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

FORM 10-Q
(Mark one)

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

For the quarterly period ended June 30, 2021

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.)

95 Sawyer Road, Suite 110, Waltham, MA 02453
(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 August 3, 2021**
Class A Common Stock, $0.0001 par value	7,000,000
Common Stock, $0.0001 par value	75,741,873

CHECKPOINT THERAPEUTICS, INC.
Form 10-Q
For the Quarter Ended June 30, 2021

Table of Contents

SUMMARY OF RISK FACTORS

Our business is subject to risks of which you should be aware before making an investment decision. The risks described below are a summary of the principal risks associated with an investment in us and are not the only risks we face. You should carefully consider these risk factors, the risk factors described in Item 1A, and the other reports and documents that we have filed with the Securities and Exchange Commission ("SEC").

Risks Related to our Finances and Capital Requirements

- We have incurred significant losses since our inception and anticipate that we will incur continued losses for the foreseeable future. We have not generated any sales revenue from our development stage products, and we do not know when, or if, we will generate any revenue from sales of an approved product.
- Our short operating history makes it difficult to evaluate our business and prospects.
- Our success is contingent upon raising additional capital for our development programs and commercialization efforts, which may fail. Even if successful, our future capital raising activities may dilute our current stockholders, restrict our operations, or require us to relinquish proprietary rights.
- Our limited resources may cause us to fail to capitalize on programs or product candidates presenting commercial opportunity or high likelihood of success.

Risks Pertaining to our Business Strategy, Structure and Organization

- Our future growth and success depend on our ability to successfully develop and commercialize our product candidates, which we have yet to do.
- Our future growth depends on our acquiring or in-licensing products or product candidates and integrating such products into our business.

Risks Inherent in Drug Development and Commercialization

- Because results of preclinical studies and early clinical trials are not necessarily predictive of future results, any product candidate we advance may not have favorable results in later clinical trials. Moreover, interim, "top-line," and preliminary data from our clinical trials that we announce or publish may change, or the perceived product profile may be impacted, as more patient data or additional endpoints are analyzed.
- We may not receive the required regulatory approvals for any of our product candidates on our projected timelines, if at all, which may result in increased costs and delay our ability to generate revenue.
- If a product candidate demonstrates lack of efficacy or adverse side effects, we may need to abandon or limit the development of such product candidate.
- We may not obtain the desired labeling claims or intended uses for product promotion, or favorable scheduling classifications, to successfully promote our products.
- Even if a product candidate is approved, it may be subject to various post-marketing requirements, including studies or clinical trials, and increased regulatory scrutiny.
- Our competitors have developed or may develop treatments for our products' target indications, which could limit our product candidates' commercial opportunity and profitability.
- If our products are not broadly accepted by the healthcare community, the revenues from any such product will likely be limited.

- Any successful products liability claim related to any of our current or future product candidates may cause us to incur substantial liability and limit the commercialization of such products.

Risks Related to Reliance on Third Parties

- We rely, and will rely in the future, on third-party contract research organizations and contract manufacturers for the conduct of our preclinical and clinical studies and trials, for the completion of commercial and pre-commercial manufacturing and, eventually, for commercialization. If such third parties fail to perform contractual obligations, meet deadlines, comply with applicable regulations, or if our relationships with such third parties are disrupted, our product candidates may be delayed, and our revenue potential may be limited.

- We rely on clinical data and results obtained by third parties, which may prove inaccurate or unreliable.

Risks Relating to Legislation and Regulation Affecting the Biopharmaceutical and Other Industries

- We operate in a heavily regulated industry, and we cannot predict the impact that any future legislation or administrative or executive action may have on our operations.

- We may be subject to 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.

Risks Pertaining to Intellectual Property and Potential Disputes with Licensors Thereof

- If we are unable to maintain sufficient patent protection for our technology and products, our competitors could develop and commercialize products similar or identical to ours, impairing our ability to successfully commercialize potential products.

- We or our licensors may be subject to costly and time-consuming litigation for infringement of third-party intellectual property rights or to enforce our or our licensors' patents.

- Any dispute with our licensors may affect our ability to develop or commercialize our product candidates.

Risks Relating to Our Control by Fortress Biotech, Inc. ("Fortress")

- Fortress controls a voting majority of our common stock and has the right to receive significant share grants annually, which will result in dilution of our other stockholders and could reduce the value of our common stock.

