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

FORM 10-Q
(Mark one)

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

For the quarterly period ended September 30, 2020

OR

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

For the transition period from _____ to _____

Commission File Number 001-38128

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 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 November 3, 2020
Class A Common Stock, $0.0001 par value	7,000,000
Common Stock, $0.0001 par value	60,883,303

CHECKPOINT THERAPEUTICS, INC.
Form 10-Q
For the Quarter Ended September 30, 2020

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Item 1. Financial Statements.

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

	September 30, 2020 (Unaudited)	December 31, 2019
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 42,029	$ 26,077
Prepaid expenses and other assets	588	863
Other receivables - related party	28	26
Total current assets	42,645	26,966
Total Assets	**$ 42,645**	**$ 26,966**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 5,665	$ 7,257
Accounts payable and accrued expenses - related party	755	862
Total current liabilities	6,420	8,119
Total Liabilities	**6,420**	**8,119**
Commitments and Contingencies		
Stockholders' Equity		
Common Stock ($0.0001 par value), 95,000,000 shares authorized		
Class A common shares, 7,000,000 shares issued and outstanding as of September 30, 2020 and December 31, 2019	1	1
Common shares, 60,883,303 and 47,004,764 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	6	5
Common stock issuable, 0 and 1,459,305 shares as of September 30, 2020 and December 31, 2019, respectively	—	2,510
Additional paid-in capital	169,185	136,442
Accumulated deficit	(132,967)	(120,111)
Total Stockholders' Equity	36,225	18,847
Total Liabilities and Stockholders' Equity	**$ 42,645**	**$ 26,966**

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 September 30,		For the nine months ended September 30,	
	2020	2019	2020	2019
Revenue - related party	$ 28	$ 280	$ 1,042	$ 1,683
Operating expenses:				
Research and development	2,543	3,894	8,207	12,595
General and administrative	2,429	1,620	5,794	5,081
Total operating expenses	4,972	5,514	14,001	17,676
Loss from operations	(4,944)	(5,234)	(12,959)	(15,993)
Other income				
Interest income	14	28	103	105
Total other income	14	28	103	105
Net Loss	**$ (4,930)**	**$ (5,206)**	**$ (12,856)**	**$ (15,888)**
Loss per Share:				
Basic and diluted net loss per common share outstanding	$ (0.09)	$ (0.15)	$ (0.24)	$ (0.48)
Basic and diluted weighted average number of common shares outstanding	56,405,734	34,561,844	53,040,215	33,178,567

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 September 30, 2020

	Class A Common Shares		Common Shares		Common Shares Issuable	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balances at June 30, 2020	**7,000,000**	**$ 1**	**50,980,004**	**$ 5**	**$ 0**	**$ 143,005**	**$ (128,037)**	**$ 14,974**
Issuance of common shares, net of offering costs - At-the-market offering	—	—	2,311,062	—	—	5,813	—	5,813
Issuance of common shares, net of offering costs - Public offering	—	—	7,321,429	1	—	18,911	—	18,912
Issuance of common shares - Founders Agreement	—	—	240,808	—	—	731	—	731
Stock-based compensation expense	—	—	30,000	—	—	725	—	725
Net loss	—	—	—	—	—	—	(4,930)	(4,930)
Balances at September 30, 2020	**7,000,000**	**$ 1**	**60,883,303**	**$ 6**	**$ 0**	**$ 169,185**	**$ (132,967)**	**$ 36,225**

For the Nine Months Ended September 30, 2020

	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, 2019	**7,000,000**	**$ 1**	**47,004,764**	**$ 5**	**$ 2,510**	**$ 136,442**	**$ (120,111)**	**$ 18,847**
Issuance of common shares, net of offering costs - At-the-market offering	—	—	3,614,344	—	—	8,417	—	8,417
Issuance of common shares, net of offering costs - Public offering	—	—	7,321,429	1	—	18,911	—	18,912
Issuance of common shares - Founders Agreement	—	—	1,732,684	—	(2,510)	3,307	—	797
Stock-based compensation expense	—	—	1,107,340	—	—	2,095	—	2,095
Exercise of warrants	—	—	102,742	—	—	13	—	13
Net loss	—	—	—	—	—	—	(12,856)	(12,856)
Balances at September 30, 2020	**7,000,000**	**$ 1**	**60,883,303**	**$ 6**	**$ 0**	**$ 169,185**	**$ (132,967)**	**$ 36,225**

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

For the Three Months Ended September 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 June 30, 2019	**7,000,000**	**$ 1**	**29,960,034**	**$ 3**	**$ —**	**$ 113,284**	**$ (106,079)**	**$ 7,209**
Issuance of common shares, net of offering costs - At-the-market offering	—	—	1,142,298	—	—	3,341	—	3,341
Stock-based compensation expense	—	—	9,000	—	—	833	—	833
Issuance of common shares - Founders Agreement	—	—	28,555	—	—	92	—	92
Exercise of warrants	—	—	26,146	—	—	—	—	—
Net loss	—	—	—	—	—	—	(5,206)	(5,206)
Balances at September 30, 2019	**7,000,000**	**$ 1**	**31,166,033**	**$ 3**	**$ —**	**$ 117,550**	**$ (111,285)**	**$ 6,269**

For the Nine Months Ended September 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	—	—	2,230,524	—	—	7,709	—	7,709
Stock-based compensation expense	—	—	769,652	—	—	2,444	—	2,444
Issuance of common shares - Founders Agreement	—	—	1,016,178	—	(1,748)	1,946	—	198
Exercise of warrants	—	—	73,525	—	—	—	—	—
Net loss	—	—	—	—	—	—	(15,888)	(15,888)
Balances at September 30, 2019	**7,000,000**	**$ 1**	**31,166,033**	**$ 3**	**$ —**	**$ 117,550**	**$ (111,285)**	**$ 6,269**

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 nine months ended September 30,	
	2020	2019
Cash Flows from Operating Activities:		
Net loss	$ (12,856)	$ (15,888)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	2,095	2,444
Issuance of common shares - Founders Agreement	797	198
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	275	632
Other receivables - related party	(2)	1,252
Accounts payable and accrued expenses	(1,926)	(5,282)
Net cash used in operating activities	(11,617)	(16,644)
Cash Flows from Financing Activities:		
Issuance of common shares - Public offering	20,500	—
Offering costs for the issuance of common stock - Public offering	(1,361)	—
Proceeds from issuance of common stock - At-the-market offering	8,684	7,904
Offering costs for the issuance of common stock - At-the-market offering	(267)	(195)
Proceeds from the exercise or warrants	13	—
Net cash provided by financing activities	27,569	7,709
Net increase in cash and cash equivalents	15,952	(8,935)
Cash and cash equivalents at beginning of period	26,077	21,995
Cash and cash equivalents at end of period	**$ 42,029**	**$ 13,060**
Supplemental disclosure of noncash investing and financing activities:		
Issuance of common shares - Founders Agreement	$ 2,510	$ 1,748
Issuance of common shares - Public offering (offering costs incurred but not paid)	$ 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 immunotherapy and targeted oncology 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 September 30, 2020, the Company had an accumulated deficit of $133.0 million.

In September 2020, the Company completed an underwritten public offering in which it sold7,321,429 shares of its common stock at a price of $2.80 per share for gross proceeds of approximately $20.5 million. Total net proceeds from the offering were approximately $18.9 million, net of underwriting discounts and offering expenses of approximately $1.6 million. The shares were sold under a Registration Statement (No. 333-221493) on Form S-3, filed with the Securities and Exchange Commission ("SEC").

During the nine months ended September 30, 2020, the Company sold a total of3,614,344 shares of common stock under an At-the-Market Issuance Sales Agreement for aggregate total gross proceeds of approximately $8.7 million at an average selling price of $2.40 per share, resulting in net proceeds of approximately $8.4 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 September 30, 2020 will be sufficient to fund its anticipated operating cash requirements for at least one year from the filing 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. In addition to the foregoing, based on the Company's current assessment, the Company does not expect any material impact on its long-term development timeline and its liquidity due to the worldwide spread of the coronavirus ("COVID-19"). However, the Company is continuing to assess the effect on its operations by monitoring the spread of COVID-19, as well as the effect of the COVID-19 pandemic on the Company's clients, vendors, and business partners, and the actions implemented to combat the virus throughout the world.

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

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 notes 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 notes 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, 2019, which were included in the Company's Form 10-K, and filed with the SEC on March 11, 2020. 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.

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.

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

Annual Equity Fee

Under the Founders Agreement with Checkpoint dated March 17, 2015, and amended and restated on July 11, 2016 (the "Founders Agreement"), Fortress is entitled to an annual equity fee on January 1 of each year 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 1,459,305 shares of common stock to Fortress on June 4, 2020 for the Annual Equity Fee, representing 2.5% of the fully-diluted outstanding equity of Checkpoint on January 1, 2020. The Company did not have enough unreserved authorized shares under its Certificate of Incorporation on January 1, 2020 to issue the shares for the Annual Equity Fee, therefore, in December 2019, Fortress and Checkpoint mutually agreed to defer the issuance until such time as the Checkpoint Charter has been amended in order to increase the number of authorized shares that may be issued thereunder. At the Company's 2020 Annual Meeting of Stockholders held on June 4, 2020, its stockholders approved an amendment to its certificate of incorporation to increase the number of authorized shares of common stock available to issue. Because the number of outstanding shares issuable to Fortress was determinable on January 1, 2020 prior to the issuance of the December 31, 2019 financial statements, the Company recorded approximately $2.5 million in research and development expense and a credit to Common shares issuable - Founders Agreement during the year ended December 31, 2019.

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.

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

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.

Certain of the Company's financial instruments are not measured at fair value on a recurring basis but are recorded at amounts that approximate their fair value due to their liquid or short-term nature, such as accounts payable and accrued expenses.

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

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

- 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.

Coronavirus Aid, Relief and Economic Security Act ("CARES Act")

In response to the COVID-19 pandemic, the Coronavirus Aid, Relief and Economic Security Act ("CARES Act") was signed into law on March 27, 2020. The CARES Act, among other things, includes tax provisions relating to refundable payroll tax credits, deferment of employer's social security payments, net operating loss utilization and carryback periods and modifications to the net interest deduction limitations. At this time, the Company does not believe that the CARES Act will have a material impact on its income tax provision for 2020. The Company will continue to evaluate the impact of the CARES Act on its financial position, results of operations and cash flows.

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

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 September 30, 2020 and 2019, that were excluded from the computation of diluted net loss per share, as they would be anti-dilutive:

	September 30,	
	2020	2019
Warrants (Note 6)	3,224,455	4,207,447
Stock options (Note 6)	220,000	110,000
Unvested restricted stock (Note 6)	4,013,199	3,402,151
Total	7,457,654	7,719,598

Recently Issued Accounting Standards

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-13, *"Financial Instruments – Credit Losses"* as amended by ASU 2019-10. The ASU sets forth a "current expected credit loss" (CECL) model which requires the Company to measure all expected credit losses for financial instruments held at the reporting date based on historical experience, current conditions, and reasonable supportable forecasts. This replaces the existing incurred loss model and is applicable to the measurement of credit losses on financial assets measured at amortized cost and applies to some off-balance sheet credit exposures. This ASU is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years, with early adoption permitted. In November 2019, the FASB issued ASU 2019-10, "*Financial Instruments - Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842) Effective Dates"*, which deferred the effective dates for the Company, as a smaller reporting company, until fiscal year 2023. The Company is currently assessing the impact of the adoption of this ASU on its financial statements.

In December 2019, the FASB issued ASU No. 2019-12, *"Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes"* ("ASU 2019-12"), which is intended to simplify various aspects related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020, with early adoption permitted. The Company will adopt the new guidance in the first quarter of 2021 and the adoption of this guidance is not expected to have a material impact on the condensed financial statements.

In August 2020, the FASB issued ASU No. 2020-06, "*Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity"*, which simplifies accounting for convertible instruments by removing major separation models required under current GAAP. The ASU removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception and it also simplifies the diluted earnings per share calculation in certain areas. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption will be permitted. The Company is currently evaluating the impact of this standard on its condensed financial statements.

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

Recently Adopted Accounting Standards

In August 2018, the FASB issued 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 adopted ASU No. 2018-13 as of January 1, 2020. 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. 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 connection with the license agreement with Dana-Farber, 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 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 paid 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 $27.6 million upon TGTX's successful achievement of certain clinical development, regulatory and first commercial sale milestones. This is comprised of up to approximately $8.4 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 September 30, 2020 and 2019, the Company recognized approximately $7,000 and $267,000, respectively, in revenue from its collaboration agreement in the Condensed Statements of Operations. For the nine months ended September 30, 2020 and 2019, the Company recognized approximately $1.0 million, which included a milestone of $925,000 upon the 12th patient dosed in a phase 1 clinical trial for the anti-PD-L1 antibody cosibelimab (formerly referred to as CK-301) during March 2020 and $1.6 million, respectively, in revenue related to the collaboration agreement in the Condensed Statements of Operations.

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

Adimab, LLC

In October 2015, Fortress entered into a collaboration agreement with Adimab , LLC ("Adimab") to discover and optimize antibodies using their proprietary core technology platform. Under this agreement, Adimab optimized cosibelimab, 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, Inc. ("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 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.

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 license agreement Jubilant is eligible to receive payments up to an aggregate of approximately $89.0 million upon the Company's successful achievement of certain 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 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 September 30, 2020 and 2019, the Company recognized approximately $21,000 and $13,000, respectively, in revenue related to the sublicense agreement in the Condensed Statements of Operations. For the nine months ended September 30, 2020 and 2019, the Company recognized approximately $67,000 and $37,000, respectively, in revenue related to the sublicense agreement in the Condensed Statements of Operations.

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

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 nine months ended September 30, 2020, the Company recognized the achievement of a clinical development milestone under its collaboration agreement with TGTX based upon their dosing of a 12th patient in a phase 1 clinical trial of cosibelimab.

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 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 Founders Agreement was further amended to change the issuance date of the Annual Equity Fee from the anniversary date of the Founders Agreement to January 1 of each year beginning in 2018.

Checkpoint Therapeutics, Inc.
Notes to Condensed Financial Statements
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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 the three months ended September 30, 2020 and 2019, the Company recognized $125,000 in expense on its Condensed Statements of Operations related to the MSA. For the nine months ended September 30, 2020 and 2019, the Company recognized $375,000 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 September 30, 2020 and 2019, the Company recognized approximately $28,000 in expense in its Condensed Statements of Operations related to the advisory agreement, including approximately $13,000 in expense related to annual equity incentive grants. For the nine months ended September 30, 2020 and 2019, the Company recognized approximately $84,000 and $76,000, respectively, in expense in its Condensed Statements of Operations related to the advisory agreement, including approximately $39,000 and $31,000, respectively, 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 September 30, 2020, and December 31, 2019, there was no litigation against the Company.

Checkpoint Therapeutics, Inc.
Notes to Condensed Financial Statements
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Note 6 – Stockholders' Equity

Common Stock

At the Company's 2020 Annual Meeting of Stockholders held on June 4, 2020, its stockholders approved an amendment to its certificate of incorporation to increase the number of authorized shares of common stock available to issue by 35,000,000 to 95,000,000 with a par value of $0.0001 per share, of which 7,000,000 shares are designated as "Class A common stock." The amendment was filed with the Secretary of State of the State of Delaware on June 4, 2020.

As of September 30, 2020, and December 31, 2019, 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 stockholders. The holders of common stock are entitled to one vote per share of common stock held. The Class A common stockholders 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.

In September 2020, the Company completed an underwritten public offering in which it sold 7,321,429 shares of its common stock at a price of $2.80 per share for gross proceeds of approximately $20.5 million. Total net proceeds from the offering were approximately $18.9 million, net of underwriting discounts and offering expenses of approximately $1.6 million. The shares were sold under the S-3.

During the nine months ended September 30, 2020, the Company sold a total of 3,614,344 shares of common stock under an At-the-Market Issuance Sales Agreement for aggregate total gross proceeds of approximately $8.7 million at an average selling price of $2.40 per share, resulting in net proceeds of approximately $8.4 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 offering noted above. Accordingly, the Company issued 273,379 shares of common stock to Fortress and recorded expense of approximately $797,000 related to these stock grants, which is included in general and administrative expenses in the Company's Condensed Statements of Operations for the nine months ended September 30, 2020.

Pursuant to the Founders Agreement, the Company issued 1,459,305 shares of common stock to Fortress on June 4, 2020 for the Annual Equity Fee, representing 2.5% of the fully-diluted outstanding equity of Checkpoint on January 1, 2020. The Company did not have enough unreserved authorized shares under its Certificate of Incorporation on January 1, 2020 to issue the shares for the Annual Equity Fee, therefore, in December 2019, Fortress and Checkpoint mutually agreed to defer the issuance until such time as the Checkpoint Charter has been amended in order to increase the number of authorized shares that may be issued thereunder.

The S-3 is currently the Company's only active shelf registration statement. Subsequent to the offerings noted above, approximately $12.3 million of securities remain 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.

Checkpoint Therapeutics, Inc.
Notes to Condensed Financial Statements
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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 2020 to increase the shares available for issuance to 9,000,000 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 September 30, 2020, 4,298,465 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 nine months ended September 30, 2020:

	Number of Shares	Weighted Average Grant Date Fair Value
Non-vested at December 31, 2019	3,303,839	$ 4.29
Granted	1,107,340	2.39
Vested	(397,980)	4.31
Non-vested at September 30, 2020	4,013,199	$ 3.77

As of September 30, 2020, there was $3.5 million of total unrecognized compensation cost related to non-vested restricted stock, which is expected to be recognized over a weighted-average period of 2.0 years. This amount does not include, as of September 30, 2020, 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 nine months ended September 30, 2020:

	Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Outstanding as of December 31, 2019	160,000	$ 3.64	8.56
Granted	60,000	2.04	
Outstanding as of September 30, 2020	220,000	$ 3.20	8.29

Upon the exercise of stock options, the Company will issue new shares of its common stock. As of September 30, 2020,no outstanding stock options were vested and exercisable.

Checkpoint Therapeutics, Inc.
Notes to Condensed Financial Statements
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Warrants

A summary of warrant activities for the nine months ended September 30, 2020 is presented below:

	Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Outstanding as of December 31, 2019	4,207,447	$ 6.81	1.25
Exercised	(102,742)	0.13	
Expired	(880,250)	7.00	
Outstanding as of September 30, 2020	3,224,455	$ 6.97	0.19

Upon the exercise of warrants, the Company will issue new shares of its common stock. During the nine months ended September 30, 2020, the Company issued 102,742 common shares and received $13,000.

