings for regulatory approvals to commercialize the product. In addition, Adimab is eligible to receive royalty payments based on a tiered low single digit percentage of net sales.

NeuPharma, Inc.

In March 2015, Fortress entered into an exclusive license agreement with NeuPharma to develop and commercialize novel irreversible, 3rd generation EGFR inhibitors, including CK-101, on a worldwide basis other than certain Asian countries. On the same date, Fortress assigned all of its right and interest in the EGFR inhibitors to the Company. Under the terms of the license agreement, the Company paid NeuPharma an up-front licensing fee of $1.0 million, and NeuPharma is eligible to receive payments of up to an aggregate of approximately $40.0 million upon the Company's successful achievement of certain clinical development and regulatory milestones in up to three indications, of which $22.5 million are due upon various regulatory approvals to commercialize the products. In addition, NeuPharma is eligible to receive payments of up to an aggregate of $40.0 million upon the Company's successful achievement of certain sales milestones based on aggregate net sales, in addition to royalty payments based on a tiered mid to high-single digit percentage of net sales.

In September 2016, the Company dosed the first patient in a Phase 1/2 clinical study of CK-101, which is currently ongoing as of June 30, 2019.

In connection with the license agreement with NeuPharma, in March 2015, Fortress entered into an option agreement with TGTX, a related party, which agreement was assigned to the Company by Fortress on the same date, for a global collaboration of certain compounds licensed. The option agreement expired on December 31, 2018.

Also, in connection with the license agreement with NeuPharma, the Company entered into a Sponsored Research Agreement with NeuPharma for certain research and development activities. Effective January 11, 2016, TGTX agreed to assume all costs associated with this Sponsored Research Agreement and paid the Company for all amounts previously paid by the Company. This assumption of costs by TGTX survives any termination or expiration of the option agreement. For the three months ended June 30, 2019 and 2018, the Company did not recognize any revenue in connection with the Sponsored Research Agreement in the Condensed Statements of Operations. For the six months ended June 30, 2019 and 2018, the Company recognized $0 and approximately $31,000, respectively, in revenue in connection with the Sponsored Research Agreement in the Condensed Statements of Operations.

Teva Pharmaceutical Industries Ltd. (through its subsidiary, Cephalon, Inc.)

In December 2015, Fortress entered into a license agreement with Teva Pharmaceutical Industries Ltd. through its subsidiary, Cephalon, Inc. ("Cephalon"). This agreement was assigned to the Company by Fortress on the same date. Under the terms of the license agreement, Checkpoint obtained an exclusive, worldwide license to Cephalon's patents relating to CEP-8983 and its small molecule prodrug, CEP-9722, a PARP inhibitor, which the Company referred to as CK-102. The Company paid Cephalon an up-front licensing fee of $0.5 million. In August 2018, the Company gave notice to Cephalon of its intention to terminate the license agreement, which became effective in February 2019.

Jubilant Biosys Limited

In May 2016, the Company entered into a license agreement with Jubilant Biosys Limited ("Jubilant"), whereby the Company obtained an exclusive, worldwide license to Jubilant's family of patents covering compounds that inhibit BET proteins such as BRD4, including CK-103. Under the terms of the agreement, the Company paid Jubilant an up-front licensing fee of $2.0 million, included in research and development expenses on the Company's Statements of Operations for the year ended December 31, 2016. In March 2017, the Company expensed a non-refundable milestone payment of $0.4 million upon the successful completion of toxicology studies under the terms of the license agreement with Jubilant, which is included in the Company's Statements of Operations for the year ended December 31, 2017. Jubilant is eligible to receive payments up to an aggregate of approximately $89.0 million upon the Company's successful achievement of certain preclinical, clinical development, and regulatory milestones, of which $59.5 million are due upon various regulatory approvals to commercialize the products. In addition, Jubilant is eligible to receive payments up to an aggregate of $89.0 million upon the Company's successful achievement of certain sales milestones based on aggregate net sales, in addition to royalty payments based on a tiered low to mid-single digit percentage of net sales.

In connection with the license agreement with Jubilant, the Company entered into a sublicense agreement with TGTX, a related party, to develop and commercialize the compounds licensed in the field of hematological malignancies, while the Company retains the right to develop and commercialize these compounds in the field of solid tumors. Under the terms of the Sublicense Agreement, TGTX paid the Company $1.0 million, representing an upfront licensing fee, and the Company is eligible to receive substantive potential milestone payments up to an aggregate of approximately $87.2 million upon TGTX's successful achievement of clinical development and regulatory milestones. This is comprised of up to approximately $25.5 million upon TGTX's successful completion of three clinical development milestones for two licensed products, and up to approximately $61.7 million upon the achievement of five regulatory approvals and first commercial sales in specified territories for two licensed products. In addition, the Company is eligible to receive potential milestone payments up to an aggregate of $89.0 million upon TGTX's successful achievement of certain sales milestones based on aggregate net sales by TGTX, for two licensed products, in addition to royalty payments based on a mid-single digit percentage of net sales by TGTX. TGTX also pays the Company 50% of IND enabling costs and patent expenses. For the three months ended June 30, 2019 and 2018, the Company recognized approximately $13,000 and $127,000, respectively, in revenue related to the sublicense agreement in the Condensed Statements of Operations. For the six months ended June 30, 2019 and 2018, the Company recognized approximately $24,000 and $394,000, respectively, in revenue related to the sublicense agreement in the Condensed Statements of Operations.

The collaborations with TGTX each contain single material performance obligations under Topic 606, which is the granting of a license that is functional intellectual property. The Company's performance obligation was satisfied at the point in time when TGTX had the ability to use and benefit from the right to use the intellectual property. The performance obligations of the original agreements were satisfied prior to the adoption of Topic 606. The performance obligation of the amendment to the collaboration agreement was satisfied in June 2019.

The milestone payments are based on successful achievement of clinical development, regulatory, and sales milestones. Because these payments are contingent on the occurrence of a future event, they represent variable consideration and are constrained and included in the transaction price only when it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur. The sales-based royalty payments are recognized as revenue when the subsequent sales occur. The Company also receives variable consideration for certain research and development, out-of-pocket material costs and patent maintenance related activities that are dependent upon the Company's actual expenditures under the collaborations and are constrained and included in the transaction price only when it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur. Revenue is recognized approximately when the amounts become due because it relates to an already satisfied performance obligation. For the six months ended June 30, 2019, the Company did not receive any milestone or royalty payments.

Note 4 - Related Party Agreements

Founders Agreement and Management Services Agreement with Fortress

Effective March 17, 2015, the Company entered into a Founders Agreement with Fortress, which was amended and restated on July 11, 2016 (the "Founders Agreement"). The Founders Agreement provides, that in exchange for the time and capital expended in the formation of Checkpoint and the identification of specific assets the acquisition of which resulted in the formation of a viable emerging growth life science company, the Company assumed $2.8 million in debt that Fortress accumulated under a promissory note through National Securities Corporation for expenses and costs of forming Checkpoint, and the Company shall also: (i) issue annually to Fortress, on the anniversary date of the Founders Agreement, shares of common stock equal to two and one-half percent (2.5%) of the fully-diluted outstanding equity of Checkpoint at the time of issuance; (ii) pay an equity fee in shares of common stock, payable within five (5) business days of the closing of any equity or debt financing for Checkpoint or any of its respective subsidiaries that occurs after the effective date of the Founders Agreement and ending on the date when Fortress no longer has majority voting control in Checkpoint's voting equity, equal to two and one-half percent (2.5%) of the gross amount of any such equity or debt financing; and (iii) pay a cash fee equal to four and one half percent (4.5%) of Checkpoint's annual net sales, payable on an annual basis, within ninety (90) days of the end of each calendar year. In the event of a change in control (as it is defined in the Founders Agreement), Checkpoint will pay a one-time change in control fee equal to five times (5x) the product of (i) monthly net sales for the twelve (12) months immediately preceding the change in control and (ii) four and one-half percent (4.5%). The Founders Agreement has a term of fifteen years, after which it automatically renews for one-year periods unless Fortress gives the Company notice of termination. The Founders Agreement will also automatically terminate upon a change of control.

In October 2017, the Founder's Agreement was further amended to change the issuance date of the Annual Equity Fee from the anniversary date of the Agreement to January 1 of each year beginning in 2018.

Effective March 17, 2015, the Company entered into a Management Services Agreement (the "MSA") with Fortress. Pursuant to the terms of the MSA, for a period of five (5) years, Fortress will render advisory and consulting services to the Company. Services provided under the MSA may include, without limitation, (i) advice and assistance concerning any and all aspects of Checkpoint's operations, clinical trials, financial planning and strategic transactions and financings and (ii) conducting relations on behalf of the Company with accountants, attorneys, financial advisors and other professionals (collectively, the "Services"). The Company is obligated to utilize clinical research services, medical education, communication and marketing services and investor relations/public relation services of companies or individuals designated by Fortress, provided those services are offered at market prices. However, the Company is not obligated to take or act upon any advice rendered from Fortress and Fortress shall not be liable for any of the Company's actions or inactions based upon their advice. Fortress and its affiliates, including all members of its Board of Directors, have been contractually exempt from fiduciary duties to the Company relating to corporate opportunities. In consideration for the Services, the Company will pay Fortress an annual consulting fee of $0.5 million (the "Annual Consulting Fee"), payable in advance in equal quarterly installments on the first business day of each calendar quarter in each year, provided, however, that such Annual Consulting Fee shall be increased to $1.0 million for each calendar year in which the Company has net assets in excess of $100 million at the beginning of the calendar year. For each of the three months ended June 30, 2019 and 2018, the Company recognized $125,000 in expense in its Condensed Statements of Operations related to the MSA. For each of the six months ended June 30, 2019 and 2018, the Company recognized $250,000 in expense in its Condensed Statements of Operations related to the MSA.

Caribe BioAdvisors, LLC

In December 2016, the Company entered into an advisory agreement effective January 1, 2017 with Caribe BioAdvisors, LLC ("Caribe"), owned by Michael Weiss, to provide the advisory services of Mr. Weiss as Chairman of the Board. Pursuant to the agreement, Caribe will be paid an annual cash fee of $60,000, in addition to any and all annual equity incentive grants paid to members of the board. For the three months ended June 30, 2019 and 2018, the Company recognized approximately $24,000 and $20,000, respectively, in expense in its Condensed Statements of Operations related to the advisory agreement, including approximately $9,000 and $5,000, respectively, in expense related to annual equity incentive grants. For the six months ended June 30, 2019 and 2018, the Company recognized $48,000 and $40,000, respectively, in expense in its Condensed Statements of Operations related to the advisory agreement, including $18,000 and $10,000 in expense related to annual equity incentive grants.

Note 5 - Commitments and Contingencies

Leases

The Company is not a party to any leases for office space or equipment.

License Agreements

The Company has undertaken to make contingent milestone payments to the licensors of its portfolio of product candidates. In addition, the Company would pay royalties to such licensors based on a percentage of net sales of each product candidate following regulatory marketing approval (See Note 3).

Litigation

The Company recognizes a liability for a contingency when it is probable that liability has been incurred and when the amount of loss can be reasonably estimated. When a range of probable loss can be estimated, the Company accrues the most likely amount of such loss, and if such amount is not determinable, then the Company accrues the minimum of the range of probable loss. As of June 30, 2019 and December 31, 2018, there was no litigation against the Company.

Note 6 - Stockholders' Equity

Common Stock

The Company is authorized to issue 60,000,000 common shares with a par value of $0.0001 per share, of which 7,000,000 shares are designated as "Class A common stock." As of June 30, 2019 and December 31, 2018, there were 7,000,000 shares of Class A common stock issued and outstanding to Fortress. Dividends are to be distributed pro-rata to the Class A and common stock holders. The holders of common stock are entitled to one vote per share of common stock held. The Class A common stock holders are entitled to a number of votes per share equal to 1.1 times a fraction, the numerator of which is the sum of the shares of outstanding common stock and the denominator of which is the number of shares of Class A common stock. Accordingly, the holder of shares of Class A common stock will be able to control or significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. Each share of Class A common stock is convertible, at the option of the holder thereof, into one (1) fully paid and non-assessable share of common stock subject to adjustment for stock splits and combinations.

In November 2017, the Company filed a shelf registration statement on Form S-3 (the "S-3"), which was declared effective in December 2017. Under the S-3, the Company may sell up to a total of $100 million of its securities. In connection with the S-3, the Company entered into an At-the-Market Issuance Sales Agreement (the "ATM") with Cantor Fitzgerald & Co., Ladenburg Thalmann & Co. Inc. and H.C. Wainwright & Co., LLC (each an "Agent" and collectively, the "Agents"), relating to the sale of shares of common stock. Under the ATM, the Company pays the Agents a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of common stock.

During the six months ended June 30, 2019, the Company sold a total of 1,088,226 shares of common stock under the ATM for aggregate total gross proceeds of approximately $4.5 million at an average selling price of $4.12 per share, resulting in net proceeds of approximately $4.4 million after deducting commissions and other transaction costs.

Pursuant to the Founders Agreement, the Company issued to Fortress 2.5% of the aggregate number of shares of common stock issued in the ATM offering noted above. Accordingly, the Company issued 27,195 shares of common stock to Fortress and recorded expense of approximately $106,000 related to these stock grants, which is included in general and administrative expenses in the Company's Condensed Statements of Operations for the six months ended June 30, 2019.

Pursuant to the Founders Agreement, the Company issued 960,428 shares of common stock to Fortress for the Annual Equity Fee, representing 2.5% of the fully-diluted outstanding equity of Checkpoint on January 1, 2019 (see Notes 2 and 4).

Subsequent to the second quarter, through July 30, 2019, the Company sold a total of 1,001,485 shares of common stock under the ATM for aggregate total gross proceeds of approximately $3.1 million at an average selling price of $3.06 per share, resulting in net proceeds of approximately $3.0 million after deducting commissions and other transaction costs.

The S-3 is currently the Company's only active shelf registration statement. Subsequent to the offerings noted above, approximately $61.5 million of the shelf remains available for sale under the S-3. The Company may offer the securities under the S-3 from time to time in response to market conditions or other circumstances if it believes such a plan of financing is in the best interests of its stockholders. The Company believes that the S-3 provides it with the flexibility to raise additional capital to finance its operations as needed.

Equity Incentive Plan

The Company has in effect the Amended and Restated 2015 Incentive Plan ("2015 Incentive Plan'). The 2015 Incentive Plan was adopted in March 2015 by our stockholders. Under the 2015 Incentive Plan, the compensation committee of the Company's board of directors is authorized to grant stock-based awards to directors, officers, employees and consultants. An amendment to the 2015 Incentive Plan was approved by stockholders in June 2017 to increase the shares available for issuance to 5,000,000 shares. The plan expires 10 years from the effective date of the amendment and limits the term of each option to no more than 10 years from the date of grant.

As of June 30, 2019, 1,534,805 shares are available for issuance under the 2015 Incentive Plan.

Restricted Stock

Certain employees, directors and consultants have been awarded restricted stock. The restricted stock vesting consists of milestone and time-based vesting. The following table summarizes restricted stock award activity for the six months ended June 30, 2019:

	Number of Units	Weighted Average Grant Date Fair Value
Nonvested at December 31, 2018	2,932,106	$ 4.22
Granted	781,652	3.35
Forfeited	(21,000)	3.16
Vested	(180,626)	1.06

Nonvested at June 30, 2019	3,512,132	$ 4.34

As of June 30, 2019, there was $4.2 million of total unrecognized compensation cost related to non-vested restricted stock, which is expected to be recognized over a weighted-average period of 1.2 years. This amount does not include, as of June 30, 2019, 333,334 shares of restricted stock outstanding which are performance-based and vest upon achievement of certain corporate milestones. The expense is recognized over the vesting period of the award. Stock-based compensation for milestone awards will be measured and recorded if and when it is probable that the milestone will be achieved.

Stock Options

The following table summarizes stock option award activity for the six months ended June 30, 2019:

	Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Outstanding as of December 31, 2018	60,000	$ 5.43	8.09
Granted	50,000	3.25	9.57
Outstanding as of June 30, 2019	110,000	$ 4.44	8.49

Upon the exercise of stock options, the Company will issue new shares of its common stock.

Warrants

A summary of warrant activities for the six months ended June 30, 2019 is presented below:

	Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Outstanding as of December 31, 2018	4,280,972	$ 6.69	2.33
Exercised	(47,379)	-	-
Outstanding as of June 30, 2019	4,233,593	$ 6.77	1.78

Upon the exercise of warrants, the Company will issue new shares of its common stock.

Stock-Based Compensation

The following table summarizes stock-based compensation expense for the three and six months ended June 30, 2019 and 2018 ($ in thousands):

	For the three months ended June 30,		For the six months ended June 30,	
	2019	2018	2019	2018
Research and development	$ 184	$ (392)	$ 380	$ 288
General and administrative	629	464	1,231	921
Total stock-based compensation expense	$ 813	$ 72	$ 1,611	$ 1,209

Note 7 - Accounts Payable and Accrued Expenses

At June 30, 2019 and December 31, 2018, accounts payable and accrued expenses consisted of the following ($ in thousands):

	June 30, 2019	December 31, 2018
Accounts payable	$ 3,872	$ 9,750
Accrued compensation	200	439
Research and development	2,735	1,751
Other	286	377
Accounts payable and accrued expenses - related party	921	776
Total accounts payable and accrued expenses	$ 8,014	$ 13,093

Item 2. Financial Information.

Management's Discussion and Analysis of the Results of Operations

Forward-Looking Statements

Statements in the following discussion and throughout this report that are not historical in nature are "forward-looking statements." You can identify forward-looking statements by the use of words such as "expect," "anticipate," "estimate," "may," "will," "should," "intend," "believe," and similar expressions, although not all forward-looking statements contain these identifying words. Although we believe the expectations reflected in these forward-looking statements are reasonable, such statements are inherently subject to significant risks and uncertainties and we can give no assurances that our expectations will prove to be correct. Actual results could differ materially from those described in this report because of numerous factors, many of which are beyond our control. These factors include, without limitation, those described under Item 1A "Risk Factors." We undertake no obligation to update these forward-looking statements to reflect events or circumstances after the date of this report or to reflect actual outcomes.

Overview

We are a clinical-stage, immuno-oncology biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for patients with solid tumor cancers. We are currently evaluating our lead small-molecule, targeted anti-cancer agent, CK-101, in a Phase 1/2 clinical trial for the treatment of patients with EGFR mutation-positive NSCLC. In addition, we are currently evaluating our lead antibody product candidate, cosibelimab (formerly referred to as CK-301), an anti-PD-L1 antibody licensed from the Dana-Farber Cancer Institute, in an ongoing Phase 1 clinical trial in checkpoint therapy-naïve patients with selected recurrent or metastatic cancers, including ongoing cohorts intended to support one or more biologics license application ("BLA") submissions.

We have also entered into various collaboration agreements with TGTX, a related party, to develop and commercialize certain assets in connection with our licenses in the field of hematological malignancies, while we retain the right to develop and commercialize these assets in solid tumors.

In September 2018, we announced preliminary interim safety and efficacy data from our ongoing Phase 1/2 clinical trial of CK-101. The data were presented in an oral presentation at the IASLC 19th World Conference on Lung Cancer in Toronto. Enrollment in the trial is ongoing to identify the optimal dose with a new softgel capsule formulation to maximize therapeutic effect, following which a Phase 3 trial is planned to initiate in treatment-naïve EGFR mutation-positive NSCLC patients.

In May 2019, we announced interim results from our ongoing multicenter Phase 1 clinical trial of anti-PD-L1 antibody cosibelimab.

To date, we have not received approval for the sale of any product candidate in any market and, therefore, have not generated any product sales from any product candidates. In addition, we have incurred substantial operating losses since our inception, and expect to continue to incur significant operating losses for the foreseeable future and may never become profitable. As of June 30, 2019, we have an accumulated deficit of $106.1 million.

We are a majority-controlled subsidiary of Fortress.

Checkpoint Therapeutics, Inc. was incorporated in Delaware on November 10, 2014 and commenced principal operations in March 2015. Our executive offices are located at 2 Gansevoort Street, 9th Floor, New York, NY 10014. Our telephone number is (781) 652-4500 and our email address is ir@checkpointtx.com.

Results of Operations

Comparison of the Three Months Ended June 30, 2019 and 2018

Revenue

For the three months ended June 30, 2019, revenue was approximately $1.1 million compared to approximately $0.1 million for the three months ended June 30, 2018, an increase of $1.0 million. Revenue for the current period primarily consisted of $1.0 million from TGTX related to an upfront licensing fee due upon the signing of an amendment to the collaboration agreement. Revenue for the three months ended June 30, 2018 consisted of $0.1 million from TGTX related to the sublicense agreement for CK-103.

Research and Development Expenses

Research and development expenses primarily consist of personnel related expenses, including salaries, benefits, travel, and other related expenses, stock-based compensation, payments made to third parties for license and milestone costs related to in-licensed products and technology, payments made to third party contract research organizations for preclinical and clinical studies, investigative sites for clinical trials, consultants, the cost of acquiring and manufacturing clinical trial materials, costs associated with regulatory filings and patents, laboratory costs and other supplies.

For the three months ended June 30, 2019, research and development expenses were approximately $4.1 million, compared to $5.5 million for the three months ended June 30, 2018, a decrease of $1.4 million. The decrease is primarily attributable to costs for the manufacture of material of cosibelimab incurred in the second quarter of 2018 and not replicated in the current quarter. The current period research and development expenses primarily consisted of $2.3 million related to clinical costs for our product candidates, $1.1 million related to manufacturing costs of our product candidates, and $0.2 million related to stock compensation expense. The prior period research and development expenses primarily consisted of $4.0 million related to manufacturing costs of our product candidates, $0.3 million related to preclinical development activities for our product candidates and $1.3 million related to clinical costs for our product candidates. The prior period research and development expenses were partially offset by a credit of $0.4 million in stock compensation expense, which resulted from the remeasurement of the fair value of a grant to a non-employee at the reporting period.

We anticipate our research and development expenses to remain relatively consistent in future periods in 2019.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related expenses, including stock-based compensation, for executives and other administrative personnel, recruitment expenses, professional fees and other corporate expenses, including investor relations, legal activities, and facilities-related expenses.

For the three months ended June 30, 2019, general and administrative expenses were approximately $1.8 million, compared to $1.4 million for the three months ended June 30, 2018, an increase of $0.4 million. The current period general and administrative expenses primarily consisted of stock compensation expense of $0.6 million, $0.3 million related to salary expenses, $0.3 million related to legal and accounting fees and $0.1 million related to our issuance of shares to Fortress pursuant to the Founders Agreement in connection with the sale of shares of our common stock under an At-the-Market Issuance Sales Agreement (the "ATM"). The prior period general and administrative expenses primarily consisted of $0.5 million related to stock compensation expense, $0.2 million related to salary expenses and $0.2 million related to legal and accounting fees.

We anticipate our general and administrative expenses will remain relatively consistent in future periods in 2019.