- We have entered into certain agreements with Fortress and may have received better terms from unaffiliated third parties.

Risks Related to Conflicts of Interest

- The Chairman of our Board of Directors is also the Executive Chairman, President, and Chief Executive Officer of TG Therapeutics, Inc. ("TGTX"). We have entered a collaboration agreement and a sublicense agreement with TGTX, and as a result, certain conflicts of interest may arise.

- We share certain directors with Fortress, which could create conflicts of interest between us and Fortress.

Item 1. Financial Statements.

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

	June 30, 2021 (Unaudited)	December 31, 2020
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 65,124	$ 40,772
Prepaid expenses and other assets	844	1,804
Other receivables - related party	155	20
Total current assets	66,123	42,596
Total Assets	**$ 66,123**	**$ 42,596**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 8,346	$ 6,367
Accounts payable and accrued expenses - related party	903	850
Total current liabilities	9,249	7,217
Total Liabilities	**9,249**	**7,217**
Commitments and Contingencies		
Stockholders' Equity		
Common Stock ($0.0001 par value), 135,000,000 and 95,000,000 shares authorized as of June 30, 2021 and December 31, 2020, respectively		
Class A common shares, 7,000,000 shares issued and outstanding as of June 30, 2021 and December 31, 2020	1	1
Common shares, 75,741,873 and 62,420,439 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively	8	6
Common stock issuable, 0 and 1,742,449 shares as of June 30, 2021 and December 31, 2020, respectively	—	4,617
Additional paid-in capital	215,706	173,947
Accumulated deficit	(158,841)	(143,192)
Total Stockholders' Equity	56,874	35,379
Total Liabilities and Stockholders' Equity	**$ 66,123**	**$ 42,596**

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

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

	For the three months ended June 30,		For the six months ended June 30,	
	2021	2020	2021	2020
Revenue - related party	$ 155	$ 42	$ 223	$ 1,014
Operating expenses:				
Research and development	7,198	3,029	11,411	5,664
General and administrative	2,114	1,687	4,487	3,365
Total operating expenses	9,312	4,716	15,898	9,029
Loss from operations	(9,157)	(4,674)	(15,675)	(8,015)
Other income				
Interest income	13	29	26	89
Total other income	13	29	26	89
Net Loss	**$ (9,144)**	**$ (4,645)**	**$ (15,649)**	**$ (7,926)**
Loss per Share:				
Basic and diluted net loss per common share outstanding	$ (0.12)	$ (0.09)	$ (0.21)	$ (0.15)
Basic and diluted weighted average number of common shares outstanding	75,492,853	51,802,451	72,912,456	51,338,963

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

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

For the Three Months Ended June 30, 2021

	Class A Common Shares		Common Shares		Common Shares Issuable	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balances at March 31, 2021	**7,000,000**	**$ 1**	**72,163,822**	**$ 7**	**$ —**	**$ 203,864**	**$ (149,697)**	**$ 54,175**
Issuance of common shares, net of offering costs - At-the-market offering	—	—	3,374,674	1	—	10,823	—	10,824
Issuance of common shares – Founders Agreement	—	—	84,365	—	—	253	—	253
Stock-based compensation expense	—	—	119,012	—	—	766	—	766
Net loss	—	—	—	—	—	—	(9,144)	(9,144)
Balances at June 30, 2021	**7,000,000**	**$ 1**	**75,741,873**	**$ 8**	**$ —**	**$ 215,706**	**$ (158,841)**	**$ 56,874**

For the Six Months Ended June 30, 2021

	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, 2020	**7,000,000**	**$ 1**	**62,420,439**	**$ 6**	**$ 4,617**	**$ 173,947**	**$ (143,192)**	**$ 35,379**
Issuance of common shares, net of offering costs - At-the-market offering	—	—	10,399,983	2	—	34,715	—	34,717
Issuance of common shares - Founders Agreement	—	—	2,002,439	—	(4,617)	5,504	—	887
Stock-based compensation expense	—	—	919,012	—	—	1,540	—	1,540
Net loss	—	—	—	—	—	—	(15,649)	(15,649)
Balances at June 30, 2021	**7,000,000**	**$ 1**	**75,741,873**	**$ 8**	**$ —**	**$ 215,706**	**$ (158,841)**	**$ 56,874**