Stock-Based Compensation

The following table summarizes stock-based compensation expense for the three and nine months ended September 30, 2020 and 2019 ($ in thousands):

	For the three months ended September 30,		For the nine months ended September 30,	
	2020	2019	2020	2019
Research and development	$ 157	$ 179	$ 462	$ 559
General and administrative	568	654	1,633	1,885
Total stock-based compensation expense	$ 725	$ 833	$ 2,095	$ 2,444

Note 7 - Accounts Payable and Accrued Expenses

At September 30, 2020 and December 31, 2019, accounts payable and accrued expenses consisted of the following ($ in thousands):

	September 30, 2020	December 31, 2019
Accounts payable	$ 2,467	$ 3,079
Accrued compensation	326	414
Research and development	2,289	3,496
Other	583	268
Total accounts payable and accrued expenses	$ 5,665	$ 7,257

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." Additionally, many of these risks and uncertainties are currently elevated by and may or will continue to be elevated by the COVID-19 pandemic. 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 immunotherapy and targeted oncology company focused on the acquisition, development and commercialization of novel treatments for patients with solid tumor cancers. We are evaluating our lead antibody product candidate, cosibelimab, a potential best-in-class anti-PD-L1 antibody licensed from the Dana-Farber Cancer Institute, in an ongoing global, open-label, multicohort Phase 1 clinical trial in checkpoint therapy-naïve patients with selected recurrent or metastatic cancers, including ongoing cohorts in locally advanced and metastatic cutaneous squamous cell carcinoma intended to support one or more applications for marketing approval. In addition, we are evaluating our lead small-molecule, targeted anti-cancer agent, CK-101, a third-generation EGFR inhibitor, as a potential new treatment for patients with EGFR mutation-positive non-small cell lung cancer.

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 2020, we announced updated interim results from the ongoing global, open-label, multicohort Phase 1 clinical trial of our anti-PD-L1 antibody, cosibelimab, in patients with advanced cancers, including the registration-enabling cohort of patients with metastatic cutaneous squamous cell carcinoma. The interim results were presented in an e-poster at the European Society for Medical Oncology ("ESMO") Virtual Congress 2020.

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 September 30, 2020, we have an accumulated deficit of $133.0 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 September 30, 2020 and 2019

Revenue

For the three months ended September 30, 2020, revenue was approximately $28,000 compared to approximately $280,000 for the three months ended September 30, 2019, a decrease of $252,000. Revenue for the three months ended September 30, 2019 included $238,000 from TGTX for the purchase of clinical material of cosibelimab.

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 ("CROs") 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 September 30, 2020, research and development expenses were approximately $2.5 million, compared to $3.9 million for the three months ended September 30, 2019, a decrease of $1.4 million. The current period research and development expenses primarily consisted of $2.0 million related to clinical costs for our product candidates and $0.2 million related to stock compensation expense. The prior 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.

We anticipate our research and development expenses to increase modestly for the remainder of 2020.

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 September 30, 2020, general and administrative expenses were approximately $2.4 million, compared to $1.6 million for the three months ended September 30, 2019, an increase of $0.8 million. The current period general and administrative expenses primarily consisted of stock compensation expense of $0.6 million, $0.7 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, $0.3 million for salary expense, $0.3 million related to legal and accounting fees and $0.1 million related to investor relation fees. The prior period general and administrative expenses primarily consisted of stock compensation expense of $0.7 million, $0.3 million related to salary expenses, $0.2 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.

We anticipate our general and administrative expenses will remain relatively consistent for the remainder of 2020.

Comparison of the Nine Months Ended September 30, 2020 and 2019

Revenue

For the nine months ended September 30, 2020, revenue was approximately $1.0 million compared to approximately $1.7 million for the nine months ended September 30, 2019, a decrease of $0.7 million. Revenue for the current period primarily consisted of $1.0 million from TGTX related to the collaboration agreement, including a milestone of $925,000 upon the 12th patient dosed in a phase 1 clinical trial for cosibelimab during March 2020. Revenue for the nine months ended September 30, 2019 consisted period primarily consisted of $1.6 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 $0.6 million for the purchase of clinical material of cosibelimab.

Research and Development Expenses

For the nine months ended September 30, 2020, research and development expenses were approximately $8.2 million, compared to $12.6 million for the nine months ended September 30, 2019, a decrease of $4.4 million. The current period's research and development expenses primarily consisted of $6.0 million related to clinical costs for our product candidates, $0.9 million related to the manufacturing costs of our product candidates, and $0.5 million related to stock compensation expense. The prior period's research and development expenses primarily consisted of $6.8 million related to clinical costs for our product candidates, $4.0 million related to manufacturing costs of our product candidates, and $0.6 million related to stock compensation expense.

General and Administrative Expenses

For the nine months ended September 30, 2020, general and administrative expenses were approximately $5.8 million, compared to $5.1 million for the nine months ended September 30, 2019, an increase of $0.7 million. The current period's general and administrative expenses primarily consisted of stock compensation expense of $1.6 million, $0.8 million related to salary expenses, $0.8 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, $0.7 million related to legal and accounting fees and $0.5 million related to investor relation fees. The prior period's general and administrative expenses primarily consisted of stock compensation expense of $1.9 million, $0.8 million related to salary expenses, $0.8 million related to legal and accounting fees and $0.2 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.

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 September 30, 2020, we had an accumulated deficit of $133.0 million.

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 September 30, 2020 are sufficient to fund our anticipated operating cash requirements for at least one year from the filing date of this Quarterly Report on Form 10-Q.

In addition to the foregoing, based on the Company's current assessment, the Company does not expect any material impact on its long-term development timeline and its liquidity due to the worldwide spread of COVID-19. However, the Company is continuing to assess the effect on its operations by monitoring the spread of COVID-19, as well as the effect of the COVID-19 pandemic on the Company's clients, vendors, and business partners, and the actions implemented to combat the virus throughout the world.

Cash Flows for the Nine Months Ended September 30, 2020 and 2019

Operating Activities

Net cash used in operating activities was approximately $11.6 million for the nine months ended September 30, 2020, compared to approximately $16.6 million for the nine months ended September 30, 2019. The decrease in net cash used in operating activities was primarily related to a decrease in manufacturing of cosibelimab clinical supply in the current period.

Investing Activities

There were no investing activities for the nine months ended September 30, 2020 and 2019.

Financing Activities

Net cash provided by financing activities was $27.6 million for the nine months ended September 30, 2020. Cash provided by financing activities related to net proceeds of $19.1 million from the issuance of common stock as part of our underwritten public offering in September 2020 and net proceeds of $8.4 million from the issuance of common stock as part of our At-the-Market Issuance Sales Agreement (the "ATM") offerings. Net cash provided by financing activities for the nine months ended September 30, 2019 related to net proceeds of $7.7 million from the issuance of common stock as part of our ATM offering.

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 September 30, 2020, 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 September 30, 2020 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. Additionally, many of these risks and uncertainties are currently elevated by and may or will continue to be elevated by the COVID-19 pandemic.

Risks Related to Our Business and Industry

Major public health issues, and specifically the pandemic caused by the spread of COVID-19, could have an adverse impact on our financial condition and results of operations and other aspects of our business.

In December 2019, a novel strain of coronavirus, COVID-19, was first detected in Wuhan, China, and has since spread around the world. On March 11, 2020, the World Health Organization declared that the rapidly spreading COVID-19 outbreak had evolved into a pandemic. In response to the pandemic, many governments around the world are implementing a variety of measures to reduce the spread of COVID-19, including travel restrictions and bans, instructions to residents to practice social distancing, quarantine advisories, shelter-in-place orders and required closures of non-essential businesses.

The COVID-19 pandemic has negatively impacted the global economy, disrupted global supply chains, and created significant volatility and disruption of financial markets. Although COVID-19 has not had a material adverse effect on our business to date, no assurance can be given that it will not in the future if the situation persists or worsens. The extent to which the coronavirus impacts our business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning the coronavirus and the actions to contain the coronavirus or treat its impact, among others.

Should the coronavirus continue to spread, our business operations could be delayed or interrupted. For instance, our clinical trials may be affected by the pandemic. Site initiation, participant recruitment and enrollment, participant dosing, distribution of clinical trial materials, study monitoring and data analysis may be paused or delayed due to changes in hospital or university policies, federal, state or local regulations, prioritization of hospital resources toward pandemic efforts, or other reasons related to the pandemic. If the coronavirus continues to spread, some participants and clinical investigators may not be able to comply with clinical trial protocols. For example, quarantines or other travel limitations (whether voluntary or required) may impede participant movement, affect sponsor access to study sites, or interrupt healthcare services, and we may be unable to conduct our clinical trials. Infections and deaths related to the pandemic may disrupt the United States' and other countries' healthcare and healthcare regulatory systems. Such disruptions could divert healthcare resources away from, or materially delay FDA or other regulatory review and/or approval with respect to, our clinical trials. It is unknown how long these disruptions could continue, were they to occur. Any elongation or de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and study of our product candidates.

We currently rely on third parties, such as contract laboratories, contract research organizations, medical institutions and clinical investigators to conduct these studies and clinical trials. If these third parties themselves are adversely impacted by restrictions resulting from the coronavirus outbreak we will likely experience delays and/or realize additional costs. We also rely on third parties for the manufacture of our product candidates for preclinical and clinical testing. Disruptions to the global supply chain could impact our or our third-party manufacturers' ability to obtain raw materials or other products necessary to manufacture and distribute our product candidates. As a result, our efforts to obtain regulatory approvals for, and to commercialize, our product candidates may be delayed or disrupted.

The Company's employees have been and are currently being affected by the COVID-19 pandemic. Our office and management personnel are mostly working remotely and the Company may need to enact further precautionary measures to help minimize the risk of our employees being exposed to the coronavirus. If these conditions worsen, or last for an extended period of time, the Company's ability to manage its business may be impaired, and operational risks, cybersecurity risks and other risks the Company faced even prior to the pandemic may be elevated.

The potential economic impact brought by and the duration of the pandemic may be difficult to assess or predict, however it has already caused, and is likely to result in further, significant disruption of global financial markets, which may reduce our ability to access capital either at all or on favorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the spread of the coronavirus could materially and adversely affect our business and the value of our common stock.

The ultimate impact of the current pandemic, or any other health epidemic, is highly uncertain and will depend on future developments that cannot be predicted with confidence, such as the duration of the outbreak, the severity of COVID-19, and the effectiveness of actions to contain and treat for COVID-19. Although, as of the date of this Quarterly Report on Form 10-Q, we do not expect any material impact on our long-term activity, we do not yet know the full extent of potential delays or impacts on our business, our clinical trials, our research programs, healthcare systems or the global economy as a whole, which could have a material adverse effect on our business, financial condition and results of operations and cash flows.

We currently have no drug products for sale. We are completely 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 have no drug products for sale, currently generate no revenues from sales of any drug products, and may never be able to develop or commercialize a marketable drug.

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

- developing our technology platform;
- identifying, developing, formulating, 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, including ultimately gaining approval to market a drug product, which may not occur;

- obtaining sufficient quantities of our product candidates from our third-party manufacturers to meet clinical trial needs and, if approved, to meet 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 a 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 establish;

- maintaining patent protection and regulatory exclusivity for our product candidates; and

- obtaining market acceptance for our product candidates.

Each of these requirements will require substantial time, effort, and financial resources.

We intend to use data from our ongoing Phase 1 clinical trial of cosibelimab, conducted outside the United States ("U.S."), to support one or more U.S. biologics license application ("BLA") submissions in checkpoint therapy-naïve patients with selected recurrent or metastatic cancers, including cutaneous squamous cell carcinoma ("CSCC"). In January 2020, we announced that we had discussed with the Food and Drug Administration ("FDA") this strategy in CSCC. We believe, based on published FDA guidance documents, public statements of companies with comparable product candidates, public statements by the director of the FDA's Oncology Center of Excellence, and recent interactions with the FDA, that exclusively foreign clinical data from a single study may be acceptable to support marketing approval(s) under FDA regulations.

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 our product candidates will require additional preclinical or clinical development, management of preclinical, clinical and manufacturing activities, regulatory approval in the jurisdictions in which we plan to market the product, obtaining manufacturing supply, building of a commercial organization, and significant marketing efforts before we generate any revenues from product sales, which may not occur. We are not permitted to market or promote any of our product candidates in the U.S. or any other jurisdiction before we receive regulatory approval from the FDA or any comparable foreign regulatory authority, respectively, 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 other 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/or 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 any 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 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 ("IRB"), or ethics committee, as applicable, approval at each site;
- recruiting a sufficient number of suitable 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 from the FDA or any comparable foreign regulatory authority;
- adding new clinical trial sites; or
- availability of raw materials 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, 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 candidate, 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, or such revenues may not be generated at all. 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, by other regulatory agencies in the United States, by the European Medicines Agency and by any comparable foreign regulatory authority 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 CROs 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, 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 approval, 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, which only apply to certain drug products, 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 studies, including 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 current Good Manufacturing Practice ("cGMP") requirements enforced by the FDA through its establishment inspection program. We are required by law to establish adequate oversight and control over raw materials, components and finished products furnished by our third-party suppliers and contract manufacturers, but 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, restrictions on imports and exports, 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, potential for breach of contract claims, damage to our reputation and potential for product liability claims.

If the contract 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.

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 or adverse events 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 adverse events, 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 adverse events that prevented further development of the compound. In the event that our clinical trials reveal a high or unacceptable severity and prevalence of adverse events, 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. Adverse events or 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. Adverse events or 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, including specific warnings, black box warnings, adverse reactions, precautions, and/or contraindications;

- regulatory authorities may suspend or withdraw their approval of the product, and/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, or any 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.

If one or more of our product candidates that we may license or acquire is approved, the approved product candidate will be subject to ongoing requirements and review by 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 any 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, civil claims, and/or criminal charges 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, untitled letters, import alerts, and/or inspection observations;
- 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, consent decrees, and/or the imposition of civil or criminal penalties.

The FDA's policies, or the policies of any other applicable regulatory authority, may change and/or additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates, or negatively affect those products for which we may have already received regulatory approval, if any. 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 be subject to the various actions listed above, including losing 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 process, 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 United States Patent and Trademark Office ("USPTO"). The FDA typically conducts a review of proposed product brand names, including an evaluation of the 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 ("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 ("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 ("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 by the FDA, or any similar regulatory authority outside the United States, is limited 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, or any other similar regulatory authority outside the United States. In addition to the regulatory approval required for new drug products, new formulations or indications for an approved product also require 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 prevented or 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 products is limited to those indications that are specifically approved by the FDA, or any 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 certain 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 penalties, 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 U.S. 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 U.S. 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 U.S., 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 70% 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 to enroll in the 340B Drug Pricing Program to include certain critical access hospitals, freestanding cancer hospitals, rural referral centers, and sole community hospitals, but exempting orphan drugs from the ceiling price requirements for these covered entities;

- 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 ("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. On December 12, 2019, the House of Representatives passed broad legislation that would, among other provisions, require the Department of Health and Human Services ("HHS") to negotiate drug prices and impose price caps calculated in part by international reference pricing. Failure by a manufacturer to reach an agreement with HHS on the negotiated price could result in significant penalties for prescription drug manufacturers. While we cannot predict which proposals may ultimately become law, the proposals 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. HHS finalized Medicare fee-for-service hospital payment reductions for Part B drugs acquired through the 340B Drug Pricing Program, which remains subject to ongoing legal proceedings. 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, released two pharmaceutical importation models in December 2019: (1) a Notice of Proposed Rulemaking to permit importation of pharmaceuticals from Canada, and (2) draft FDA guidance permitting manufacturers to import their own pharmaceuticals that were originally intended for marketing in other countries.

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 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.

Most recently, in July 2020, President Trump signed four Executive Orders directing HHS to take several steps to lower costs on prescription drugs. Many of the policy changes included in the Executive Orders were proposed in President Trump's May 2018 Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. The Executive Orders cover a range of policies, including but not limited to (i) tying the prices paid by the U.S. government (e.g., Medicare) for drugs and biological products to prices paid in other countries; (ii) ensuring that rebates that drug makers pay to pharmacy benefit managers and insurers in the Medicare Part D program get passed directly to patients when they purchase a medication, so long as the change is not projected to increase Federal spending, Medicare beneficiary premiums or patients' total out-of-pocket costs; and (iii) allowing states, wholesalers and pharmacies to import FDA-approved drugs from Canada and other countries and sell them in the U.S. if the FDA deems them safe. Many of these policy proposals have been considered in recent legislative and regulatory proposals. The impact and timing of these Executive Orders is uncertain, as the directives contained therein would require agency rulemaking and implementation. These policy proposals, if implemented, could significantly impact the pharmaceutical industry in the U.S. and adversely affect our ability to generate revenues or commercialize our product candidates in the U.S.

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 ("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 any similar regulatory authority outside the United States. Some of our competitors have ongoing clinical trials for product candidates that treat the same indications that we are targeting for 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 candidates 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, if approved, 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, if approved, 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;
- any potential differentiation of the drug versus available therapies;
- the timing of market introduction of such product candidates 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 candidates in a broader patient group (i.e. based on actual use);
- 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, including those 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 them 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 our own 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 CROs and site management organizations to conduct some of our preclinical studies and all of our clinical trials for our product candidates, and plan to do the same for any future product candidate. We expect to continue to rely on third parties, such as CROs, 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 reduces our control over these activities but does not relieve us of our responsibilities. For example, we 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 practices 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 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 and/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 CROs or site management organizations terminate, we may not be able to enter into arrangements with alternative CROs or site management organizations or to do so on commercially reasonable terms. Switching or adding additional CROs or site management organizations involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO 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 CROs or site management organizations, there can be no assurance that we will not encounter similar challenges or delays in the future. Forces beyond our control, including the impacts of COVID-19, could disrupt the ability of our third-party CROs, site management organizations, clinical data management organizations, medical institutions and clinical investigators to conduct our preclinical studies and our clinical trials for our product candidates and for any future product candidate.

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, if and when our product candidates are approved. 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, and plan to do so for commercial manufacture of any of our product candidates that may 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 may 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, while still being required by law to establish adequate oversight and control over products furnished by that third party;
- the possible breach of the manufacturing agreement by the third party;

- manufacturing delays if our third-party manufacturers are unable to obtain raw materials due to supply chain disruptions, 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. Forces beyond our control, including the effects of the COVID-19 pandemic, could disrupt the global supply chain and impact our or our third-party manufacturers' ability to obtain raw materials or other products necessary to manufacture our product candidates. 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 third-party manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for a product candidate, the commercial launch of that product candidate 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 third-party manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit an NDA or BLA to the FDA. We are required by law to establish adequate oversight and control over raw materials, components and finished products furnished by our third-party manufacturers, but we do not control the day-to-day manufacturing operations of, and are dependent on, our third-party 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, restrictions on imports and exports, 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 third-party 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 third-party 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 may 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, if approved, 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 well-studied 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, if approved, commercialize the 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 and/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 or third-party contractors 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 or third-party contractors 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 or third-party contractors 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 and/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 and/or effectively 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 USPTO 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 the 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 U.S. 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 USPTO 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 USPTO, 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 U.S. 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 patents or that we infringe their patents; or provoke those parties to petition the USPTO 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 U.S. 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 $133.0 million as of September 30, 2020. 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 may receive regulatory approval, including building our own commercial organizations to address certain markets. We will require additional capital for the further development and, if approved, 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 September 30, 2020 are sufficient to fund our anticipated operating cash requirements for at least one year from the filing 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, if approved, 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 studies 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 third-party 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, if approved.