Comparison of the Six Months Ended June 30, 2019 and 2018

Revenue

For the six months ended June 30, 2019, revenue was approximately $1.4 million compared to approximately $0.5 million for the six months ended June 30, 2018, an increase of $0.9 million. Revenue for the current period primarily consisted of $1.4 million from TGTX related to the collaboration agreement, including a $1.0 million upfront licensing fee due upon the signing of an amendment to the agreement and approximately $0.3 million for the purchase of clinical material of cosibelimab (formerly referred to as CK-301). Revenue for the six months ended June 30, 2018 consisted primarily of $0.4 million from TGTX related to the sublicense agreement for CK-103, $44,000 from TGTX in connection with the collaboration agreement and $31,000 from TGTX in connection with the Sponsored Research Agreement with NeuPharma.

Research and Development Expenses

For the six months ended June 30, 2019, research and development expenses were approximately $8.7 million, compared to $12.4 million for the six months ended June 30, 2018, a decrease of $3.7 million. The decrease is primarily attributable to costs for the manufacture of material of cosibelimab incurred in the first half of 2018 and not replicated in the current period. The current period research and development expenses primarily consisted of $4.6 million related to clinical costs for our product candidates, $2.9 million related to manufacturing costs of our product candidates, and $0.4 million related to stock compensation expense. The prior period research and development expenses primarily consisted of consisted of $8.1 million related to manufacturing costs of our product candidates, $0.9 million related to preclinical development activities for our product candidates, $2.4 million related to clinical costs for our product candidates and $0.3 million related to stock compensation expense.

General and Administrative Expenses

For the six months ended June 30, 2019, general and administrative expenses were approximately $3.5 million, compared to $3.5 million for the six months ended June 30, 2018. The current period general and administrative expenses primarily consisted of stock compensation expense of $1.2 million, $0.6 million related to salary expenses, $0.6 million related to legal and accounting fees and $0.1 million related to our issuance of shares to Fortress pursuant to the Founders Agreement in connection with the sale of shares of our common stock under an ATM. The prior period general and administrative expenses primarily consisted of stock compensation expense of $0.9 million, $0.6 million related to our issuance of shares to Fortress in connection with our March 2018 common stock offering pursuant to the Founders Agreement, $0.6 million related to salary expenses and $0.5 million related to legal and accounting fees.

Liquidity and Capital Resources

We have incurred substantial operating losses since our inception, and expect to continue to incur significant operating losses for the foreseeable future and may never become profitable. As of June 30, 2019, we had an accumulated deficit of $106.1 million.

During the six months ended June 30, 2019, we sold a total of 1,088,226 shares of common stock under the ATM for aggregate total gross proceeds of approximately $4.5 million at an average selling price of $4.12 per share, resulting in net proceeds of approximately $4.4 million after deducting commissions and other transactions costs.

Our major sources of cash have been proceeds from the sale of equity securities. We expect to use these proceeds primarily for general corporate purposes, which may include financing our growth, developing new or existing product candidates, and funding capital expenditures, acquisitions and investments. We currently anticipate that our cash and cash equivalent balances at June 30, 2019, combined with the additional capital raised in the third quarter of 2019, are sufficient to fund our anticipated operating cash requirements for at least one year from the date of this Quarterly Report on Form 10-Q.

Cash Flows for the Six Months Ended June 30, 2019 and 2018

Operating Activities

Net cash used in operating activities was $13.2 million for the six months ended June 30, 2019, compared to $11.7 million for the six months ended June 30, 2018. The increase in net cash used in operating activities was primarily related to the payment of manufacturing and other product development activities for our product candidates in the current period that were incurred in the fourth quarter of 2018.

Investing Activities

There were no investing activities for the six months ended June 30, 2019 and 2018.

Financing Activities

Net cash provided by financing activities for the six months ended June 30, 2019 related to net proceeds of $4.4 million from the issuance of common stock as part of our ATM offering. Net cash provided for the six months ended June 30, 2018 related to net proceeds of $20.8 million from the issuance of common stock as part of our underwritten public offering in March 2018.

Off-Balance Sheet Arrangements

We are not party to any off-balance sheet transactions. We have no guarantees or obligations other than those which arise out of normal business operations.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

N/A.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

We maintain “disclosure controls and procedures,” as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and our Principal Financial Officer, to allow timely decisions regarding required disclosure.

The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

With respect to the quarter ended June 30, 2019, under the supervision and with the participation of our management, we conducted an evaluation of the effectiveness of the design and operations of our disclosure controls and procedures. Based upon this evaluation, our Chief Executive Officer and Principal Financial Officer have concluded that our disclosure controls and procedures are effective.

Management does not expect that our internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control systems are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in a cost-effective control system, no evaluation of internal control over financial reporting can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been or will be detected.

Changes in Internal Control over Financial Reporting:

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter ended June 30, 2019 which have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Part II. Other Information

Item 1. Legal Proceedings.

We are not involved in any litigation that we believe could have a material adverse effect on our financial position or results of operations. There is no action, suit, proceeding, inquiry or investigation before or by any court, public board, government agency, self-regulatory organization or body pending or, to the knowledge of our executive officers, threatened against or affecting our company or our officers or directors in their capacities as such.

Item 1A. Risk Factors

The following information sets forth risk factors that could cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. You should carefully consider the risks described below, in addition to the other information contained in this report and our other public filings, before making an investment decision. Our business, financial condition or results of operations could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.

Risks Related to Our Business and Industry

We currently have no drug products for sale. We are heavily dependent on the success of our product candidates, and we cannot give any assurances that any of our product candidates will receive regulatory approval or be successfully commercialized.

To date, we have invested a significant portion of our efforts and financial resources in the acquisition and development of our product candidates. As an early stage company, we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical area. Our future success is substantially dependent on our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize such product candidates. Our product candidates are currently in preclinical development or in clinical trials. Our business depends entirely on the successful development and commercialization of our product candidates, which may never occur. We currently generate no revenues from sales of any drugs, and we may never be able to develop or commercialize a marketable drug.

The successful development, and any commercialization, of our technologies and any product candidates would require us to successfully perform a variety of functions, including:

- developing our technology platform;
- identifying, developing, manufacturing and commercializing product candidates;
- entering into successful licensing and other arrangements with product development partners;
- achieving clinical endpoints to support preparation of approval applications;
- participating in regulatory approval processes;

- formulating and manufacturing products;
- obtaining sufficient quantities of our product candidates from our third-party manufacturers as required to meet clinical trial needs and commercial demand at launch and thereafter;
- establishing and maintaining agreements with wholesalers, distributors and group purchasing organizations on commercially reasonable terms;
- conducting sales and marketing activities including hiring, training, deploying and supporting our sales force and creating market demand for our product candidates through our own marketing and sales activities, and any other arrangements to promote our product candidates that we may later establish;
- maintaining patent protection and regulatory exclusivity for our product candidates; and
- obtaining market acceptance for our product candidates.

Our operations have been limited to organizing our company, acquiring, developing and securing our proprietary technology and identifying and obtaining preclinical data or clinical data for various product candidates. These operations provide a limited basis for you to assess our ability to continue to develop our technology, identify product candidates, develop and commercialize any product candidates we are able to identify and enter into successful collaborative arrangements with other companies, as well as for you to assess the advisability of investing in our securities. Each of these requirements will require substantial time, effort and financial resources.

Each of our product candidates will require additional preclinical or clinical development, management of preclinical, clinical and manufacturing activities, regulatory approval in multiple jurisdictions, obtaining manufacturing supply, building of a commercial organization, and significant marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the US Food and Drug Administration ("FDA") or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates.

Preclinical development is highly speculative and has a high risk of failure.

Three of our five current product candidates are in preclinical development, and, thus, have never been used in humans. Preclinical development is highly speculative and carries a high risk of failure. We can provide no assurances that preclinical toxicology and/or preclinical activity of our product candidates will support moving any of these product candidates into clinical development. If we are unsuccessful in our preclinical development efforts for any of these product candidates and they fail to reach clinical development, it would have a material adverse effect on our business and financial condition.

Delays in clinical testing could result in increased costs to us and delay our ability to generate revenue.

Although we are planning for certain clinical trials relating to our product candidates, there can be no assurance that the FDA, or comparable foreign regulatory authority, will accept our proposed trial designs. We may experience delays in our clinical trials and we do not know whether current or planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- obtaining regulatory approval to commence a trial;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining institutional review board, or IRB, or ethics committee, as applicable, approval at each site;
- recruiting suitable and sufficient number of patients to participate in a trial;
- clinical sites deviating from trial protocol or dropping out of a trial;
- having patients complete a trial or return for post-treatment follow-up;
- developing and validating companion diagnostics on a timely basis, if required;
- obtaining resolution for any clinical holds that arise;

- adding new clinical trial sites; or

- manufacturing sufficient quantities of product candidate for use in clinical trials.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Furthermore, we intend to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and we intend to have agreements governing their committed activities, however, we will have limited influence over their actual performance.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs or ethics committees of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

We may not receive regulatory approval for our product candidates, or their approval may be delayed, which would have a material adverse effect on our business and financial condition.

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by the European Medicines Agency ("EMA") and similar regulatory authorities outside the United States. Failure to obtain marketing approval for one or more of our product candidates or any future product candidate will prevent us from commercializing the product candidate. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party contract research organizations and other third-party vendors to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. One or more of our product candidates or any future product candidate may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. If any of our product candidates or any future product candidate receives marketing approval, the accompanying label may limit the approved use of our drug by severity of disease, patient group, or include contraindications, interactions, or warnings, which could limit sales of the product.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical studies or clinical trials. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

Under the FDA's accelerated approval regulations, the FDA may grant marketing approval for a new drug product on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely, based on epidemiologic, therapeutic, pathophysiologic, or other evidence, to predict clinical benefit or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. While we may undertake development programs for one or more of our product candidates that we believe, if successful, could support a submission for marketing approval under the accelerated approval regulations, we may ultimately fail to meet the criteria to do so, which may cause delays in the approval or rejection of an application.

If we experience delays in obtaining approval or if we fail to obtain approval of one or more of our product candidates or any future product candidate, the commercial prospects for our product candidates may be harmed and our ability to generate revenue will be materially impaired.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates or any future product candidate for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. The regulatory authority may also require the label to contain warnings, contraindications, or precautions that limit the commercialization of that product. Any of these scenarios could compromise the commercial prospects for one or more of our product candidates or any future product candidate.

In all interactions with regulatory authorities, the company is exposed to liability risks under the Foreign Corrupt Practices Act or similar anti-bribery laws.

If any of our product candidates are approved and our contract manufacturer fails to produce the product in the volumes that we require on a timely basis, or fails to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may face delays in the commercialization of our product candidates or be unable to meet market demand, and may lose potential revenues.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls, and the use of specialized processing equipment. We intend to enter into development and supply agreements with contract manufacturers for the completion of pre-commercialization manufacturing development activities and the manufacture of commercial supplies for each of our product candidates. Any termination or disruption of our relationships with our contract manufacturers may materially harm our business and financial condition, and frustrate any commercialization efforts for each respective product candidate.

All of our contract manufacturers must comply with strictly enforced federal, state and foreign regulations, including cGMP requirements enforced by the FDA through its facilities inspection program, and we have little control over their compliance with these regulations. Any failure to comply with applicable regulations may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval, and would limit the availability of our product and customer confidence in our product. Any manufacturing defect or error discovered after products have been produced and distributed could result in even more significant consequences, including costly recall procedures, re-stocking costs, damage to our reputation and potential for product liability claims.

If the commercial manufacturers upon whom we rely to manufacture one or more of our product candidates, and any future product candidate we may in-license, fails to deliver the required commercial quantities on a timely basis at commercially reasonable prices, we would likely be unable to meet demand for our products and we would lose potential revenues.

Our approach to the discovery and development of our product candidates is unproven, and we do not know whether we will be able to develop any products of commercial value.

Our product candidates are emerging technologies and, consequently, it is conceivable that such technologies may ultimately fail to become commercially viable drugs to treat human patients with cancer or other diseases.

If serious adverse or unacceptable side effects are identified during the development of one or more of our product candidates or any future product candidate, we may need to abandon or limit our development of some of our product candidates.

If one or more of our product candidates or any future product candidate are associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. In our industry, many compounds that initially showed promise in early stage testing have later been found to cause serious side effects that prevented further development of the compound. In the event that our clinical trials reveal a high or unacceptable severity and prevalence of side effects, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development or deny approval of one or more of our product candidates or any future product candidate for any or all targeted indications. The FDA could also issue a letter requesting additional data or information prior to making a final decision regarding whether or not to approve a product candidate. The number of requests for additional data or information issued by the FDA in recent years has increased, and resulted in substantial delays in the approval of several new drugs. Undesirable side effects caused by one or more of our product candidates or any future product candidate could also result in the inclusion of unfavorable information in our product labeling, denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, and in turn prevent us from commercializing and generating revenues from the sale of that product candidate. Drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial and could result in potential product liability claims.

Additionally, if one or more of our product candidates or any future product candidate receives marketing approval and we or others later identify undesirable side effects caused by this product, a number of potentially significant negative consequences could result, including:

- regulatory authorities may require the addition of unfavorable labeling statements, specific warnings or a contraindication;
- regulatory authorities may suspend or withdraw their approval of the product, or require it to be removed from the market;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product; or
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of any of our product candidates or any future product candidate or could substantially increase our commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from its sale.

Even if one or more of our product candidates receives regulatory approval, it and any other products we may market will remain subject to substantial regulatory scrutiny.

One or more of our product candidates that we may license or acquire will also be subject to ongoing requirements and review of the FDA and other regulatory authorities. These requirements include labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market 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 of the drug, and requirements regarding company presentations and interactions with health care professionals.

The FDA, or other regulatory authority, may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. The FDA and other applicable regulatory authorities closely regulate the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and other applicable regulatory authorities impose stringent restrictions on manufacturers' communications regarding off-label use and if we do not market our products for only 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 adverse events or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such products, operations, 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;

- suspension or withdrawal of marketing or regulatory approvals;
- suspension of any ongoing clinical trials;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

The FDA's policies, or the policies of other applicable regulatory authorities, may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained.

We will need to obtain FDA approval of any proposed product brand names, and any failure or delay associated with such approval may adversely impact our business.

A pharmaceutical product cannot be marketed in the U.S. or other countries until we have completed a rigorous and extensive regulatory review processes, including approval of a brand name. Any brand names we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the USPTO. The FDA typically conducts a review of proposed product brand names, including an evaluation of potential for confusion with other product names. The FDA may also object to a product brand name if it believes the name inappropriately implies medical claims. If the FDA objects to any of our proposed product brand names, we may be required to adopt an alternative brand name for our product candidates. If we adopt an alternative brand name, we would lose the benefit of our existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product brand name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

Our current and future relationships with customers and third-party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, which may constrain the business or financial arrangements and relationships through which we sell, market and distribute any product candidates for which we obtain marketing approval. In addition, we may be subject to transparency laws and patient privacy regulation by U.S. federal and state governments and by governments in foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs, such as Medicare and Medicaid;
- federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower or *qui tam* actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for 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 their respective implementing regulations, which impose obligations on covered healthcare providers, health plans, and healthcare clearinghouses, as well as their business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal Open Payments program, which requires manufacturers of certain approved drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to "payments or other transfers of value" made to physicians, which is defined to include doctors, dentists, optometrists, podiatrists and chiropractors, and teaching hospitals and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by the physicians and their immediate family members. Data collection began on August 1, 2013 with requirements for manufacturers to submit reports to CMS by March 31, 2014 and 90 days after the end each subsequent calendar year. Disclosure of such information was made by CMS on a publicly available website beginning in September 2014; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third- party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; 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.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, which could have a material adverse effect on our business. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including our collaborators, is found not to be in compliance with applicable laws, it may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also materially affect our business.

Regulatory approval for any approved product is limited by the FDA, and any similar regulatory authorities outside the United States, to those specific indications and conditions for which clinical safety and efficacy have been demonstrated.

Any regulatory approval is limited to those specific diseases and indications for which a product is deemed to be safe and effective by the FDA and any similar regulatory authorities outside the United States. In addition to the regulatory approval required for new formulations, any new indication for an approved product also requires regulatory approval. If we are not able to obtain regulatory approval for any desired future indications for our products, our ability to effectively market and sell our products may be reduced and our business may be adversely affected.

While physicians may choose to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical studies and approved by the regulatory authorities, our ability to promote the products is limited to those indications that are specifically approved by the FDA, or the similar regulatory authority outside the United States. These "off-label" uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the U.S. generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict promotion by pharmaceutical companies on the subject of off-label use. If our promotional activities fail to comply with these regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow FDA, or any applicable foreign regulatory authority, rules and guidelines relating to promotion and advertising may cause the FDA, or such applicable foreign regulatory authority, to suspend or withdraw an approved product from the market, require a recall or institute fines, or could result in disgorgement of money, operating restrictions, injunctions or criminal prosecution, any of which could harm our business.

We are subject to new legislation, regulatory proposals and managed care initiatives that may increase our costs of compliance and adversely affect our ability to market our products, obtain collaborators and raise capital.

In the US and some foreign jurisdictions, there have been a number of proposed and enacted legislative and regulatory changes regarding the healthcare system that could prevent or delay marketing approval of one or more of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any of our product candidates for which we obtain marketing approval.

Among policy makers and payors in the US and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access. In the US, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively, the "ACA," was enacted in 2010 and made significant changes to the United States' healthcare system. The ACA and any revisions or replacements of that Act, any substitute legislation, and other changes in the law or regulatory framework could have a material adverse effect on our business.

Among the provisions of the ACA of importance to our potential product candidates are:

- an annual, nondeductible fee on any entity that manufactures, or imports specified 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 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- expansion of healthcare fraud and abuse laws, including the federal False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for non-compliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 138% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expansion of the entities eligible for discounts under the 340B Drug Pricing Program;
- the new requirements under the federal Open Payments program and its implementing regulations;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians;
- a new regulatory pathway for the approval of biosimilar biological products, all of which will impact existing government healthcare programs and will result in the development of new programs; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

The Supreme Court upheld the ACA in the main challenge to the constitutionality of the law in 2012. Specifically, the Supreme Court held that the individual mandate and corresponding penalty was constitutional because it would be considered a tax by the federal government. The Supreme Court also upheld federal subsidies for purchasers of insurance through federally facilitated exchanges in a decision released in June 2015.

President Trump ran for office on a platform that supported the repeal of the ACA, and one of his first actions after his inauguration was to sign an Executive Order instructing federal agencies to waive or delay requirements of the ACA that impose economic or regulatory burdens on states, families, the health-care industry and others. Modifications to or repeal of all or certain provisions of the ACA have been attempted in Congress as a result of the outcome of the recent presidential and congressional elections, consistent with statements made by the incoming administration and members of Congress during the presidential and congressional campaigns and following the election.

In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of the ACA. The Budget Resolution is not a law. However, it is widely viewed as the first step toward the passage of legislation that would repeal certain aspects of the ACA. In March 2017, following the passage of the budget resolution for fiscal year 2017, the United States House of Representatives passed legislation known as the American Health Care Act of 2017, which, if enacted, would amend or repeal significant portions of the ACA. Attempts in the Senate in 2017 to pass ACA repeal legislation, including the Better Care Reconciliation Act of 2017, so far have been unsuccessful. At the end of 2017, Congress passed the Tax Cuts and Jobs Act, which repealed the penalty for individuals who fail to maintain minimum essential health coverage as required by the ACA. Following this legislation, Texas and 19 other states filed a lawsuit alleging that the ACA is unconstitutional as the individual mandate was repealed, undermining the legal basis for the Supreme Court's prior decision. On December 14, Texas federal district court judge Reed O'Connor issued a ruling declaring that the ACA in it is entirety is unconstitutional. While this decision has no immediate legal effect on the ACA and its provisions, this lawsuit is ongoing and the outcome through the appeals process may have a significant impact on our business.

The Bipartisan Budget Act of 2018, the "BBA," which set government spending levels for Fiscal Years 2018 and 2019, revised certain provisions of the ACA. Specifically, beginning in 2019, the BBA increased manufacturer point-of-sale discounts off negotiated prices of applicable brand drugs in the Medicare Part D coverage gap from 50% to 70%, ultimately increasing the liability for brand drug manufacturers. Further, this mandatory manufacturer discount applied to biosimilars beginning in 2019.

The 116th Congress has explored legislation intended to address the cost of prescription drugs. Notably, the major committees of jurisdiction in the Senate (Finance Committee, Health, Education, Labor and Pensions Committee, and Judiciary Committee), have marked up legislation intended to address various elements of the prescription drug supply chain. Proposals include a significant overhaul of the Medicare Part D benefit design, addressing patent "loopholes", and efforts to cap the increase in drug prices. The House Energy and Commerce Committee approved drug-related legislation intended to increase transparency of drug prices and also curb anti-competitive behavior in the pharmaceutical supply chain. In addition, the House Ways & Means Committee approved legislation intended to improve drug price transparency, including for drug manufacturers to justify certain price increases. While we cannot predict what proposals may ultimately become law, the elements under consideration could significantly change the landscape in which the pharmaceutical market operates.

The Trump Administration has also taken several regulatory steps to redirect ACA implementation. The Department of Health and Human Services ("HHS") finalized Medicare fee-for-service hospital payment reductions for Part B drugs acquired through the 340B Drug Pricing Program, which has been overturned by the courts. HHS also has signaled its intent to pursue reimbursement policy changes for Medicare Part B drugs as a whole that likely would reduce hospital and physician reimbursement for these drugs.

HHS has made numerous other proposals aimed at lowering drug prices for Medicare beneficiaries and increasing price transparency. These proposals include giving Medicare Advantage and Part D plans flexibility in the availability of drugs in "protected classes," more transparency in the cost of drugs, including the beneficiary's financial liability, and less costly alternatives and permitting the use of step therapy as a means of prior authorization. HHS has also proposed requiring pharmaceutical manufacturers disclose the prices of certain drugs in direct-to-consumer television advertisements. The proposal related to protected classes has been withdrawn and the disclosure requirements have been rejected by the courts. In addition, a proposed rule that would have passed drug rebates to consumers at the point of sale also has been withdrawn. However, it appears the Trump Administration will continue to explore its authority to make regulatory changes to the pharmaceutical industry. For example, the Trump Administration released an Advance Notice of Proposed Rulemaking related to an international price index model. It is unclear what eventually will be proposed, but the President has alluded to the concept of "most favored nation" pricing with regards to U.S. drug purchasing. In addition, HHS, in conjunction with the FDA, announced that it will be exploring a reimportation pathway in certain instances and for certain drugs.

HHS also has taken steps to increase the availability of cheaper health insurance options, typically with fewer benefits and less generous coverage. The Administration has also signaled its intention to address drug prices and to increase competition, including by increasing the availability of biosimilars and generic drugs. As these are regulatory actions, a new administration could undo or modify these efforts.

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 receive for any approved drug. Any reduction in reimbursement from Medicare or other government healthcare 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 commercialize our drugs.

Legislative proposals such as expanding the Medicaid drug rebate program to the Medicare Part D program, providing authority for the government to negotiate drug prices under the Medicare Part D program and lowering reimbursement for drugs covered under the Medicare Part B program have been raised in Congress, but have been met with opposition and have not been enacted so far.