For the Three Months Ended June 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 March 31, 2020	**7,000,000**	**$ 1**	**48,038,506**	**$ 5**	**$ 2,510**	**$ 137,094**	**$ (123,392)**	**$ 16,218**
Issuance of common shares, net of offering costs - At-the-market offering	—	—	1,303,282	—	—	2,604	—	2,604
Issuance of common shares- Founders Agreement	—	—	1,491,876	—	(2,510)	2,576	—	66
Stock-based compensation expense	—	—	146,340	—	—	731	—	731
Net loss	—	—	—	—	—	—	(4,645)	(4,645)
Balances at June 30, 2020	**7,000,000**	**$ 1**	**50,980,004**	**$ 5**	**$ —**	**$ 143,005**	**$ (128,037)**	**$ 14,974**

For the Six Months Ended June 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	—	—	1,303,282	—	—	2,604	—	2,604
Issuance of common shares - Founders Agreement	—	—	1,491,876	—	(2,510)	2,576	—	66
Stock-based compensation expense	—	—	1,077,340	—	—	1,370	—	1,370
Exercise of warrants	—	—	102,742	—	—	13	—	13
Net loss	—	—	—	—	—	—	(7,926)	(7,926)
Balances at June 30, 2020	**7,000,000**	**$ 1**	**50,980,004**	**$ 5**	**$ —**	**$ 143,005**	**$ (128,037)**	**$ 14,974**

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

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

	For the six months ended June 30,	
	2021	**2020**
Cash Flows from Operating Activities:		
Net loss	$ (15,649)	$ (7,926)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,540	1,370
Issuance of common shares - Founders Agreement	887	66
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	960	144
Other receivables - related party	(135)	(16)
Accounts payable and accrued expenses	2,032	(339)
Net cash used in operating activities	(10,365)	(6,701)
Cash Flows from Financing Activities:		
Proceeds from issuance of common stock - At-the-market offering	35,614	2,666
Offering costs for the issuance of common stock - At-the-market offering	(897)	(62)
Offering costs for the issuance of common stock - Public offering	—	(69)
Proceeds from the exercise of warrants	—	13
Net cash provided by financing activities	34,717	2,548
Net increase (decrease) in cash and cash equivalents	24,352	(4,153)
Cash and cash equivalents at beginning of period	40,772	26,077
Cash and cash equivalents at end of period	**$ 65,124**	**$ 21,924**
Supplemental disclosure of noncash investing and financing activities:		
Issuance of common shares - Founders Agreement	$ 4,617	$ 2,510

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 June 30, 2021, the Company had an accumulated deficit of $158.8 million.

During the six months ended June 30, 2021, the Company sold a total of10,399,983 shares of common stock under an At-the-Market Issuance Sales Agreement ("ATM"), at an average selling price of $3.42 per share, resulting in aggregate total gross proceeds of approximately $35.6 million and net proceeds of approximately $34.7 million after deducting approximately $0.9 million in commissions and other transaction costs.

The Company expects to continue to use the proceeds from previous financing transactions primarily for general corporate purposes, which may include financing the Company's growth, developing new or existing product candidates, and funding capital expenditures, acquisitions and investments. The Company currently anticipates that its cash and cash equivalents balances at June 30, 2021 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.

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 effects of the COVID-19 pandemic on the Company's operations, as well as 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 condensed financial statements should be read in conjunction with the Company's audited financial statements and notes thereto for the year ended December 31, 2020, which were included in the Company's Form 10-K, and filed with the SEC on March 12, 2021. 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 highly liquid 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 in July 2016 and October 2017 (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. Due to the nature of the Company's assets and stage of development, future share prices and shares outstanding cannot be estimated prior to the issuance of the Annual Equity Fee. 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 1,742,449 shares of common stock to Fortress for the Annual Equity Fee, representing 2.5% of the fully diluted outstanding equity of Checkpoint on January 1, 2021. Because the number of outstanding shares issuable to Fortress was determinable on January 1, 2021 prior to the issuance of the December 31, 2020 financial statements, the Company recorded approximately $4.6 million in research and development expense and a credit to Common shares issuable - Founders Agreement during the year ended December 31, 2020.