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 September 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 Quarterly Report on Form 10-Q;
- 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, which became effective as of March 17, 2015 and was amended and restated on July 11, 2016, 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 January 1 of each year. 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.

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 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, 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	Amendment No. 5, dated September 24, 2020, to the Executive Employment Agreement dated October 13, 2015, by and between Checkpoint Therapeutics, Inc. and James F. Oliviero III. #
10.2	Master Services Agreement between Samsung Biologics Co., Ltd. and Checkpoint Therapeutics, Inc., effective November 8, 2017 *
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 November 6, 2020.
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 November 6, 2020.
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 November 6, 2020.
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 November 6, 2020.
101	The following financial information from the Company's Quarterly Report on Form 10-Q for the period ended September 30, 2020, 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).

Management Compensation Arrangement.
*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: November 6, 2020

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

Exhibit 10.1

FIFTH AMENDMENT TO EXECUTIVE EMPLOYMENT AGREEMENT

Fifth Amendment (this "Amendment") dated as of September 24, 2020 to the Executive Employment Agreement (the "Agreement") dated October 13, 2015, as amended, by and between Checkpoint Therapeutics, Inc. (the "Company" or "Checkpoint") and James F. Oliviero III ("Oliviero"). All capitalized terms not otherwise defined herein shall have the meanings given to them in the Agreement.

WHEREAS, on October 13, 2015, Oliviero received a grant of 1,000,000 restricted shares of Checkpoint common stock, $0.0001 par value (the "Shares");

WHEREAS, on September 27, 2016, Oliviero and the Company entered into a first amendment to the Agreement, effective as of such date, to amend the vesting schedule of the Shares;

WHEREAS, on December 15, 2016, Oliviero and the Company agreed to further amend the vesting schedule of the Shares in the Agreement;

WHEREAS, on January 30, 2018, Oliviero and the Company agreed to further amend the vesting schedule of the Shares in the Agreement;

WHEREAS, on October 7, 2019, Oliviero and the Company agreed to further amend the vesting schedule of the Shares in the Agreement;

WHEREAS, the Company believes that it is in its best interest to further amend the vesting schedule in the Agreement; and

WHEREAS, the Company and Oliviero have agreed to amend the Agreement.

NOW THEREFORE, in consideration of the foregoing and of the mutual covenants hereinafter set forth, the parties agree as follows:

1. Amendments.

Section 3.4.3 of the Agreement, as amended, with regard to the Shares shall be amended by deleting the following vesting schedule:

Vesting Date		Number of Shares Vested
The earlier to occur of: (A) October 13, 2020 or (B) the termination of Executive's (as defined in the Employment Agreement) employment as a result of his death or Disability (as defined in the Employment Agreement)		444,444

The later to occur of: (A) the Company's achievement of a fully-diluted Market Capitalization (as defined in the Employment Agreement) of $500,000,000 or (B) September 1, 2020, *provided*, however, that should Executive's (as defined in the Employment Agreement) employment with the Company terminate as a result of his death or Disability (as defined in the Employment Agreement) and prior to such termination or within four months of such termination (as provided by Section 4.5.4(iii)), any Market Capitalization milestone is achieved, the respective Shares for such achieved Market Capitalization milestone(s) shall immediately vest and become non-forfeitable.		111,111
The later to occur of: (A) the Company's achievement of a fully-diluted Market Capitalization (as defined in the Employment Agreement) of $750,000,000 or (B) September 1, 2020, *provided*, however, that should Executive's (as defined in the Employment Agreement) employment with the Company terminate as a result of his death or Disability (as defined in the Employment Agreement) and prior to such termination or within four months of such termination (as provided by Section 4.5.4(iii)), any Market Capitalization milestone is achieved, the respective Shares for such achieved Market Capitalization milestone(s) shall immediately vest and become non-forfeitable.		111,111
The earlier to occur of: (A) the Company's first Corporate Development Transaction (as defined in the Employment Agreement) or (B) the first FDA approval of a Company product or medical device		166,667

The earlier to occur of: (A) the Company's second Corporate Development Transaction (as defined in the Employment Agreement) or (B) a second FDA approval of a Company product or medical device		166,667

and inserting the following vesting schedule:

Vesting Date		Number of Shares Vested
The earlier to occur of: (A) January 1, 2022 or (B) the termination of Executive's (as defined in the Employment Agreement) employment as a result of his death or Disability (as defined in the Employment Agreement)		444,444
The later to occur of: (A) the Company's achievement of a fully-diluted Market Capitalization (as defined in the Employment Agreement) of $500,000,000 or (B) January 1, 2022, *provided*, however, that should Executive's (as defined in the Employment Agreement) employment with the Company terminate as a result of his death or Disability (as defined in the Employment Agreement) and prior to such termination or within four months of such termination (as provided by Section 4.5.4(iii)), any Market Capitalization milestone is achieved, the respective Shares for such achieved Market Capitalization milestone(s) shall immediately vest and become non-forfeitable.		111,111

The later to occur of: (A) the Company's achievement of a fully-diluted Market Capitalization (as defined in the Employment Agreement) of $750,000,000 or (B) January 1, 2022, *provided*, however, that should Executive's (as defined in the Employment Agreement) employment with the Company terminate as a result of his death or Disability (as defined in the Employment Agreement) and prior to such termination or within four months of such termination (as provided by Section 4.5.4(iii)), any Market Capitalization milestone is achieved, the respective Shares for such achieved Market Capitalization milestone(s) shall immediately vest and become non-forfeitable.		111,111
The earlier to occur of: (A) the Company's first Corporate Development Transaction (as defined in the Employment Agreement) or (B) the first FDA approval of a Company product or medical device		166,667
The earlier to occur of: (A) the Company's second Corporate Development Transaction (as defined in the Employment Agreement) or (B) a second FDA approval of a Company product or medical device		166,667

2. Effect on the Agreement.

(a) Upon the effectiveness of this Amendment, each reference in the Agreement to "this Agreement" "hereunder", "hereof", "herein" or words of like import shall mean and be a reference to the Agreement as amended hereby.

(b) Except as expressly amended, the Agreement and all other documents and agreements executed and/or delivered in connection therewith, shall remain in full force and effect.

3. Governing Law.

This Amendment shall be binding upon and inure to the benefit of the parties hereto and their respective successors and assigns and shall be governed by and construed

in accordance with the laws of the State of New York without regard to its conflict of laws principles.

4. Counterparts.

This Amendment may be executed by the parties hereto in one or more counterparts, each of which shall be deemed an original and all of which when taken together shall constitute one and the same agreement.

IN WITNESS WHEREOF, Checkpoint Therapeutics, Inc. and James F. Oliviero III have executed this Amendment to the Executive Employment Agreement as of the date first written above.

CHECKPOINT THERAPEUTICS, INC.

By: /s/ Michael Weiss
Michael S. Weiss
Chairman of the Board of Directors

/s/ James F. Oliviero III
James F. Oliviero III

Exhibit 10.2

Execution Version

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT BOTH (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED. SUCH EXCLUDED INFORMATION HAS BEEN MARKED WITH "[*]."

MASTER SERVICES AGREEMENT

between

SAMSUNG BIOLOGICS CO., LTD.

and

CHECKPOINT THERAPEUTICS, INC.

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MASTER SERVICES AGREEMENT

THIS MASTER SERVICES AGREEMENT (this "**MSA**") is made and entered into as of the date of last signature below (the "**Effective Date**") by and between **Checkpoint Therapeutics, Inc.**, a Delaware corporation having its principal place of business at 2 Gansevoort St., 9th Floor, New York, NY 10014 (**"Client"**), and **Samsung BioLogics Co., Ltd.**, a company with offices at 300, Songdo bio-daero, Yeonsu-gu, Incheon, 21987, Republic of Korea (**"SBL"**). Client and SBL are sometimes referred to herein individually as a **"Party"** and collectively as the **"Parties".**

WHEREAS, Client and SBL wish to enter into a business relationship whereby SBL will provide Client with certain biologics manufacturing services;

NOW, THEREFORE, in consideration of the mutual promises, covenants and agreements hereinafter set forth and for other valuable consideration, the Parties agree as follows:

SECTION 1 DEFINITIONS

1.1 "Acceptance Procedure" shall mean the review of the Batch Related Documents and test(s) of the Product, if necessary, to verify that the Product delivered meets the Specifications and complies with Regulatory Authority requirements, conducted by Client after SBL's release of the Product, to determine whether to accept the same, in accordance with the applicable QAG as modified from time to time by written agreement between the Parties.

1.2 "Affected Party" is defined in Section 17.3.

1.3 "Affiliate" shall mean any corporation, company, partnership or other entity which directly or indirectly, controls, is controlled by or is under common control with either Party hereto. A corporation or other entity shall be regarded as controlling another corporation or other entity if it owns or directly or indirectly controls more than fifty percent (50 %) of the voting stock or other ownership interest of the corporation or other entity, or if possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of the corporation or other entity or the power to elect or appoint more than fifty percent (50 %) of the members of the governing body of the corporation or other entity.

1.4 "Applicable Laws" shall mean any and all applicable laws of any jurisdiction which are applicable to any of the Parties in carrying out activities described in this MSA or any PSAs that may be in effect from time to time, and shall include all statutes, enactments, acts of legislature, laws, ordinances, rules, regulations, notifications, guidelines, directions, directives and orders of any Regulatory Authority, statutory authority, stock exchange, securities regulatory agency, tribunal, board, or court or any central or state government or local authority or other governmental entity in such jurisdictions.

1.5 "Background IP" shall mean Intellectual Property which has been owned and/or controlled by a Party prior to the Effective Date or outside, or not relating to, the performance of the MSA and any pertinent PSA.

1.6 "Batch" shall mean Product Manufactured by SBL from a single run of the applicable Manufacturing Process.

1.7 "Batch Record" is defined in the applicable QAG.

1.8 "Batch Related Documents" means Manufacturing Documentation in support of the SBL's release of a Product.

1.9 "Binding Year" shall be defined in the applicable PSA.

1.10 "Business Day" shall mean a day on which commercial banks are open for business in both the Republic of Korea and New York, New York.

1.11 "Cell Line" shall mean the aliquot of cells supplied to SBL by Client to perform the Services and their progeny.

1.12 "Certificate of Analysis" is defined in the applicable QAG.

1.13 "Certificate of Compliance" is defined in the applicable QAG.

1.14 "Change" is defined in Section 6.1.

1.15 "Client" is defined in the preamble.

1.16 "Client Materials" shall mean Client reagents and other materials supplied by Client or its third party supplier to be used in the Service hereunder, as each is further defined in the PSA and/or applicable QAG. In the case of a Drug Product PSA, Client Materials shall also include Drug Substance and/or other active pharmaceutical ingredients, which may or may not be Manufactured by SBL.

1.17 "Client Technology" shall mean know-how, technology, research and other information of Client including and relating to the Manufacturing Process, analytical methods, quality control analysis, specifications, transportation and storage requirements provided by Client to SBL in connection with this MSA and applicable PSA.

1.18 "Clinical Product" shall mean a Drug Substance or Drug Product which is Manufactured by SBL pursuant to a PSA and which is to be used by Client in a research study or studies that investigate the safety of human use or prospectively assign human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.

1.19 "Commercial Product" shall mean a Drug Substance or Drug Product which is Manufactured by SBL which is intended for commercial sale and use by humans and for importation or exportation into countries or regions designated in each PSA.

1.20 "Commercially Reasonable Efforts" shall mean with respect to an activity to be carried out by a Party, the carrying out of such activity in a diligent manner, which, in the case of SBL, requires using the efforts of sufficient numbers of personnel appropriately qualified by experience and training, in the application of such resources as would be reasonably applied by a qualified manufacturer of biologics for human use adhering to recognized standards in the manufacture and testing of such products, or, in the case of Client, using such efforts as would be typically be used in the biopharmaceutical industry by companies of comparable resources and expertise. "Commercially Reasonable Efforts" requires prompt assignment of responsibility for such task or activity to specific qualified employee(s) and allocation of resources designed to advance progress with respect to such task or activity but does not require the taking of actions which would require either Party to violate Applicable Laws or break any existing contractual commitments with third parties which were entered into prior to the Effective Date, the performance of which at such time was not reasonably foreseeable to be in conflict, or otherwise inconsistent, with such Party's obligations under the MSA or any PSA.

1.21 "Common Raw Materials" is defined in Section 5.3.1.

1.22 "Confidential Information" is defined in Section 10.1.

1.23 "Control" (including, with correlative meanings, "Controlled") means possession, directly or indirectly, of power to direct or cause the direction of management or policies (whether through ownership of securities or other ownership interest, by contract or otherwise) of that person or entity and/or the ownership of more than 50% of the voting shares of that person or entity.

1.24 "Core Team" is defined in Section 3.3.

1.25 "current Good Manufacturing Practices" or "cGMP" shall mean current good manufacturing practices and regulations applicable to the Manufacture of Product that are promulgated by any Regulatory Authority, including as promulgated under and in accordance with (i) the U.S. Federal Food, Drug and Cosmetic Act, Title 21 of the U.S. Code of Federal Regulations, Parts 210, 211, 600, 601 and 610, (ii) relevant EU legislation, including European Directive 2003/94/EC or national implementations of that Directive, (iii) relevant guidelines, including the EU Guidelines for Good Manufacturing Practices for Medicinal Products (Eudralex Vol. 4 and Annexes thereto), (iv) International Conference on Harmonisation Good Manufacturing Practice Guide for Active Pharmaceuticals Ingredients and (v) and any analogous set of regulations, guidelines or standards as defined, from time to time, by any relevant Regulatory Authority having jurisdiction over the development, manufacture or commercialization of the Product, as applicable, in each case as in effect as of the date such manufacturing for the Product are or were conducted.

1.26 "Damages" means any damages, costs, expenses, fines, penalties (including reasonable attorneys' fees and costs), losses and liabilities.

1.27 "Disclosing Party" is defined in Section 10.1.

1.28 "Drug Product" means a finished or intermediate dosage form that contains a Drug Substance, generally, but not necessarily, in association with one or more other ingredients.

1.29 "Drug Substance" means an active ingredient that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the human body, but does not include intermediates used in the synthesis of such ingredient.

1.30 "Effective Date" is defined in the preamble.

1.31 "EMA" shall mean the European Medicines Agency, or any successor agency.

1.32 "Engineering Batch" shall mean a Batch that is intended to demonstrate the transfer of the Manufacturing Process to the Facility. After Manufacture, Client shall have the right to make whatever further use of non-cGMP Engineering Batches as it shall determine, provided that Client pays for such Batches according to this MSA, such use is not for human use and does not violate any Applicable Laws. SBL makes no warranty that Engineering Batches will meet cGMP or the Specifications. If SBL determines that an Engineering Batch does meet cGMP and the Specifications, it will release such Engineering Batch as a cGMP Batch, and thereafter Client shall be entitled to use such Engineering Batch for human use.

1.33 "Facility" shall mean one or more of the manufacturing facilities of SBL where the Services shall be performed, located at 300, Songdo bio-daero, Yeonsu-gu, Incheon, 21987, Republic of Korea.

1.34 "FDA" shall mean the United States Food and Drug Administration or any successor agency thereto.

1.35 "Firm Period" shall be defined in the applicable PSA.

1.36 "Force Majeure Event" is defined in Section 17.3.

1.37 "Implementation Plan and Budget" is defined in Section 6.2(b).

1.38 "Indemnified Party" is defined in Section 13.3.

1.39 "Indemnifying Party" is defined in Section 13.3.

1.40 "Intellectual Property" is shall mean (a) patents, patent rights, provisional patent applications, patent applications, designs, registered designs, registered design applications, industrial designs, industrial design applications and industrial design registrations, including any and all divisions, continuations, continuations-in-part, extensions, restorations, substitutions, renewals, registrations, revalidations, reexaminations, reissues or additions, including supplementary certificates of protection, of or to any of the foregoing items; (b) copyrights, copyright registrations, copyright applications, original works of authorship fixed in any tangible medium of expression, including literary works (including all forms and types of computer software, including all source code, object code, firmware, development tools, files, records and data, and all documentation related to any of the foregoing), pictorial and graphic works; (c) trade secrets, technology, developments, discoveries and improvements, know-how, proprietary rights, formulae, confidential and proprietary information, technical information, techniques, inventions, designs, drawings, procedures, processes, models, formulations, manuals and systems, whether or not patentable or copyrightable, including all biological, chemical, biochemical, toxicological, pharmacological and metabolic material and information and data relating thereto and formulation, clinical, analytical and stability information and data which have actual or potential commercial value and are not available in the public domain; (d) trademarks, trademark registrations, trademark applications, service marks, service mark registrations, service mark applications, business marks, brand names, trade names, trade dress, names, logos and slogans, Internet domain names, and all goodwill associated therewith; and (e) all other intellectual property or proprietary rights, in each case whether or not subject to statutory registration or protection.

1.41 "Joint Steering Committee" or "JSC" is defined in Section 3.2.1.

1.42 "Manufacturing" or to "Manufacture" shall mean the manufacturing of the Product, and any services relating to such manufacturing, including, but not limited to, testing, quality control, documentations, archiving, handling, storage and packaging, release and delivery of the Product, to be performed by SBL at the Facility under the MSA and any applicable PSA.

1.43 "Manufacturing Documentation" shall mean data acquired and generated, documents and records describing or otherwise related to the Manufacturing Process including, without limitation: documents and records consisting of or containing process descriptions, requirements and specifications; Client Materials and Specifications; analytical methods, process trend and variability data; validations protocols and reports; process development reports; Batch Records; Batch Related Documents, and SOPs, including, without limitation, SOP's for the Raw Materials handling, the Manufacturing operations, equipment operation, in-process, final Product and stability quality control testing, quality assurance, validation, storage and shipping.

1.44 "Manufacturing Process" shall mean the mutually agreed production process and analytical methods for the Manufacturing of the Product pursuant to the applicable PSA, as summarily described in the applicable QAG and as described in the Manufacturing Documentation, as such process may be changed from time to time in accordance with the MSA.