The administration can rely on its existing statutory authority to make policy changes that could have an impact on the drug industry. For example, the Medicare program has in the past proposed to test alternative payment methodologies for drugs covered under the Part B program and currently is proposing to pay hospitals less for Part B-covered drugs purchased through the 340B Drug Pricing Program.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for drugs. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the US Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare products and services. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect:

- our ability to generate revenues and achieve or maintain profitability;
- the demand for any products for which we may obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- the level of taxes that we are required to pay; and
- the availability of capital.

In addition, governments may impose price controls, which may adversely affect our future profitability.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad.

We cannot predict the likelihood, nature or extent of how government regulation that may arise from future legislation or administrative or executive action taken by the U.S. presidential administration may impact our business and industry. In particular, the U.S. President has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. Notably, on January 23, 2017, President Trump ordered a civilian hiring freeze for all executive departments and agencies, including the FDA, which prohibits the FDA from filling employee vacancies or creating new positions. Under the terms of the order, the freeze was to remain in effect until implementation of a plan to be recommended by the Director for the Office of Management and Budget ("OMB") in consultation with the Director of the Office of Personnel Management, to reduce the size of the federal workforce through attrition. An under-staffed FDA could result in delays in FDA's responsiveness or in its ability to review submissions or applications, issue regulations or guidance or implement or enforce regulatory requirements in a timely fashion or at all. This hiring freeze was lifted later in 2017. Moreover, on January 30, 2017, President Trump issued an Executive Order, applicable to all executive agencies, including the FDA, which requires that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This Executive Order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations to offset any incremental cost of a new regulation and approximate the total costs or savings associated with each new regulation or repealed regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within OMB on February 2, 2017, the administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. It is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

In addition, on October 12, 2017, the President released an Executive Order intended to promote health care choices and competition and on June 24, 2019, the President released an Executive Order intended to improve price transparency and quality transparency. These may push HHS, FDA, and other relevant agencies to engage in rulemaking that may impact the pharmaceutical industry.

Public concern regarding the safety of drug products could delay or limit our ability to obtain regulatory approval, result in the inclusion of unfavorable information in our labeling, or require us to undertake other activities that may entail additional costs.

In light of widely publicized events concerning the safety risk of certain drug products, the FDA, members of Congress, the Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and the establishment of risk management programs. The Food and Drug Administration Amendments Act of 2007, or FDAAA, grants significant expanded authority to the FDA, much of which is aimed at improving the safety of drug products before and after approval. In particular, the new law authorizes the FDA to, among other things, require post-approval studies and clinical trials, mandate changes to drug labeling to reflect new safety information and require risk evaluation and mitigation strategies for certain drugs, including certain currently approved drugs. It also significantly expands the federal government's clinical trial registry and results databank, which we expect will result in significantly increased government oversight of clinical trials. Under the FDAAA, companies that violate these and other provisions of the new law are subject to substantial civil monetary penalties, among other regulatory, civil and criminal penalties. The increased attention to drug safety issues may result in a more cautious approach by the FDA in its review of data from our clinical trials. Data from clinical trials may receive greater scrutiny, particularly with respect to safety, which may make the FDA or other regulatory authorities more likely to require additional preclinical studies or clinical trials. If the FDA requires us to conduct additional preclinical studies or clinical trials prior to approving any of our product candidates, our ability to obtain approval of this product candidate will be delayed. If the FDA requires us to provide additional clinical or preclinical data following the approval of any of our product candidates, the indications for which this product candidate is approved may be limited or there may be specific warnings or limitations on dosing, and our efforts to commercialize our product candidates may be otherwise adversely impacted.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for one or more of our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. Some of our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. Available therapies for the indications we are pursuing can also affect enrollment in our clinical trials. Patient enrollment is affected by other factors including:

- the severity of the disease under investigation;
- the eligibility criteria for the study in question;
- the perceived risks and benefits of the product candidate under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the number of clinical trials sponsored by other companies for the same patient population;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidate or future product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

Our product candidates are in scientific areas of intense competition from many large pharmaceutical and biotechnology companies, many of which are significantly further along in development or are already on the market with competing products. We expect competition for our product candidates will intensify, and new products may emerge that provide different or better therapeutic alternatives for our targeted indications.

The biotechnology and pharmaceutical industries are subject to rapid and intense technological change. We face, and will continue to face, competition in the development and marketing of our product candidates from academic institutions, government agencies, research institutions and biotechnology and pharmaceutical companies. There can be no assurance that developments by others will not render one or more of our product candidates obsolete or noncompetitive. Furthermore, new developments, including the development of other drug technologies and methods of preventing the incidence of disease, occur in the pharmaceutical industry at a rapid pace. These developments may render one or more of our product candidates obsolete or noncompetitive.

Our product candidates will compete with other product candidates with similar indications.

Competitors may seek to develop alternative formulations that do not directly infringe on our in-licensed patent rights. The commercial opportunity for one or more of our product candidates could be significantly harmed if competitors are able to develop alternative formulations outside the scope of our in-licensed patents. Compared to us, many of our potential competitors have substantially greater:

- capital resources;
- development resources, including personnel and technology;
- clinical trial experience;
- regulatory experience;
- expertise in prosecution of intellectual property rights; and
- manufacturing, distribution and sales and marketing experience.

As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than we are able to or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize one or more of our product candidates. Our competitors may also develop drugs that are more effective, safe, useful and less costly than ours and may be more successful than us in manufacturing and marketing their products.

Our commercial success depends upon us attaining significant market acceptance of our product candidates, if approved for sale, among physicians, patients, healthcare payors and major operators of cancer and other clinics.

Even if we obtain regulatory approval for one or more of our product candidates, the product may not gain market acceptance among physicians, health care payors, patients and the medical community, which are critical to commercial success. Market acceptance of any product candidate for which we receive approval depends on a number of factors, including:

- the efficacy and safety as demonstrated in clinical trials;
- the timing of market introduction of such product candidate as well as competitive products;
- the clinical indications for which the drug is approved;
- acceptance by physicians, major operators of cancer clinics and patients of the drug as a safe and effective treatment;
- the safety of such product candidate seen in a broader patient group, including its use outside the approved indications;
- the availability, cost and potential advantages of alternative treatments, including less expensive generic drugs;
- the availability of adequate reimbursement and pricing by third-party payors and government authorities;
- the relative convenience and ease of administration of the product candidate for clinical practices;
- the product labeling or product insert required by the FDA or regulatory authority in other countries;
- the approval, availability, market acceptance and reimbursement for a companion diagnostic, if any;
- the prevalence and severity of adverse side effects; and
- the effectiveness of our sales and marketing efforts.

If any product candidate that we develop does not provide a treatment regimen that is as beneficial as, or is perceived as being as beneficial as, the current standard of care or otherwise does not provide patient benefit, that product candidate, if approved for commercial sale by the FDA or other regulatory authorities, likely will not achieve market acceptance. Our ability to effectively promote and sell any approved products will also depend on pricing and cost-effectiveness, including our ability to produce a product at a competitive price and our ability to obtain sufficient third-party coverage or reimbursement. If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, patients and third-party payors, our ability to generate revenues from that product would be substantially reduced. In addition, our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources, may be constrained by FDA rules and policies on product promotion, and may never be successful.

If approved, our product candidates may face competition from less expensive generic products of competitors and, if we are unable to differentiate the benefits of our product candidates over these less expensive alternatives, we may never generate meaningful product revenues.

Generic therapies are typically sold at lower prices than branded therapies and are generally preferred by hospital formularies and managed care providers of health services. We anticipate that, if approved, our product candidates will face increasing competition in the form of generic versions of branded products of competitors that have lost or will lose their patent exclusivity. In the future, we may face additional competition from a generic form of our own candidates when the patents covering it begin to expire, or earlier if the patents are successfully challenged. If we are unable to demonstrate to physicians and payers that the key differentiating features of our product candidates translate to overall clinical benefit or lower cost of care, we may not be able to compete with generic alternatives.

Reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our products profitably.

There is significant uncertainty related to the third-party coverage and reimbursement of newly approved drugs. Such third-party payors include government health programs such as Medicare, managed care providers, private health insurers and other organizations. We intend to seek approval to market our product candidates in the U.S., Europe and other selected foreign jurisdictions. Market acceptance and sales of our product candidates in both domestic and international markets will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for any of our product candidates and may be affected by existing and future health care reform measures. Government and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new drugs and, as a result, they may not cover or provide adequate payment for our product candidates. These payors may conclude that our product candidates are less safe, less effective or less cost-effective than existing or future introduced products, and third-party payors may not approve our product candidates for coverage and reimbursement or may cease providing coverage and reimbursement for these product candidates.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our products. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. If reimbursement of our future products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, it may impact the market acceptance of our products and we may be unable to achieve or sustain profitability.

In some foreign countries, particularly in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidate. To obtain reimbursement or pricing approval in some countries, we may be required to conduct additional clinical trials that compare the cost-effectiveness of our product candidates to other available therapies. If reimbursement of our product candidates is unavailable or limited in scope or amount in a particular country, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability of our products in such country.

If we are unable to establish sales, marketing and distribution capabilities or to enter into agreements with third parties to market and sell our product candidates, we may not be successful in commercializing our product candidates if and when they are approved.

We currently do not have a marketing or sales organization for the marketing, sales and distribution of pharmaceutical products. In order to commercialize any product candidate that receives marketing approval, we would need to build marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. In the event of successful development and regulatory approval of one or more of our product candidates or any future product candidate, we expect to build a targeted specialist sales force to market or co-promote the product. There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future products;

- the lack of complementary or other products to be offered by sales personnel, which may put us at a competitive disadvantage from the perspective of sales efficiency relative to companies with more extensive product lines; and

- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

As an alternative to establishing our own sales force, we may choose to partner with third parties that have well-established direct sales forces to sell, market and distribute our products.

We rely, and expect to continue to rely, on third parties to conduct our preclinical studies and clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials or complying with applicable regulatory requirements.

We rely on third-party contract research organizations and site management organizations to conduct some of our preclinical studies and all of our clinical trials for our product candidates and for any future product candidate. We expect to continue to rely on third parties, such as contract research organizations, site management organizations, clinical data management organizations, medical institutions and clinical investigators, to conduct some of our preclinical studies and all of our clinical trials. The agreements with these third parties might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, that could delay our product development activities.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our preclinical studies and clinical trials are conducted in accordance with the general investigational plan and protocols for the trial and for ensuring that our preclinical studies are conducted in accordance with good laboratory practice ("GLP") as appropriate. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices ("GCPs") for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of our clinical research organizations fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

The third parties with whom we have contracted to help perform our preclinical studies or clinical trials may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our preclinical studies or clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

If any of our relationships with these third-party contract research organizations or site management organizations terminate, we may not be able to enter into arrangements with alternative contract research organizations or site management organizations or to do so on commercially reasonable terms. Switching or adding additional contract research organizations or site management organizations involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new contract research organization or site management organization commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines. Though we carefully manage our relationships with our contract research organizations or site management organizations, there can be no assurance that we will not encounter similar challenges or delays in the future.

We contract with third parties for the manufacture of our product candidates for preclinical and clinical testing and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or any future product candidate or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not have any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical and clinical testing, as well as for commercial manufacture if any of our product candidates if they receive marketing approval. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or any future product candidate or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

We also expect to rely on third-party manufacturers or third-party collaborators for the manufacture of commercial supply of any product candidates for which our collaborators or we obtain marketing approval. We may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- manufacturing delays if our third-party manufacturers give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreement between us;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

We rely on our third-party manufacturers to produce or purchase from third-party suppliers the materials necessary to produce our product candidates for our preclinical and clinical trials. There are a limited number of suppliers for raw materials that we use to manufacture our drugs and there may be a need to assess alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidates for our preclinical and clinical trials, and if approved, ultimately for commercial sale. We do not have any control over the process or timing of the acquisition of these raw materials by our third-party manufacturers. Any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing preclinical or clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our preclinical or clinical trials, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit a new drug application ("NDA") or BLA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturers for compliance with cGMP regulations for manufacture of our product candidates. Third-party manufacturers may not be able to comply with the 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 product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

One or more of the product candidates that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply or a second source for bulk drug substance or the manufacture of drug product. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers. We may incur added costs and delays in identifying and qualifying any replacement manufacturers. The U.S. DEA restricts the importation of a controlled substance finished drug product when the same substance is commercially available in the United States, which could reduce the number of potential alternative manufacturers for one or more of our product candidates.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue.

We rely on clinical data and results obtained by third parties that could ultimately prove to be inaccurate or unreliable.

As part of our strategy to mitigate development risk, we seek to develop product candidates with validated mechanisms of action and may utilize biomarkers to assess potential clinical efficacy early in the development process. This strategy necessarily relies upon clinical data and other results obtained by third parties that may ultimately prove to be inaccurate or unreliable. Further, such clinical data and results may be based on products or product candidates that are significantly different from our product candidates or any future product candidate. If the third-party data and results we rely upon prove to be inaccurate, unreliable or not applicable to our product candidates or future product candidate, we could make inaccurate assumptions and conclusions about our product candidates and our research and development efforts could be compromised.

If we breach any of the agreements under which we license rights to one or more of product candidates from others, we could lose the ability to continue to develop and commercialize this product candidate.

Because we have in-licensed the rights to all of our product candidates from third parties, if there are any disputes between us and any of our licensors regarding our rights under our license agreements, our ability to develop and commercialize these product candidates may be adversely affected. Any uncured, material breach under any of our license agreements could result in our loss of exclusive rights to one or more of our product candidates and may lead to a complete termination of our related product development efforts.

We may not be able to manage our business effectively if we are unable to attract and retain key personnel.

We may not be able to attract or retain qualified management and commercial, scientific and clinical personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. If we are not able to attract and retain necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we have established, comply with federal and state health-care fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, bribery, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation, as well as civil and criminal liability. The precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other civil and/or criminal sanctions.

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for one or more of our product candidates or a future product candidate we may license or acquire and may have to limit their commercialization.

The use of one or more of our product candidates and any future product candidate we may license or acquire in clinical trials and the sale of any products for which we obtain marketing approval expose us to the risk of product liability claims. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Product liability claims might be brought against us by consumers, health care providers or others using, administering or selling our products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- withdrawal of clinical trial participants;
- suspension or termination of clinical trial sites or entire trial programs;
- decreased demand for any product candidates or products that we may develop;
- initiation of investigations by regulators;
- impairment of our business reputation;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;

- loss of revenues;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize our product candidate or future product candidates.

We have obtained, and will continue to obtain, limited product liability insurance coverage for any and all of our current and future clinical trials. However, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. When needed we intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for one or more of our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

Our future growth depends on our ability to identify and acquire or in-license products and if we do not successfully identify and acquire or in-license related product candidates or integrate them into our operations, we may have limited growth opportunities.

An important part of our business strategy is to continue to develop a pipeline of product candidates by acquiring or in-licensing products, businesses or technologies that we believe are a strategic fit with our focus on novel combinations of immuno-oncology antibodies and small molecule targeted anti-cancer agents. Future in-licenses or acquisitions, however, may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention to develop acquired products or technologies;
- difficulty or inability to secure financing to fund development activities for such acquired or in-licensed technologies in the current economic environment;
- incurrence of substantial debt or dilutive issuances of securities to pay for acquisitions;
- higher than expected acquisition and integration costs;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. In particular, we may compete with larger pharmaceutical companies and other competitors in our efforts to establish new collaborations and in-licensing opportunities. These competitors likely will have access to greater financial resources than us and may have greater expertise in identifying and evaluating new opportunities. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. Although we believe that the safety procedures for handling and disposing of these materials comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

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

Despite the implementation of security measures, our internal computer systems are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Any system failure, accident or security breach that causes interruptions in our operations could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed clinical trials for one or more of our product conducts could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability and the further development of one or more of our product candidates may be delayed.

Risks Related to Intellectual Property

If we are unable to obtain and maintain patent protection for our technology and products or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection in the United States and other countries with respect to our product candidates or any future product candidate that we may license or acquire and the methods we use to manufacture them, as well as successfully defending these patents and trade secrets against third-party challenges. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and product candidates, and by maintenance of our trade secrets through proper procedures. We will only be able to protect our technologies from unauthorized use by third parties to the extent that valid and enforceable patents or trade secrets cover them in the market they are being used or developed.

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 or in a timely manner. It is also possible that we will fail to identify any patentable aspects of our research and development output and methodology, and, even if we do, an opportunity to obtain patent protection may have passed. Given the uncertain and time-consuming process of filing patent applications and prosecuting them, it is possible that our product(s) or process(es) originally covered by the scope of the patent application may have changed or been modified, leaving our product(s) or process(es) without patent protection. If our licensors or we fail to obtain or maintain patent protection or trade secret protection for one or more product candidates or any future product candidate we may license or acquire, third parties may be able to leverage our proprietary information and products without risk of infringement, which could impair our ability to compete in the market and adversely affect our ability to generate revenues and achieve profitability. Moreover, should we enter into other collaborations we may be required to consult with or cede control to collaborators regarding the prosecution, maintenance and enforcement of licensed patents. 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, no consistent policy regarding the breadth of claims allowed in pharmaceutical or biotechnology patents has emerged to date in the U.S. The patent situation outside the U.S. is even more uncertain. 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 a first filing, or in some cases not at all. Therefore, we cannot know with certainty whether we or our licensors were the first to make the inventions claimed in patents or pending patent applications that we own or licensed, or that we or our licensors were the first to file for patent protection of such inventions. In the event that a third party has also filed a U.S. patent application relating to our product candidates or a similar invention, depending upon the priority dates claimed by the competing parties, we may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office to determine priority of invention in the U.S. The costs of these proceedings could be substantial and it is possible that our efforts to establish priority of invention would be unsuccessful, resulting in a material adverse effect on our U.S. patent position. As a result, the issuance, scope, validity, enforceability and commercial value of our or any of our respective licensors' 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. For example, the federal courts of the United States have taken an increasingly dim view of the patent eligibility of certain subject matter, such as naturally occurring nucleic acid sequences, amino acid sequences and certain methods of utilizing same, which include their detection in a biological sample and diagnostic conclusions arising from their detection. Such subject matter, which had long been a staple of the biotechnology and biopharmaceutical industry to protect their discoveries, is now considered, with few exceptions, ineligible in the first instance for protection under the patent laws of the United States. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in those licensed from a third-party.

In addition, U.S. patent laws may change, which could prevent or limit us from filing patent applications or patent claims to protect products and/or technologies or limit the exclusivity periods that are available to patent holders, as well as affect the validity, enforceability, or scope of issued patents. For example, on September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include changes to transition from a "first-to-invent" system to a "first-to-file" system and to the way issued patents are challenged. The formation of the Patent Trial and Appeal Board now provides a quicker and less expensive process for challenging issued patents. The United States Patent Office recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first inventor-to-file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office, or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. The costs of these proceedings could be substantial and it is possible that our efforts to establish priority of invention would be unsuccessful, resulting in a material adverse effect on our US patent position. An adverse determination in any such submission, patent office trial, proceeding or litigation could reduce the scope of, render unenforceable, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Even if our 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 does not foreclose challenges to its inventorship, scope, validity or enforceability. Therefore, 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 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 product candidates might expire before or shortly after such product 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.

We depend on our licensors for the maintenance and enforcement of intellectual property covering certain of our product candidates and have limited control, if any, over the amount or timing of resources that our licensors devote on our behalf, or whether any financial difficulties experienced by our licensors could result in their unwillingness or inability to secure, maintain and enforce patents protecting certain of our product candidates.

We depend on our licensors to protect the proprietary rights covering our antibody and certain of our small molecule product candidates and we have limited, if any, control over the amount or timing of resources that they devote on our behalf, or the priority they place on, maintaining patent rights and prosecuting patent applications to our advantage. Moreover, we have limited, if any, control over the strategies and arguments employed in the maintenance of patent rights and the prosecution of patent applications to our advantage.

Our licensors, depending on the patent or application, are responsible for maintaining issued patents and prosecuting patent applications for our antibody and certain of our small molecule product candidates. We cannot be sure that they will perform as required. Should they decide they no longer want to maintain any of the patents licensed to us, they are required to afford us the opportunity to do so at our expense. If our licensors do not perform, and if we do not assume the maintenance of the licensed patents in sufficient time to make required payments or filings with the appropriate governmental agencies, we risk losing the benefit of all or some of those patent rights. Moreover, and possibly unbeknownst to us, our licensors may experience serious difficulties related to their overall business or financial stability, and they may be unwilling or unable to continue to expend the financial resources required to maintain and prosecute these patents and patent applications. While we intend to take actions reasonably necessary to enforce our patent rights, we depend, in part, on our licensors to protect a substantial portion of our proprietary rights and to inform us of the status of those protections and efforts thereto.

Our licensors may also be notified of alleged infringement and be sued for infringement of third-party patents or other proprietary rights. We may have limited, if any, control or involvement over the defense of these claims, and our licensors could be subject to injunctions and temporary or permanent exclusionary orders in the U.S. or other countries. Our licensors are not obligated to defend or assist in our defense against third-party claims of infringement. We have limited, if any, control over the amount or timing of resources, if any, that our licensors devote on our behalf or the priority they place on defense of such third-party claims of infringement.

Because of the uncertainty inherent in any patent or other litigation involving proprietary rights, we or our licensors may not be successful in defending claims of intellectual property infringement alleged by third parties, which could have a material adverse effect on our results of operations. Regardless of the outcome of any litigation, defending the litigation may be expensive, time-consuming and distracting to management.

Because it is difficult and costly to protect our proprietary rights, we may not be able to ensure their protection.

The degree of future protection for our proprietary rights is uncertain, because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage, in addition to being costly and time consuming to undertake. For example:

- our licensors might not have been the first to make the inventions covered by each of our pending patent applications and issued patents;
- our licensors might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate our product candidates or any future product candidate technologies;
- it is possible that none of the pending patent applications licensed to us will result in issued patents;
- the scope of our issued patents may not extend to competitive products developed or produced by others;
- the issued patents covering our product candidates or any future product candidate may not provide a basis for market exclusivity for active products, may not provide us with any competitive advantages, or may be challenged by third parties;
- we may not develop additional proprietary technologies that are patentable; or
- intellectual property rights of others may have an adverse effect on our business.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our issued patents or other intellectual property. To counter infringement or unauthorized use, we may be required to file one or more actions for patent infringement, which can be expensive and time consuming. Any claims we assert against accused infringers could provoke these parties to assert counterclaims against us alleging invalidity of our or certain of our subsidiaries' patents or that we infringe their patents; or provoke those parties to petition the PTO to institute inter partes review against the asserted patents, which may lead to a finding that all or some of the claims of the patent are invalid. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our pending patents at risk of being invalidated, rendered unenforceable, or interpreted narrowly. Because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. Furthermore, adverse results on US patents may affect related patents in our global portfolio.

If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in any litigation would harm our business.