Stock-Based Compensation Expenses

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

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

Fair Value Measurement

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

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

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

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

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

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

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

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); and
- the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract (i.e., the promise to transfer the good or service is distinct within the context of the contract).

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

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

- variable consideration;
- constraining estimates of variable consideration;
- the existence of a significant financing component in the contract;
- noncash consideration; and
- 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.

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

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; and

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.

Income Taxes

The Company records income taxes using the asset and liability method. Deferred income tax assets and liabilities are recognized for the future tax effects attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective income tax bases, and operating loss and tax credit carryforwards. The Company establishes a valuation allowance if management believes it is more likely than not that the deferred tax assets will not be recovered based on an evaluation of objective verifiable evidence. For tax positions that are more likely than not to be sustained upon audit, the Company recognizes the largest amount with a greater than 50% likelihood of being realized. The Company does not recognize any portion of the benefit for tax positions that are not more likely than not to be sustained upon audit.

Net Loss per Share

Net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Since dividends are declared, paid and set aside among the holders of shares of common stock and Class A common stock pro-rata on an as-if-converted basis, the two-class method of computing net loss per share is not required. Diluted net loss per share does not reflect the effect of shares of common stock to be issued upon the exercise of stock options and warrants, as their inclusion would be anti-dilutive. The following table summarizes potentially dilutive securities outstanding at June 30, 2021 and 2020 that were excluded from the computation of diluted net loss per share, as they would be anti-dilutive:

	June 30,	
	2021	**2020**
Warrants (Note 6)	13,191	4,104,705
Stock options (Note 6)	270,000	200,000
Unvested restricted stock (Note 6)	4,277,201	4,089,198
Total	4,560,392	8,393,903

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. The CARES Act did not have a material impact on the Company's income tax provision. 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)

On December 27, 2020, the President of the United States signed the Consolidated Appropriations Act, 2021 ("Consolidated Appropriations Act") into law. The Consolidated Appropriations Act is intended to enhance and expand certain provisions of the CARES Act, allows for the deductions of expenses related to the Payroll Protection Program funds received by companies, and provides an update to meals and entertainment expensing for 2021. The Consolidated Appropriations Act did not have a material impact to the Company's income tax provision for 2020. The Company will continue to evaluate the impact of the Consolidated Appropriations Act on its financial position, results of operations and cash flows.

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 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 financial statements.

Recently Adopted Accounting Standards

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 adopted the new guidance in the first quarter of 2021 and the adoption of this guidance did not to have a material impact on its financial statements.

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

Note 3 – License Agreements

Dana-Farber Cancer Institute

In March 2015, the Company entered into an exclusive license agreement with Dana-Farber Cancer Institute ("Dana Farber") to develop a portfolio of fully human immuno-oncology targeted antibodies. Under the terms of the license agreement, the Company paid Dana-Farber an up-front licensing fee of $1.0 million and, on May 11, 2015, granted Dana-Farber 500,000 shares of common stock, valued at $32,500 or $0.065 per share. The license agreement included an anti-dilution clause that maintained Dana-Farber's ownership at 5% until such time that the Company raised $10 million in cash in exchange for common shares. Pursuant to this provision, on September 30, 2015, the Company granted to Dana-Farber an additional 136,830 shares of common stock valued at approximately $0.6 million and the anti-dilution clause thereafter expired. Dana-Farber is eligible to receive payments of up to an aggregate of approximately $21.5 million for each licensed product upon the Company's successful achievement of certain clinical development, regulatory and first commercial sale milestones. In addition, Dana-Farber is eligible to receive up to an aggregate of $60.0 million upon the Company's successful achievement of certain sales milestones based on aggregate net sales, in addition to royalty payments based on a tiered low to mid-single digit percentage of net sales. Dana-Farber also receives an annual license maintenance fee of $50,000, which is creditable against future milestone payments or royalties. 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. The Company also receives an annual license maintenance fee, which is creditable against future milestone payments or royalties. TGTX also pays the Company for its out-of-pocket costs of material used by TGTX for their development activities. For the three months ended June 30, 2021 and 2020, the Company recognized approximately $100,000 and $14,000, respectively , in revenue related to the collaboration agreement in the Condensed Statements of Operations. For the six months ended June 30, 2021 and 2020, the Company recognized approximately $145,000 and $968,000, respectively, in revenue related to the collaboration agreement in the Condensed Statements of Operations. The revenue for the six months ended June 30, 2020 included a milestone of $925,000 upon the 12th patient dosed in a phase 1 clinical trial for the anti-PD-L1 antibody cosibelimab during March 2020.