1.45 "Manufacturing Process Transfer" means the Commercially Reasonable Efforts of the parties undertaken pursuant to the Manufacturing Process Transfer Plan to transfer the Manufacturing Process (together with copies of relevant books and records) in SBL's possession or under its control, to Client as set forth in greater detail in the Manufacturing Process Transfer Plan. SBL shall only be obligated to use its Commercially Reasonable Efforts in the implementation of the Manufacturing Transfer Plan, and in no case shall SBL personnel be required to visit the site of Client or any third party manufacturer. For the avoidance of doubt, the foregoing prohibition shall not be construed as a basis for SBL refusing to assist in the transfer of analytical methods to an independent laboratory, including a visit by SBL personnel to such site to assist in method transfer, if, and only as, reasonably necessary, and at Client's cost and expense. For the avoidance of doubt, Manufacturing Process Transfer shall include, without limitation, the transfer of data, information, or samples of validated or SBL manufactured or partially manufactured Products or other indicia measured at various points during Manufacture, to the extent SBL possesses such data, information, or samples. SBL shall not be obligated to deliver the proprietary process information contained in any drug master file with respect to which SBL has granted Client a right of reference. SBL shall provide Manufacturing Process Transfer services with a capacity of one (1) full time employee equivalent ("FTE") month for each of upstream, downstream and analytics, for a total maximum of three (3) FTE months. SBL will have no obligation to provide Manufacturing Process Transfer services more than twelve (12) months after termination of the MSA or applicable PSA. For clarity, SBL's assistance shall be time-based, and SBL shall in no way guarantee or ensure that after Manufacturing Process Transfer services is complete, Client or its third-party manufacturer will be able to manufacture the Product.

1.46 "Manufacturing Process Transfer Plan" means that plan addressing orderly Manufacturing Process Transfer, to be prepared in writing and reasonably agreed to by the parties within the forty (40) Business Day period following notice from Client to SBL of its intention to commence Manufacturing Process Transfer.

1.47 "Non-Affected Party" is defined in Section 17.3.

1.48 "Non-Conforming Product" shall mean an entire Batch of Product, any portion of which fails to conform to the Specifications, cGMP (if applicable), and any other mutually agreed upon written express requirements for SBL to follow under the applicable PSA and the applicable QAG.

1.49 "Party" and "Parties" is defined in the preamble.

1.50 "Pilot Batch" means a Batch of Product designated as a pilot Batch which shall not comply with cGMP and is not required to meet the Specifications.

1.51 "Pre-Approval Inspection" means an on-site inspection of the Facility by the Regulatory Authority prior to granting the Regulatory Approval for a Commercial Product as required by various Regulatory Authorities to ensure that the Manufacturing Process and the Facility meet the appropriate requirements and comply with cGMP.

1.52 "Process Validation Batch" shall mean a Batch of Commercial Product produced from a process validation run conducted by SBL hereunder to (i) demonstrate and document the consistency and reproducibility of the Manufacturing Process at the Facility, and (ii) support the Regulatory Approval of both the Product Manufactured and the Manufacturing Process at the Facility each as defined in the Project Plan.

1.53 "Product" shall mean Clinical Product or Commercial Product to be Manufactured by SBL pursuant to this MSA and any applicable PSA.

1.54 "Product Purchase Commitment" is defined in Section 5.7.

1.55 "Product specific agreement" or "PSA" is defined in Section 2.1.

1.56 "Project Management Team Leader" is defined in Section 3.3.2.

1.57 "Project Plan" shall mean a formal, approved document used to guide both project execution and project control. The primary uses of the Project Plan are to document planning assumptions and decisions, facilitate communication among project stakeholders, and document approved scope, cost, and schedule baselines. The Project Plan will contain the description and overall objectives of the Services for Manufacturing a Product and shall include, among other things: (a) JSC and Core Team membership rosters, (b) change request procedures, (c) details, intentions, and deliverables for Technology Transfer, (d) project schedule, (e) detailed procurement plan, as needed, and (f) project budgets and invoicing plans.

1.58 "PSA Effective Date" shall mean the effective date of any PSA governed by this MSA.

1.59 "Purchase Order" is defined in Section 5.6.

1.60 "Quality Agreement" or "QAG" shall mean that certain quality agreement between the Parties that governs their respective responsibilities related to quality systems and quality requirements for the Product(s) Manufactured hereunder, including quality control, testing and release of such Product(s) at the Facility. Clinical Products and Commercial Products shall have separate forms of QAGs.

1.61 "Quarter" means each period of three (3) consecutive calendar months beginning on January 1, April 1, July 1, or October 1.

1.62 "Raw Materials" shall mean those materials that are used in the Manufacturing Process, including, but not limited to, chemicals, reagents, filters, excipients, disposable consumables, and secondary packaging materials. Raw Materials exclude the Client Materials.

1.63 "Receiving Party" is defined in Section 10.1.

1.64 "Reference Standards" shall mean materials for standards prepared by Client and/or SBL in accordance with the applicable QAG.

1.65 "Regulatory Approval" shall mean all approvals, licenses, registrations or authorizations thereof of any national, regional, state or local regulatory agency, department, bureau or other governmental entity in any jurisdiction where the Product is marketed or intended to be marketed, necessary for the manufacture and sale of the Product, which manufacturing includes the Manufacturing of the Products at the Facility.

1.66 "Regulatory Authority" shall mean any national (e.g., the FDA), supra-national (e.g., the EMA), regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity, in any jurisdiction responsible for granting the Regulatory Approval.

1.67 "SBL Assignable Error" means:
[*].

1.68 "Service" or "Services" is defined in Section 2.1.

1.69 "Service Fee" is defined in Section 9.1.

1.70 "Specialized Raw Materials" is defined in Section 5.3.1.

1.71 "Specification(s)" shall mean the observable and measurable characteristics of the Products, Client Materials, or Raw Materials, as the case maybe, and the criteria for their storage, handling, packaging and shipping, which details are provided in documentation as reviewed and approved in writing by the Parties.

1.72 "Standard Operating Procedure(s)" or "SOP(s)" shall mean the standard operating procedures established by and mutually agreed upon by both Parties regarding the Manufacturing Process.

1.73 "Technology Transfer" shall mean the activities by the Parties necessary to Manufacture the Product for Client at the Facility or otherwise conduct the Services, as further described in the applicable PSA and/or Project Plan which may include: (i) transfer of the Client Technology and Client Material from Client to SBL; (ii) implementation of the Manufacturing Process at the Facility, including establishing a small scale Manufacturing Process model at SBL; (iii) all Manufacturing Process fit activities, including required small- and large-scale process development and validation work as allocated between the Parties to SBL and process engineering required to modify / equip, qualify and validate the Facility for the Manufacturing of the Commercial Product; (iv) stability testing, if applicable, for the Product required for licensure; (v) comparability testing to the appropriate reference product, and (vi) regulatory support for all Regulatory Approvals, each as further described in the Project Plan.

1.74 "Term" is defined in Section 15.1.

1.75 "Warehouse" shall mean SBL's warehouse for storage of the Product located at 300, Songdo bio-daero, Yeonsu-gu, Incheon, 21987, Republic of Korea.

SECTION 2 RELATED AGREEMENTS AND EXHIBITS

2.1 **Product specific agreements.** Pursuant to one or more product specific agreements entered into and mutually agreed from time to time by duly authorized representatives of the Parties (**"Product specific agreements" or "PSAs"**), SBL will perform manufacturing services for Client as specified in such PSAs and applicable Project Plan and in accordance with the terms and conditions of this MSA (**"Services"**). Each PSA shall refer to this MSA and contain as applicable (i) a high level scope of work of the Services to be performed under such PSA which describes key activities, (ii) the Product for which Samsung will perform such Services for Client, (iii) a description of the Cell Line; (iv) fees to be paid to SBL by Client for the Services with a general timing plan for invoicing and a more detailed plan to be in the Project Plan, (v) if the Services pertain to the manufacture of the Product, the number of batches of Product to be manufactured by SBL and delivered to Client and the Specifications, (vi) any other deliverables, (vii) the Samsung facility where the Services are to be performed, and (viii) the Regulatory Approvals to be obtained by the Parties. Services shall be governed by the terms and conditions of this MSA, the applicable PSA, and any applicable Quality Agreement. In the event of a conflict between a Quality Agreement and either any provision of this MSA or any PSA, the MSA or PSA shall control except with respect to Product quality terms, in which case, the Quality Agreement will control. In the event of a conflict between any provision of this MSA and the PSA, this MSA shall control, except as otherwise explicitly specified in the PSA.

2.2 **Project Plan.** Concurrently with the execution of a PSA or within a reasonable time after the PSA effective date, the Parties shall agree upon a Project Plan which will specify in detail scope and schedule of the Services, including Technology Transfer and Manufacture. The Project Plan shall also set forth the JSC members (if applicable), Core Team members, and Project Management Team Leader for the Services as well as the frequency and duration of meetings. The Project Plan may be updated as needed by the mutual agreement of the Client and SBL and is governed by and incorporated into the applicable PSA by reference. If there is a conflict between the Project Plan and the applicable PSA, the PSA shall control. If any of the assumptions shared in writing by the Parties and on which the Parties have relied in defining the scope of the activities required to effect the Technology Transfer and/or other Services including but not limited to Manufacture, and the associated timeframes, fees, expenditures and costs proves to be invalid, or if for any reason other than a Party's negligence in planning, it becomes apparent that additional activities are required as part of or in connection with the Technology Transfer and/or other Services including but not limited to Manufacture, the Parties shall (acting reasonably and in good faith) discuss and seek to agree appropriate revisions to the Technology Transfer activities, and associated timelines and pricing.

2.3 **Quality Agreement (QAG).** The Parties shall agree upon and finalize a Quality Agreement in good faith within a reasonable period time after each PSA Effective Date which shall cover such PSA. No Manufacturing of Products for human use shall be conducted without an agreed upon, applicable QAG.

Clinical Products and Commercial Products shall have separate QAGs. The Quality Agreement may be amended from time to time, subject to the JSC's approval followed by the Parties' written agreement pursuant to Section 17.9 (if applicable), which is incorporated herein by reference.

SECTION 3 MANAGEMENT OF SERVICE

3.1 **General.** Each Party will be responsible for its internal decision making process and for reasonably informing the other Party of decisions affecting the Service in a regular and timely manner. Without limiting the foregoing, the Parties shall establish the joint committees or teams set forth herein to advise the Parties on certain matters including, without limitation, Facility modification, Technology Transfer, and optimization of the Manufacturing operation relating to the Product.

3.2 Joint Steering Committee.

3.2.1 **Formation and Composition.** The applicable Project Plan will set forth a Joint Steering Committee for that Product (the "**Joint Steering Committee**" or "**JSC**") if the Parties mutually agree that such JSC is necessary. The JSC will be a cross-functional committee composed of an equal number of representatives appointed by each of Client and SBL with each of Client and SBL having at least three (3) representatives, and with one (1) representative from each of Client and SBL having oversight for quality activities, and with one (1) representative from each of Client and SBL having oversight for manufacturing and supply chain activities, including the transfer and implementation of the Manufacturing Process at the Facility. Either Party may replace any or all of its representatives at any time. Such Party shall notify, in writing, of such replacement to the other Party.

3.2.2 **Responsibilities.** The JSC shall (i) establish and oversee the governance structure for the Service including the formation of any subcommittee hereunder; (ii) monitor any Facility modification and the Technology Transfer and Manufacturing strategy of the Product at the Facility, including strategies for the Regulatory Approval of the Facility to Manufacture the Product; (iii) provide strategic guidance to the Core Team as required by the Project Plan; (iv) conduct high level project stage reviews with the Core Team as required by the Project Plan at appropriate milestones or completion of key deliverables or a sequence of event to review and approve key deliverables, evaluate the Core Team's progress and performance, all in order to ensure that the Manufacturing Process is being implemented appropriately; (v) advise on and/or resolve business, manufacturing, supply chain, quality, regulatory or other issues unresolved at the Core Team level; (vi) review and recommend for approval by the Parties any changes to the MSA or the applicable PSA; (vii) review and approve changes to the Specifications, analytical methods, the Manufacturing Process, the Facility or equipment as escalated to the JSC by the Core Team or by a Party pursuant to Section 3.6 below; (viii) review completion of the Service; (ix) settle disputes or disagreements unresolved by a subcommittee; and (x) perform such other functions as appropriate to further the purposes of the MSA as determined by the Parties. For the avoidance of doubt, the JSC shall be a reviewing and consultative body, without authority to make decisions not otherwise concurred in by the Parties.

3.3 Core Team.

3.3.1 **Formation and Composition.** The applicable Project Plan will set forth a Core Team for that Product (the " **Core Team**"). The Core Team shall be composed of an equal number of representatives from each of SBL and Client, with up to four (4) representatives appointed by each of Client and SBL. Such representatives will include the Project Management Team Leaders of Client and SBL as well as such of their representatives from manufacturing, technical operations, supply chain, quality assurance, quality control, regulatory affairs or other individuals with expertise and responsibilities for those functions required from time-to-time to execute the Facility modification, the Technology Transfer and Manufacturing. Either Party may replace any or all of its representatives at any time. Such Party shall notify, in writing, of such replacement to the other Party.

3.3.2 **Appointment of Project Management Team Leader.** Each Party shall appoint a Project Management Team Leader (each, a "**Project Management Team Leader**") to act as the primary contact for such Party in connection with matters related to the Service. Each Project Management Team Leader, unless otherwise mutually agreed, shall serve as the leaders of the Core Team. A Party may replace its Project Management Team Leader at any time and from time to time for any reason. Such Party shall notify, in writing, of such replacement to the other Party.

3.3.3 **Responsibilities.** The Core Team shall (i) develop and maintain the Project Plan and monitor, review and manage the Service according to the MSA and applicable PSA; (ii) conduct project stage reviews with the JSC as required by the Project Plan at appropriate milestones or completion of key deliverables or a sequence of event to review key deliverables, review its progress and performance against plans; (iii) develop a change management process to identify, review and recommend any significant changes in the project scope, time, fee or risk to the JSC; (iv) investigate and resolve business, manufacturing, supply chain, quality, regulatory or other issues arising during the Service; (v) review and escalate to the JSC, as needed, changes to the Project Plan or applicable QAG; (vi) review and recommend to the JSC changes to the Specifications, analytical methods, the Manufacturing Process, the Facility or equipment; (vii) coordinate the activities of the Parties relating to the Manufacturing hereunder, including but not limited to: managing the technical operations and quality aspects of routine manufacturing, conducting Product testing technical operations and quality aspects of routine manufacturing, conducting Product testing and release, and managing supply chain activities including shipping and delivery logistics; (viii) report periodically on operation and quality progress and performance; and (ix) perform such other tasks and undertake such other responsibilities as may be specifically delegate to the Core Team by mutual agreement of the Parties. For the avoidance of doubt, the Core Team shall be without authority to make decisions not otherwise concurred in by the Parties.

3.4 Meetings

3.4.1 **JSC.** The JSC shall meet by audio or video teleconference or in-person as agreed by the JSC or as necessary to make determinations as required of it. Any member of the JSC may designate a substitute to attend and perform the functions of that member at any meeting of the JSC and each Party may, in its reasonable discretion, invite non-member representatives of such Party to attend such meeting with advance notice to the other Party; provided, however, such non-member representatives are subject to enforceable obligations of confidentiality to the inviting Party.

3.4.2 **Core Team.** The Core Team shall meet by audio or video teleconference or in-person as agreed by the Core Team. Any member of the Core Team may designate a substitute to attend and perform the functions of that member at any meeting of the Core Team and each Party may, in its reasonable discretion, invite non-member representatives of such Party to attend such meetings with advance notice to the other Party; provided, however, such non-member representatives are subject to enforceable obligations of confidentiality to the inviting Party.

3.4.3 Travel **Expenses.** Each Party shall be responsible for all of its own expenses of traveling to and participating in any joint committee or team meeting, including the JSC and Core Team.

3.5 **Decisions.** All decisions of JSC, the Core Team and any other joint committee or team formed under the MSA or any applicable PSA, except as expressly set forth herein, shall be made by the unanimous agreement of its members or their designated representatives, with a Party's members of designated representatives having, in the aggregate, one (1) vote (with the casting of fractional votes being impermissible), and shall be reflected in written meeting minutes which summarily address topics discussed, delegation of work, schedules and decision of such committee or team. SBL shall prepare written minutes of the JSC and Core Team within fifteen (15) Business Days of the meeting to which they relate, which shall be subject to approval by the authorized representatives of the Parties; provided, however, no joint committee or team herein may amend or waive any provision of the MSA or applicable PSA, including without limitation, the financial terms set forth in Section 9. The MSA or any PSA may be amended, and provision of the MSA or any PSA may be waived, pursuant to Section 17.9 only.

3.6 Disputes.

3.6.1 **General.** In the event that the Core Team and any other joint committee or team formed under the MSA or any applicable PSA, is unable, despite the good faith efforts of all members, to resolve a disputed issue that is within the purview of such joint committee or team within ten (10) Business Days of meeting request by either Party, the disputed issue shall be referred immediately by such joint committee or team to the JSC. If the disputes still cannot be resolved within an additional twenty (20) Business Days of meeting request by the JSC, the matter may be handled in accordance with Section 16.

3.6.2 Project **Management Team Leaders.** Subject to Section 3.6.1, the Project Management Team Leaders (or their respective designees) will in good faith attempt to mutually resolve in a

timely fashion any disagreement with respect to the Service hereunder, which could reasonably affect the quality of the Manufacturing of the Product, including without limitation, the related management processes and operations, control of production planning and scheduling, prioritization decisions, allocation of resources, timing of in-process and release testing, oversight of auxiliary facilities (e.g., in-process tests that need to be conducted at laboratories other than those at the Facility), Facility modification, the Technology Transfer, registration and troubleshooting decisions, and any other matters relating to implementation of the Manufacturing Process and the Manufacturing of the Product hereunder.

SECTION 4 SERVICES

4.1 **Services.** During the Term, in accordance with and subject to the terms and conditions set forth in this MSA, applicable PSA, and the applicable QAG, SBL shall provide the Services to Client relating to the Product(s). SBL shall at all times make Commercially Reasonable Efforts to complete the Services in accordance with the timelines set forth in the applicable PSA. Except as otherwise expressly set forth in the MSA, applicable PSA, or the applicable QAG or as otherwise mutually agreed in writing by the Parties, SBL shall be responsible at its own cost and discretion for operating and maintaining the Facility.

4.2 **Compliance with Applicable Law.** Subject to the provisions of Section 6 below, SBL shall maintain the Facility in accordance with cGMP and in such condition as will allow SBL to Manufacture the Products in accordance with the terms of the MSA and the applicable QAG. SBL shall perform the Services under the MSA in conformance with cGMP, if applicable, any requirements of the Regulatory Authorities that shall be mutually agreed upon by the Parties, and all Applicable Laws.