Our ability to develop, manufacture, market and sell one or more of our product candidates or any future product candidate that we may license or acquire depends upon our ability to avoid infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the general fields of fully human immuno-oncology targeted antibodies and targeted anti-cancer agents and cover the use of numerous compounds and formulations in our targeted markets. Because of the uncertainty inherent in any patent or other litigation involving proprietary rights, we and our licensors may not be successful in defending intellectual property claims asserted by third parties, which could have a material adverse effect on our results of operations. Regardless of the outcome of any litigation, defending the litigation may be expensive, time-consuming and distracting to management. In addition, because patent applications can take many years to issue, there may be currently pending applications that are unknown to us, which may later result in issued patents that one or more of our product candidates may infringe. There could also be existing patents of which we are not aware that one or more of our product candidates may infringe, even if only inadvertently.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and biopharmaceutical industries generally. If a third-party claims that we infringe their patents or misappropriated their technology, we could face a number of issues, including:

- infringement and other intellectual property claims which, with or without merit, can be expensive and time consuming to litigate and can divert management's attention from our core business;
- substantial damages for past infringement which we may have to pay if a court decides that our product infringes a competitor's patent;
- a court prohibiting us from selling or licensing our product unless the patent holder licenses the patent to us, which it would not be required to do;
- if a license is available from a patent holder, we may have to pay substantial royalties or grant cross licenses to our patents; and
- redesigning our processes so they do not infringe, which may not be possible or could require substantial funds, time, and may result in an inferior or less-desirable process or product.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

We may need to license certain intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property, including patent rights that are important or necessary to the development and commercialization of our products. It may be necessary for us to use the patented or proprietary technology of third parties, whom may or may not be interested in granting such a license, to commercialize our products, in which case we would be required to obtain a license from these third parties on commercially reasonable terms, or our business could be harmed, possibly materially.

If we fail to comply with our obligations in our intellectual property licenses and funding arrangements with third parties, we could lose rights that are important to our business.

We are currently a party to license agreements with Dana-Farber, Adimab, NeuPharma and Jubilant. In the future, we may become party to additional licenses that are important for product development and commercialization. If we fail to comply with our obligations under current or future license and funding agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any product or utilize any technology that is covered by these agreements or may face other penalties under the agreements. Such an occurrence could materially and adversely affect the value of a product candidate being developed under any such agreement or could restrict our drug discovery activities. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that we or these employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Even if frivolous or unsubstantiated in nature, litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management and the implicated employee(s).

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

In addition to seeking patent protection for our product candidates or any future product candidate, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position, particularly where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We limit disclosure of such trade secrets where possible but we also seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who do have access to them, such as our employees, our licensors, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and may unintentionally or willfully disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. 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. Moreover, 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 were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

Risks Related to Our Finances and Capital Requirements

We have incurred significant losses since our inception. We expect to incur losses for the foreseeable future, and may never achieve or maintain profitability.

We are an emerging growth company with a limited operating history. We have focused primarily on in-licensing and developing our product candidates, with the goal of supporting regulatory approval for these product candidates. We have incurred losses since our inception in November 2014, and have an accumulated deficit of $106.1 million as of June 30, 2019. We expect to continue to incur significant operating losses for the foreseeable future. We also do not anticipate that we will achieve profitability for a period of time after generating material revenues, if ever. If we are unable to generate revenues, we will not become profitable and may be unable to continue operations without continued funding. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the timing or amount of increased expenses or when or if, we will be able to achieve profitability. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if:

- one or more of our product candidates are approved for commercial sale, due to our ability to establish the necessary commercial infrastructure to launch this product candidate without substantial delays, including hiring sales and marketing personnel and contracting with third parties for warehousing, distribution, cash collection and related commercial activities;

- we are required by the FDA or foreign regulatory authorities, to perform studies in addition to those currently expected;

- there are any delays in completing our clinical trials or the development of any of our product candidates;
- we execute other collaborative, licensing or similar arrangements and the timing of payments we may make or receive under these arrangements;
- there are variations in the level of expenses related to our current and future development programs;
- there are any product liability or intellectual property infringement lawsuits in which we may become involved;
- there are any regulatory developments affecting product candidates of our competitors; and
- one or more of our product candidate receives regulatory approval.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue from our development stage products, and we do not know when, or if, we will generate any revenue. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

- obtain regulatory approval for one or more of our product candidates, or any future product candidate that we may license or acquire;
- manufacture commercial quantities of one or more of our product candidates or any future product candidate, if approved, at acceptable cost levels; and
- develop a commercial organization and the supporting infrastructure required to successfully market and sell one or more of our product candidates or any future product candidate, if approved.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

Our short operating history makes it difficult to evaluate our business and prospects.

We were incorporated in November 2014 and have only been conducting operations with respect to our product candidates since March 2015. Our operations to date have been limited to preclinical and clinical operations and the in-licensing of our product candidates. We have not yet demonstrated an ability to successfully complete clinical trials, obtain regulatory approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions about our future performance may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to expand our capabilities to support increased clinical and manufacturing activities and future potential commercial activities. We may not be successful in adding such capabilities.

We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any past quarterly period as an indication of future operating performance.

We do not have any products that are approved for commercial sale and therefore do not expect to generate any revenues from product sales in the foreseeable future, if ever.

We have not generated any product related revenues to date, and do not expect to generate any such revenues for at least the next several years, if at all. To obtain revenues from sales of our product candidates, we must succeed, either alone or with third parties, in developing, obtaining regulatory approval for, manufacturing and marketing products with commercial potential. We may never succeed in these activities, and we may not generate sufficient revenues to continue our business operations or achieve profitability.

We will require substantial additional funding which may not be available to us on acceptable terms, or at all. If we fail to raise the necessary additional capital, we may be unable to complete the development and commercialization of our product candidates, or continue our development programs.

Our operations have consumed substantial amounts of cash since inception. We expect to significantly increase our spending to advance the preclinical and clinical development of our product candidates and launch and commercialize any product candidates for which we receive regulatory approval, including building our own commercial organizations to address certain markets. We will require additional capital for the further development and commercialization of our product candidates, as well as to fund our other operating expenses and capital expenditures. We currently anticipate that our cash and cash equivalent balances at June 30, 2019, combined with the additional capital raised in the third quarter of 2019, are sufficient to fund our anticipated operating cash requirements for at least one year from the date of this Quarterly Report on Form 10-Q.

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates. We may also seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available. Any of these events could significantly harm our business, financial condition and prospects.

Our future funding requirements will depend on many factors, including, but not limited to:

- the timing, design and conduct of, and results from, preclinical and clinical trials for our product candidates;
- the potential for delays in our efforts to seek regulatory approval for our product candidates, and any costs associated with such delays;
- the costs of establishing a commercial organization to sell, market and distribute our product candidates;
- the rate of progress and costs of our efforts to prepare for the submission of an NDA or BLA for any of our product candidates or any product candidates that we may in-license or acquire in the future, and the potential that we may need to conduct additional clinical trials to support applications for regulatory approval;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with our product candidates, including any such costs we may be required to expend if our licensors are unwilling or unable to do so;
- the cost and timing of securing sufficient supplies of our product candidates from our contract manufacturers for clinical trials and in preparation for commercialization;
- the effect of competing technological and market developments;
- the terms and timing of any collaborative, licensing, co-promotion or other arrangements that we may establish;
- if one or more of our product candidates are approved, the potential that we may be required to file a lawsuit to defend our patent rights or regulatory exclusivities from challenges by companies seeking to market generic versions of one or more of our product candidates; and
- the success of the commercialization of one or more of our product candidates.

Future capital requirements will also depend on the extent to which we acquire or invest in additional complementary businesses, products and technologies, but we currently have no commitments or agreements relating to any of these types of transactions.

In order to carry out our business plan and implement our strategy, we anticipate that we will need to obtain additional financing from time to time and may choose to raise additional funds through strategic collaborations, licensing arrangements, public or private equity or debt financing, bank lines of credit, asset sales, government grants, or other arrangements. We cannot be sure that any additional funding, if needed, will be available on terms favorable to us or at all. Furthermore, any additional equity or equity-related financing may be dilutive to our stockholders, and debt or equity financing, if available, may subject us to restrictive covenants and significant interest costs. If we obtain funding through a strategic collaboration or licensing arrangement, we may be required to relinquish our rights to certain of our product candidates or marketing territories.

Our inability to raise capital when needed would harm our business, financial condition and results of operations, and could cause our stock price to decline or require that we wind down our operations altogether.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish proprietary rights.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, grants and license and development agreements in connection with any collaborations. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We will continue to incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we will continue to incur significant legal, accounting and other expenses under the Sarbanes-Oxley Act of 2002, as well as rules subsequently implemented by the SEC. These rules impose various requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and appropriate corporate governance practices. Our management and other personnel have devoted and will continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

The Sarbanes-Oxley Act of 2002 requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. As a result, we are required to periodically perform an evaluation of our internal controls over financial reporting to allow management to report on the effectiveness of those controls, as required by Section 404 of the Sarbanes-Oxley Act. Additionally, our independent auditors will be required to perform a similar evaluation and report on the effectiveness of our internal controls over financial reporting. These efforts to comply with Section 404 and related regulations have required, and continue to require, the commitment of significant financial and managerial resources. While we anticipate maintaining the integrity of our internal controls over financial reporting and all other aspects of Section 404, we cannot be certain that a material weakness will not be identified when we test the effectiveness of our control systems in the future. If a material weakness is identified, we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources, costly litigation or a loss of public confidence in our internal controls, which could have an adverse effect on the market price of our stock.

A target business may not be in compliance with the provisions of the Sarbanes-Oxley Act regarding the adequacy of internal controls. The development of the internal controls of any such entity to achieve compliance with the Sarbanes-Oxley Act may increase the time and costs necessary to complete any such acquisition. Furthermore, any failure to implement required new or improved controls, or difficulties encountered in the implementation of adequate controls over our financial processes and reporting in the future, could harm our operating results or cause us to fail to meet our reporting obligations. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our securities.

We are an "emerging growth company" and a "smaller reporting company," and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an "emerging growth company" as that term is used in the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"), and may remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of the initial public offering of our common stock, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our outstanding common stock that are held by non-affiliates exceeds $700 million as of the prior June 30, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of our audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this Annual Report on Form 10-K;

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;

- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;

- disclosure obligations regarding executive compensation; and

- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

Further, Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such an election to opt out is irrevocable. We have elected to opt out of such extended transition period which means that when a standard is issued or revised and it has different application dates for public or private companies, we, as an emerging growth company, will adopt the new or revised standard. This may make comparison of our financial statements with another public company which has opted into using the extended transition period difficult or impossible because of the potential differences in accountant standards used.

We are also a smaller reporting company, and we will remain a smaller reporting company until the fiscal year following the determination that our voting and non-voting common shares held by non-affiliates is more than $250 million measured on the last business day of our second fiscal quarter, or our annual revenues are more than $100 million during the most recently completed fiscal year and our voting and non-voting common shares held by non-affiliates is more than $700 million measured on the last business day of our second fiscal quarter. Similar to emerging growth companies, smaller reporting companies are able to provide simplified executive compensation disclosure, are exempt from the auditor attestation requirements of Section 404, and have certain other reduced disclosure obligations, including, among other things, being required to provide only two years of audited financial statements and not being required to provide selected financial data, supplemental financial information or risk factors.

We have elected to take advantage of certain of the reduced reporting obligations. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be reduced or more volatile.

Our results of operations and liquidity needs could be materially negatively affected by market fluctuations and economic downturns.

Our results of operations could be materially negatively affected by economic conditions generally, both in the U.S. and elsewhere around the world. Concerns over inflation, energy costs, geopolitical issues, the availability and cost of credit, the U.S. mortgage market and residential real estate market in the U.S. could contribute to increased volatility and diminished expectations for the economy and the markets going forward. These factors, potentially combined with volatile oil prices, declining business and consumer confidence and increased unemployment, may precipitate an economic recession and fears of a possible depression. Domestic and international equity markets may experience heightened volatility and turmoil. These events and any market upheavals may have an adverse effect on us. In the event of a market downturn, our results of operations could be adversely affected by those factors in many ways, including making it more difficult for us to raise funds if necessary, and our stock price may further decline.

Risks Relating to Securities Markets and Investment in Our Stock

The market price and trading volume of our common stock has been volatile. Our stock may continue to be subject to substantial price and volume fluctuations due to a number of factors, many of which are beyond our control and may prevent our stockholders from reselling our common stock at a profit.

The market prices for securities of biotechnology and pharmaceutical companies have historically been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies.

The market price and trading volume of our common stock has been highly volatile and is likely to continue to be highly volatile and may fluctuate substantially due to many factors, including:

- announcements relating to the clinical development of our product candidates;

- announcements concerning the progress of our efforts to obtain regulatory approval for and commercialize our product candidates or any future product candidate, including any requests we receive from the FDA, or comparable regulatory authorities outside the United States, for additional studies or data that result in delays or additional costs in obtaining regulatory approval or launching these product candidates, if approved;
- the depth and liquidity of the market for our common stock;
- investor perceptions about us and our business;
- market conditions in the pharmaceutical and biotechnology sectors or the economy as a whole;
- price and volume fluctuations in the overall stock market;
- the failure of one or more of our product candidates or any future product candidate, if approved, to achieve commercial success;
- announcements of the introduction of new products by us or our competitors;
- developments concerning product development results or intellectual property rights of others;
- litigation or public concern about the safety of our potential products;
- actual fluctuations in our quarterly operating results, and concerns by investors that such fluctuations may occur in the future;
- deviations in our operating results from the estimates of securities analysts or other analyst comments;
- additions or departures of key personnel;
- health care reform legislation, including measures directed at controlling the pricing of pharmaceutical products, and third-party coverage and reimbursement policies;
- developments concerning current or future strategic collaborations; and
- discussion of us or our stock price by the financial and scientific press and in online investor communities.

Fortress controls a voting majority of our common stock.

Pursuant to the terms of the Class A common stock held by Fortress, Fortress is entitled to cast, for each share of Class A common stock held by Fortress, the number of votes that is equal to one and one-tenth (1.1) times a fraction, the numerator of which is the sum of the shares of outstanding common stock and the denominator of which is the number of shares of outstanding Class A common stock. Accordingly, as long as Fortress owns any shares of Class A common stock, they will be able to control or significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of Fortress may not always coincide with the interests of other stockholders, and Fortress may take actions that advance its own interests and are contrary to the desires of our other stockholders. Moreover, this concentration of voting power may delay, prevent or deter a change in control of us even when such a change may be in the best interests of all stockholders, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of Checkpoint or our assets, and might affect the prevailing market price of our common stock.

Fortress has the right to receive a significant grant of shares of our common stock annually which will result in the dilution of your holdings of common stock upon each grant, which could reduce their value.

Under the terms of the Founders Agreement, Fortress has the right to receive an annual grant of shares of our common stock equal to 2.5% of the fully-diluted outstanding equity at the time of issuance, on the anniversary of the date of the Founders Agreement, which became effective as of March 17, 2015 and was amended and restated on July 11, 2016. This annual issuance of shares to Fortress will dilute your holdings in our common stock and, if the value of Checkpoint has not grown over the prior year, would result in a reduction in the value of your shares.

In October 2017, the Founder's Agreement was amended to change the issuance date of the annual grant of shares from the anniversary date of the Agreement to January 1 of each year.

We might have received better terms from unaffiliated third parties than the terms we receive in our agreements with Fortress.

The agreements we entered into with Fortress in connection with the separation include a Management Services Agreement and the Founders Agreement. While we believe the terms of these agreements are reasonable, they might not reflect terms that would have resulted from arm's-length negotiations between unaffiliated third parties. The terms of the agreements relate to, among other things, payment of a royalty on product sales and the provision of employment and transition services. We might have received better terms from third parties because, among other things, third parties might have competed with each other to win our business.

The Chairman of our Board of Directors is also the Executive Chairman, President and Chief Executive Officer of TG Therapeutics, Inc. ("TGTX"), with whom we have a collaboration agreement and a sublicense agreement, and as a result during the term of these agreements certain conflicts of interest may arise which will require the attention of our officers and independent directors who are unaffiliated with TGTX.

In connection with our license agreement with Dana-Farber and Adimab, we entered into a collaboration agreement with TGTX to develop and commercialize the anti-PD-L1 and anti-GITR antibody research programs, including cosibelimab (formerly referred to as CK-301), in the field of hematological malignancies. Michael S. Weiss, our Chairman of the Board of Directors, is also the Executive Chairman, President and Chief Executive Officer of TGTX. As such, as the collaboration agreement proceeds, certain conflicts of interest may arise between us and TGTX. Those conflicts will have to be resolved by our officers and directors who are unaffiliated with TGTX, and also by officers and directors of TGTX who are unaffiliated with us. This may lead to less than desirable complications and costs to both companies, which could harm our results of operations.

In connection with our license agreement with Jubilant, we entered into a sublicense agreement with TGTX to develop and commercialize the Jubilant family of patents covering compounds that inhibit BET proteins such as BRD4, including CK-103, in the field of hematological malignancies. As such, as the sublicense agreement proceeds, certain conflicts of interest may arise between us and TGTX. Those conflicts will have to be resolved by our officers and directors who are unaffiliated with TGTX, and also by officers and directors of TGTX who are unaffiliated with us. This may lead to less than desirable complications and costs to both companies, which could harm our results of operations.

The dual roles of our directors who also serve in similar roles with Fortress could create a conflict of interest and will require careful monitoring by our independent directors.

We share some directors with Fortress which could create conflicts of interest between the two companies in the future. While we believe that the Founders Agreement and the Management Services Agreement were negotiated by independent parties on both sides on arm's length terms, and the fiduciary duties of both parties were thereby satisfied, in the future situations may arise under the operation of both agreements that may create a conflict of interest. We will have to be diligent to ensure that any such situation is resolved by independent parties. In particular, under the Management Services Agreement, Fortress and its affiliates are free to pursue opportunities which could potentially be of interest to Checkpoint, and they are not required to notify Checkpoint prior to pursuing the opportunity. Any such conflict of interest or pursuit by Fortress of a corporate opportunity independent of Checkpoint could expose us to claims by our investors and creditors, and could harm our results of operations.

We may become involved in securities class action litigation that could divert management's attention and harm our business.

The market price and trading volume of our common stock has been highly volatile and is likely to continue to be highly volatile. In addition, the stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of biotechnology and pharmaceutical companies. These broad market fluctuations may cause the market price of our stock to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. We may become involved in this type of litigation in the future. Litigation often is expensive and diverts management's attention and resources, which could adversely affect our business.

Item 2. Recent Sales of Unregistered Securities.

During the period covered by this report, we have not issued any unregistered securities. We have not furnished information under this item to the extent that such information previously has been included in our Annual Report on Form 10-K.

Item 6. Exhibits

Exhibit No.	Description
10.1	Amended and Restated Collaboration Agreement by and between Checkpoint Therapeutics, Inc. and TG Therapeutics, Inc. dated June 19, 2019.*
31.1	Certification of Chief Executive Officer of Checkpoint Therapeutics, Inc. pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated August 8, 2019.
31.2	Certification of Principal Financial Officer of Checkpoint Therapeutics, Inc. pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated August 8, 2019.
32.1	Certification of Chief Executive Officer of Checkpoint Therapeutics, Inc. pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated August 8, 2019.
32.2	Certification of Principal Financial Officer of Checkpoint Therapeutics, Inc. pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated August 8, 2019.
101	The following financial information from the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2019, formatted in Extensible Business Reporting Language (XBRL): (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statement of Stockholders' Equity, (iv) the Condensed Consolidated Statements of Cash Flows, and (v) Notes to the Condensed Consolidated Financial Statements (filed herewith).

*Certain portions of this exhibit have been omitted pursuant to Item 601(b)(10) of Regulation S-K.

SIGNATURES

Pursuant to the requirements of the Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Checkpoint Therapeutics, Inc.
(Registrant)

Date: August 8, 2019

By: /s/ James F. Oliviero
James F. Oliviero
President and Chief Executive Officer
(Principal Executive Officer)

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Section 2: EX-10.1 (EXHIBIT 10.1)

Exhibit 10.1

Certain identified information has been excluded from the document because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

AMENDED AND RESTATED COLLABORATION AGREEMENT

THIS AMENDED AND RESTATED COLLABORATION AGREEMENT (the "**Agreement**") is dated as of June 19, 2019 by and between Checkpoint Therapeutics, Inc., a Delaware corporation organized having its place of business at 2 Gansevoort Street, New York, NY 10014 ("**CTI**"), and TG Therapeutics, Inc. located at 2 Gansevoort Street, New York, NY 10014 ("**TGTX**"). CTI, on the one hand, and TGTX, on the other hand, shall each be referred to herein as a "**Party**" or, collectively, as the "**Parties**."

RECITALS:

WHEREAS, CTI is party to that certain license agreement (the "License Agreement") dated March 3, 2015 with Dana Farber Cancer Institute ("DFCI");

WHEREAS, DFCI is the owner of certain rights in the DFCI Technology; and

WHEREAS, DFCI has licensed rights to the DFCI Technology to CTI; and

WHEREAS, CTI is permitted to extend the rights granted to it under the DFCI Technology to Affiliates (as defined in the License Agreement); and

WHEREAS, CTI has developed and licensed the rights to Additional PD-L1 Intellectual Property, including rights under CTI Patents (as defined, below) and that certain collaboration agreement ("Collaboration Agreement") dated January 22, 2019 with Adimab LLC ("Adimab"), a true and correct copy of which is attached hereto as Exhibit A; and

WHEREAS, TGTX, an Affiliate of CTI, is engaged in the research, development, manufacturing and commercialization of pharmaceutical products, and TGTX is interested in developing and commercializing products based on the DFCI Patents and Additional PD-L1 Intellectual Property (together, the "Licensed Technology"); and

WHEREAS, the Parties signed a Collaboration Agreement (the "**Original Agreement**") on March 3, 2015 (the "**Effective Date**"), and the Parties wish to amend such Original Agreement as provided herein; and

WHEREAS, CTI desires to continue to collaborate with TGTX and extend to TGTX the rights granted to it under the Licensed Technology in order to benefit the public by disseminating the results of its research via the commercial development, manufacture, distribution and use of Licensed Products (as defined below); and

WHEREAS, TGTX desires to continue to collaborate with CTI and to exercise the rights granted to CTI, on an exclusive basis, so that it can exclusively use, develop and commercialize the Licensed Technology in and for a defined field of use; and

WHEREAS, in the event TGTX is no longer an Affiliate of CTI, TGTX and CTI intend for the rights extended to TGTX hereunder to continue as a Sublicense (as defined in the License Agreement) as permitted by Section 2.3 of the License Agreement and Section 3.2(b)(ii) of the Collaboration Agreement with Adimab.

NOW, THEREFORE, in consideration of the foregoing and of the various promises and undertakings set forth herein, the Parties agree as follows:

ARTICLE I
DEFINITIONS

Unless otherwise specifically provided herein, the following terms shall have the following meanings:

1.1 **"Affiliate"** means a Person or entity that controls, is controlled by or is under common control with a Party, but only for so long as such control exists. For the purposes of this Section 1.1, 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 the management and policies of such Person or entity, whether by the ownership of at least 50% of the voting stock of such entity, or by contract or otherwise. TGTX and CTI acknowledge and agree that TGTX is an Affiliate of CTI.