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

NeuPharma, Inc.

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

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, the Company paid Jubilant an up-front licensing fee of $2.0 million, and 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, TGTX paid the Company $1.0 million, representing an upfront licensing fee, and the Company is eligible to receive substantive potential milestone payments up to an aggregate of approximately $87.2 million upon TGTX's successful achievement of clinical development and regulatory milestones. This is comprised of up to approximately $25.5 million upon TGTX's successful completion of three clinical development milestones for two licensed products, and up to approximately $61.7 million upon the achievement of five regulatory approvals and first commercial sales in specified territories for two licensed products. In addition, the Company is eligible to receive potential milestone payments up to an aggregate of $89.0 million upon TGTX's successful achievement of certain sales milestones based on aggregate net sales by TGTX, for two licensed products, in addition to royalty payments based on a mid-single digit percentage of net sales by TGTX. TGTX also pays the Company 50% of IND enabling costs and patent expenses. For the three months ended June 30, 2021 and 2020, the Company recognized approximately $55,000 and $28,000, respectively, in revenue related to the sublicense agreement in the Condensed Statements of Operations. For the six months ended June 30, 2021 and 2020, the Company recognized approximately $78,000 and $46,000, 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. These amounts 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. As this revenue relates to an already satisfied performance obligation, it is recognized approximately when the amounts become due. For the six months ended June 30, 2021, the Company did not receive any milestone or royalty payments.

Note 4 – Related Party Agreements

Founders Agreement and Management Services Agreement with Fortress

Effective March 17, 2015, the Company entered into a Founders Agreement with Fortress, which was amended in July 2016 and October 2017. 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. Further, the Company shall: (i) issue annually to Fortress, on January 1 of each year, 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.

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

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.The MSA shall be automatically extended for additional five-year periods unless Fortress or the Company provides notice to the other party of its desire not to automatically extend the term. For the three months ended June 30, 2021 and 2020, the Company recognized $125,000 in expense on its Condensed Statements of Operations related to the MSA. For the six months ended June 30, 2021 and 2020, the Company recognized $250,000 in expense on its Condensed Statements of Operations related to the MSA.

Caribe BioAdvisors, LLC

In December 2016, the Company entered into an advisory agreement effective January 1, 2017 with Caribe BioAdvisors, LLC ("Caribe"), owned by Michael Weiss, to provide the advisory services of Mr. Weiss as Chairman of the Board. Pursuant to the agreement, Caribe will be paid an annual cash fee of $60,000, in addition to any and all annual equity incentive grants paid to members of the board. For the three months ended June 30, 2021 and 2020, 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 six months ended June 30, 2021 and 2020, the Company recognized approximately $55,000 and $56,000, respectively, in expense in its Condensed Statements of Operations related to the advisory agreement, including approximately $25,000 and $26,000, 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 June 30, 2021, and December 31, 2020, there was no litigation against the Company.

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

Note 6 – Stockholders' Equity

Common Stock

At the Company's 2021 Annual Meeting of Stockholders held on June 9, 2021, its stockholders approved an amendment to the Company's certificate of incorporation to increase the number of authorized shares of common stock available to issue by 40,000,000 to 135,000,000 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 10, 2021.

As of June 30, 2021 and December 31, 2020, there were7,000,000 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 2020, the Company filed a shelf registration statement on Form S-3 (the "S-3"), which was declared effective in December 2020. 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 ATM with Cantor Fitzgerald & Co., Ladenburg Thalmann & Co. Inc. and H.C. Wainwright & Co., LLC (each an "Agent" and collectively, the "Agents") relating to the sale of shares of common stock. Under the ATM, the Company pays the Agents a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of common stock.

During the six months ended June 30, 2021, the Company sold a total of10,399,983 shares of common stock under an ATM, at an average selling price of $3.42 per share, resulting in aggregate total gross proceeds of approximately $35.6 million and net proceeds of approximately $34.7 million after deducting approximately $0.9 million in commissions and other transaction costs.