4.3 **Project Personnel.** SBL shall adequately staff the Facility with personnel necessary (including consultants and contractors), who have sufficient technical expertise by virtue of training and experience to perform its obligations under the MSA and any applicable PSA. Notwithstanding anything to the contrary and in addition to the JSC and Core Team meetings described in Section 3 above, Client and SBL may arrange for core project personnel to have regular meetings, which shall be by audio or video teleconference. The Project Plan shall specify the frequency and duration of such meetings; provided that the associated costs for meetings requested solely by Client in excess of the number set forth in the Project Plan shall be passed through to Client by SBL, unless such meeting is for the purpose of addressing a deficiency in Manufacturing caused by SBL Assignable Error or assessing remediation thereof.

4.4 **Subcontract.** SBL may subcontract any portion of the Services without approval from Client; provided, however, that SBL will not subcontract or otherwise engage subcontractors or other third party agents to manufacture, conduct quality control testing, or perform Services directly related to manufacturing or quality control testing without the prior written approval of Client, which shall not be unreasonably withheld, conditioned, or delayed. Notwithstanding any subcontracting, SBL shall be primarily obligated to Client for any subcontracted services as if it were providing the Services itself, and shall be jointly and severally liable to Client for the performance of any such Service. The preceding sentence is not meant to nor shall it be construed as altering or eliminating any mutually agreed upon limitations of

liability contained within this MSA or any applicable PSA. Every subcontractor or other third party agent of SBL performing pursuant to this Section 4.4 shall be required by SBL to agree in writing to comply with relevant portions of this MSA, together with pertinent PSAs and QAGs. For the avoidance of doubt, SBL shall not directly or indirectly use on its own behalf or through any subcontractor, other vendor or any third party in the performance of this MSA or any PSA, any invention, technology, data or information that would require Client to obtain a license from SBL not otherwise granted pursuant to this MSA or an applicable PSA, or obtain a license from any such subcontractor, vendor or third party a license in order to make, have, made, use, offer for sell, sell, import or otherwise exploit any Product, unless Client has agreed in advance in writing.

4.5 **Development and Manufacturing Site.** Except as is provided in Section 4.4 or otherwise agreed by Client, all Services shall be performed by SBL at the Facility.

4.6 Access to the Facility.

4.6.1 SBL shall accommodate visits by Client personnel in the Facility during operational hours during the Term, upon Client's request, to coordinate, expedite and guide the Service. Client will provide SBL with written notice at least one (1) month prior to any visit, and the Parties shall decide on a mutually agreeable date, duration, visitor list, and agenda prior to the visit. Additionally, Client may, at no cost to SBL, request up to two (2) of its personnel to be on-site at the Facility to observe and consult with SBL during the performance of Services under this MSA and such additional personnel in such numbers as deemed necessary by Client shall be accommodated upon mutual agreement. SBL shall make reasonable efforts to provide such Client personnel working space and access to guest wireless connections. All applicable out-of-pocket expenses associated with such on-site Client personnel shall be passed through to Client by SBL.

4.6.2 While at the Facility, all such Client personnel shall have reasonable access to all areas as are relevant to SBL's performance of the Service hereunder, provided that SBL may reasonably restrict Client personnel's access to those portions of the Facility as it deems reasonably necessary for safety, confidentiality and cGMP, and visitors admitted pursuant to this Section, upon request of SBL, shall comply with SBL policies and procedures as they apply to SBL personnel generally while at the Facility.

4.7 **Manufacturing Documentation**. SBL shall maintain in the English language, complete, true and accurate Manufacturing Documentation, and shall keep them in strict confidence and shall not use them for purposes other than providing or performing the Service or other obligations hereunder. SBL shall maintain all such Manufacturing Documentation for at least that period specified in the applicable QAG or such longer period as may be required by Applicable Law. Upon written request of Client and at mutually agreeable times, Client shall have the right to review Manufacturing Documentation, including the Batch Records, at the Facility as further defined in the applicable QAG; provided, however, SBL shall not delay any such request of Client for more than fifteen (15) Business Days. Client may also request scanned or printed copies of such Manufacturing Documentation, but shall be responsible for reasonable costs associated therewith. SBL shall record and maintain such records, data, documentation

and other information in the language as so required in the applicable QAG or as so required by a Regulatory Authority and in compliance with Applicable Law, or as otherwise may be set forth in an applicable PSA. The form and style of Batch documents, including, but not limited to, Batch production records, lot packaging records, equipment set up control, operating parameters, and data printouts, raw material data, and laboratory notebooks are the exclusive property of SBL. Notwithstanding anything to the contrary, SBL SOPs not specific to the Client's Products may be provided to Client for on-site review if deemed necessary by both SBL and Client. Such SOPs cannot be removed from the SBL premises, copied, photographed or otherwise replicated, but to the extent required for filing in connection with any Regulatory Approval related to a Product including, but not limited to, an IND, BLA or MAA, SBL will file, maintain and update such SOPs with appropriate Regulatory Authorities by means of a Drug Master File, Common Technical Document or other means by which such SOPs may remain confidential, but available by reference to Client to effect Regulatory Approvals, and SBL shall formally authorize such reference.

SECTION 5 SERVICE DESCRIPTIONS

5.1 **Technology Transfer Requirements.** The Parties shall make their personnel available at the Facility to enable the transfer and implementation in accordance with the Project Plan. Client shall transfer to and grant SBL the limited license set forth below in Section 11.2 in respect of the Reference Standards, Client Technology, Client Materials, and Cell Line In the event that Client agrees to utilize SBL's [*] portal for Technology Transfer, Client agrees that (a) in the event of any relevant change that affects a Client user's authorization to use such portal, Client shall promptly notify SBL so that SBL may disable their usernames and remove / change passwords in order to secure the SBL Portal and (b) Client shall ensure that all of Client's users have up-to-date antivirus software installed on the computer devices used to access such portal.

5.2 **Facility Modification and Equipment.** Except as otherwise specifically provided herein to the contrary, and upon mutual agreement of the Parties, Client and SBL will agree on what equipment in the Facility is necessary to perform the Services, and if it is necessary or Client deems it necessary to procure additional equipment beyond that which is in the Facility as of the applicable PSA Effective Date, the Core Team shall determine equitable allocation of costs including, as applicable, procurement, validation, installation, maintenance, commissioning, and decommissioning/validation (which determination shall be escalated to the JSC if in dispute). Thereafter, if any additional equipment is necessary at the request of Client, such costs shall be dealt with by the Change provisions of this MSA. SBL shall modify the Facility and engineer, procure, install, commission, test, qualify, troubleshoot and validate necessary equipment and instruments in order to accommodate Manufacture of the Product at the Facility, as further described in the Project Plan and applicable QAG. Except as provided in this Section 5.2 or any applicable PSA, the Facility, Warehouse and all the equipment shall be maintained, tested, validated, calibrated and qualified for their intended uses by SBL at SBL's expense. For the avoidance of doubt, it shall be the responsibility of SBL to effect such changes at the Facility including, but not limited to changes in equipment, as are required by changes in laws, rules or regulations related to the manufacture, handling, storage, packaging and disposal of biologics generally, compliance therewith being necessary in order for SBL to hold itself out as a qualified manufacturer of biologics for

human use. It shall be the responsibility of SBL to obtain, maintain and pay all costs associated with establishment licenses required for the Facility, the Warehouse and any other facilities used by SBL in the performance of its obligations under this MSA and any applicable PSA.

5.3 Raw Materials.

5.3.1 **Management**. SBL shall procure and maintain a reasonable quantity of the Raw Materials, required for the Services in accordance with the MSA and any applicable PSA, as further described in the applicable QAG. On a per-Product basis, the Core Team shall finalize the categorization of the Raw Materials into Raw Materials which shall be used for that specific Product only ("**Specialized Raw Materials**"), Raw Materials which can be used across multiple products and/or customers ("**Common Raw Materials**"), and Raw Materials which will not be charged on a cost- plus basis to the Client, and shall attach such list to the applicable PSA. Such list of Common Raw Materials and Specialized Raw Materials may be amended from time to time, subject to the Parties' approval. Prior to the commencement of Manufacture, the Core Team shall agree on estimates for quantities of Raw Materials anticipated to be consumed in the Manufacture of each Batch. Although SBL will make Commercially Reasonable Efforts to use no more than those amounts, SBL will not be responsible for Raw Materials used in excess of the agreed-upon estimate; provided, however, that SBL shall be responsible for any such excessive use, loss, spoilage, or waste of such Raw Materials caused by an SBL Assignable Error. In order to become effective, SBL's reasonable strategies regarding Raw Material safety stock and sourcing from qualified vendors shall be agreed upon by Client. In the event SBL is not able to utilize any capacity reserved to Manufacture Product according to an agreed-upon forecast or manufacturing plan due to Client's failure to agree to such reasonable strategies, then Client shall be responsible for the costs of such reserved capacity regardless of whether it is utilized or not.

5.3.2 **Data Transfer**. Client and SBL shall agree on the Specifications for the Raw Materials, including without limitation analytical methods, supplier information including supplier site information, and other information concerning the stability, storage, and safety thereof that are available and required for the Manufacturing hereunder, as further described in the applicable QAG.

5.3.3 **Testing and Evaluation**. SBL or vendors qualified by SBL shall perform all testing and evaluation of the Raw Materials as required by the Specifications for the Raw Materials and the cGMPs, as further described in the applicable QAG, if applicable. SBL shall not release any Raw Materials from quarantine that do not meet their Specifications or are not otherwise suitable for cGMP use.

5.3.4 **Storage.** SBL shall secure sufficient and suitable cGMP storage facilities and/or equipment at the Facility that meet the Specifications for storage of the Raw Materials. SBL shall preserve and protect the Raw Materials from loss and damage while in SBL's possession, consistent with reasonable technical and business judgment, the Specifications and any relevant SOPs or other instructions provided by Client; provided however, SBL shall be responsible [*] and [*] only in cases of SBL Assignable Error or breach of this Section 5.3.4. In all other cases, Client shall be

responsible for the risk of loss of the Raw Materials. Upon obsolescence, or upon expiration or earlier termination of a PSA, Client shall be responsible for the loss of Raw Material purchased in reliance on a Purchase Order, Firm Period, or Binding Year which Client fails to honor and SBL cannot reasonably otherwise utilize such Raw Material.

5.3.5 **Service Fee Related to Raw Material.** Common Raw Materials and Specialized Raw Materials will be charged on a cost-plus basis to Client in accordance with Sections 9.1(ii) and 9.2.2, subject to any changes in the scope of work.

5.4 Client Materials.

5.4.1 **Management.** Client shall provide to SBL free of charge, either by itself or through its third party supplier, Client Materials in amounts reasonably necessary to carry out the Services as agreed by the Parties. The applicable PSA shall set forth the exact timing of such provision of Client Materials to SBL. SBL shall make Commercially Reasonable Efforts to import the Client Materials to the Republic of Korea in a timely manner, provided that Client provides reasonable assistance. The title to such Client Materials shall remain at all times with the Client. Prior to the commencement of Manufacture, the Core Team shall agree on estimates of quantities for Client Material anticipated to be consumed in the Manufacture of each Batch. Although SBL will make Commercially Reasonable Efforts to use no more than those amounts, SBL will not be responsible for Client Materials used in excess of the agreed-upon estimate; provided, however, that SBL shall be responsible for [*] caused by an SBL Assignable Error, and further provided that SBL shall not be liable for the monetary value of [*], as reasonably agreed to by the Parties and set forth in the Quality Agreement. In order to become effective, SBL's reasonable strategies regarding Client Material safety stock and sourcing from qualified vendors shall be agreed to by Client. In the event SBL is not able to utilize any capacity reserved to Manufacture Product according to an agreed- upon forecast or manufacturing plan due to Client's failure to agree to such reasonable strategies, then Client shall be responsible for the costs of such reserved capacity regardless of whether it is utilized or not.

5.4.2 **Data Transfer.** Client shall provide SBL with the Specifications of the Client Materials, including without limitation analytical methods, supplier information, and other information concerning the stability, storage, and safety thereof that are available and required for the Manufacturing hereunder, as further described in the applicable QAG.

5.4.3 **Testing and Evaluation.** SBL shall perform testing of the Client Materials in accordance with the applicable QAG and/or Client's instruction prior to the performance of the Manufacturing hereunder, in order to determine whether such Client Materials meet the Specification described in the applicable QAG (if applicable). SBL shall inform Client of (a) any damage to the Client Materials received that is visually obvious (e.g., damaged or punctured containers and temperature monitoring results outside of predetermined Specifications) within [*] Business Days after SBL's receipt of the Client Materials and (b) any non-conformance of the Client Materials to Specification either: (i) [*] after SBL's receipt of the Client Materials or (ii) if release testing of Client Materials

is not to be performed until it is needed for Manufacture, within sixty (60) calendar days after such release testing is performed; or (iii) as is otherwise agreed between the Parties. If, prior to performing any Service on the Client Materials, SBL determines that such Client Materials are defective or damaged, SBL shall not perform the Service on such Client Materials and shall follow Client's written instructions regarding disposal or return of such Client materials to Client, such disposal or return to be at Client's discretion and cost.

5.4.4 **Storage.** SBL shall secure sufficient and suitable cGMP storage facilities and/or equipment at the Facility that meet the Specifications for storage of reasonable quantities of Client Materials in light of quantities of Product anticipated to be Manufactured. SBL shall preserve and protect the Client Materials from loss and damage while in SBL's possession, consistent with reasonable technical and business judgment, the Specifications and any relevant SOPs or other instructions provided by Client; provided that SBL shall only be liable for loss and damage after [*] and [*] or breach of this Section 5.4.4. In all other cases, Client shall be responsible for the risk of loss of the Client Materials.

5.4.5 **Service Fee Related to Client Material.** Handling fees relating to the Client Material will be charged to Client in accordance with Sections 9.1(iii) and 9.2.3.

5.5 **Forecasts.** For each Commercial Product, the Parties shall determine a mutually agreeable mechanism for forecasting of each Product, which shall be detailed in writing and attached to each relevant PSA. For Clinical Product, the Parties shall agree upon the number and schedule of Batches to be Manufactured by SBL in the applicable PSA.

5.6 **Purchase Orders.** For each Clinical Product or Commercial Product, Client shall notify SBL in a binding form and procedure to be agreed upon in the applicable PSA requesting a specific amount of Product to be Manufactured (a "**Purchase Order**").

5.7 **Product Purchase Commitment.** As further set forth in a PSA, during the Term the Parties may agree that Client will purchase a minimum quantity of batches of a certain Product in a given year (a "**Product Purchase Commitment**").

5.8 Batch Failure during Manufacture

5.8.1 If, during Manufacture of a Batch and prior to SBL's Batch release, the Core Team determines that a Batch is Non-Conforming Product (a "**Batch Failure**"), [*]. Client shall be responsible for the costs and fees of the Raw Materials and Client Materials for the replacement Batch as if it were the failed Batch (*i.e.,* Client shall only be invoiced the applicable cost of the Raw

Materials and Client Materials actually used to Manufacture the conforming, cGMP compliant replacement Batch). Client shall use Commercially Reasonable Efforts to ensure that SBL has adequate Client Materials to Manufacture such Batches and Client's failure to provide such Client Materials shall relieve SBL of its obligations to provide a remedy pursuant to this Section 5.8. The remedies contained in Section 5.8 of this MSA shall be the sole and exclusive remedies of Client regarding a Batch Failure and a Batch Failure shall not constitute a material breach of this MSA or a PSA unless SBL fails to provide the remedies contained in this Section 5.8.

5.8.2 The Parties shall conduct a root cause analysis (including an analysis of whether the Batch Failure was the fault of SBL, Client, neither or both) of the Batch Failure, which shall be done through SBL's deviation process and which result will be reviewed and confirmed by the JSC. If either the Core Team does not agree on the Batch Failure root cause, and the JSC does not agree on the results of the Core Team's Batch Failure root cause analysis, the Parties shall refer review of such root cause analysis to an independent mutually agreed-on laboratory or firm with international repute, acting as a neutral arbiter, to conduct a root cause analysis of the Batch Failure. The costs of the independent laboratory will be borne by the Party responsible for the Batch Failure, as determined by the independent laboratory, whose written decision shall be binding on the Parties. If the independent laboratory is paid in advance of a final written determination, the Parties shall share equally such expense, and the Party at fault shall reimburse the other Party for its share of any such expenses paid after there has been a final written determination made by the independent laboratory.

5.8.3 The PSA applicable to such Product Batch Failure shall set forth responsibility among the Parties for the following costs in the event of a Batch Failure: (1) the SBL Service Fee to Manufacture the failed Batch; (2) SBL's costs to procure the Raw Materials used in the failed Batch plus applicable SBL handling fees associated with such Raw Materials; (3) SBL handling fees associated with the applicable Client Materials used in the failed Batch; and (4) Client's cost to procure the Client Materials (which shall not include Cell Line) used in the failed Batch which amount is to be calculated based on the actual replacement value (as opposed to the market value) of such materials as supported by reasonable documentary evidence by Client.

5.8.4 In the event that any of the foregoing procedures results in a Batch being delivered in a different year than the year in which the original Batch was ordered for delivery by Client, the Service Fee for such re-Manufactured Batch shall be the Service Fee in effect in the Year in which such re-Manufactured Batch is actually delivered by SBL unless the root cause analysis determined the Batch Failure resulted from SBL Assignable Error, in which case, the Service Fee in effect at the time of the Purchase Order for the failed Batch shall apply.

5.9 Storage, Packaging and Delivery.

5.9.1 **Service Deliverables other than Products.** Storage, packaging and delivery of the Service deliverables other than Products Manufactured hereunder shall be made in accordance with the terms of this MSA, applicable PSA, Project Plan, applicable QAG and the Applicable Laws.

5.9.2 Products.

(a) Release by SBL and Acceptance by Client.

(i) SBL shall perform all testing in accordance with the Specifications of the Product and release the Product in accordance with the terms of the applicable QAG. Upon such release SBL shall deliver to Client a copy of the Manufacturing Documentation in support of the SBL's release of the Product for each Batch ("**Batch Related Documents**"), including a Certificate of Analysis and Certificate of Compliance, in accordance with the applicable QAG;

(ii) **Acceptance of Product.** Client will complete the Acceptance Procedure and determine the acceptability of such Product in accordance with the applicable QAG and notify SBL of the result within the latter of [*] of SBL's release of Product or Client's receipt of the Batch Related Documents. Upon Client's acceptance, SBL will have no liability for such Product once entrusted to the carrier (the Parties shall use good-faith efforts to minimize the time-period between Client's acceptance and SBL's delivery to the carrier), except as set forth in Section 5.9.2(a)(iv) regarding Latent Defects. If Client does not reject such Product within the [*] period, the Product will be deemed to have been accepted by Client and SBL will have no liability for such Product once entrusted to the carrier (the Parties shall use good-faith efforts to minimize the time-period between Client's acceptance and SBL's delivery to the carrier), except (A) as set forth in Section 5.9.2(a)(iv) regarding Latent Defects or (B) due to a breach of SBL's obligations with regard to (I) handling or storage or (II) the Specifications insofar as they relate to packaging and shipping.