1.2 "**Antibody**" means any antibody, any gene expressing such an antibody, any hybridoma producing such antibody, or any fragment, variant, derivative or construct thereof, or antibody fusion protein produced therefrom (including PEDgylated or multimeric versions thereof, whether polyclonal, monoclonal, multi-specific antibodies (e.g., bi-specific antibodies), human, humanized, chimeric, murine, synthetic, or from any other source), including without limitation (a) the full immunoglobin molecules (e.g., the IgG, IgM, IgE, IgA, and IgD molecules), and (b) the antigen binding portions including Fab, Fab', F(ab')2, Fv, dAb, and CDR fragments, chimeric antibodies, diabodies, polypeptides, linear antibodies and single-chain antibodies (scFv) that contain any portion of an immunoglobulin that is sufficient to confer specific binding to an antigen.

1.3 **"Autoimmune Diseases"** means any disease which results from a loss of immune tolerance to self-antigens, including without limitation multiple sclerosis, rheumatoid arthritis, systemic lupus erythematosus, sjogren syndrome, celiac disease, Graves' disease, myasthenia gravis, Type I diabetes, idiopathic thrombocytopenic purpura, pemphigus vulgaris, among others, including any presentation or manifestation thereof.

1.4 **"Calendar Quarter**" means each three-month period commencing January 1, April 1, July 1 or October 1, provided however that (a) the first Calendar Quarter of the Term shall extend from the Effective Date to the end of the first full Calendar Quarter thereafter, and (b) the last Calendar Quarter of the Term shall end upon the termination or expiration of this Agreement.

1.5 **"Calendar Year"** means the period beginning on the 1st of January and ending on the 31st of December of the same year, provided however that (a) the first Calendar Year of the Term shall commence on the Effective Date and end on December 31 of the same calendar year as the Effective Date, and (b) the last Calendar Year of the Term shall commence on January 1 of the Calendar Year in which this Agreement terminates or expires and end on the date of termination or expiration of this Agreement.

1.6 **"Combination Product"** means a product (a) containing a Licensed Product together with one or more other active ingredients, or (b) with one or more products, devices, pieces of equipment or components, but sold for an integrated price (e.g., with the purchase of one product the customer gets a coupon for the other) or for a single price.

1.7 **"Commercialization"** or **"Commercialize"** means any and all activities undertaken at any time for a particular Licensed Product and that relate to the manufacturing, marketing, promoting, distributing, importing or exporting for sale, offering for sale, and selling of the Licensed Product, and interacting with Regulatory Authorities regarding the foregoing.

1.8 **"Commercially Reasonable Efforts"** means, with respect to the efforts to be expended by a Party or such Party's applicable Affiliate with respect to any objective, such reasonable, diligent, and good faith efforts normally used to accomplish a similar objective under similar circumstances by a similarly-situated company. Commercially Reasonable Efforts will not mean that a Party commits that it or such Party's applicable Affiliate will actually accomplish the applicable task.

1.9 **"Controlled**" means, with respect to (a) DFCI Patents, (b) Know-How, (c) Antibodies, (d) DFCI Materials, or (e) Additional PD-L1 Intellectual Property, that a Party or one of its Affiliates owns or has a license or sublicense to such DFCI Patents, Know-How, Antibodies, DFCI Material (or in the case of DFCI Material, has the right to physical possession of such material), or Additional PD-L1 Intellectual Property, and has the ability to grant a license or sublicense to, or assign its right, title and interest in and to, such DFCI Patents, Know-How, Antibodies, DFCI Material, or Additional PD-L1 Intellectual Property as provided for in this Agreement without violating the terms of any agreement or other arrangement with any Third Party.

1.10 **"Covered"** means, with respect to a Licensed Product, that the practicing, manufacturing, importing, using, selling, or offering for sale of such Licensed Product would, but for ownership of or a license granted hereunder under Additional PD-L1 Intellectual Property or DFCI's relevant DFCI Patents, infringe a Valid Claim of Additional PD-L1 Intellectual Property or DFCI's relevant DFCI Patents in the country in which the activity occurs (or, in the case of a Valid Claim that has not yet issued, would infringe such Valid Claim if it were to issue).

1.11 **"Derivative**" means a DFCI Antibody that has (a) been modified via isotype switching; (b) undergone a modification of effector function; (c) been adapted to enable the antibody to carry payloads; (d) been altered to change the expression characteristics, stability or biological half-life of the antibody; or (e) been mutated using an affinity maturation strategy designed to modify the affinity of either the variable regions and/or the constant regions of the antibody for any ligands, antigens or receptors. Derivatives may be full length antibodies, monoclonal and polyclonal antibodies, multispecific antibodies (e.g., bi-specific antibodies) and antibody fragments (including Fab, Fab', F(ab')2, Fy fragments, diabodies, linear antibodies and single-chain antibodies), in each case, of any origin, whether human, humanized, chimeric or otherwise.

1.12 "Development" or "Develop" means, with respect to a Licensed Product, the performance of all preclinical and clinical development (including, without limitation, toxicology, pharmacology, test method development and stability testing, process development, formulation development, quality control development, statistical analysis), clinical trials, and manufacturing and regulatory activities that are required to obtain Regulatory Approval of such Licensed Product.

1.13 DFCI Antibodies" means the Antibodies supplied by or on behalf of DFCI to CTI under this Agreement as identified in Schedule 4.

1.14 "DFCI Know-How" means any and all Know-How that (a) is Controlled by DFCI or any of its Affiliates as of the Effective Date and (b) was developed in the laboratory of Dr. Wayne Marasco in the performance of research directly pertaining to the DFCI Patents and (c) is necessary for CTI to research, Develop, manufacture, use, or Commercialize Licensed Products. The DFCI Know-How is described in Schedule 2 hereto.

1.15 [Reserved]

1.16 "DFCI Patents" means (a) those patents and patent applications set forth on Schedule 1 hereto; (b) any additions, divisionals, continuations, conversion, supplemental examinations, extensions, term restorations, registrations, reinstatements, amendments, reissuances, corrections, substitutions, re-examinations, registrations, revalidations, supplementary protection certificates, renewals, and foreign counterparts of the patents and patent applications mentioned in clause (a) above; (c) all patents issuing from any of the patents and patent applications mentioned in clause (a) or (b) above and any foreign counterparts of any such patents and patent applications, and which shall include, in any case, patents surviving post grant review and *inter partes* review.

1.17 "DFCI Technology" means the DFCI Patents, DFCI Know-How, DFCI Antibodies, Derivatives, and DFCI Materials.

1.18 "EMA" means the European Medicines Agency or any successor agency.

1.19 "European Commission" means the authority within the European Union that has the legal authority to grant Regulatory Approvals in the European Union based on input received from the EMA or other competent Regulatory Authorities.

1.20 "FDA" means the United States Food and Drug Administration, or a successor federal agency thereto.

1.21 "Field" means all prophylactic, palliative, therapeutic or diagnostic uses in humans or animals for the prevention, diagnosis and treatment of hematological malignancies, including, without limitation, all Leukemia's, Lymphoma's, Multiple Myeloma and Waldentroms Macroglobulemia, but specifically excluding use in chimeric antigen receptor technology. Additionally, upon exercise of the Autoimmune Option, the Field shall include the prevention, diagnosis and treatment of Autoimmune Diseases.

1.22 "First Commercial Sale" means, with respect to a Licensed Product in any country, the first commercial transfer or disposition for value of such Licensed Product in the Field in such country to a Third Party, by TGTX, by an Affiliate of TGTX or by a Sublicensee after Regulatory Approval therefor has been obtained in such country, for cash or non-cash consideration to which a fair market value can be assigned for purposes of determining Net Sales.

1.23 "**GAAP**" means United States generally accepted accounting principles.

1.24 "Governmental Body" means any: (a) nation, principality, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (b) federal, state, local, municipal, foreign or other government; (c) governmental or quasi-governmental authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, board, instrumentality, officer, official, representative, organization, unit, body or entity and any court or other tribunal); (d) multi-national or supranational organization or body; or (e) individual, entity, or body exercising, or entitled to exercise, any executive, legislative, judicial, administrative, regulatory, police, military or taxing authority or power of any nature.

1.25 "Know-How" means any scientific or technical information, results and data of any type whatsoever, in any intangible form whatsoever, that is not in the public domain or otherwise publicly known and is not claimed or disclosed in a patent or pending patent application, including practices, protocols, regulatory filings, scientific techniques, works of authorship, plans, data (including, but not limited to, pharmacological, biological, chemical, toxicological, clinical and analytical information, quality control, trial and stability data), data analyses, reports, studies and procedures, designs for experiments and tests and results of experimentation and testing (including results of research or development), summaries and information contained in submissions to and information from ethical committees, the FDA or other Regulatory Authorities, and manufacturing process and development information. The fact that an item is known to the public shall not be taken to exclude the possibility that a compilation including the item, and/or a development relating to the item, is (and remains) not known to the public. "Know-How" excludes Additional PD-L1 Intellectual Property, DFCI Patents, DFCI Antibodies, and DFCI Materials.

1.26 "Law" or **"Laws"** means all applicable laws, statutes, rules, regulations, ordinances and other pronouncements having the binding effect of law of any Governmental Body.

1.27 "Licensed Product" means any pharmaceutical product, in any dosage form, preparation, composition, formulation, presentation or package configuration, (a) that is Covered in whole or in part by a Valid Claim in the DFCI Patents or Additional PD-L1 Intellectual Property, (b) that incorporates, constitutes, or contains DFCI Antibodies or Derivatives as an active ingredient, or (c) that shares at least [*]% of the amino acid sequence identity (combined or in the aggregate) to all the complementarity determining regions (CDRs) of any DFCI Antibodies or Derivatives and made using DFCI Technology or Additional PD-L1 Intellectual Property.

1.28 "Licensed Process" means processes which, (a) in the course of being practiced, is Covered in whole or in part by a Valid Claim in the Additional PD-L1 Intellectual Property or DFCI Patents, or (b) which incorporates or uses DFCI Antibodies or Derivatives in whole or in part.

1.29 "NDA" means a New Drug Application submitted pursuant to the requirements of the FDA, as more fully defined in 21 U.S. CFR § 314.3 et seq., a Biologics License Application submitted pursuant to the requirements of the FDA, as more fully defined in 21 U.S. CFR § 601, and any equivalent application submitted in any country, including a European Marketing Authorization Application, together, in each case, with all additions, deletions or supplements thereto.

1.30 "NDA Approval" means the receipt of notice from the relevant US Regulatory Authority that an NDA for a Licensed Product has met all the criteria for marketing approval.

1.31 "Net Sales" means the gross income derived by TGTX or its Affiliates or Sublicensees to unrelated Third Parties for a Licensed Product in the Field in bona-fide arms-length transactions, less the following deductions, which may not exceed reasonable and customary amounts in the country in which the transaction occurs:

(a) Normal and customary trade, quantity, cash and discounts and credits allowed and taken;

(b) Discounts, refunds, rebates, chargebacks, retroactive price adjustments, and any other allowances given and taken which effectively reduce the net selling price, including, without limitation, Medicaid rebates, institutional rebates or volume discounts;

(c) Product returns and allowances;

(d) Administrative fees paid to group purchasing organizations (e.g., Medicare) and government-mandated rebates;

(e) Shipping, handling, freight, postage, insurance and transportation charges, but all only to the extent included as a separate line item in the gross amount invoiced;

(f) Any tax, tariff or duties imposed on the sale, delivery or use of the Licensed Product, including, without limitation, sales, use, excise or value added taxes and customs and duties, but all only to the extent included as a separate line item (e.g., "taxes") in the gross amount invoiced.

(g) Bad debt actually written off during the accounting period (provided, that any bad debt write-off so taken which is later reversed shall be added back to Net Sales in the accounting period in which the reversal occurs).

No deduction shall be made for any item of cost incurred by TGTX, its Affiliates or Sublicensees in Developing or Commercializing Licensed Products except as permitted pursuant to clauses (a) through (g) of the foregoing.

Net Sales includes the fair market value of any non-cash consideration from sale of Licensed Products received by TGTX, its Affiliates or Sublicenses. Licensed Products are considered "sold" when billed, invoiced, or payment is received, whichever occurs first.

Notwithstanding the foregoing, amounts invoiced by TGTX and its Affiliates and Sublicensees for sales of Licensed Products among TGTX and its Sublicensees and their respective Affiliates for resale shall not be included in the computation of Net Sales except where such purchasing party is an end user or consumer of Licensed Products.

Net Sales of any Combination Product (as defined below) for the purpose of calculating royalties due under this Agreement shall be determined on a country-by-country basis as follows: the Net Sales of the Combination Product (prior to application of the following adjustment) shall be multiplied by the fraction A/(A+B), where A is the net selling price in such country of a Licensed Product without the additional active ingredient in the Combination Product, if sold separately for the same dosage as contained in the Combination Product, and B is the net selling price in such country of any other active ingredients (or delivery device) in the combination if sold separately for the same dosage (or form) as contained in the Combination Product. All net selling prices of the elements of such end-user product or service shall be calculated as the average net selling price of the said elements during the applicable accounting period for which the Net Sales are being calculated. In the event that, in any country, no separate sale of either such above-designated Licensed Product (containing only such Licensed Product and no other active ingredients) or any one or more of the active ingredients included in such Combination Product are made during the accounting period in which the sale was made or if the net selling price for an active ingredient cannot be determined for an accounting period, Net Sales for purposes of determining payments under this Agreement shall be calculated by multiplying the sales price of the Combination Product by the fraction C/(C+D) where C is the standard fully-absorbed manufacturing cost of the Licensed Product portion of the combination, and D is the standard fully-absorbed manufacturing cost of the other active ingredients or components included in the Combination Product, as determined by TGTX using its standard accounting procedures consistently applied. In the event that the standard fully-absorbed manufacturing cost of the Licensed Product and/or the other active ingredients or components included in such Combination Product cannot be determined, Net Sales allocable to the Licensed Product in each such country shall be determined by mutual agreement reached in good faith by the parties prior to the end of the accounting period in question based on an equitable method of determining same that takes into account, on a country-by-country basis, all relevant factors (including variations in potency, the relative contribution of each active ingredient in the combination, and relative value to the end user of each active ingredient).

1.32 "Person" means any natural person, corporation, firm, business trust, joint venture, association, organization, company, partnership or other business entity, or any government or agency or political subdivision thereof.

1.33 "Phase I Trial" means a clinical trial of a Licensed Product in human patients designated as a Phase I Trial and conducted primarily for the purpose of determining the safety of and/or the metabolism and pharmacologic actions of the Licensed Product in humans, as described under 21 CFR § 312.21(a) (as hereafter modified or amended) and any of its foreign equivalents. For purposes of this definition, Phase I Trial shall specifically exclude trials in healthy volunteers.

1.34 "Phase II Trial" means a clinical trial of a Licensed Product, designated as a Phase II Trial and the principal purpose of which is to make a preliminary determination that such Licensed Product is safe and active in a patient population for its intended use and is designed to obtain sufficient information about such Licensed Product's efficacy to permit the design of a Phase III Trial(s), and generally consistent with 21 CFR § 312.21(b). For purposes of this definition, Phase II trial shall specifically exclude expansion cohorts from Phase I Trial(s).

1.35 "Phase III Trial" means a clinical trial of a Licensed Product in human patients, which is designated as a Phase III Trial or a pivotal trial and is designed (a) to establish that the Licensed Product is safe and efficacious for its intended use; (b) to define warnings, precautions and adverse reactions that are associated with the Licensed Product in the dosage range to be prescribed; and (c) to be, either by itself or together with one or more other clinical trials having a comparable design and size, the final human clinical trial in support of Regulatory Approval of the Licensed Product, and (d) consistent with 21 CFR § 312.21(c) (as hereafter modified or amended) and any of its foreign equivalents.

1.36 "Regulatory Authority" means (a) the FDA, (b) the EMA or the European Commission, or (c) any regulatory body with similar regulatory authority over pharmaceutical or biotechnology products in any other jurisdiction anywhere in the world.

1.37 "Regulatory Approval" means any and all approvals, licenses, registrations, or authorizations of the relevant Regulatory Authority, necessary for the Development, manufacture, use, storage, import, transport and Commercialization of a given Licensed Product in a particular country or jurisdiction. For the avoidance of doubt, Regulatory Approval outside of the United States shall include any pricing or marketing approval needed prior to the sale of a Licensed Product in the Field.

1.38 "Royalty Term" means, on a Licensed Product-by-Licensed Product and country-by-country basis, the period from the First Commercial Sale of a given Licensed Product in such country until the later of (i) twelve (12) years after First Commercial Sale of the applicable Licensed Product in such country, or (ii) the expiry of the last-to-expire DFCI Patent or Additional PDL-1 Intellectual Property containing a Valid Claim to the Licensed Product in such country.

1.39 "Sublicensee" means a Person, other than an Affiliate of TGTX, to which TGTX (or its Affiliate) has, pursuant to Section 2.3, granted sublicense rights under any of the license rights granted under Section 2.1. **"Sublicense**" shall be construed accordingly.

1.40 "**Sublicense Revenue**" means any payments or other consideration that TGTX actually receives from a Sublicensee as consideration for the grant of a Sublicense, including, without limitation, milestone payments, license fees, license maintenance fees and equity. Sublicense Revenue excludes (i) purchases of equity or debt of TGTX, (ii) payments made for TGTX's performance of any research, Development, or Commercialization of any Licensed Product, (iii) (b) royalties on Net Sales (or, in the case of a profit sharing deal structure, shares of net profits) which are covered in Section 5.9, and (iv) any payment or reimbursement of any costs or expenses incurred by TGTX for filing, prosecution, maintenance, or defense of any DFCI Patents or CTI Patents. In the event such consideration received from a Sublicensee is not cash, Sublicense Revenue shall be calculated by TGTX based on the fair market value of such consideration, at the time of the transaction, assuming an arm's length transaction made in the ordinary course of business.

1.41 **"Tax"** or **"Taxes"** means any federal, state, local or foreign income, gross receipts, license, payroll, employment, excise, severance, stamp, occupation, premium, windfall profits, environmental, customs duties, capital stock, franchise, profits, withholding, social security, unemployment, disability, real property, personal property, sales, use, transfer, registration, value added, alternative or add-on minimum, estimated, or other tax of any kind whatsoever, including any interest, penalty, or addition thereto, whether disputed or not.

1.42 **"Third Party"** means any Person other than Adimab, DFCI, CTI, TGTX, or Affiliates of either of them, or any Sublicensees.

1.43 **"Third Party Action"** means any claim or action made by a Third Party against a Party that claims that a Licensed Product, or its use, Development, manufacture or sale infringes such Third Party's intellectual property rights.

1.44 **"United States"** or **"US"** means the United States of America and its territories and possessions.

1.45 "**Valid Claim**" means (a) a claim of an issued and unexpired patent that has not been held permanently revoked, invalid or unenforceable by a patent office, court or other governmental agency of competent jurisdiction in a final and non-appealable judgment (or judgment from which no appeal was taken within the allowable time period) and that is not admitted to be invalid or unenforceable through reissue, disclaimer or otherwise (i.e. only to the extent the subject matter is disclaimed or is sought to be deleted or amended through reissue or (b) a claim of a pending patent application within DFCI Patents or Additional PD-L1 Intellectual Property that has not been abandoned, finally rejected or expired without the possibility of appeal or refiling, provided that (i) Valid Claim shall exclude any such pending claim in an application that has not been granted within the latter of five (5) years after the Effective Date or seven (7) years following the earliest priority filing date for such application (unless and until such claim is granted) and (ii) Valid Claim will exclude any such pending claim that does not have a reasonable bona fide basis for patentability, in either case of (i) or (ii), unless and until such claim is granted. Notwithstanding the foregoing, in the event that a claim in a pending patent application is involved in an interference action declared by the US Patent and Trademark Office or any analogous patentability determination by any other national patent office, and, at the time such proceeding is filed or initiated such claim is a Valid Claim, the time period set forth in subsection (i) above will be stayed for the pendency of such proceeding.

1.46 "**CTI Patents**" means (a) that patent applications set forth as CTI Patents in Schedule 1 hereto; (b) any additions divisionals, continuations, conversion, supplemental examinations, extensions, term restorations, registrations, reinstatements, amendments, reissuances, corrections, substitutions, re-examinations, registrations, revalidations, supplementary protection certificates, renewals, and foreign counterparts of the patent application mentioned in clause (a) above; (c) all patents issuing from the patent applications mentioned in clause (a) or (b) above and any foreign counterparts of any such patents and patent applications, and which shall include, in any case, patents surviving post grant review and *inter partes* review.

1.47 "**Marketing Approval**" each means, within any given country, approval to market a Licensed Product legally as a drug or biologic, including approval of a Biologic License Application (as defined in the U.S. Federal Food, Drug and Cosmetics Act and the regulations promulgated thereunder (21 C.F.R. §§ 600-680) in the United States, or approval of a comparable filing in the United States or any other jurisdiction. Pricing approval need not be obtained in order for Marketing Approval to be achieved.

1.48 "**Additional PD-L1 Intellectual Property**" means CTI Patents and any patents licensed to CTI under the Collaboration Agreement with Adimab (namely, Adimab Program Antibody Patents and Adimab Platform Patents).

1.49 "**Licensed Patents**" means DFCI Patents, CTI Patents, Adimab Program Antibody Patents and Adimab Platform Patents.

1.50 "**Adimab Program Antibody Patents**" means (a) that patent applications set forth in Schedule 1 hereto; (b) any additions divisionals, continuations, conversion, supplemental examinations, extensions, term restorations, registrations, reinstatements, amendments, reissuances, corrections, substitutions, re-examinations, registrations, revalidations, supplementary protection certificates, renewals, and foreign counterparts of the patent application mentioned in clause (a) above; (c) all patents issuing from the patent applications mentioned in clause (a) or (b) above and any foreign counterparts of any such patents and patent applications, and which shall include, in any case, patents surviving post grant review and *inter partes* review.

1.51 "**Adimab Platform Patents**" means (a) that patent applications set forth in Schedule 1 hereto; (b) any additions divisionals, continuations, conversion, supplemental examinations, extensions, term restorations, registrations, reinstatements, amendments, reissuances, corrections, substitutions, re-examinations, registrations, revalidations, supplementary protection certificates, renewals, and foreign counterparts of the patent application mentioned in clause (a) above; (c) all patents issuing from the patent applications mentioned in clause (a) or (b) above and any foreign counterparts of any such patents and patent applications, and which shall include, in any case, patents surviving post grant review and *inter partes* review.

1.52 **CTI Antibodies**" means the Antibodies supplied by or on behalf of CTI to TGTX under this Agreement as identified in Schedule 3.