Pursuant to the Founders Agreement, the Company issued to Fortress2.5% of the aggregate number of shares of common stock issued in the offering noted above. Accordingly, the Company issued 259,990 shares of common stock to Fortress and recorded expense of approximately $887,000 related to these stock grants, which is included in general and administrative expenses in the Company's Condensed Statements of Operations for the six months ended June 30, 2021.

Pursuant to the Founders Agreement, the Company issued 1,742,449 shares of common stock to Fortress for the Annual Equity Fee, representing2.5% of the fully diluted outstanding equity of Checkpoint on January 1, 2021 (see Notes 2 and 4).

As of June 30, 2021, approximately $60.3 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.

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 June 30, 2021,3,319,453 shares are available for issuance under the 2015 Incentive Plan.

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

Restricted Stock

Certain employees, directors and consultants have been awarded restricted stock. The restricted stock vesting consists of milestone and time-based vesting. The following table summarizes restricted stock award activity for the six months ended June 30, 2021:

	Number of Shares	Weighted Average Grant Date Fair Value
Non-vested at December 31, 2020	3,869,896	$ 3.61
Granted	919,012	2.70
Vested	(511,707)	3.81
Non-vested at June 30, 2021	4,277,201	$ 3.39

As of June 30, 2021, there was $3.8 million of total unrecognized compensation cost related to non-vested restricted stock, which is expected to be recognized over a weighted-average period of 1.9 years. This amount does not include, as of June 30, 2021, 333,334 shares of restricted stock outstanding which are performance-based and vest upon achievement of certain corporate milestones. The expense is recognized over the vesting period of the award. Stock-based compensation for milestone awards will be measured and recorded if and when it is probable that the milestone will be achieved.

Stock Options

The following table summarizes stock option award activity for the six months ended June 30, 2021:

	Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Outstanding as of December 31, 2020	220,000	$ 3.20	8.04
Granted	50,000	2.85	
Outstanding as of June 30, 2021	270,000	$ 3.14	7.94
Vested and exercisable as of June 30, 2021	50,000	$ 2.56	7.94

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

The Company used the Black-Scholes option pricing model for determining the estimated fair value of stock-based compensation related to stock options. The table below summarizes the assumptions used:

	For the Six Months Ended June 30,	
	2021	2020
Risk-free interest rate	1.04% - 1.50 %	1.02 %
Expected dividend yield	—	—
Expected term in years	10.0	10.0
Expected volatility	100.65% - 102.71 %	101.27 %

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

Warrants

A summary of warrant activities for the six months ended June 30, 2021 is presented below:

	Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Outstanding as of December 31, 2020	57,515	$ 5.39	1.22
Expired	(44,324)	7.00	
Outstanding as of June 30, 2021	13,191	$ 0.00	4.33

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

Stock-Based Compensation

The following table summarizes stock-based compensation expense for the three and six months ended June 30, 2021 and 2020 ($ in thousands):

	For the three months ended June 30,		For the six months ended June 30,	
	2021	2020	2021	2020
Research and development	$ 158	$ 161	$ 319	$ 305
General and administrative	608	570	1,221	1,065
Total stock-based compensation expense	$ 766	$ 731	$ 1,540	$ 1,370

Note 7 - Accounts Payable and Accrued Expenses

At June 30, 2021 and December 31, 2020, accounts payable and accrued expenses consisted of the following ($ in thousands):

	June 30, 2021	December 31, 2020
Accounts payable	$ 5,081	$ 3,438
Accrued compensation	289	535
Research and development	2,775	2,009
Other	201	385
Total accounts payable and accrued expenses	$ 8,346	$ 6,367

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, an anti-programmed death-ligand 1 ("PD-L1") antibody licensed from the Dana-Farber Cancer Institute ("Dana-Farber"), 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 ("CSCC") intended to support one or more applications for marketing approval. In addition, we are evaluating our lead small-molecule, targeted anti-cancer agent, olafertinib (formerly CK-101), a third-generation epidermal growth factor receptor ("EGFR") inhibitor, as a potential new treatment for patients with EGFR mutation-positive non-small cell lung cancer ("NSCLC").