(iii) **Non-Conforming.** If, during the Acceptance Procedure, any Product is determined by Client or SBL as Non-Conforming Product, at the option of Client, SBL shall take Commercially Reasonable Efforts to promptly Manufacture replacement Product (except to the extent prohibited by cGMP or applicable QAG) and deliver to Client the quantity of the Product equivalent to the quantity of Non-Conforming Product on a date to be mutually agreed by the Parties and such replacement Batch shall be invoiced and paid for as if it were the original Non-Conforming Product. If SBL does not confirm the non-conformity, the Parties shall refer to an independent and mutually agreed-on laboratory or firm with international repute to test the disputed Product. The costs of the independent

laboratory will be borne by the Party responsible for the Batch Failure, as determined by the independent laboratory, whose written decision shall be binding on the Parties. If the independent laboratory is paid in advance of a final written determination, the Parties shall share equally such expense, and the Party at fault shall reimburse the other Party for its share of any such expenses paid after there has been a final written determination made by the independent laboratory. Section 5.9.2(a) (i) and (ii) shall apply to such replaced Product *mutatis mutandis*. Responsibility for the costs of such Non-Conforming Product shall be as if such Non-Conforming Product is a Batch Failure and Section 5.8.2 – 5.8.4 shall apply to such Non-Conforming Product *mutatis mutandis*. The remedies contained in this Section 5.9.2 shall be the sole and exclusive remedy of client for Non- Conforming Product.

(iv) **Latent Defect.** At any time after completion of review of the Batch Related Documents, if Client finds any hidden defects of the Product which could not have been reasonably discovered through the review of the Batch Related Documents (**"Latent Defect"**), Client shall promptly give notice of such claim in writing to SBL. In such case, if Client proves the Latent Defect is solely due to SBL Assignable Error, the above Section 5.9.2(a)(iii) and Section 13.1 shall apply. If no written claim for Latent Defect of the Product is received by SBL within [*] discovery of the Latent Defect, the Product shall be deemed as irrevocably accepted. Notwithstanding anything to the contrary; such claim for Latent Defect must be made within a time period to be set forth in the applicable PSA, but in no event after the expiration date of the Product. For the avoidance of doubt, a Latent Defect is a defect in existence at the time of completion of the Acceptance Procedure.

(b) **Delivery.** Shipping conditions, title transfer to Client and risk of loss for the Product Manufactured hereunder shall be [*]. The Parties further agree as follows:

(i) At the time of SBL's release of the Product and prior to each pick-up by Client or Client's designated carrier, SBL shall propose to Client a delivery schedule of the Product, in order for the Parties to agree on it in advance for each pick-up. SBL shall schedule Delivery with the carrier selected and paid for by Client;

(ii) SBL shall not deliver the Product until it has been instructed to by Client in accordance with the applicable QAG. Client shall confirm specific delivery instructions with SBL prior to SBL release. Upon SBL's release of Product, SBL shall store the Manufactured Product as described in Section 5.9.2(c) and Client shall compensate SBL for storage costs for the Manufactured Product stored with SBL for more than sixty (60) calendar days following release, as set forth in the applicable PSA;

(iii) SBL shall provide Client with invoice, packing lists, supporting export documents as specified by Client by separate delivery and shipment documentation instructions, together with each shipment of the Product (or such other deliverables); and

(iv) In cooperation with Client and subject to the delivery schedule agreed by the Parties, SBL shall adhere to the first-expire-first-out (FEFO) principle in shipping all released Product.

(c) Storage, Packaging and Shipping Container.

(i) Pursuant to the terms of this MSA and any applicable PSA, SBL shall store the Products Manufactured hereunder.

(ii) SBL shall store, package, label and prepare shipment according to the Specifications for the Product Manufactured hereunder, the applicable QAG and the SOPs, and using storage and/or shipping containers determined in the applicable PSA.

(iii) If Client does not direct SBL to prepare Manufactured Product to be picked up by Client or Client's designated carrier with a pick-up date within [*] of Client's receipt of the Batch Related Documents, SBL shall store the Product at the Warehouse and Client shall pay storage fees to SBL as set forth in Section 9.1 for the period of storage at the Warehouse in excess of [*] from release until the actual delivery date, in accordance with the applicable PSA.

(iv) SBL shall store and handle all Manufactured Product in accordance with applicable storage and handling Specifications, including all times when SBL and Client agree that SBL shall store Manufactured Product per Section 5.9.2(c)(iii), but shall have no obligation regarding risk of loss and damage of Manufactured Product in its possession unless such loss or damage resulted from SBL's negligence or willful misconduct.

5.10 **Supply Interruptions**. On a PSA by PSA basis, the Parties will discuss appropriate steps to alleviate any expected or actual shortfall in Manufactured Product. The Parties may agree on a PSA by PSA basis, in what events, if any, such a supply failure could constitute a material breach of this MSA or a PSA.

SECTION 6 CHANGES TO THE SPECIFICATIONS, ANALYTICAL METHODS, MANUFACTURING PROCESS, FACILITY OR EQUIPMENT

6.1 **Approval for Change.** SBL shall not make any change to the Manufacturing Process, the Services, or the Specifications (a "**Change**"), without the prior written consent of Client in accordance with the applicable QAG.

6.2 **Changes Required by cGMP, Regulatory Authorities or Requested by Client.** Except as otherwise expressly set forth to the contrary in the applicable QAG, in the event that cGMP, a Regulatory Authority, Applicable Law, or any other regulatory or legal authority requires, or Client requests, a Change, SBL shall accommodate such requirements or requests, subject to the following:

(a) Client shall promptly notify SBL in writing of the required and/or requested Change(s), and provide information necessary for SBL to evaluate the effect of such Change(s); provided, however, in the event SBL first learns of a required Change it shall notify Client thereof in writing, and SBL shall promptly advise Client as to any (i) additional equipment required, modifications to the Facility or equipment, and/or additional equipment and the Facility qualification and validation requirements; (ii) Manufacturing Process development, transfer, scale-up, testing, qualification, or validation requirements; (iii) regulatory requirements pursuant to such Changes; (iv) changes to the Manufacturing scheduling and/or Product delivery schedule; and (v) other impacts on the Facility or SBL's ability to manufacture products (including the Products) in the Facility, if any, which may result from such Change(s). The notification and formal approval procedure of such Changes shall be in accordance with the applicable QAG (i.e., change control procedures) (if applicable). The Parties shall meet in a timely manner to identify and discuss such Changes as appropriate;

(b) Prior to implementation of any such Change(s), SBL, subject to Section 5.2, shall provide Client with an estimated plan and budget of the reasonable and necessary costs that would be incurred by SBL as a result of the implementation of any such Change(s), including, but not limited to for (i) process and analytical development; (ii) equipment and/or the Facility modifications, qualification, validation, maintenance, and decommissioning/disposal; (iii) process and analytical validation; (iv) document revisions or changes, the Facility, equipment, and system modifications or changes; (v) additional stability testing; and (vi) preparing submissions to Regulatory Authorities (collectively, the "**Implementation Plan and Budget**"). Following review and approval by Client of such Implementation Plan and Budget, subject to the Core Team's approval and agreement followed by the Parties' written agreement pursuant to Section 17.9 (if applicable), SBL shall commence implementation of such Change(s);

(c) During any such implementation, SBL shall provide Client with regular updates on the progress of implementation. Subject to any timeframe imposed by Applicable Law, SBL shall exercise Commercially Reasonable Efforts to implement the Change according to

the Implementation Plan and Budget's target completion date. SBL shall provide written notice to Client if SBL becomes aware of any cause which may create delay with the implementation of Changes. Following any such notice, both Parties shall discuss an amendment of Implementation Plan and Budget; and

(d) Upon the approval of the Implementation Plan and Budget for Change(s), both Parties shall negotiate in good faith to determine the allocation of the costs incurred by SBL for the implementation of any such Change(s) between the Parties, in accordance with the following principles:

(i) the costs for the general Facility Changes required by cGMP, any Regulatory Authority, or any Applicable Laws related to the maintaining the Manufacturing Facility by SBL as set forth in Section 7.2, shall be borne by SBL, provided that where the Change relates exclusively or partially to the Manufacture of Product in which case the costs shall be borne by Client fully or proportionally, respectively;

(ii) the costs for the Changes other than (i) above, and requested by Client and required uniquely to the Manufacture of the Product and beneficial solely to Client shall be borne by Client; and

(iii) the costs for the Changes other than (i) and (ii) above shall be discussed in good faith by the Parties to achieve equitable allocation of costs.

SECTION 7 REGULATORY APPROVALS AND INSPECTIONS.

7.1 **Regulatory Approvals.** SBL shall provide reasonable assistance and cooperation in order for Client to obtain and maintain the Regulatory Approvals. The direct costs and fees associated with such assistance and cooperation, to the extent not detailed in the MSA or PSA shall be borne by Client, or as otherwise mutually agreed between the Parties. As specified in the applicable PSA, the Parties shall agree on which Regulatory Approvals are to be obtained.

7.2 **Regulatory Approvals for the Facility .** SBL shall obtain and continuously maintain all approvals, licenses, registrations or authorizations of any federal, state or local regulatory agency, department, bureau or other governmental entity (other than the Regulatory Approvals, which will be obtained or maintained by Client) that are required to Manufacture and ship the Product at the Facility and perform the Services including, but not limited to, cGMP Manufacture.

7.3 **Regulatory Inspections.** SBL shall facilitate on-site inspections of the Facility conducted by Regulatory Authorities. SBL shall notify Client according to the applicable QAG provisions of any contacts or inquiries by the Regulatory Authorities, including inspections, Pre-Approval Inspections, sample requests, and written correspondence and its result, related to the Manufacture of Product by SBL at the Facility, as further defined in the applicable QAG. Any direct expenses or costs incurred by SBL for

such inspections including Pre-Approval Inspections at the Facility shall be borne by Client. Unless prohibited by the pertinent Regulatory Authority, Client shall be entitled to witness any inspection or audit by a Regulatory Authority of the Facility or Warehouse related to the Manufacture of Product by SBL at the Facility. Further, Client shall be entitled to attend, as an observer, any wrap-up meeting between SBL and a Regulatory Authority related to such an inspection related to the Services or the Manufacture of Product by SBL at the Facility. SBL shall timely provide Client with a copy of any Form 483, inspection report or regulatory letter issued by a Regulatory Authority, and shall provide Client a meaningful opportunity to review and comment upon any response of SBL thereto. Client's comments in such regard shall be considered in good faith and be given due regard by SBL in formulating any proposed response to a Regulatory Authority.

7.4 **Regulatory Support.** During the Term, SBL will assist Client with all regulatory matters relating to Services and Manufacture and review the Common Technical Document pertaining to the Products, as it relates to Chemistry, Manufacturing and Controls, and make such corrections as are necessary to accurately reflect the Products, in each case at Client's request and reasonable expense; provided, however, SBL shall review and correct such documents as they relate to SBL activities at no charge to Client (updates will be made with respect to regulatory filings for which Client has engaged SBL and paid the associated flat rate fees for support). In addition, SBL will maintain at SBL's expense, the relevant Drug Master File, including any updates thereto, and shall provide a letter authorizing Client to reference SBL's Drug Master Files on file with the FDA and other Regulatory Authorities in connection with the pursuit of Regulatory Approval for the Products.

SECTION 8 QUALITY COMPLIANCE

8.1 **Quality Agreement**. Both Parties shall adhere to the provisions of the applicable QAG and the Parties agree that all elements of quality assurance, quality control and the like shall be governed by the terms and conditions of the applicable QAG. In the event of a conflict between the MSA and the applicable QAG, the MSA shall prevail over those of the applicable QAG with the exception of Product quality-related matters, cGMP and related regulatory requirements in which case, the terms of the applicable QAG shall prevail.

8.2 **Responsibility for Recalled Product**. For a Commercial Product, either Party shall notify the other Party as soon as practicably possible if any Commercial Product is the subject of a threatened or actual recall by a Regulatory Authority, (a "**Recall**") which may be attributable to any Service or Manufacture by or on behalf of SBL hereunder. Client shall be responsible for conducting all Recalls and shall make all decisions regarding, and in all events shall have sole authority for, conducting any recalls, market withdrawals or corrections with respect to the Product and SBL shall at all times exercise Commercially Reasonable Efforts to provide its assistance and cooperation to Client in conducting such Recalls to the extent the Recall arises out of SBL's Manufacture of Product. Details regarding the roles and responsibilities of the Parties in regard to Recalls are set forth in the applicable QAG. If such Recall results solely from SBL Assignable Error, SBL shall be responsible for direct and documented out-of- pocket costs associated with such Recall subject to the limitation of liability sections of the PSA applicable to such Recalled Product and, subject to written instructions of Client to the contrary, will use

its Commercially Reasonable Efforts to replace the Recalled Products with new Products, contingent upon the receipt from Client free-of-charge of all Client Materials required for the Manufacture of the replacement Product. If SBL is unable to replace the Recalled or returned Products (except where this inability results from a failure to receive the Client Materials), then SBL [*]. In all other circumstances, Recalls will be made at Client's cost and expense. The provisions of this Section 8.2 shall not apply to any Clinical Product and shall be Client's sole and exclusive remedy with respect to a Recall due to the delivery of Non-Conforming Product.

For the purpose of this Section, Recall expenses shall not include the [*] or [*] that is the subject of the Recall. If SBL and Client cannot agree which Party is at fault or whether a Recall was reasonably beyond the control of the Parties, then an independent third-party technical expert of international repute, acceptable to both Parties, shall be designated to make such determination. The designated technical expert shall not be an employee, consultant, officer, director or shareholder of, or otherwise associated with, or have been retained during the prior five (5) years by, or be retained during the ensuing five (5) years, by SBL, Client or their respective Affiliates. The technical expert's determination will be, in the absence of fraud or manifest error, binding and conclusive upon the Parties. The cost of designating such technical expert shall be borne by the Party determined at fault, and if neither Party is determined to be at fault, then the cost of such technical expert shall be borne by both Parties in equal proportion.

8.3 Records & Audit.

8.3.1 **Audit by Client.** Upon Client's request, but no more than [*], SBL shall accept an audit of the Facility and, if necessary in the judgment of Client, the Warehouse, by Client and allow Client to inspect and audit the Facility and, if necessary in the judgment of Client, the Warehouse, and Manufacture of the Product solely to ascertain compliance by SBL with the terms of this MSA or any applicable PSA; provided, however that in the event Client uses a designee, SBL must provide prior written consent, which shall not be unreasonably withheld, conditioned or delayed. SBL shall be reimbursed for its reasonable costs for audits beyond the audit described in the first sentence of this Section 8.3.1, except for audits conducted to measure corrective action or remediation following a finding of deficiency either by Client in a previous audit or by a Regulatory Authority or as is contemplated by Section 8.3.2(ii). Client shall not be limited in the number of its audits conducted to measure corrective action or remediation, and such audits shall not count against the limit expressed in the first sentence of this Section 8.3.1. SBL will make Commercially Reasonable Efforts to require vendors or subcontractors to accept an audit or visit to their facilities by Client upon similar notice as described in Section 8.3.2 below.

8.3.2 **Audit Notice.** Client shall provide SBL with a written notice at least [*] prior to the initiation of the audit of the Facility and, if necessary in the judgment of Client, the Warehouse, set forth in Section 8.3.1, which shall be conducted on a mutually agreeable date and time, and with a mutually agreed duration, agenda, and number of attendees, which in the case of Client shall not be limited to less than three (3) without the consent of Client. Notwithstanding the foregoing, if the audit is required for cause (i) due to safety reasons or other reasons that necessitates immediate audit of or visit to the Facility or (ii) due to the SBL Assignable Error, the foregoing sentence shall not apply

and Client may conduct such audit or visit by providing SBL with a prior notice by email. Access to SBL's facilities shall be coordinated with SBL so as to minimize disruption to SBL's ability to perform services for its other clients. Client representatives must comply with all of SBL's generally applicable cGMP, confidentiality and security procedures and protocols during such observations, consultations, and inspections. SBL shall at all times cooperate and provide all the necessary documents reasonably required by Client during such audit; provided that, to the extent necessary, SBL may redact or withhold documents to protect the confidential information of its other clients. Client shall be solely responsible for any costs and liability caused by Client's or its representatives' failure to comply with SBL's security, safety or confidentiality procedures.

SECTION 9 CONSIDERATION AND PAYMENT TERMS

9.1 **Consideration**. In consideration for SBL's performing the Service and other obligations undertaken by SBL pursuant to a PSA, Client shall pay SBL amounts as set forth in the applicable PSA (the "**Service Fee**"); (ii) a handling surcharge of a certain percentage or certain amount to be set forth in the applicable PSA of the costs of Raw Materials paid by SBL (including but not limited to taxes and customs duties/fees); (iii) a handling surcharge of a certain percentage or certain amount to be set forth in the applicable PSA related to the Client Materials (which shall be based on the actual costs of such materials as supported by reasonable documentary evidence as opposed to the market value thereof); and (iv) storage fees as set forth in the relevant PSA.

9.2 Invoices.

9.2.1 **Service Fee of the Project Stages and Batches.** According to the invoicing plan set forth in the applicable Project Plan or applicable PSA, or upon SBL's release of a Batch of Product, as applicable, SBL shall invoice Client for the Service Fee set forth in the applicable PSA.

9.2.2 **Raw Materials.** With respect to the Raw Materials, SBL shall submit invoices to Client for the applicable Raw Materials cost (including any agreed upon safety stock) as set forth according to Section 9.1 as follows. SBL shall submit an invoice to Client (i) for the cost of Specialized Raw Materials procured upon receipt of the invoice from vendors/suppliers; and (ii) for the cost of Common Raw Materials used by SBL's completion of such project stage or upon SBL's release of a Batch of Product as applicable. Notwithstanding the foregoing, the Parties shall collaborate in the selection of the vendors of the Raw Materials. All such vendors shall be approved by Client before supplying SBL with Raw Materials for Product.

9.2.3 **Client Materials.** With respect to the Client Materials, which shall be supplied by Client to SBL at no cost during SBL's performance the Service, SBL shall submit an invoice to Client in an amount as set forth in Section 9.1 upon SBL's completion of such project stage of the Service SBL's release of a Batch of Product, as applicable.

9.3 **Payment**.

9.3.1 **Mode of Payment; Foreign Exchange**. All payments to SBL due under the MSA or any applicable PSA shall be made within [*] from the receipt of the SBL's invoice in USD $ by means of telegraphic transfer to the account with the bank designated by SBL in the foregoing invoice. For the purpose of computing payment amounts incurred in a currency other than USD$, such currency shall be converted into USD$ using the basic exchange rate published by Bloomberg (or its successor institution) on its website "http://www.bloomberg.com/markets/currencies" (or any other website that may be used by Bloomberg or its successor institution for publication of currency exchange rates) at the opening of business on such invoice date.