ARTICLE II
LICENSES AND OTHER RIGHTS

2.1 Grant of License to TGTX.

(a) Subject to the terms and conditions of this Agreement, the Collaboration Agreement with Adimab, the excluded rights under Section 3.2(b)(ii) of the Collaboration Agreement with Adimab, the License Agreement, and the reserved rights described in Section 2.4 and Section 2.5 of the License Agreement, effective immediately at the time TGTX is no longer deemed to be an Affiliate of CTI (following receipt by one Party of a written notice from the other Party), CTI hereby grants to TGTX, and TGTX hereby accepts, an exclusive, worldwide, royalty-bearing right and license (with the right to sublicense, subject to the provisions of Section 2.3) under the Additional PD-L1 Intellectual Property and DFCI Patents to (i) research, Develop, manufacture, have manufactured, use, import and Commercialize and have Commercialized the Licensed Products, in and for the Field and (ii) to practice and have practiced any Licensed Processes, in and for the Field. CTI and its Affiliates grant no licenses or rights by implication, estoppel or otherwise under any other patent applications or patents owned in whole or in part by CTI other than as expressly set forth herein.

(b) Pursuant to an obligation imposed on a sublicensee under Section 3.2(b)(iii) of the Collaboration Agreement with Adimab, TGTX, by executing this Agreement, explicitly agrees to comply with all applicable terms of the Collaboration Agreement with Adimab, including Section 9.3 (Commitments Regarding Program-Benefited Antibodies) thereof.

2.2 Affiliates. Effective immediately at the time TGTX is no longer deemed to be an Affiliate of CTI (following receipt by one Party of a written notice from the other Party), TGTX is entitled to extend its licenses under this Article II to its Affiliates, consistent with all of the terms and conditions of this Agreement. If TGTX does extend its license and an Affiliate assumes obligations under the Agreement, TGTX shall be responsible and liable for the acts or omissions of the Affiliate in the exercise of rights under this Agreement. If CTI has a claim arising under this Agreement against an Affiliate, CTI may seek a remedy directly against TGTX and may, but is not required to, seek a remedy against the Affiliate. Any termination of the Agreement under Article X as to TGTX also constitutes termination as to any Affiliates.

2.3 Grant of Sublicenses by TGTX. Effective immediately at the time TGTX is no longer deemed to be an Affiliate of CTI (following receipt by one Party of a written notice from the other Party), TGTX shall have the right, in its sole discretion, to grant Sublicenses, in whole or in part, under the license granted in Section 2.1; provided, however, that the granting by TGTX of a Sublicense shall not relieve TGTX of any of its obligations hereunder; and provided, further, that TGTX's right to grant a Person a Sublicense shall be subject to TGTX including within such Sublicense express provisions binding the Sublicensee to terms and condition consistent with those contained herein. TGTX shall be and remain fully responsible and primarily liable for the compliance by Sublicensees with the terms and conditions of this Agreement (as applicable to them) as if such Sublicensees were TGTX hereunder. TGTX shall promptly provide a copy of each executed sublicense agreement and any modifications of the sublicense agreement (provided that such copy may be redacted to remove commercially sensitive terms that are not necessary to confirm compliance with the terms and conditions of this Agreement) following execution of such agreement.

2.4 Delivery of DFCI Know-How, DFCI Antibodies, and CTI Antibodies. Effective immediately at the time TGTX is no longer deemed to be an Affiliate of CTI, CTI shall deliver to TGTX DFCI Know-How, DFCI Antibodies, and CTI Antibodies within sixty (60) days of the Effective Date of this Agreement.

2.5 Extension of Rights. During such time as TGTX is deemed an Affiliate of CTI, CTI extends to TGTX all of its rights under the Collaboration Agreement with Adimab (except Adimab Materials, Optioned Program Antibody Know-How and Program Antibody Know-How), License Agreement (except CAIX) subject to the terms and conditions of this Agreement, the Collaboration Agreement with Adimab and the License Agreement, provided that such rights shall be limited to the Field and shall exclude the right to make and have made Licensed Products. TGTX hereby assumes the obligations of CTI under the Collaboration Agreement with Adimab and License Agreement with respect to its exercise of rights thereunder. Such extension of rights shall automatically terminate at the time TGTX is no longer deemed to be an Affiliate of CTI. It is the intention of TGTX and CTI for this Agreement to be consistent with the Collaboration Agreement with Adimab and the License Agreement. During the term of this Agreement, if CTI shall default on any obligations owed Adimab or DFCI then TGTX shall have the right to cure such defaults and set any amounts incurred by TGTX in curing such defaults against any future payments TGTX may owe to CTI.

ARTICLE III
RIGHTS, DUTIES AND DILIGENCE

3.1 Diligence by TGTX. TGTX shall use Commercially Reasonable Efforts to Develop and to Commercialize Licensed Products targeting PD-L1 and GITR in the Field. The Parties acknowledge that TGTX may Develop and Commercialize Licensed Products that are a Combination Product containing one or more DFCI Antibodies, CTI Antibodies, or Derivatives thereof. Except as otherwise provided herein or agreed upon in writing, CTI agrees that it will not make, use or sell Licensed Products in the Field ("Exclusivity Covenant"). In addition, TGTX shall have the option (the "Autoimmune Option") to include Autoimmune Diseases in the Field by providing notice to CTI and making a $1,000,000 payment. Such Autoimmune Option can be exercised up to 7 years from the date of the Original Agreement.

3.2 Projected Milestone Dates. TGTX shall use its commercially reasonable efforts to meet the following milestones ("Milestones") by the dates specified in this paragraph, subject to annual adjustment as described below.

For purposes of this Section 3.2, CTI will consider efforts of an Affiliate or Sublicensee as efforts of TGTX.

(a) Milestone Dates for a Licensed Product Targeting PD-L1

Milestone	**Achievement Date**
– [*] for first PD-L1 Licensed Product	[*] years from the Effective Date
– [*] for first PD-L1 Licensed Product	[*] years from the Effective Date
– [*] for first PD-L1 Licensed Product	[*] years from the Effective Date
– [*] for first PD-L1 Licensed Product	[*] years from the Effective Date
– [*] for first PD-L1 Licensed Product	[*] years from the Effective Date
– [*] for first PD-L1 Licensed Product	[*] years from the Effective Date
– [*] for first PD-L1 Licensed Product	[*] Years from the Effective Date

(b) Milestone Dates for a Licensed Product Targeting GITR

Milestone	**Achievement Date**
– [*] for first GITR Licensed Product	[*] years from the Effective Date
– [*] for first GITR Licensed Product	[*] years from the Effective Date
– [*] for first GITR Licensed Product	[*] years from the Effective Date
– [*] for first GITR Licensed Product	[*] years from the Effective Date
– [*] for first GITR Licensed Product	[*] years from the Effective Date
– [*] for first GITR Licensed Product	[*] years from the Effective Date
– [*] for first GITR Licensed Product	[*] Years from the Effective Date

3.3 Adjustments. The parties acknowledge that since the program is in early pre-clinical development that the dates included in the Milestone table above are rough estimates to provide Adimab, DFCI and CTI a preliminary projection of what can be achieved by what dates, the accuracy of which the parties agree is impossible to predict and will be based on many factors completely outside the control of TGTX and its Diligence Efforts. On an annual basis, with its report contained below, TGTX will, in good faith, update the dates in the Milestones table above to provide CTI an updated assessment of the timing of the upcoming milestones. Upon providing such update, the table above shall be deemed amended notwithstanding Section 11.5 hereof.

3.4 Development and Commercialization Reports. Within 50 days of the Effective Date and at least 10 days before each anniversary of the Effective Date, TGTX shall provide to CTI a written report describing the efforts by TGTX, or any Affiliates or Sublicensees, to bring one or more Licensed Products to the marketplace. The report must be in sufficient detail to permit CTI to monitor TGTX' compliance with the due diligence provisions of this Agreement.

TGTX shall include at least the following in these reports: (a) a summary of TGTX' progress toward meeting the goals and objectives that had been established for the previous year; (b) a summary of TGTX' goals and objectives for the ensuing year for developing and commercializing Licensed Products, including an identification of Licensed Products that TGTX intends to develop, if any; and (c) to the extent not covered by the foregoing, a summary of TGTX' progress in meeting the Milestone timelines above.

If multiple technologies are covered by this Agreement, the progress report must provide the information set forth above for each Licensed Product.

3.5 Failure to Perform. TGTX's failure to use commercially reasonable efforts to perform any due diligence requirement provided in Section 3.1 through 3.4 is grounds for CTI to terminate this Agreement according to Section 10.2(d); provided that CTI shall only have the right to terminate this Agreement with respect to the specific Licensed Product for which such failure is claimed and the Agreement shall remain in full force and effect for the remaining Licensed Products. In the alternative, CTI may terminate the Exclusivity Covenant (if such failure occurs while TGTX is an Affiliate of CTI) or convert the exclusive licenses granted under this Agreement to a non-exclusive license (if such failure occurs after the time TGTX ceases to be an Affiliate of CTI), as further provided in Section 3.6, as to the specific Licensed Product for which such failure is claimed.

3.6 Conversion to Non-exclusive License. If (i) the Exclusivity Covenant is terminated as provided in Section 3.5 or (ii) the exclusive license granted under this Agreement is converted to a non-exclusive license for any Licensed Product as provided in Section 3.5, this Agreement is automatically amended as follows as it relates to such Licensed Product; (a) the exclusive license of Section 2.1 becomes a non-exclusive license, (b) TGTX loses the right to grant sublicenses under Section 2.3; provided that any sublicense granted prior to such conversion shall continue and not be affected by such conversion, (c) the obligations of Sections 3.1 through 3.4 continue to apply, (d) the obligation under Section 3.10 no longer applies, (e) TGTX has no further rights or obligations under Article VI; provided that CTI shall keep TGTX apprised of any new filings of patent applications and issuance of patents that fall within the DFCI Patents, and (f) CTI has the sole right to pursue apparent infringements and the terms of Article VI no longer apply.

3.7 Costs and Expenses. As between CTI and TGTX, (a) TGTX shall be solely responsible for all costs and expenses related to Development, and Commercialization of the Licensed Products, including without limitation costs and expenses associated with all preclinical activities and clinical trials, and all regulatory filings and administrative proceedings relating to Licensed Products in the Field and (b) CTI shall be the sole and exclusive manufacturer of Licensed Products for TGTX and its Affiliates and Sublicensees, such that TGTX and its Affiliates and Sublicensees shall purchase all of its requirements of Licensed Products from CTI and will not make or have made Licensed Products directly or through its Affiliates or Sublicensees unless CTI is unable to provide sufficient supplies at competitive prices, the terms of which shall be negotiated in a manufacturing and supply agreement. In such case, TGTX may manufacture Licensed Products provided TGTX obtains all necessary licensing rights for such manufacture. TGTX shall be solely responsible for the costs of such additional licenses to manufacture Licensed Products. With the exception of the above, CTI shall be solely responsible for all costs and expenses related to CMC including without limitation, CMC development and scale-up, CMC validation, analytical method development and validation, stability testing, manufacturing, finishing and release. TGTX shall reimburse CTI for CTI's out-of-pocket cost for Licensed Product used by TGTX for its Development activities and shall pay CTI a manufacturing transfer price for Commercial supplies equal to CTI's out-of-pocket cost of Licensed Product plus the lesser of: (a) 30% of such cost and (b) 3% of Net Sales generated by the materials supplied The Parties agree to execute a manufacturing and supply agreement within a reasonable time after the execution of the Agreement on these terms and including such other customary and reasonable terms.

3.8 .**Patent Marking**. TGTX agrees that with respect to each unit or package of Licensed Products sold in a given country, TGTX shall comply with the customary patent marking laws and practices of such country as to the applicable Additional PD-L1 Intellectual Property and DFCI Patents.

3.9 Trademarks. As between TGTX and CTI, TGTX shall have the sole authority to select trademarks for Licensed Products and shall own all such trademarks. CTI does not grant TGTX the right to use any trademarks of CTI, Adimab, DFCI or its respective Affiliates.

3.10 U.S. Manufacture. To the extent TGTX manufactures Licensed Products (e.g. if TGTX and CTI agree that CTI will no longer be the sole manufacturer of Licensed Products), TGTX shall manufacture Licensed Products leased, used or sold in the United States substantially in the United States as required by 35 U.S.C. 204 and 37 C.F.R. 401 et. seq., as amended. TGTX shall also require any Affiliate(s) or Sublicensee(s) to comply with this U.S. manufacture requirement. Notwithstanding the foregoing, if TGTX or its Affiliate(s) or Sublicensee(s) determines that it is not commercially feasible or reasonable to manufacture such Licensed Products in the United States or determines that it is necessary to have additional manufacturers outside the United States for back-up supply or to supply Licensed Products outside the United States, then CTI agrees to make reasonable efforts to assist TGTX, or its Affiliate(s) or Sublicensee(s), as applicable, at TGTX' expense, in obtaining any necessary permission from the appropriate government authorities to manufacture such Licensed Products outside the United States.

3.11 Other Government Laws. TGTX shall comply with, and ensure that its Affiliates and Sublicensees comply with, all government statutes and regulations that relate to Licensed Products. These include but are not limited to FDA statutes and regulations, the Export Administration Act of 1979, as amended, codified in 50 App. U.S.C. 2041 et seq. and the regulations promulgated thereunder or other applicable export statutes or regulations.

3.12 **Publicity**. TGTX, its Affiliate and Sublicensees are not permitted to use the names of CTI, DFCI, its related entities or its employees, or any adaptations thereof, in any advertising, promotional or sales literature, or in any securities report required by the Securities and Exchange Commission (except as required by law), without the prior written consent of CTI, Adimab and/or DFCI in each case. However, TGTX may (a) refer to publications in the scientific literature by employees of Adimab, DFCI, or CTI or (b) state that a license from Adimab, DFCI, or CTI has been granted as provided in this Agreement.

3.13 **Other Agreements**. In the event that TGTX determines to conduct a clinical trial of a Licensed Product in the Field in the United States, TGTX shall consider in good faith and discuss with DFCI the potential of engaging DFCI to serve as a clinical site for such clinical trial; provided that (a) DFCI has the appropriate expertise and patient population to conduct the clinical trial, and (b) DFCI is economically competitive with other sites having substantially similar expertise and patient populations to conduct such clinical trial.

ARTICLE IV
REGULATORY MATTERS

4.1 **Regulatory Filings.** As between CTI and TGTX, TGTX (or its applicable Affiliate) shall own and maintain all regulatory filings made after the Effective Date for Licensed Products and all Regulatory Approvals for Licensed Products. Once per year, representatives from CTI may visit TGTX and review all such regulatory filings, provided such representatives do not have a conflict of interest or involvement with any competitive companies or technologies and agree to TGTX's confidentiality agreement.

ARTICLE V
Financial Provisions

5.1 **Upfront Fee**. Upon the signing of the Original Agreement, TGTX paid CTI an up-front, non-creditable, non-refundable fee in the amount of Five Hundred Thousand Dollars ($500,000). Upon the signing of this Agreement, TGTX shall pay CTI a non-creditable, non-refundable fee in the amount of One Million Dollars ($1,000,000).

5.2 **Maintenance Fee**. Within thirty (30) days following the second anniversary of the Effective Date and each anniversary thereafter, TGTX shall pay CTI an annual license maintenance fee in the amount of [*] Dollars ($[*]). Such fees are creditable against milestone payments due pursuant to Section 5.6, royalties due pursuant to Section 5.7 or Sublicense Revenue Share Payments (as defined in Section 5.9).

5.3 **Reserved**.

5.4 **Milestone Payments.**

(a) **PD-L1-based Milestones.** As further partial consideration for CTI's grant of the rights to TGTX hereunder, TGTX shall pay to CTI the following one-time, PD-L1 targeting product-based milestone payments with regard to each Licensed Product targeting PD-L1 (as specifically set forth below). TGTX will pay the relevant milestone payment within thirty (30) days of such achievement.

PD-L1 Targeting Product-based Milestone Events	Milestone Payment
[*]*	$[*]
[*]	$[*]
[*]	$[*]
[*]	$[*]
[*]	$[*]
[*]	$[*]
[*]	$[*]
[*]	$[*]
[*]	$[*]

* [*].

If a later-stage PD-L1 targeting product-based clinical milestone event is achieved for any Licensed Product targeting PD-L1 without one or more earlier-stage clinical milestone events having been achieved for that Licensed Product, then TGTX shall pay the PD-L1 Milestone Payment(s) for such previous clinical milestone event(s) along with the payment for the most recently achieved milestone event. If a milestone event related to [*] is achieved without one or more of the clinical milestone events being achieved, then TGTX shall pay the PD-L1 Milestone Payment(s) for such previous clinical milestone event(s) along with the payment for the first milestone event related to [*].

(b) **GITR-based Milestones.** As further partial consideration for CTI's grant of the rights to TGTX hereunder, TGTX shall pay to CTI the following one-time, GITR targeting product-based milestone payments with regard to each Licensed Product targeting GITR (as specifically set forth below). TGTX will pay the relevant milestone payment within thirty (30) days of such achievement.

GITR Targeting Product-based Milestone Events	Milestone Payment
[*]	$[*]
[*]	$[*]
[*]	$[*]
[*]	$[*]
[*]	$[*]
[*]	$[*]

(c) **Combination Approval Milestones.** If any of the above milestones in (a) and (b) are triggered as a result of a combination approval of two or more Licensed Products or combination clinical trial of two or more Licensed Products, only one milestone payment (the higher payment) shall be due to CTI as if the combination was a single Licensed Product.

(d) **Aggregate Net Sales Achievement Milestones:** As further consideration for CTI's grant of the rights to TGTX hereunder, TGTX shall pay to CTI the following one-time milestone payments upon first achievement of worldwide Net Sales (as specifically set forth below) by TGTX and its Affiliates and Sublicensees. TGTX will pay the relevant milestone payment within 90 days of such achievement.

Aggregate Net Sales Achievement Milestones	
The first time aggregate worldwide Net Sales for all Licensed Products exceeds $[*] in any Calendar Year	$[*]
The first time aggregate worldwide Net Sales for all Licensed Products exceeds $[*] in any Calendar Year	$[*]
The first time aggregate worldwide Net Sales for all Licensed Products exceeds $[*] in any Calendar Year	$[*]
The first time aggregate worldwide Net Sales for all Licensed Products exceeds $[*] in any Calendar Year	$[*]

5.5 Royalty, Etc. Payments for Licensed Products.

(a) With respect to Net Sales of all Licensed Products: As further consideration for CTI's grant of the rights to TGTX hereunder, TGTX shall pay to CTI a royalty of on aggregate annual worldwide Net Sales of all such Licensed Products by TGTX and its Affiliates and Sublicensees (but excluding Net Sales of a given Licensed Product after its applicable Royalty Term) at the percentage rates set forth below:

Annual Worldwide Net Sales of All Licensed Products per Calendar Year (US Dollars)	**Incremental Royalty Rate**
For Net Sales of such Licensed Products from $0 up to and including $[*]	[*]%
For that portion of Net Sales of such Licensed Products that is greater than $[*]	[*]%

(b) In no event shall the manufacture of a Licensed Product give rise to a royalty/payment in the nature of royalties obligation until the particular unit of Licensed Product is sold; but if Net Sales of a particular unit of Licensed Product might or might not be subject to a royalty/payment in the nature of royalties payment (e.g., manufactured in Country A where the Royalty Term has expired but sold in Country B where the Royalty Term has not expired), the sale shall be deemed to be subject to a royalty/payment in the nature of royalties payment. For clarity, TGTX's obligation to pay royalties to CTI under Section 5.7(a) is imposed only once with respect to the same unit of Licensed Product regardless of the number of DFCI Patents pertaining thereto or the number of times such Licensed Product has been sold or transferred to a Person.

(c) On a Licensed Product by Licensed Product and country-by-country basis, upon expiration of the Royalty Term for a Licensed Product in a country, the rights, licenses and sublicenses granted to TGTX hereunder with respect to such Licensed Product in such country shall continue in effect but become fully paid-up, royalty-free, and perpetual.

(d) Reserved.

(e) Reserved.

(f) In the event that a Licensed Product in a country is not Covered by a Valid Claim of a Licensed Patent, royalties with respect to such Licensed Product in such country shall be reduced by [*] percent ([*]%) of the applicable royalty rate as set forth in Section 5.5 (a) and shall be due for the period commencing with the First Commercial Sale of such Licensed Product in such country and ending ten (10) years from date of such First Commercial Sale.

(g) Notwithstanding the above, in no event shall the royalty rates set forth in Section 5.7(a) be reduced under 5.7(d), (e), and (f) above by more than [*]% collectively.

5.6 Timing of Royalty Payment. Royalties/payments in the nature of royalties payable under Section 5.5 shall be payable on actual Net Sales and shall accrue at the time provided therefor by US GAAP. Royalty/payment in the nature of royalties obligations that have accrued during a particular Calendar Quarter shall be paid, on a Calendar Quarter basis, within 80 days after the end of each Calendar Quarter during which the royalty/payment in the nature of royalties obligation accrued; provided that within 40 days after the conclusion of each Calendar Year TGTX shall provide notice to CTI of any adjustments necessary to account for any royalties/payment in the nature of royalties which were overpaid or underpaid for such prior Calendar Year's Calendar Quarters, and the Parties shall promptly true-up based on such adjustments, provided however, the lapse of such 50-day period shall not impact the right of TGTX to credit any over-payments discovered during an audit against future royalties due under Section 5.5 hereof.

5.7 Sublicense Revenue. TGTX shall pay to CTI [*] percent ([*]%) of all Sublicense Revenue received by TGTX ("**Sublicense Revenue Share Payments**"). Sublicense Revenue Share Payments shall be paid, on a Calendar Quarter basis, within 80 days after the end of each Calendar Quarter during which the respective Sublicense Revenue is received.

5.8 Royalty Reports and Records Retention. Within 50 days after the end of each Calendar Quarter during which Licensed Products have been sold, TGTX shall deliver to CTI, together with the applicable royalty/payment in the nature of royalties payment due, a written report, on a Licensed Product-by-Licensed Product (and specifying non-Covered status, as applicable) and country-by-country basis, of (a) (a) Number of Licensed Products manufactured and sold by TGTX, and any Affiliates or Sublicensees, in each country; (b) gross invoiced (or otherwise charged) amounts of sales, by TGTX and its Affiliates and Sublicensees, of Licensed Products subject to royalty payments for such Calendar Quarter (and, if non-Covered, subject to royalty/payment in the nature of royalties payments for such Calendar Quarter), (c) amounts deducted by category (following the definition of Net Sales) from such gross invoiced amounts to calculate Net Sales, (d) Net Sales subject to royalty or royalty/payment in the nature of royalties payments for such Calendar Quarter and Calendar Year to date, and (e) the corresponding royalty or royalty/payment in the nature of royalties, and (f) the nature and amount of Sublicense Revenue received by TGTX. Such report shall be deemed "Confidential Information" of TGTX subject to the obligations of Article VII of this Agreement. For three years after each sale of a Licensed Product (whether Covered or not), TGTX shall keep (and shall ensure that its Affiliates and Sublicensees shall keep) complete and accurate records of such sale in sufficient detail to confirm the accuracy of the royalty or royalty/payment in the nature of royalties calculations hereunder.

5.9 CTI shall be solely responsible for paying directly to DFCI all payments due to DFCI under Section 5 of the License Agreement that arise out of the exercise of rights by TGTX under this Agreement, including, without limitation, royalties on TGTX's Net Sales. Likewise, CTI shall be solely responsible for paying directly to Adimab all payments due to Adimab under Section 4 of the Collaboration Agreement with Adimab that arise out of the exercise of rights by TGTX under this Agreement, including, without limitation, royalties on TGTX's Net Sales.