We have also entered into various collaboration agreements with TG Therapeutics, Inc. ("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 and November 2020, we announced updated interim results from our ongoing Phase 1 clinical trial of cosibelimab. The data were presented in poster presentations at the ESMO Virtual Congress 2020 and the Society for Immunotherapy of Cancer 35th Anniversary Annual Meeting. In May 2021, we announced the completion of enrollment for the metastatic CSCC every two-week dosing cohort. We continue to enroll locally advanced CSCC patients in an every two-week dosing cohort and metastatic CSCC patients in an every three-week dosing to support one or more BLA submissions to the FDA for cosibelimab based on this ongoing clinical trial. The primary endpoint for each cohort is objective response rate, and secondary endpoints include duration of response, progression-free survival, and overall survival.

In November 2020, updated results from the previously untreated high PD-L1 expressing patients with advanced NSCLC cohort of the Phase 1 clinical trial of cosibelimab were presented at the Society for Immunotherapy of Cancer 35th Anniversary Annual Meeting.

To date, we have not received approval for the sale of any product candidate in any market and, therefore, have not generated any product sales from any product candidates. In addition, we have incurred substantial operating losses since our inception, and expect to continue to incur significant operating losses for the foreseeable future and may never become profitable. As of June 30, 2021, we have an accumulated deficit of $158.8 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 95 Sawyer Road, Suite 110, Waltham, MA 02453. Our telephone number is (781) 652-4500 and our email address is ir@checkpointtx.com.

Critical Accounting Policies and Use of Estimates

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States of America ("GAAP"). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our financial statements. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are described in more detail in Note 2 – Significant Accounting Policies in the notes to the Company's unaudited condensed financial statements contained in this Quarterly Report on Form 10-Q, and specifically Note 2 – Significant Accounting Policies – Stock Based Compensation Expense for a description of our estimates for calculating the fair value of stock option grants.

Results of Operations

Comparison of the Three Months Ended June 30, 2021 and 2020

Revenue

For the three months ended June 30, 2021, revenue was approximately $155,000 compared to approximately $42,000 for the three months ended June 30, 2020, an increase of $113,000. The change was due to increased patent fees related to our collaborations with TGTX in the current period.

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 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 June 30, 2021, research and development expenses were approximately $7.2 million, compared to $3.0 million for the three months ended June 30, 2020, an increase of $4.2 million. The current period research and development expenses primarily consisted of $3.2 million related to clinical costs for our product candidates, $3.0 million related to manufacturing costs and $0.2 million related to stock compensation expense. The prior period research and development expenses primarily consisted of $2.2 million related to clinical costs for our product candidates, $0.3 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 for the remainder of 2021.

General and Administrative Expenses

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

For the three months ended June 30, 2021, general and administrative expenses were approximately $2.1 million, compared to $1.7 million for the three months ended June 30, 2020, an increase of $0.4 million. The current period general and administrative expenses primarily consisted of stock compensation expense of $0.6 million, $0.3 million related to 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 $0.6 million, $0.3 million related to salary expenses, $0.3 million related to legal and accounting fees, $0.2 million related to investor relation 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 2021.

Comparison of the Six Months Ended June 30, 2021 and 2020

Revenue

For the six months ended June 30, 2021, revenue was approximately $0.2 million compared to approximately $1.0 million for the six months ended June 30, 2020, a decrease of $0.8 million. The current period revenue consisted of patent and license maintenance fees related to our collaborations with TGTX. The prior period revenue 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.

Research and Development Expenses

For the six months ended June 30, 2021, research and development expenses were approximately $11.4 million, compared to $5.7 million for the six months ended June 30, 2020, an increase of $5.7 million. The current period research and development expenses primarily consisted of $5.6 million related to clinical costs for our product candidates, $4.0 million related to manufacturing costs and $0.3 million related to stock compensation expense. The prior period research and development expenses primarily consisted of $3.9 million related to clinical costs for our product candidates, $0.8 million related to the manufacturing costs of our product candidates, and $0.3 million related to stock compensation expense.