9.3.2 **Taxes**. All prices and charges are exclusive of any applicable taxes, levies, imposts, duties and fees of whatever nature imposed by any law or regulations in any country in respect of the Services, importation or exportation of Raw Materials, Client Materials, Batches, and Product, which shall be paid by Client. For the avoidance of doubt, the foregoing shall not include any taxes imposed on the income or profit of SBL and any withholding tax lawfully levied on any payment to be made by Client to SBL, each of which shall be solely borne by SBL. Client shall pay or reimburse SBL for all customs duties and taxes in connection with the purchase, sale, importation or exportation of any Raw Materials, Client Materials, Batches, or Product or the provision of Services, except to the extent such duties and taxes are recoverable by or refundable to SBL. SBL agrees to assist Client in claiming exemption under double taxation or similar agreement or treaty from time to time in force to obtain a refund of any customs duties, value added taxes, and other taxes payable by SBL.

9.3.3 **Price Adjustments**. The Service Fees as set forth in the applicable PSA, shall be adjusted annually, on the last day of January, effective January 1 of each year during the Term, by the percentage change in the consumer price index as published by the Bank of Korea for the immediately preceding twelve (12) months. The relevant date for price adjustment under this Section shall be the issue date of SBL's invoice.

9.3.4 **Default Interest.** Any amount that is not paid by a Party to the other when due under the MSA or any PSA shall bear default interest at the rate of ten percent (10%) per annum, or such lesser maximum rate allowed by Applicable Law, from the day following the due date until paid in full. In the event there is an amount which is invoiced by SBL but not paid by Client for more than six (6) months after the due date, such event shall be considered a material breach of the relevant PSA.

SECTION 10 CONFIDENTIALITY

10.1 **Confidential Information.** "**Confidential Information**" shall mean any data, know-how and other information, whether technical or non-technical disclosed by one Party (hereinafter the "**Disclosing Party**") or otherwise became known to the other Party (hereinafter the "**Receiving Party**") hereunder relating to the subject matter of the MSA, regardless of form or manner of disclosure, i.e., whether disclosed in writing, in electronic file or format or in other tangible manner, or orally, visually or in other intangible manner. If a Party intends to disclose such information in writing, in electronic file or format or in other tangible manner, such Party will make reasonable efforts to indicate it is confidential; and if

to disclose orally, visually or in other intangible manner, such Party will make reasonable efforts to reduce it in summary form in writing or in electronic file or format, identified as confidential and delivered to the other Party within thirty (30) days after such oral or visual disclosure; provided, however, in each case, a failure to do so shall not constitute a breach of this term nor shall deny, negate or destroy the confidential nature thereof, and no such failure shall serve as conclusive evidence that the disclosed information shall not be considered Confidential Information by and between the Parties. Furthermore, the existence and terms of the MSA shall be deemed to be the Confidential Information of both Parties and any information, data or results disclosed by SBL to Client relating to the Product, the Services or Manufacture under this MSA or any PSA, as well as the Manufacturing Process, the Project Plan and the Specifications shall be the Confidential Information of Client, unless otherwise specifically identified as SBL Confidential Information by the terms of this Agreement. The Parties acknowledge and agree that the Manufacturing Process and the Project Plan may contain a mixture of both Party's Background IP, ownership of which shall not be affected by this MSA.

Notwithstanding the foregoing, Confidential Information shall not include the information, which as evidenced by written records:

(a) was at the time of disclosure by the Disclosing Party hereunder publicly known or available;
(b) after disclosure by the Disclosing Party hereunder, became publicly known or available by publication or otherwise, other than by an authorized act or omission by the Receiving Party;
(c) was in the possession of the Receiving Party without confidentiality restriction at the time of the disclosure by the Disclosing Party hereunder;
(d) was lawfully received from any third party having the lawful right to make such disclosure, without obligation of confidentiality; or
(e) was independently developed by the Receiving Party's directors, officers or employees without reference to the Confidential Information, as demonstrated by records created contemporaneously with such development.

10.2 **Confidentiality.** The Receiving Party recognizes the proprietary and confidential nature of the Disclosing Party's Confidential Information and agrees that no right, title, ownership, license, or interest of any character in the Disclosing Party's Confidential Information other than as specifically granted herein, is conveyed or transferred to the Receiving Party. Both Parties further agree to maintain the Disclosing Party's Confidential Information in confidence and not to disclose or divulge the Disclosing Party's Confidential Information, in whole or in part, to any third party, and not use the Disclosing Party's Confidential Information for any purpose other than pursuing the MSA. Each Party shall guard such Confidential Information using the same degree of care as it normally uses to guard its own confidential or proprietary information of like importance, but in any event no less than reasonable care. The Receiving Party shall limit disclosure of the Disclosing Party's Confidential Information to its and those of its Affiliates' directors, officers, employees, consultants and agents ("**Representatives**") who have a need to know the Disclosing Party's Confidential Information for performance of the Service and implementation of the MSA, provided that, the Receiving Party shall undertake procedures to ensure that each of its Representatives to whom the Disclosing Party's Confidential Information is disclosed

understands (i) the confidential nature of the Disclosing Party's Confidential Information and (ii) that he or she is under an obligation similar to those contained herein to hold the Disclosing Party's Confidential Information disclosed strictly confidential.

10.3 **Authorized Disclosures.** Disclosure is permitted in the event that (a) the Disclosing Party's Confidential Information is reasonably required to obtain or maintain any Regulatory Approvals for the Products in any or all jurisdictions or (b) the Disclosing Party needs to disclose such Confidential Information to comply with Applicable Law; provided that such Receiving Party shall exercise its Commercially Reasonable Efforts to limit disclosure of the Disclosing Party's Confidential Information to that which is necessary for compliance and to otherwise maintain the confidentiality of the Confidential Information.

10.4 **Survival of confidential obligations.** The confidential obligations of the Receiving Party shall survive for a period of five (5) years from the expiration or termination of this MSA.

10.5 **Return of the Confidential Information.** All written, printed or other tangible Confidential Information of the Disclosing Party disclosed under the MSA, and all copies thereof shall be returned to the Disclosing Party (or destroyed at the Disclosing Party's request) by the Receiving Party within thirty (30) business days from the written request by the Disclosing Party. All Confidential Information disclosed electronically shall be completely deleted and destroyed by the Receiving Party within thirty (30) business days from the written request by the Disclosing Party. Notwithstanding the foregoing, (i) digital backup files automatically generated by the Receiving Party's customary electronic data processing system may be retained and properly stored as confidential files for the sole purpose of backup and will be deleted in accordance with the Receiving Party's retention policy, and (ii) a single copy of the Confidential Information may be retained in the secured files of the Receiving Party for the sole purpose of determining the scope of obligations incurred by it under the MSA provided that the Receiving Party shall keep such Confidential Information in confidence and will use the Confidential Information solely to comply with the terms of the MSA as well as the applicable law, rule and regulation.

SECTION 11 OWNERSHIP OF MATERIALS AND INTELLECTUAL PROPERTY

11.1 **Reference Standard, Client Technology, Client Materials, Cell Line, and Product.** SBL hereby understands and agrees that all rights to, titles of and interests in the Reference Standards, Client Technology, Client Materials, Cell Line, Product, the Manufacturing Process and any work in process or semi processed goods thereof belong to Client, unless otherwise provided herein.

11.2 **Background Intellectual Property.** It is acknowledged that each Party possesses Background IP. Any Intellectual Property relating to the Reference Standards, Client Technology, Client Materials and Cell Line owned and/or controlled by Client as of the date of provision of such Reference Standards, Client Technology, Client Materials and Cell Line by Client to SBL pursuant to Section 5.1, shall be deemed to be included in the Background IP of Client. Client hereby grants SBL a royalty-free, non- transferable, revocable and non-sublicensable and fully-paid-up right and license to use such Intellectual

Property relating to such Reference Standards, Client Technology, Client Materials, Cell Line, during the Term for the sole purposes of Manufacturing of the Product or Services in accordance with the MSA.

11.3 **Inventions.** Any Intellectual Property arising out of or resulting from the Service under the MSA, including but not limited to those contained in the Manufacturing Documentation, shall be hereinafter collectively called an "**Invention**".

11.3.1 **Client Invention.** Any Invention that is [*] by one or more employees or officers of SBL (or its third party consultant or subcontractor) and does not constitute an SBL Invention shall be a "Client Invention". SBL shall notify Client of such Client Invention(s) to Client immediately after SBL, the Project Management Team Leader, respective project personnel, SBL employees or officers or other applicable third parties working for SBL hereunder makes, conceives or reduces to practice such Client Invention, and shall take all necessary measures so that Client would have the sole and exclusive ownership of any and all Client Invention. Client may use any Client Invention for any purpose, including filing patent application and SBL shall provide reasonable cooperation to Client at the expense of Client (as to all reasonable out-of-pocket expenses incurred by SBL that are supported by adequate documentation). In the event that SBL wishes to use the Client Invention for purposes outside the scope of the MSA, Client hereby grants SBL a [*] to use such Client Invention. This Section 11.3 shall survive the expiration or earlier termination and continue in effect as long as the intellectual property right to such Client Invention is legally valid.

11.3.2 **SBL Invention.** Any Invention that is [*] by one or more employees or officers of SBL (or its third party consultant or subcontractor) and which is not derived from, or arises out of Client Background IP or Client's Confidential Information or any other proprietary right of Client or its third party vendors, contractors, or other partners or clients under or in connection with the MSA, shall be the property of SBL ("**SBL Invention**"), and shall not be deemed to be Client Invention or Joint Invention for the purposes of the MSA. No Background IP of SBL and the SBL Invention shall be incorporated into the Product or Manufacturing Process without the joint review and approval of both Parties and the terms of a license to use such Background IP or SBL Invention shall be agreed upon prior to such incorporation.

11.3.3 **Client-SBL Joint Invention.** Any Invention that is [*] by one or more employees, or officers of SBL (or its third party consultant or subcontractor) or their respective Affiliates, on the one hand and one or more employees, officers, agents or contractors of Client (or its Affiliates) on the other hand and which is not derived from, or arises out of either Party's Background IP or Confidential Information or any other proprietary right of a Party or its third party vendors, contractors, or other partners or clients under or in connection with the MSA, shall be jointly owned by Client and SBL (a "**Joint Invention**"), and shall not be a Client Invention or SBL Invention for the purposes of the MSA. Subject to the terms and conditions of the MSA, any such Joint Invention may be exploited by SBL or Client without compensation and liability of other obligation (including accounting obligations) to the other Party, and each Party has a non-exclusive, royalty-free, worldwide license, with the right to sublicense, under its interest in such Joint Inventions and any Intellectual Property rights (including

patents) covering the same, for any purpose; provided that in the event of sublicense, each Party shall make written notice to the other Party of the fact. This license shall continue for the life of the applicable right.

SECTION 12 WARRANTIES.

12.1 **The Parties General Warranties.** Each Party warrants and represents that: (i) it has the corporate power and authority to enter into this MSA and has taken all necessary action on its part required to authorize the execution, delivery and performance of this Agreement; (ii) it is aware of no legal, contractual or other restriction, limitation or condition that might adversely affect its ability to enter into this MSA and perform its obligations hereunder; (iii) it is duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is incorporated; (iv) this MSA (a) has been duly executed and delivered by a duly authorized representative of it, and (b) is the legal, valid and binding obligation of it, enforceable against it in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or other similar laws now or hereafter in effect relating to or affecting creditors' rights generally; and (v) the execution, delivery and performance of this Agreement by it does not and will not (a) violate any Applicable Laws applicable to it, or (b) violate or conflict with any provision of its Articles of Incorporation or By-laws or other organizational documents.

12.2 **Client's Warranties**. Client represents, warrants and covenants to SBL that as of the Effective Date of the MSA and during the Term: (a) Client will comply with all Applicable Laws, and that it will keep SBL informed of any information known to Client which would affect SBL's provision of the Service hereunder and (c) to the best of its knowledge, SBL's use of the Client Materials, Manufacturing Process, and Client Technology for the purpose of the Service and to the extent as set forth in the MSA will not infringe any third party's Intellectual Property rights.

12.3 **SBL's Warranties**. SBL represents, warrants and covenants that:

12.3.1 As of the Effective Date and during the Term, (i) SBL is the lawful owner, lessee, operator, or licensee of the Facility, equipment, machinery, as well as permissions required, to enable SBL to perform its obligations under this MSA, and (ii) to the best of SBL's knowledge none of the SBL Inventions or SBL Background IP infringes any third party Intellectual Property Right

12.3.2 All Product Batches, at the time of delivery to Client's designated carrier, shall (a) conform to the Specifications (except for Pilot Batches and Engineering Batches unless otherwise agreed) ; (b) be Manufactured, packaged, handled and stored in compliance with the requirements of cGMPs (except for Pilot Batches and Engineering Batches unless otherwise agreed) and all Applicable Laws; (c) comply with the Standard Operating Procedures; (d) be Manufactured in compliance with the Quality Agreement; and (e) be transferred free and clear of any liens, claims or encumbrances of any kind.

12.3.3 (i) SBL is not nor has it ever been, and (ii) SBL has not used, and will not use, the services of any person excluded, debarred, suspended (or subject to exclusion, debarment or suspension) under

21 U.S.C. §335(a) or (b) or otherwise disqualified by Applicable Law, including, the FDA Debarment List (http://www.fda.gov/ora/compliance_ref/debar/default.htm), as amended or replaced from time to time, in connection with any of the Services or Manufacturing performed under this MSA or any PSA. SBL agrees to notify Client promptly in the event of any violation of SBL's obligations under this Section. This certification applies to SBL and its respective officers, agents, and employees as well as subcontractors performing on behalf of SBL under this Agreement

12.4 **No Other Warranties.** THE REPRESENTATIONS AND WARRANTIES CONTAINED IN THIS SECTION ARE EXPRESSLY IN LIEU OF AND EXCLUDE, AND THE PARTIES HEREBY EXPRESSLY DISCLAIM AND NEGATE, TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAWS, ALL OTHER REPRESENTATIONS AND WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED (ARISING BY OPERATION OF LAW OR OTHERWISE), INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, EVEN IF THAT PURPOSE IS KNOWN.

SECTION 13 INDEMNIFICATION

13.1 **Indemnification by SBL.** SBL shall indemnify and hold harmless Client, its Affiliates, and their respective officers, directors, employees or agents from and against any Damages arising or resulting from any third party (which shall exclude Client Affiliates) claims to the extent such Damages are relating to, arising out of, in connection with, or resulting from claims, demands, or actions based upon

(i) gross negligence or willful misconduct; (ii) breach of the MSA or any PSA; (iii) violation of Applicable Law, in the case of clauses (i) through (iii) of or by SBL or its officers, directors, employees or agents, including any subcontractor or vendor used in the Manufacture of Product, or (iv) any claim that SBL's use of SBL Background IP infringes any third party's Intellectual Property rights, except to the extent that such Damages are caused by the causes as set forth in Section 13.2 for which Client is obliged to indemnify.

13.2 **Indemnification by Client.** Client shall indemnify and hold harmless SBL, its Affiliates, and their respective officers, directors, employees or agents from and against any Damages arising or resulting from any third party (which shall exclude SBL Affiliates) claims to the extent such Damages are relating to, arising out of, in connection with, or resulting from claims, demands or actions based upon (i) gross negligence or willful misconduct, (ii) any claim that SBL's use of the Client Materials, Manufacturing Process, and Client Technology for the purpose of the Services and solely to the extent as set forth in the MSA infringes any third party's Intellectual Property rights, (iii) breach of the MSA or any PSA, or (iv) violation of Applicable Law, in each case except to the extent that such Damages are caused by the causes as set forth in Section 13.1 for which SBL is obliged to indemnify and in the case of clauses (i), (iii), and (iv) of or by Client or its officers, directors, employees, or agents.

13.3 **Indemnification Procedure.** The foregoing indemnification by SBL or Client shall be conditioned, if and to the extent Damages are based on or related to a third party claim, upon a Party who intends to claim indemnification under Sections 13.1 and 13.2 (the "**Indemnified Party**") (i) providing written notice to the other Party (" **Indemnifying Party**") within twenty (20) calendar days after the Indemnified

Party have been given written notice of such third party claim, provided that absence or delay of such prior written notice will not relieve the Indemnifying Party of its obligation to indemnify except to the extent such absence or delay materially prejudices the Indemnifying Party's ability to defend the third party claim; (ii) permitting the Indemnifying Party, upon timely notice by the Indemnified Party, the opportunity to assume full responsibility (at the Indemnifying Party's cost and expense) for the investigation and defense of any such claim with counsel reasonably satisfactory to the Indemnified Party, provided, however, the Indemnifying Party shall keep the Indemnified Party informed as to the progress of the defense of any claim and that the Indemnified Party shall cooperate in such defense and shall make available all records, materials and witness reasonably requested by the Indemnifying Party in connection therewith; and (iii) not settling or compromising any such claim without the Indemnifying Party's prior written consent, with such consent not to be unreasonably denied, withheld or conditioned. Furthermore, the Indemnifying Party shall not settle or compromise any such claim without the Indemnified Party's prior written consent; provided, however, no such consent shall be required if such settlement or compromise involves only the payment of money, does not require a finding or admission of fault or guild on the party of the Indemnified Party, and provides for a general release of the Indemnified Party.

SECTION 14 DISCLAIMER OF CONSEQUENTIAL DAMAGES; LIMITATION OF LIABILITY

14.1 **Disclaimer of Consequential Damages.** EXCEPT FOR DAMAGES BASED ON OR RELATED TO A THIRD PARTY CLAIM ARISING UNDER SECTIONS 13.1 AND 13.2, OR BASED ON GROSS NEGLIGENCE OR WILLFUL MISCONDUCT, NEITHER PARTY WILL BE LIABLE UNDER THIS AGREEMENT FOR ANY SPECIAL, PUNITIVE, CONSEQUENTIAL, INCIDENTAL OR OTHER INDIRECT DAMAGES OF ANY TYPE OR NATURE, WHETHER BASED IN CONTRACT, TORT, STRICT LIABILITY, NEGLIGENCE OR OTHERWISE, INCLUDING LOSS OF PROFITS OR REVENUES.

14.2 **Limitation of Liability.** Specific caps on Damages shall be set forth in the applicable PSA.

SECTION 15 TERM AND TERMINATION OF AGREEMENT

15.1 **Term.** This MSA will become effective as of the Effective Date and will be in effect for as long as a PSA is in effect (the "**Term**"). Each PSA will have its own initial term as stated therein. Each PSA for clinical supply shall automatically renew for successive terms of one (1) year each or upon execution of a PSA for commercial supply, whichever is earlier, and each PSA for commercial supply, including supply of stocking inventories in advance of Regulatory Approval, shall automatically renew for successive terms of three (3) years each, unless a Party gives written notice to the other Party of its intention to not renew a PSA for clinical supply ninety (90) days prior to the end of the then current PSA term, or a Party gives written notice to the other Party of its intention to not renew a PSA for commercial supply thirty-six (36) months prior to the end of the then current PSA term.