5.10 Reserved.

5.11 Books and Audits.

TGTX shall keep, and shall require its Affiliates and Sublicensees to keep, true books of account containing an accurate record (together with supporting documentation) of all data necessary for determining the amounts payable to CTI. TGTX shall keep it records at its principal place of business or the principal place of business of the appropriate division of TGTX to which this Agreement relates and shall require its Affiliates and Sublicenses to keep their books and records in the same manner.

(a) Commencing on the earlier of (i) the First Commercial Sale (of the first Licensed Product to have a First Commercial Sale) or (ii) receipt of Sublicense Revenue, and continuing until one Calendar Year after the conclusion of the final Royalty Term, upon the written request of CTI, and not more than once in each Calendar Year, TGTX shall permit, shall cause its Affiliates to permit, an independent certified public accounting firm of nationally recognized standing selected by CTI (who has not been engaged by CTI to provide services in any other capacity at any time during the three-year period before such selection), and reasonably acceptable to TGTX or such Affiliate, to have access to and to review, during normal business hours upon reasonable prior written notice, the applicable records of TGTX and its Affiliates to verify the accuracy of the royalty payments and Sublicense Revenue Share Payments. Such review may cover: (i) the records for the Calendar Year ending not more than three years before the date of such request, and (ii) only those periods that have not been subject to a prior audit.

(b) If such accounting firm concludes that additional amounts were owed during such period, TGTX shall pay the additional royalties and/or royalties/payment in the nature of royalties within 15 days after the date such public accounting firm delivers to TGTX such accounting firm's written report. If such accounting firm concludes that an overpayment was made, such overpayment shall be fully creditable against amounts payable in subsequent payment periods. If TGTX disagrees with such calculation, TGTX may contest such calculation in writing – at which point the parties will work in good faith to submit the matter to a mediator for resolution. If the parties are unable to reach an agreement via mediation, then TGTX may initiate a court action to seek to recover the additional payment or to increase the amount of credit or reimbursement. CTI shall pay for the cost of any audit by CTI, unless TGTX has underpaid CTI by 5% or more for a specific royalty period, in which case TGTX shall pay for the reasonable costs of audit, as well as any additional sum that would have been payable to CTI had the TGTX reported correctly, plus interest as set forth in Section 4.14.

(c) Each Party shall treat all information that it receives under this Section 5.10 in accordance with the confidentiality provisions of Article VII of this Agreement, and shall cause its accounting firm to enter into an acceptable confidentiality agreement with the audited Party obligating such firm to retain all such financial information in confidence pursuant to such confidentiality agreement, except to the extent necessary for a Party to enforce its rights under the Agreement.

5.12 Mode of Payment and Currency. All payments to CTI under this Agreement, whether or not in respect of Net Sales or milestone events, shall be made by deposit of US Dollars in the requisite amount to the following, which CTI may from time to time amend by advance written notice to TGTX.

by check:

Checkpoint Therapeutics, Inc.
2 Gansevoort Street
New York, NY 10014

by wire transfer:

[To be provided]

Conversion of sales or expenses recorded in local currencies to Dollars will be performed in a manner consistent with TGTX's normal practices used to prepare its audited financial statements for external reporting purposes, provided that such practices use a widely accepted source of published exchange rates. Based on the resulting Net Sales in US Dollars, the then applicable royalties/payment in the nature of royalties shall be calculated.

5.13 Late Payments. If a Party does not receive payment of any sum due to it on or before the due date therefor, simple interest shall thereafter accrue on the sum due to such Party from the due date until the date of payment at a rate equal to the lesser of (a) US dollar one-month LIBOR plus 300 basis points, or (b) the maximum rate permissible under applicable Law. Accrual and payment of interest shall not be deemed to excuse or cure breaches of contract arising from late payment or nonpayment. Waiver or deferral by CTI of any payment owed under any paragraph under this Article V may not be construed as a waiver or deferral of any subsequent payment owed by TGTX to CTI.

5.14 Taxes. All amounts due hereunder exclude all applicable sales, use, and other taxes and duties, and TGTX shall be responsible for payment of all such taxes (other than taxes based on CTI's income) and duties and any related penalties and interest, arising from the payment of amounts due under this Agreement. The Parties agree to cooperate with one another and use Commercially Reasonable Efforts to avoid or reduce tax withholding or similar obligations in respect of royalties, payments in the nature of royalties, milestone payments, and other payments made by TGTX to CTI under this Agreement. To the extent TGTX is required to withhold taxes on any payment to CTI, TGTX shall pay the amounts of such taxes to the proper governmental authority in a timely manner and promptly transmit to CTI official receipts issued by the appropriate taxing authority and/or an official tax certificate, or such other evidence as CTI may reasonably request, to establish that such taxes have been paid. CTI shall provide TGTX any tax forms that may be reasonably necessary in order for TGTX to not withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. CTI shall use Commercially Reasonable Efforts to provide any such tax forms to TGTX at least 45 days before the due date for any payment for which CTI desires that TGTX apply a reduced withholding rate. Each Party shall provide the others with reasonable assistance to enable the recovery, as permitted by applicable law, 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. CTI shall indemnify and hold TGTX harmless from and against any penalties, interest or other tax liability arising from any failure by TGTX (at the express request of CTI) to withhold or by reduction (at the express request of CTI) in its withholding.

5.15 Currency Conversion. If any currency conversion is required in connection with any payment owed to CTI, the conversion will be made at the buying rate for the transfer of such other currency as quoted by the Wall Street Journal on the last business day of the applicable accounting period in the case of any payment payable with respect to a specified accounting period or, in the case of any other payment, the last business day before the date the payment is due.

ARTICLE VI
Patents

6.1 Patent Prosecution and Maintenance.

(a) **DFCI Patents and Additional PD-L1 Intellectual Property**. TGTX shall reimburse CTI for [*]% of the patent expenses incurred under the License Agreement and incurred for the filing, maintenance and prosecution of patents included in Additional PD-L1 Intellectual Property for which CTI is responsible.

(b) **New or Revised Applications**. CTI will, upon learning from DFCI of an intention to file or revise one or more patent applications which are DFCI Patents subject to the License grant in Article II, promptly inform TGTX of such intention, and will provide TGTX with the opportunity to comment on the content of such DFCI patent application before CTI sends comments to DFCI on such filing. CTI shall include any such reasonable TGTX comments in the comments to be sent to DFCI. CTI will inform TGTX of CTI's intention to file or revise one or more patent applications which are included in Additional PD-L1 Intellectual Property for which CTI is responsible subject to the License grant in Article II and will provide TGTX with the opportunity to comment on the content of such one or more patent applications. CTI shall take into account any such reasonable TGTX comments.

(c) **Liaising.** CTI shall keep TGTX promptly and regularly informed of the course of the filing and prosecution of DFCI Patents and patents included in Additional PD-L1 Intellectual Property for which CTI is responsible or related proceedings (e.g., interferences, oppositions, reexaminations, reissues, revocations or nullifications) in a timely manner, and to reasonably take into consideration the advice and recommendations of TGTX.

(d) **Election Not to File/Prosecute/Maintain DFCI Patents and Patents Included in Additional PD-L1 Intellectual Property for which CTI is Responsible.** TGTX acknowledges and agrees that CTI and DFCI shall not be required to file, prosecute or maintain patents included in Additional PD-L1 Intellectual Property for which CTI is responsible and DFCI Patents, respectively, provided, however, if DFCI decides to not pursue or maintain any such DFCI Patents then CTI shall promptly notify TGTX so the Parties can determine if they would like to assume responsibility for such activities in DFCI's name but at the Parties expense. The same notice applies to any decision made by CTI to drop a case included in Additional PD-L1 Intellectual Property for which CTI is responsible. In either event, TGTX will no longer owe any royalty obligation on account of such (country-level) DFCI Patents or patents included in Additional PD-L1 Intellectual Property for which CTI is responsible assumed by the Parties or TGTX, as the case might be. Similarly, to the extent CTI does not want to continue funding the patent costs of any portion of DFCI Patents, CTI will notify TGTX and give TGTX an opportunity to assume responsibility for such Patents at TGTX's expense, in which case TGTX shall owe DFCI directly the royalties due under the License Agreement and shall no longer owe royalty obligation to CTI on account of such (country-level) DFCI Patents assumed by TGTX. The Parties acknowledge that if neither CTI nor TGTX continues funding patent costs then such portion of DFCI Patents will no longer be included as DFCI Patents. The same course of action will be followed by the Parties in connection with patents included in Additional PD-L1 Intellectual Property for which CTI is responsible.

6.2 Certification under Drug Price Competition and Patent Restoration Act. Each of TGTX and CTI shall provide within a reasonable time written notice to the other of any certification of which they become aware filed pursuant to 21 U.S.C. Section 355(b)(2)(A) (or any amendment or successor statute thereto) claiming that any DFCI Patents covering a Licensed Product, or the manufacture or use of each of the foregoing, are invalid or unenforceable, or that infringement will not arise from the manufacture, use or sale in the US of a Licensed Product by a Third Party.

6.3 Listing of Patents. To the extent a DFCI Patent and/or a patent included in Additional PD-L1 Intellectual Property is applicable in support of a label associated with an approval to market a Licensed Product, TGTX shall have the sole right to determine which of such DFCI Patents and/or a patents included in Additional PD-L1 Intellectual Property, if any, shall be listed for inclusion in the Approved Drug Products with Therapeutic Equivalence Evaluations publication pursuant to 21 U.S.C. Section 355, any equivalent publication for biologics, or any successor Law in the United States, together with any comparable Laws in any other country. CTI will co-operate with TGTX to list any of said DFCI Patents and patents included in Additional PD-L1 Intellectual Property.

6.4 Enforcement of Patents.

(a) **Notice.** If either TGTX or CTI believes that a Licensed Patent is being infringed in the Field by a Third Party or if a Third Party claims that any Licensed Patent is invalid or unenforceable, the Party possessing such knowledge or belief shall notify the other and provide it with details of such infringement, misappropriation or claim that are known by such Party.

(b) **Action by DFCI.**

(i) **Procedure.** TGTX acknowledges that DFCI is responsible for enforcing its DFCI Patents and prosecuting apparent infringers when, in DFCI's judgment, such action may be reasonably necessary and justified. TGTX may request that CTI request DFCI to take steps to protect the DFCI Patents from an apparent infringement. However, TGTX recognizes that before DFCI must respond to the request, TGTX shall supply CTI to provide to DFCI (i) an opinion of qualified legal counsel demonstrating to DFCI's reasonable satisfaction that an infringement of the DFCI Patents exists in a particular country and (ii) with written evidence demonstrating to DFCI's reasonable satisfaction that a Substantial Infringement of the DFCI Patents exists in a particular country ("Substantial Infringer").

(ii) DFCI has three months from the date of receiving satisfactory written evidence from CTI of a Substantial Infringement to decide whether it will seek to terminate the Substantial Infringement. DFCI shall give CTI notice of its decision by the end of this three-month period, which CTI shall promptly forward to TGTX. If DFCI notifies CTI that it intends to prosecute the alleged infringer, then DFCI has six (6) months from the date of its notice to CTI to either (a) cause the Substantial Infringement to terminate or (b) initiate legal proceedings against the infringer. If any such suit is brought by DFCI in its own name, or jointly with CTI if required by law, it will be at DFCI's expense and on its own behalf, but DFCI shall not be obligated to bring more than one such suit at a time.

(iii) **CTI's Right to Join.** If CTI shall exercise its rights to join any legal proceeding brought by DFCI under Section 6.4 of the License Agreement, then TGTX shall have the right to join CTI under the same terms and conditions of paragraph 6.4(b)(iii) of the License Agreement.

(c) **Action by CTI and TGTX.**

(i) **Procedure.** If CTI has the right to prosecute a Substantial Infringement under Section 6.4(c) of the License Agreement, then CTI shall promptly notify TGTX, and it may initiate a legal proceeding against the alleged infringer. If CTI decides that it will not commence any legal proceeding with respect to the Substantial Infringement, then such right to prosecute a Substantial Infringement under Section 6.4(c) of the License Agreement passes to TGTX hereunder.

(ii) **TGTX's Right To Join.** TGTX independently has the right to join any legal proceeding brought by CTI under this Section 6.4 and fund up to fifty percent of the cost of the legal proceeding from the date of joining. If TGTX elects to join as a party plaintiff pursuant to this Section 6.4, TGTX may jointly participate in the action with CTI, but CTI's counsel will be lead counsel.

(iii) **Reduction of Royalties.** If CTI initiates legal proceedings under Section 6.4 of the License Agreement and TGTX joins pursuant to this Section 6.4, then TGTX shall have the same rights as CTI has under Section 6.4(c)(iii) of the License Agreement. Additionally, if TGTX prosecutes pursuant Section 6.4(i) of this Agreement after CTI decides not to prosecute and neither DFCI nor CTI independently (except as a necessary party) join the proceeding, then TGTX may deduct up to [*] percent ([*]%) of TGTX's documented costs and expenses of the proceeding (including reasonable attorney fees) from running and minimum royalties payable to CTI under Section 5.7(a) of this Agreement from sales of Licensed Products covered by the patent(s)-in suit. However, TGTX may not reduce CTI's royalty payments by more than fifty percent of the amount otherwise due under Article V. If [*] percent ([*]%) of TGTX's costs and expenses exceed the amount of royalties deducted by TGTX for any calendar year, TGTX may, to that extent, reduce the royalties due to CTI in succeeding calendar quarters for so long as TGTX is actively engaged in legal proceedings to terminate the Substantial Infringement. However, TGTX may not reduce total royalties due to CTI in a given calendar quarter by more than [*] percent ([*]%). TGTX's right to reduce royalty payments to CTI under this paragraph 6.4(c)(iii) applies only for so long as the Substantial Infringement continues.

(iv) **Settlement.** Regardless of whether CTI or DFCI is joined or joins any legal proceeding initiated by TGTX**,** TGTX acknowledges and agrees that no settlement, consent judgment or other voluntary final disposition of the legal proceeding may be entered into without the consent of DFCI and CTI.

6.5 Cooperation. If one party initiates legal proceedings to enforce the DFCI Patents pursuant to this Article VI, the other party shall cooperate with and supply all assistance reasonably requested by the party initiating the proceedings, at the initiating party's request and expense.

6.6 Distribution of Amounts Paid by Third Parties. Any amounts recovered by the Party initiating an Action pursuant to this Section 6.6, whether by settlement or judgment, shall be allocated in the following order: to reimburse the Parties for all out-of-pocket costs and expenses incurred in connection therewith, including attorneys' fees. If such recovery is insufficient to cover all such costs and expenses of both Parties, it will be shared pro-rata in proportion to the relative amount of such costs and expenses incurred by each Party. If after such reimbursement any funds remain from such damages, the remaining amount of such recovery shall be allocated as follows: the portion thereof attributable to "lost sales" in the Field shall be retained by TGTX and shall be deemed to be Net Sales for the Calendar Quarter in which the amount is actually received by TGTX and TGTX shall pay to CTI a royalty on such portion based on the royalty rates set forth in Section 5.7(a), and the portion thereof not attributable to "lost sales" and is not allocated to DFCI under Section 6.6 of the License Agreement shall be allocated 50% to TGTX and 50% to CTI.

6.7 Declaratory Judgment Actions. In the event that any third party initiates a declaratory judgment action alleging the invalidity or unenforceability of the Licensed Patents with respect to claims relating to the Field, or if any third party brings an infringement action against TGTX or its Affiliates or Sublicensees because of the exercise of the rights granted TGTX under this Agreement, then TGTX shall have the right to defend such action under its own control and at its own expense; provided, however, that TGTX acknowledges that DFCI has the right to assume control of such defense, at its own expense, if such action is directed to a DFCI Patent and DFCI in good-faith believes that assuming control of such defense is beneficial to CTI and DFCI. TGTX shall NOT enter into any settlement, consent judgment or other voluntary final disposition of any action under this Section 6.7 without the consent of the other party (the patent owner), which consent shall not be unreasonably withheld unless the settlement includes any express or implied admission of liability or wrongdoing on the other party's part, in which case the other party's right to grant or deny consent is absolute and at its sole discretion. Any recovery shall be first applied to reimburse each party pro rata for any out-of-pocket expenses it may have incurred with respect to defense of such action, and the remainder shall be retained entirely by the party controlling the action; provided, however, that any recovery for infringement will be distributed as described in Section 6.6.

ARTICLE VII
CONFIDENTIALITY

7.1 Definitions. CTI and TGTX each recognizes that during the Term, it may be necessary for a Party (the "**Disclosing Party**") to provide Confidential Information (as defined herein) to another Party (the "**Receiving Party**") that is highly valuable, the disclosure of which would be highly prejudicial to such Party. The disclosure and use of Confidential Information shall be governed by the provisions of this Article VII. Neither Party shall use the other's Confidential Information except as expressly permitted in this Agreement. For purposes of this Agreement, "**Confidential Information**" means all information (including information relating to the business, operations and products of a Party or any of its Affiliates) disclosed by the Disclosing Party to the Receiving Party and which reasonably ought to have been understood to be confidential and/or non-public information at the time disclosed to the Receiving Party, or which is designated in writing by the Disclosing Party as "Confidential" (or equivalent), or which when disclosed orally to the Receiving Party is declared to be confidential by the Disclosing Party and is so confirmed in a writing delivered to the Receiving Party within 30 days after such oral disclosure, including but not limited to any technical information, Know-How, trade secrets, or inventions (whether patentable or not), that such Party discloses to another Party under this Agreement, or otherwise becomes known to another Party by virtue of or that relates to this Agreement.

7.2 Obligation. The Parties agree that they will disclose the other Party's Confidential Information to its own (or its respective Affiliate's, or with respect to TGTX, its Sublicensees') officers, employees, consultants and agents only if and to the extent necessary to carry out their respective responsibilities under this Agreement or in accordance with the exercise of their rights under this Agreement, and such disclosure shall be limited to the maximum extent possible consistent with such responsibilities and rights. Except as set forth in the foregoing sentence, no Party shall disclose Confidential Information of the other to any Third Party without the other's prior written consent. In all events, however, any and all disclosure to a Third Party (or to any such Affiliate or Sublicensee) shall be pursuant to the terms of a non-disclosure/nonuse agreement no less restrictive than this Article VII. The Party which disclosed Confidential Information of the other to any Third Party (or to any such Affiliate or Sublicensee) shall be responsible and liable for any disclosure or use by such Third Party, Affiliate or Sublicensee (or its disclosees) which would have violated this Agreement if committed by the Party itself. No Party shall use Confidential Information of the other except as expressly allowed by and for the purposes of this Agreement. Each Party shall take such action to preserve the confidentiality of each other's Confidential Information as it would customarily take to preserve the confidentiality of its own Confidential Information (but in no event less than a reasonable standard of care). Upon expiration or termination of this Agreement, each Party, upon the other's request, shall return or destroy (at Disclosing Party's discretion) all the Confidential Information disclosed to the other Party pursuant to this Agreement, including all copies and extracts of documents, within 60 days after the request, except for one archival copy (and such electronic copies that exist as part of the Party's computer systems, network storage systems and electronic backup systems) of such materials solely to be able to monitor its obligations that survive under this Agreement.

7.3 Exceptions. The non-use and non-disclosure obligations set forth in this Article VII shall not apply to any Confidential Information, or portion thereof, that the Receiving Party can demonstrate by competent evidence:

(a) at the time of disclosure is in the public domain;

(b) after disclosure, becomes part of the public domain, by publication or otherwise, through no fault of the Receiving Party or its disclosees;

(c) is made available to the Receiving Party by an independent Third Party without obligation of confidentiality; provided, however, that to the Receiving Party's knowledge, such information was not obtained by said Third Party, directly or indirectly, from the Disclosing Party hereunder; or

(d) is independently developed by an employee of the Receiving Party not accessing or utilizing the Disclosing Party's information.

In addition, the Receiving Party may disclose information that is required to be disclosed by law, by a valid order of a court or by order or regulation of a governmental agency including but not limited to, regulations of the SEC or in the course of arbitration or litigation; provided, however, that in all cases the Receiving Party shall give the other party prompt notice of the pending disclosure and make a reasonable effort to obtain, or to assist the Disclosing Party in obtaining, a protective order or confidential-treatment order preventing or limiting (to the greatest possible extent and for the longest possible period) the disclosure and/or requiring that the Confidential Information so disclosed be used only for the purposes for which the law or regulation required, or for which the order was issued.

7.4 Third Party Information. The Parties acknowledge that the defined term "Confidential Information" shall include not only a Disclosing Party's own Confidential Information but also Confidential Information of a Third Party which is in the possession of a Disclosing Party. The Parties agree not to disclose to the other any Confidential Information of a Third Party which is in the possession of such Party, unless the other has given an express prior written consent (which specifies the owner of such Confidential Information) to receive such particular Confidential Information.

7.5 Press Release Announcing the Execution of the License Agreement and Related Disclosures. Either Party may make an initial press release announcing the execution of this Agreement, including any matter covered by this Agreement, and the Development or Commercialization of Licensed Products, but such Party shall provide the text of such planned disclosure to the other Party sufficiently in advance of the scheduled disclosure to afford such other Party a reasonable opportunity to review and comment upon the proposed text and the timing of such disclosure, and shall consider all reasonable comments of the other Party regarding such disclosure. (Provided, that no Party shall use the trademark or logo of the other Party, its Affiliates or their respective employee(s) in any publicity, promotion, news release or public disclosure relating to this Agreement or its subject matter, except as may be required by Law or required by the rules of an applicable US national securities exchange or except with the prior express written permission of such other Party, such permission not to be unreasonably withheld.)

ARTICLE VIII
REPRESENTATIONS, WARRANTIES AND COVENANTS

8.1 Representations and Warranties. (a) TGTX represents and warrants to CTI, and (b) CTI represents to TGTX, in each case as of the Effective Date:

(a) Such Party is a corporation duly organized and validly existing under the Laws of the jurisdiction of its incorporation;

(b) Such Party has all right, power and authority to enter into this Agreement, and to perform its obligations under this Agreement;

(c) Such Party has taken all action necessary to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement;

(d) This Agreement is a legal and valid obligation of such Party, binding upon such Party and enforceable against such Party in accordance with the terms of this Agreement, except as enforcement may be limited by applicable bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other Laws relating to or affecting creditors' rights generally and by general equitable principles;

(e) To the best of such party's knowledge, the execution, delivery and performance of this Agreement by such Party does not conflict with, breach or create in any Third Party the right to accelerate, terminate or modify any agreement or instrument to which such Party is a party or by which such Party is bound;

(f) To the best of such party's knowledge, all consents, approvals and authorizations from all governmental authorities or other Third Parties required to be obtained by such Party in connection with the execution and delivery of this Agreement have been obtained; and the execution, delivery and performance of this Agreement by such Party does not violate any Law of any Governmental Body having authority over such Party;

(g) No person or entity has or will have, as a result of the execution and delivery of or as a result of the transactions contemplated by this Agreement, any right, interest or valid claim against or upon such Party for any commission, fee or other compensation as a finder or broker because of any act by such Party or its Affiliates, agents or Sublicensees; and

(h) To the best of such party's knowledge, no agreement between it and any Third Party is in conflict with the rights granted to any other party pursuant to this Agreement.

8.2 Reserved.

8.3 Disclaimer. Notwithstanding the representations and warranties set forth in this Article VIII, TGTX acknowledges and accepts the risks inherent in attempting to Develop and Commercialize any pharmaceutical product. There is no implied representation that the Licensed Products can be successfully Developed or Commercialized.

8.4 CTI MAKES NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO ANY PATENT, TRADEMARK, SOFTWARE, NON-PUBLIC OR OTHER INFORMATION, DFCI MATERIALS, DFCI ANTIBODIES, KNOW-HOW, OR TANGIBLE RESEARCH PROPERTY, LICENSED OR OTHERWISE PROVIDED TO TGTX HEREUNDER AND HEREBY DISCLAIMS THE SAME.

8.5 CTI DOES NOT WARRANT THE VALIDITY OF THE LICENSED PATENTS LICENSED HEREUNDER AND MAKES NO REPRESENTATION WHATSOEVER WITH REGARD TO THE SCOPE OF THE LICENSED PATENTS OR THAT SUCH LICENSED PATENTS MAY BE EXPLOITED BY TGTX, AFFILIATE OR SUBLICENSEE WITHOUT INFRINGING OTHER PATENTS. CTI MAKES NO REPRESENTATION THAT DFCI ANTIBODIES, CTI ANTIBODIES OR THE METHODS USED IN MAKING OR USING SUCH DFCI ANTIBODIES OR CTI ANTIBODIES ARE FREE FROM LIABILITY FOR PATENT INFRINGEMENT.

ARTICLE IX
INDEMNIFICATION; LIMITATION OF LIABILITY; INSURANCE

Indemnification and Defense.

9.1 TGTX shall indemnify, defend and hold harmless (i) DFCI and its trustees officers, medical and professional staff, employees, and agents and their respective successors, heirs and assigns and (ii) CTI and its directors, officers, employees, agents and contractors (the "CTI Indemnitees"), against any liability, damage, loss or expense (including reasonable attorneys' fees and expenses of litigation) incurred by or imposed upon the CTI Indemnitees, or any one of them, in connection with any claims, suits, actions, demands or judgments arising out any theory of product liability (including but not limited to action in the form of tort, warranty, strict liability) concerning any product, process or service relating to, or developed by TGTX, its Affiliates or Sublicensees pursuant to (a) any right or license granted under this Agreement or (b) arising out of any other activities to be carried out by TGTX pursuant to this agreement. TGTX's indemnification under Section 9.1 does not apply to any liability, damage, loss or expense to the extent that it is attributable to (x) the grossly negligent activities of the CTI Indemnitees, or (y) the intentional wrongdoing or intentional misconduct of the CTI Indemnitees TGTX shall, at its own expense, provide attorneys reasonably acceptable to CTI to defend against any actions brought or filed against any party indemnified hereunder with respect to the subject of indemnity contained herein, whether or not such actions are rightfully brought.

9.2 CTI shall indemnify, defend and hold harmless TGTX and its directors, officers, employees, agents and contractors (the "TGTX Indemnitees"), against any liability, damage, loss or expense (including reasonable attorneys' fees and expenses of litigation) incurred by or imposed upon the TGTX Indemnitees, or any one of them, in connection with any claims, suits, actions, demands or judgments arising out any theory of product liability (including but not limited to action in the form of tort, warranty, strict liability) concerning (a) any product, process or service relating to, or developed by CTI, its Affiliates or Sublicensees pursuant to the License Agreement or (b) any other activities to be carried out by CTI pursuant to this agreement. CTI's indemnification under Section 9.1 does not apply to any liability, damage, loss or expense to the extent that it is attributable to (x) the grossly negligent activities of the TGTX Indemnitees, or (y) the intentional wrongdoing or intentional misconduct of the TGTX Indemnitees. CTI shall, at its own expense, provide attorneys reasonably acceptable to DFCI and TGTX to defend against any actions brought or filed against any party indemnified hereunder with respect to the subject of indemnity contained herein, whether or not such actions are rightfully brought

9.3 If any such action is commenced or claim made or threatened against a DFCI Indemnitee or CTI Indemnitee (collectively, “Indemnitees”) as to which the other Party (the “Indemnifying Party”) is obligated to indemnify it (them) or hold it (them) harmless, the Indemnitee shall promptly notify Indemnifying Party of such event. Indemnifying Party shall assume the defense of, and may settle, that part of any such claim or action commenced or made against an Indemnitee which relates to the Indemnifying Party’s indemnification and CTI may take such other steps as may be necessary to protect it. Indemnifying Party will not be liable to Indemnitees on account of any settlement of any such claim or litigation affected without Indemnifying Party’s consent. The right of Indemnifying Party to assume the defense of any action is limited to that part of the action commenced against Indemnitees that relates to Indemnifying Party’s obligation of indemnification and holding harmless.

9.4 TGTX shall require any Affiliates or Sublicensee(s) to indemnify, hold harmless and defend DFCI and CTI under the same terms set forth in Sections 9.1 – 9.4.

9.5 **Insurance.** At such time as any product, process or service relating to, or developed pursuant to, this Agreement is being commercially distributed or sold (other than for the purpose of obtaining regulatory approvals) by TGTX or by a Sublicensee, Affiliate or agent of TGTX, TGTX shall, at its sole cost and expense, procure and maintain policies of commercial general liability insurance in amounts not less than $2,000,000 per incident and $2,000,000 annual aggregate and naming the Indemnitees as additional insureds. Such commercial general liability insurance must provide (a) product liability coverage and (b) contractual liability coverage for TGTX's indemnification under Sections 9.1 through 9.5 of this Agreement. If TGTX elects to self-insure all or part of the limits described above (including deductibles or retentions which are in excess of $250,000 annual aggregate), such self-insurance program must be acceptable to the CTI, DFCI and the DFCI's associated Risk Management Foundation. The minimum amounts of insurance coverage required under these provisions may not be construed to create a limit of TGTX's liability with respect to its indemnification obligation under Sections 9.1 through 9.5 of this Agreement.

9.6 TGTX shall provide CTI with written evidence of such insurance upon request of CTI. TGTX shall provide CTI with written notice at least fifteen (15) days prior to the cancellation, non-renewal or material change in such insurance; if TGTX does not obtain replacement insurance providing comparable coverage within such fifteen (15) day period, CTI has the right to terminate this Agreement effective at the end of such fifteen (15) day period without any notice or additional waiting periods.

9.7 TGTX shall maintain such comprehensive general liability insurance beyond the expiration or termination of this Agreement during (a) the period that any product, process, or service, relating to, or developed pursuant to, this Agreement is being commercially distributed or sold (other than for the purpose of obtaining regulatory approvals) by TGTX or by a Sublicensee, Affiliate or agent of TGTX and (b) a reasonable period after the period referred to in 9.8 (a) above which in no event shall be less than fifteen (15) years.

9.8 TGTX shall require any of its Affiliates or Sublicensee(s) to, maintain insurance in favor of CTI, DFCI and the Indemnitees under the same terms set forth in Sections 9.5 – 9.7 of this Agreement.

ARTICLE X
TERM AND TERMINATION

10.1 **Term.** The term of this Agreement shall commence on the Effective Date and, unless earlier terminated as provided in this Article X, shall continue in full force and effect, on a country-by-country and Licensed Product-by-Licensed Product basis until the Royalty Term in such country with respect to such Licensed Product expires, at which time this Agreement shall expire in its entirety with respect to such Licensed Product in such country. (The **"Term"** shall mean the period from the Effective Date until the earlier of termination of this Agreement as provided in this Article X or expiration of this Agreement upon the expiration of the last-to-expire Royalty Term.) The Parties confirm that subject to the foregoing sentence, this Agreement shall not be terminated or invalidated by any future determination that any or all of the Licensed Patents have expired or been invalidated.

10.2 **Termination by CTI.** CTI has the right to immediately terminate this Agreement, the extension of rights (if such termination occurs while TGTX is an Affiliate of CTI), and all licenses granted hereunder (if such failure occurs after the time TGTX ceases to be an Affiliate of CTI), or at CTI's option to convert the exclusive license granted in Article 2.1 to a non-exclusive license (if such failure occurs after the time TGTX ceases to be an Affiliate of CTI) in accordance with Section 3.6, by providing TGTX with written notice of such, upon the occurrence of any of the following events.

(a) TGTX's Board of Director's has agreed that TGTX will cease to carry on its business with respect to Licensed Products.

(b) TGTX fails to pay when due any undisputed royalty or other undisputed payment that has become due and is payable under Article V of this Agreement and has not cured the default by making the required payment, together with interest due, within ninety days of receiving a written notice of default from CTI requesting such payment.

(c) An officer of TGTX is convicted of a felony relating to the manufacture, use, sale or importation of Licensed Products.

(d) TGTX materially breaches any other provision of this Agreement (including but not limited to due diligence obligations under Article III and insurance obligations under Section 9.7 – Section 9.10), unless TGTX has cured the breach within ninety days of receiving written notice from CTI specifying the nature of the breach; provided, however, that the due diligence obligations shall be determined on a Licensed Product by Licensed Product basis.

10.3 Termination for insolvency. TGTX or CTI may terminate this Agreement immediately upon written notice, with no further notice obligation or opportunity to cure, if TGTX or CTI shall become insolvent, shall make an assignment for the benefit of creditors, or shall have a petition in bankruptcy filed for or against it (which is not dismissed within 60 days of such filing).

10.4 Notwithstanding Sections 10.2 and 10.3, in the event of a good-faith dispute as to whether any alleged breach, default, failure or any other act or omission gives rise to a right of termination under this Agreement, is in fact a breach, default, failure or other act or omission that gives rise to a right of termination under this Agreement, termination of this Agreement in respect of such alleged breach, default, failure or other act or omission shall not take effect unless and until (y) such dispute is resolved in accordance with Section 10.7 below in favor of the Party alleging such breach, default, failure or other act or omission or (z) the non-terminating Party's denial that the alleged breach, default, failure or other act or omissions is in fact a breach, default, failure or other act or omission giving rise to a right of termination hereunder ceases to be in good faith.

10.5 Termination by TGTX. TGTX has the right to terminate this Agreement without cause by giving CTI one hundred and eighty days prior written notice in whole or on a Licensed Product by Licensed Product basis. Any milestones achieved by TGTX during this one hundred and eighty-day period will be due and payable to CTI.

10.6 Effect of Termination

(a) **No release.** Upon termination of this Agreement for any reason, nothing in this Agreement may be construed to release either party from any obligation that matured prior to the effective date of the termination.

(b) **Survival.** The provisions of Section 6.1(a) (patent expenses) Article V (Financial Provisions), Section 3.1.2 (Publicity – paragraph 10.6(c) (Inventory), Article IX (Indemnification), Sections 9.7 – 9.10 (Insurance), Article VIII (Representations and Warranties) and Section 10.7 (Dispute Resolution) survive termination or expiration of this Agreement.

(c) **Inventory.** TGTX, any Affiliate(s) and any Sublicensees whose sublicenses are not converted as provided in paragraph 10.6(d) below, may, after the effective date of termination, sell all Licensed Products that are in inventory as of the date of written notice of termination, and complete and sell Licensed Products which the licensed entity(ies) can reasonably demonstrate were in the process of manufacture as of the date of written notice of termination, provided that TGTX shall pay to CTI the royalties thereon as required by Article V and shall submit the reports required by Section 5.10 on the sales of Licensed Products.

(d) **Sublicenses.** Any Sublicenses will terminate contemporaneously with this Agreement; provided, however, that any Sublicenses that are not in default under the sublicense agreement shall, upon DFCI's and CTI's written approval, survive and remain in full force and effect so long as the Sublicensee agrees to be bound by all of the provisions of this Agreement, if not otherwise already provided for in the sublicense agreement. Such approval by DFCI and CTI shall not be unreasonably withheld and shall not require the payment of additional consideration.

(e) If (i) this Agreement is in effect at the time of the termination of the License Agreement and (ii) TGTX is not an Affiliate of CTI at such time then, upon the written approval by DFCI, this Agreement survive and remain in full force and TGTX hereby agrees to be bound by the terms of the License Agreement pursuant to Section 10.6(d) of the License Agreement. If DFCI does not approve such survival, then this Agreement shall terminate upon termination of the License Agreement. Such approval by DFCI shall not be unreasonably withheld and shall not require the payment of additional consideration.

(f) Pursuant to the License Agreement, TGTX is deemed an Affiliate of CTI, and thus at the time the License Agreement is terminated, this Agreement shall automatically terminate at such time; provided, that pursuant to Section 2.5, TGTX shall have the right to cure any breach and that CTI will not voluntarily terminate the License Agreement with TGTX's prior written consent.

10.7 Dispute Resolution.

(a) **Negotiation between the Parties.** The parties shall first attempt to resolve any controversy that arises from this Agreement, or claim for breach of the Agreement, by good faith negotiations, first between their respective business development representatives and then, if necessary, between senior representatives for the Parties.

(b) **Non-Binding Mediation.** If the controversy or claim cannot be settled through good faith negotiation between the parties, the parties agree first to try in good faith to settle their dispute by non-binding mediation under the Mediation Rules of the American Arbitration Association, before resorting to arbitration, litigation or other dispute resolution procedure.

ARTICLE XI
MISCELLANEOUS PROVISIONS

11.1 Relationship of the Parties. Nothing in this Agreement is intended or shall be deemed to constitute a partnership, agency, joint venture or employer-employee relationship between the Parties. No Party shall have any right or authority to commit or legally bind any other Party in any way whatsoever including, without limitation, the making of any agreement, representation or warranty and each Party agrees to not purport to do so.

11.2 Assignment.

(a) Any assignment not in accordance with this Section 11.2 shall be void.

(b) No assignment shall relieve the assigning Party of any of its responsibilities or obligations hereunder.

(c) TGTX may not transfer or assign its rights or licenses or delegate its obligations under this Agreement, in whole or in part, by operation of law or otherwise, to any Third Party without the prior written consent of CTI, which consent shall not be unreasonably withheld, conditioned or delayed; *provided that*, notwithstanding the foregoing, TGTX may, without such consent, assign its rights or licenses and/or delegate its obligations under this Agreement to (i) an Affiliate or (ii) a Third Party in connection with a Sale Event (and for the avoidance of doubt, at such time the extension of rights set forth in Section 2.5 shall terminate and the licenses granted to TGTX in Section 2 shall become effective). As a condition to any permitted assignment hereunder, the assignee must expressly assume, in a writing delivered to CTI and signed by a duly authorized officer of the assignee (and in a form reasonably acceptable to CTI) all of TGTX's obligations under this Agreement, whether arising before, at or after the assignment.

11.3 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.

11.4 Force Majeure. No Party shall be liable to any other Party or be deemed to have breached or defaulted under this Agreement for failure or delay in the performance of any of its obligations under this Agreement (other than obligations for the payment of money) for the time and to the extent such failure or delay is caused by or results from acts of God, earthquake, riot, civil commotion, terrorism, war, strikes or other labor disputes, fire, flood, failure or delay of transportation, omissions or delays in acting by a governmental authority, acts of a government or an agency thereof or judicial orders or decrees or restrictions or any other like reason which is beyond the control of the respective Party. The Party affected by force majeure shall provide the other Party with full particulars thereof as soon as it becomes aware of the same (including its best estimate of the likely extent and duration of the interference with its activities), and shall use Commercially Reasonable Efforts to overcome the difficulties created thereby and to resume performance of its obligations hereunder as soon as practicable, and the time for performance shall be extended for a number of days equal to the duration of the force majeure.

11.5 Entire Agreement of the Parties; Amendments. This Agreement and the Schedules hereto constitute and contain the entire understanding and agreement of the Parties respecting the subject matter hereof and cancel and supersede any and all prior or contemporaneous negotiations, correspondence, understandings and agreements between the Parties, whether oral or written, regarding such subject matter (provided, that any and all previous nondisclosure/nonuse obligations are not superseded and remain in full force and effect in addition to the nondisclosure/nonuse provisions hereof). Each Party acknowledges that it has not relied, in deciding whether to enter into this Agreement on this Agreement's expressly stated terms and conditions, on any representations, warranties, agreements, commitments or promises which are not expressly set forth within this Agreement. No modification or amendment of any provision of this Agreement shall be valid or effective unless made in a writing referencing this Agreement and signed by a duly authorized officer of each Party.

11.6 Governing Law. This Agreement shall be governed by and interpreted in accordance with the laws of the State of New York, excluding application of any conflict of laws principles.

11.7 Notices and Deliveries. Any notice, request, approval or consent required or permitted to be given under this Agreement shall be in writing and shall be deemed to have been sufficiently given if and only if delivered in person, by email or by express courier service to the Party to which it is directed at its physical or email address shown below or such other physical or email address as such Party shall have last given by such written notice to the other Party.

If to CTI, addressed to:

Checkpoint Therapeutics, Inc.
2 Gansevoort Street, 9th Floor
New York, NY 10014
Attention: James F. Oliviero, CEO
Email: jfo@checkpointtx.com

If to TGTX, addressed to:

TG Therapeutics, Inc.
2 Gansevoort Street, 9th Floor
New York, NY 10014
Attention: Sean Power, CFO
Email: sp@tgtxinc.com

11.8 Waiver. No waiver of any provision of this Agreement shall be valid or effective unless made in a writing referencing this Agreement and signed by a duly authorized officer of the waiving Party. A waiver by a Party of any of the terms and conditions of this Agreement in any instance shall not be deemed or construed to be a waiver of such term or condition for the future, or of any other term or condition hereof.

11.9 Rights and Remedies are Cumulative. Except to the extent expressly set forth herein, all rights, remedies, undertakings, obligations and agreements contained in or available upon violation of this Agreement shall be cumulative and none of them shall be in limitation of any other remedy or right authorized in law or in equity, or any undertaking, obligation or agreement of the applicable Party.

11.10 Severability. This Agreement is severable. When possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable Law, but if any provision of this Agreement is held to be to any extent prohibited by or invalid under applicable Law, such provision will be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement (or of such provision). The Parties shall make a good faith effort to replace the invalid or unenforceable provision with a valid one which in its economic effect is most consistent with the invalid or unenforceable provision.

11.11 Third Party Beneficiaries. Except for the rights of Indemnified Parties pursuant to Article IX hereof and the rights of Sublicensees set forth in Sections 2.3 and 10.6(d), the terms and provisions of this Agreement are intended solely for the benefit of each Party hereto and their respective successors or permitted assigns and it is not the intention of the Parties to confer third-party beneficiary rights upon any other person, including without limitation Sublicensees. The enforcement of any obligation of CTI under this Agreement shall only be pursued by TGTX or such Indemnified Party, and not Sublicensees (except as set forth in Sections 2.3 and 10.6(d)).

11.12 No Implied License. No right or license is granted to TGTX hereunder by implication, estoppel, or otherwise to any know-how, patent or other intellectual property right owned or controlled by CTI or its Affiliates, except by an express license granted hereunder. No right or license is granted to CTI hereunder by implication, estoppel, or otherwise to any know-how, patent or other intellectual property right owned or controlled by TGTX or its Affiliates, except by an express license granted hereunder.

11.13 No Right of Set-Off. Except as expressly provided in Article 5 of this Agreement, TGTX shall not have a right to set-off any royalties, milestones or other amount due to CTI under this Agreement against any damages incurred by TGTX for a breach by CTI of this Agreement.

11.14 Equitable Relief. Each Party recognizes that the covenants and agreements herein and their continued performance as set forth in this Agreement are necessary and critical to protect the legitimate interests of the other Party, that the other Party would not have entered into this Agreement in the absence of such covenants and agreements and the assurance of continued performance as set forth in this Agreement, and that a Party's breach or threatened breach of such covenants and agreements may cause the opposed Party irreparable harm and significant injury, the amount of which will be extremely difficult to estimate and ascertain, thus potentially making any remedy at law or in damages inadequate. Therefore, each Party agrees that an opposed Party shall be entitled to seek specific performance, an order restraining any breach or threatened breach of Article VII and all other provisions of this Agreement, and any other equitable relief (including but not limited to temporary, preliminary and/or permanent injunctive relief). This right shall be in addition to and not exclusive of any other remedy available to such other Party at law or in equity.

11.15 Interpretation. The language used in this Agreement is the language chosen by the Parties to express their mutual intent, and no provision of this Agreement shall be interpreted for or against a Party because that Party or its attorney drafted the provision.

11.16 Construction. The words "include," "includes" and "including" shall be deemed to be followed by the phrase "without limitation." All references herein to Articles, Sections and Schedules shall be deemed references to Articles and Sections of, and Schedules to, this Agreement unless the context shall otherwise require.

11.17 Counterparts. This Agreement may be executed in counterparts, each of which will be deemed an original, and all of which together will be deemed to be one and the same instrument. A facsimile or a portable document format (.pdf) copy of this Agreement, including the signature pages, will be deemed an original.

[*the remainder of this page has been left blank intentionally*]

IN WITNESS WHEREOF, the Parties have caused this Amended and Restated Collaboration Agreement to be executed and delivered by their respective duly authorized officers as of the day and year first above written.

CHECKPOINT THERAPEUTICS, INC.

By: /s/ James Oliviero

Name: James Oliviero

Title: CEO

TG THERAPEUTICS, INC.

By: /s/ Michael S. Weiss

Name: Michael S. Weiss

Title: CEO

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Section 3: EX-31.1 (EXHIBIT 31.1)

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO RULES 13A-14(A) AND 15D-14(A) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, James F. Oliviero, certify that:

1. I have reviewed this report on Form 10-Q of Checkpoint Therapeutics, 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 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 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 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.

/s/ James F. Oliviero
James F. Oliviero
President and Chief Executive Officer
(Principal Executive Officer)
August 8, 2019

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Section 4: EX-31.2 (EXHIBIT 31.2)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO RULES 13A-14(A) AND 15D-14(A) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Garrett Gray, certify that:

1. I have reviewed this report on Form 10-Q of Checkpoint Therapeutics, 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 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 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 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.

/s/ Garrett Gray
Garrett Gray

Vice President, Finance and Accounting
(Principal Financial Officer)
August 8, 2019

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Section 5: EX-32.1 (EXHIBIT 32.1)

Exhibit 32.1

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I, James F. Oliviero, Chief Executive Officer of Checkpoint Therapeutics, Inc. (the "Company"), in compliance with 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, hereby certify that, to the best of my knowledge, the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2019 (the "Report") filed with the Securities and Exchange Commission:

- Fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ James F. Oliviero
James F. Oliviero
President and Chief Executive Officer
(Principal Executive Officer)
August 8, 2019

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Section 6: EX-32.2 (EXHIBIT 32.2)

Exhibit 32.2

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I, Garrett Gray, Principal Financial Officer of Checkpoint Therapeutics, Inc. (the "Company"), in compliance with 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, hereby certify that, to the best of my knowledge, the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2019 (the "Report") filed with the Securities and Exchange Commission:

- Fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Garrett Gray
Garrett Gray
Vice President, Finance and Accounting
(Principal Financial Officer)
August 8, 2019

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