15.2 **Termination**. This MSA or a PSA may be earlier terminated as set forth in this Section 15.2.

15.2.1 **Material Breach**. A Party may terminate any PSA for a material breach by the other Party; provided, however, that the non-breaching Party shall give the breaching Party written notice of such breach and if the breaching Party fails to commence Commercially Reasonable Efforts to cure that breach within [*] after receipt of such written notice, then the non-breaching Party may terminate this Agreement on [*] written notice after expiration of such twenty [*]. This MSA shall terminate if all effective PSAs are terminated.

15.2.2 **Insolvency**. This MSA may be terminated by either Party upon written notice at any time during the MSA if the other Party: (a) files in any court pursuant to any statute a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of such Party, or of its assets; (b) proposes a written agreement of composition for extension of its debts; (c) is served with an involuntary petition against it, filed in any insolvency proceeding which is admitted in the court; or (d) makes an assignment for the benefit of its creditors. The Party affected shall immediately notify the other Party in writing of the occurrence of any of the foregoing events.

15.2.3 **Force Majeure**. Either Party may terminate a PSA in accordance with Section 17.3 in the event a Party is unable to perform its obligations pursuant to a PSA due to a Force Majeure Event.

15.2.4 **Import Failure**. Client shall be entitled to terminate a PSA upon twenty (20) Business Days' notice to SBL, if, despite the efforts of SBL pursuant to Section 5.4.1, Client Material destined for use in connection with the Services have been prohibited from entry into the Republic of South Korea by the Korean Custom Service. Such termination right shall only exist if such Client Materials have been denied entry and shall not be implicated by mere delays in the importation process. If such termination relates to efforts to import into the Republic of Korea Client Materials for the initial Batch of a Product under a PSA, the applicable PSA shall be deemed to be void *ab initio* without further cost or expense to either Party; provided, however, the Party's thereafter shall reasonably cooperate with regard to disposition of such Client Materials at the cost of Client.

15.2.5 **Other Specified Events**. The Parties may additionally terminate a PSA as set forth in the applicable PSA.

15.3 **Effect of Expiration or Termination**.

15.3.1 **Payment of Amounts Due**. Expiration or termination of the MSA or PSA for any reason shall not exempt any Party from paying to any other Party any amounts owing to such Party at the time of such expiration or termination; provided, however, with respect to a termination deemed to be *ab initio*, and up-front fee paid to SBL shall not be deemed earned and shall be returned to Client.

15.3.2 **Decommissioning**. Upon expiration or termination of a PSA for any reason, SBL shall cease and refrain from the Services described in any applicable PSA (including the Manufacturing

and supplying the Product) for Client unless otherwise provided in the following Sections 15.3.2(a) to 15.3.2(d), and both Parties shall pursue decommissioning activities as set forth hereunder.

(a) Fully Manufactured Product.

(i) If Client terminates a PSA pursuant to Section 15.2.1, 15.2.2, 15.2.3, 15.2.4 or 15.2.5, upon Client's election, SBL shall (i) deliver already fully Manufactured Product to Client in accordance with the terms and conditions of the MSA and applicable PSA or (ii) destroy such Product. If Client elected (i) above, Client shall pay the [*] and any related costs or fees for the Service relating to such Product in accordance with the terms and conditions of the MSA and applicable PSA, and if Client elected (ii) above, SBL shall [*], except in the case of Section 15.2.4 or Section 15.2.5 for which destruction Client shall pay the cost.

(ii) If SBL terminates a PSA pursuant to Section 15.2.1, 15.2.2, 15.2.3, or 15.2.5, upon SBL's election, SBL may (i) deliver the fully Manufactured Product to Client in accordance with the terms and conditions of the MSA and applicable PSA (including the current Firm Period period or Binding Year in the PSA) or (ii) destroy such Product. If SBL elected (i) above, Client shall pay the [*] and any related costs or fees for the Service relating to such Product in accordance with the terms and conditions of the MSA and applicable PSA, and if SBL elected (ii) above, Client shall bear the costs and expenses for [*]; provided, however, such costs and expenses to be borne by Client shall in no event exceed the Service Fee for the Service relating to such Product.

(iii) If a PSA is naturally expired pursuant to Section 15.1, the provisions of (ii) above shall apply

(b) Client Materials being used for the Service (Product in Process).

(i) If Client terminates a PSA pursuant to Section 15.2.1, 15.2.2, 15.2.3, 15.2.4, or 15.2.5, upon Client's election, SBL shall (i) continue to use the Client Materials being used for the Manufacturing hereunder (the Product in process) and deliver the fully Manufactured Product to Client in accordance with the terms and conditions of the MSA and applicable PSA, or (ii) deliver to Client or destroy such Product in process. If Client elected (i) above, Client shall pay the [*] and any related costs or fees for the Service relating to the fully Manufactured Product in accordance with the terms and conditions of the MSA and applicable PSA, and if Client elected (ii) above, SBL shall [*].

(ii) If SBL terminates a PSA pursuant to Section 15.2.1, 15.2.2, 15.2.3, or 15.2.5, upon SBL's election, SBL may (i) continue to use the Client Materials being used

for the Manufacturing hereunder (the Product in process) and deliver the fully Manufactured Product to Client in accordance with the terms and conditions of the MSA and applicable PSA, or (ii) destroy such Product in process. If SBL elected (i) above, Client shall pay the [*] and any related costs or fees for the Service relating to the fully Manufactured Product in accordance with the terms and conditions of the MSA, and if SBL elected (ii) above, Client shall [*].

(iii) If a PSA is naturally expired pursuant to Section 15.1, the provisions of (ii) above shall apply.

(c) Client Materials, Cell Line, and Reference Standards. Upon expiration or termination of a PSA, upon Client's election, SBL shall deliver to Client and/or destroy all remaining Client Materials (subject to Sections 15.3.2(a) and 15.3.2(b)), all remaining Cell Line vials, Reference Standards and other materials required for Manufacturing.

The costs and expenses for such activities shall be borne by the Parties as follows:

(i) If Client terminates the PSA pursuant to Section 15.2.1, 15.2.2 or 15.2.3, SBL shall [*];

(ii) If SBL terminates the PSA pursuant to Section 15.2.1, 15.2.2, 15.2.3, or 15.2.5, or Client terminates the PSA pursuant to Section 15.2.4 or 15.2.5, [*];

(iii) If a PSA is naturally expired pursuant to Section 15.1, the provisions of (ii) above shall reply.

(d) Raw Materials.

(i) If Client terminates a PSA pursuant to Section 15.2.1, 15.2.2 or 15.2.3 and if Client so elects, SBL shall deliver the remaining Raw Materials to Client for Client's payment of SBL's cost to procure such Raw Materials, or dispose of them at Client's election. SBL shall [*].

(ii) If SBL terminates a PSA pursuant to Section 15.2.1, 15.2.2, 15.2.3 or 15.2.5, or Client terminates a PSA pursuant to Section 15.2.4 or 15.4.5, SBL may deliver the remaining Raw Materials to Client or dispose of them at SBL's election. If so delivered, Client shall pay [*] to SBL and bear the costs and expenses for the [*] by SBL.

(iii) If a PSA is naturally expired pursuant to Section 15.1, the provisions of (ii) above shall apply.

(e) Outstanding Obligations Regarding Purchase of Product.

(i) If Client terminates a PSA pursuant to Section 15.2.1 or 15.2.2 Client shall be released from any outstanding binding obligations to purchase Product as of the date of notice of termination including but not limited to pursuant to a Firm Period, binding forecast, purchase order, minimum purchase commitment, or otherwise; provided, however, that Client shall purchase Product Manufactured prior to such date of notice, pursuant to the terms of this MSA and PSA.

(ii) If SBL terminates a PSA pursuant to Section 15.2.1 or 15.2.2, outstanding binding obligations to purchase Product as of the date of notice of termination shall survive termination of such PSA, including but not limited to pursuant to a Firm Period, binding forecast, purchase order, minimum purchase commitment, or otherwise.

(iii) For all other cases of termination of a PSA, subsection (ii) shall apply.

(f) **Survival**. Any termination or expiration of this MSA shall not affect any outstanding obligations due hereunder prior to such termination or expiration, nor shall it prejudice any other remedies that the parties may have under this MSA. For greater certainty, except as otherwise expressly provided, termination or expiration of this MSA, irrespective of the cause, shall not affect any rights or obligations which, from the context thereof, are intended to survive termination or expiration of this MSA, including but not limited to Sections 1, 8, 9, 10, 11, 12, 13, 14, 15, 16 and 17.2.

15.3.3 **Outbound Transfer.** Upon any termination of a PSA or in connection with its expiration, Client shall be entitled to give notice to SBL of a Manufacturing Process Transfer, which shall commence the preparation and effectuation of a Manufacturing Process Transfer Plan for the Product identified therein. In addition, Client shall be entitled to give notice to SBL of a Manufacturing Process Transfer and commence the preparation and effectuation of a Manufacturing Process Transfer Plan in the absence of a termination or expiration of a PSA in order to establish second source Manufacturing. Client shall pay SBL's reasonable costs of assistance related to effectuation of the Manufacturing Process Transfer Plan.

SECTION 16 ARBITRATION

16.1 **Informal Discussions.** Except as otherwise provided herein, in the event of any controversy or claim arising out of or relating to this MSA, or the rights or obligations of the Parties hereunder, the Parties shall first try to settle their differences amicably between themselves through the Core Team and then the JSC. Thereafter, either Party may initiate informal dispute resolution on the executive level by sending written notice of the dispute to the other Party, and within thirty (30) days after such notice appropriate executives of the Parties shall meet for attempted resolution by good faith negotiations. If such representatives are unable to resolve such disputed matter within such thirty (30) day period, either Party may refer the matter by written notice to the Chief Executive Officer of the other Party, or his/her

designee, and the Chief Executive Officer of such Party, for discussion and resolution. If such individuals or their designees are unable to resolve such dispute within thirty (30) days of such written notice, and such dispute relates to a claimed breach of this MSA, a PSA or a QAG, either Party may initiate binding arbitration proceedings in accordance with the provisions of this Article 16. For the avoidance of doubt, no claim other than a claim of a breach of this Agreement shall be subject to arbitration.

16.2 **Arbitration.** If the Parties do not fully settle a claimed breach of this MSA, a PSA or a QAG pursuant to Section 16.1, and a Party wishes to pursue the matter, each such claim shall be finally resolved by binding arbitration in accordance with the Commercial Arbitration Rules of the International Chamber of Commerce ("ICC"), and judgment on the arbitration award may be entered in any court having jurisdiction thereof to enforce the arbitration award. The arbitration shall be conducted by a panel of three neutral persons experienced in the pharmaceutical business, and within thirty (30) days after initiation of arbitration, each Party shall select one person to act as arbitrator and the two Party-selected arbitrators shall select a third arbitrator within thirty (30) days of their appointment. If the arbitrators selected by the Parties are unable or fail to agree upon the third arbitrator, the third arbitrator shall be appointed by the ICC. The place of arbitration shall be New York, New York, United States and all proceedings and communications shall be in English. Either Party may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Either Party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of that Party pending the arbitration award. The arbitrators shall have no authority to award punitive or any other type of damages not measured by a Party's direct compensatory damages, and in all cases, any decision or determination by the arbitrators shall comply with Article 14, as applicable. The Parties agree that, in the event of a good faith dispute over the nature or quality of performance under this Agreement, neither Party may terminate this Agreement until final resolution of the dispute through arbitration or other judicial determination. The Parties further agree that any payments made pursuant to this Agreement pending resolution of the dispute shall be refunded if an arbitrator or court determines that such payments are not due.

16.3 **Costs and Fees.** Each Party shall bear its own attorneys' fees, costs, and disbursements arising out of the arbitration, and shall pay an equal share of the fees and costs of the arbitrators. Absent the filing of an application to correct or vacate the arbitration award as permitted by Applicable Law, each Party shall fully perform and satisfy the arbitration award within fifteen (15) days after the service of the award on such Party.

SECTION 17 MISCELLANEOUS

17.1 **Notices.** Any notice required or permitted under the MSA shall be in writing with duly authorized signature and made to the following addresses or facsimile numbers:

If to Client:
Checkpoint Therapeutics, Inc.
2 Gansevoort St., 9th Floor

New York, NY 10014
Attention: Senior Vice President Operations Facsimile:

If to SBL:

Samsung BioLogics Co., Ltd.
300, Songdo bio-daero, Yeonsu-gu Incheon 21987, South Korea
Attention: Head of Corporate Business Operations Facsimile: +82-32-455-3242

With copy to: SBL Legal & Compliance Department

Either Party may change its designated address and facsimile number by notice to the other Party in the manner provided in this Section 17.1.

Any notice shall be deemed to have been delivered on the date of delivery of delivered personally, or on the next day of sending if sent by facsimile, or on the fifth day of posting if sent by registered or certified mail with return receipt requested and postage prepaid.

17.2 **Governing Law.** This MSA shall be construed and interpreted in accordance with the laws of State of New York, United States and all rights and remedies shall be governed by such laws without regard to principles of conflicts of law. The United Nations Convention on Contracts for the International Sale of Goods shall not apply to the transactions contemplated by the MSA.

17.3 **Effect of Force Majeure Event**. Neither Party (the "**Affected Party**") shall be liable to the other Party (the "**Non-Affected Party**") for failure or delay to perform its obligation under the MSA or any applicable PSA when such failure or delay is due to riots, storms, fires, explosions, floods, earthquakes, war, embargoes, blockades, insurrections, terrorism, an act of God or any other cause similar thereto which is beyond the control of the Affected Party including those affected upstream suppliers ("**Force Majeure Event**").

Each Party agrees to give the other Party prompt written notice of the occurrence of any Force Majeure Event, the nature thereof, and the extent to which the affected Party will be unable fully to perform its obligations under the MSA. If a condition constituting Force Majeure Event as defined herein exists for more than [*], or it is reasonably foreseeable that such Force Majeure Event will persist for more than [*], the Parties shall endeavor in good faith to negotiate a mutually satisfactory solution to the problem, if practicable, including use of a third party to fulfill the obligations hereunder of the party invoking Force Majeure Event, at the expense of the party invoking Force Majeure Event. If after good faith efforts to negotiate a mutually satisfactory solution for at least [*] the Parties have failed to reach agreement, the Non-Affected Party shall have the right to terminate this MSA upon [*] written failure.

17.4 **Assignment**. Neither Party shall assign, in whole or in part, the MSA without the prior written consent of the other Party, such approval not to be unreasonably withheld, conditioned or delayed. Notwithstanding the above, Client may, without such consent, assign the MSA to (i) its Affiliate or (ii) any purchaser of Client's rights relating to the Product or all or substantially all of the assets of Client, or of all of its capital stock, or to any successor corporation or entity resulting from any merger or consolidation of such Party with or into such corporation or entity. Notwithstanding the above, SBL may, without such consent, assign the MSA to (i) its Affiliate or (ii) any purchaser of substantially all of the assets of SBL, or of all of its capital stock, or to any successor corporation or entity resulting from any merger or consolidation of such Party with or into such corporation or entity.

17.5 **No Grant of License.** Nothing in the MSA shall affect, or grant any right to, patents, know-how or other intellectual property owned by either Party prior to the commencement of the MSA unless otherwise expressly provided in the MSA.

17.6 **No Right to Use Names.** Except as expressly provided herein, no right, expressed or implied, is granted by the MSA to use in any manner the name of either of the Parties or any other trade name, symbol, logo or trademark of the other Party in connection with the performance of the MSA, without the prior written consent of the other Party.

17.7 **Independent Contractors**. The Parties hereto are independent contractors and nothing contained in the MSA shall be deemed or construed to create a partnership, joint venture, employment, franchise, agency or fiduciary relationship between the Parties.

17.8 **Integration**. This MSA constitutes the entire agreement between the Parties relating to the subject matter of the MSA and supersedes all previous oral and written communications between the Parties with respect to the subject matter of the MSA.

17.9 **Amendment; Waiver**. Except as otherwise expressly provided herein, no alteration of or modification to the MSA shall be effective unless made in writing and executed by an authorized representative of both Parties. No course of dealing or failing of either Party to strictly enforce any term, right or condition of the MSA in any instance shall be construed as a general waiver or relinquishment of such term, right or condition. The observance of any provision of the MSA may be waived (either generally or any given instance and either retroactively or prospectively) only with the written consent of the Party granting such waiver.

17.10 **Severability**. The Parties do not intend to violate any Applicable Law. However, if any sentence, paragraph, clause or combination of the MSA is in violation of any law or is found to be otherwise unenforceable, such sentence, paragraph, clause or combination of the same shall be deleted and the remainder of the MSA shall remain binding, provided that such deletion does not alter the basic purpose and structure of the MSA.

17.11 **Construction**. The Parties mutually acknowledge that they have participated in the negotiation and preparation of the MSA. Ambiguities, if any, in the MSA shall not be construed against any Party,

irrespective of which Party may be deemed to have drafted the MSA or authorized the ambiguous provision.

17.12 **Interpretation**. The captions and headings to the MSA are for convenience only, and are to be of no force or effect in construing or interpreting any of the provisions of the MSA. Unless context otherwise clearly requires, whenever used in the MSA: (a) the words "include" or "including" shall be construed as incorporating, also, "but not limited to" or "without limitation"; (b) the words "hereof," "herein," "hereby" and derivative or similar words refer to the MSA; (c) the word "law" or "laws" shall mean any applicable, legally binding statute, ordinance, resolution, regulation, code, guideline, rule, order, decree, judgment, injunction, mandate or other legally binding requirement of a governmental authority (including a court, tribunal, agency, legislative body or other instrumentality of any (i) government or country or territory, (ii) any state, province, county, city or other political subdivision thereof, or (iii) any supranational body); and (d) all references to the word "will" are interchangeable with the word "shall" and shall be understood to be imperative or mandatory in nature. All references to days, months, quarters or years are references to calendar days, calendar months, calendar quarters, or calendar years. Whenever any matter hereunder requires consent or approval, such consent or approval shall not be unreasonably withheld or delayed.

17.13 **Counterparts**. This MSA may be executed in two or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

IN WITNESS WHEREOF, the Parties have executed the MSA as of the date first above written.

CHECKPOINT THERAPEUTICS, INC.

Signature: /s/ James F. Oliviero
Name: James F. Oliviero
Title: Chief Executive Officer

Date: _____

SAMSUNG BIOLOGICS CO., LTD.

Signature: /s/ Dr. Tae Han Kim
Name: Dr. Tae Han Kim
Title: President & CEO

Date: _____

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)
November 6, 2020

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)
November 6, 2020

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 September 30, 2020 (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)
November 6, 2020

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 September 30, 2020 (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)
November 6, 2020