General and Administrative Expenses

For the six months ended June 30, 2021, general and administrative expenses were approximately $4.5 million, compared to $3.4 million for the six months ended June 30, 2020, an increase of $1.1 million. The current period general and administrative expenses primarily consisted of stock compensation expense of $1.2 million, $0.9 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 for salary expense, $0.6 million related to legal and accounting fees and $0.2 million related to investor relation fees. The prior period general and administrative expenses primarily consisted of stock compensation expense of $1.1 million, $0.6 million related to salary expenses, $0.5 million related to legal and accounting fees, $0.4 million related to investor relation 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.

Liquidity and Capital Resources

We have incurred substantial operating losses since our inception and expect to continue to incur significant operating losses for the foreseeable future and may never become profitable. As of June 30, 2021, we had an accumulated deficit of $158.8 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 June 30, 2021 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.

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 effects of the COVID-19 pandemic on the Company's operations, as well as on the Company's clients, vendors, and business partners, and the actions implemented to combat the virus throughout the world.

Cash Flows for the Six Months Ended June 30, 2021 and 2020

Operating Activities

Net cash used in operating activities was approximately $10.4 million for the six months ended June 30, 2021, compared to approximately $6.7 million for the six months ended June 30, 2020. The increase in net cash used in operating activities was primarily related to an increase in clinical and manufacturing costs related to cosibelimab in the current period.

Investing Activities

There were no investing activities for the six months ended June 30, 2021 and 2020.

Financing Activities

Net cash provided by financing activities was $34.7 million for the six months ended June 30, 2021. Cash provided by financing activities related to net proceeds of $34.7 million from the issuance of common stock as part of our At-the-Market Issuance Sales Agreement offerings. Net cash provided by financing activities for the six months ended June 30, 2020 primarily related to net proceeds of $2.6 million from the issuance of common stock as part of our At-the-Market Issuance Sales Agreement offerings.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

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

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 Chief Financial Officer, to allow timely decisions regarding required disclosure.

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

With respect to the quarter ended June 30, 2021, 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 Chief Financial Officer have concluded that our disclosure controls and procedures are effective. Management does not expect that our internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control systems are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in a cost-effective control system, no evaluation of internal control over financial reporting can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been or will be detected.

Changes in Internal Control over Financial Reporting:

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter ended June 30, 2021 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 Finances and Capital Requirements

We have incurred significant losses since our inception and anticipate that we will incur continued losses for the foreseeable future. We 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 $158.8 million as of June 30, 2021. 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 need to establish the necessary commercial infrastructure to launch this product candidate without substantial delays, including manufacturing to build pre-commercial inventory, 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;
- we initiate one or more clinical trials to pursue additional indications for our product candidates;
- 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 candidates receives regulatory approval.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue from the sale of our development stage products, and we do not know when, or if, we will generate any revenue. 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. 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 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 believe that our cash and cash equivalents balances are sufficient to fund our anticipated operating cash requirements for at least one year from the date of issuance 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 are an "emerging growth company" and a "smaller reporting company," and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

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

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

We may expend our limited resources to pursue certain product candidates or indications 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.

Risks Related to our Business Strategy, Structure, and Organization

We currently have no drug products for sale and are dependent on the future success of our product candidates. We can give no 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, in checkpoint therapy-naïve patients with selected recurrent or metastatic cancers, including CSCC, to support one or more U.S. BLAs and comparable applications for marketing approval outside the U.S. In January 2020, we announced that we had discussed with the FDA this strategy in CSCC. Similarly, we intend to use data from our licensor's ongoing Phase 3 clinical trial of olafertinib (formerly CK-101), conducted only in China, in patients with EGFR mutation-positive NSCLC, to support a U.S. NDA and comparable applications for marketing approval outside the U.S. 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. If we prove to be incorrect, running additional studies in the U.S. will require substantial time, effort and financial resources.

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 comparable foreign regulatory authority, respectively, and we may never receive such regulatory approval for any of our product candidates.

Our future growth depends on our ability to identify and acquire or in-license products and successfully integrating such acquired or in-licensed products into our existing operations.

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.

Risks Inherent in Drug Development and Commercialization

Because results of preclinical studies and early clinical trials are not necessarily predictive of future results, any product candidate we advance may not have favorable results in later clinical trials or receive regulatory approval. Moreover, interim, "top-line," and preliminary data from our clinical trials that we announce or publish may change, or the perceived product profile may be negatively impacted, as more patient data or additional endpoints (including efficacy and safety) are analyzed.

Pharmaceutical development has inherent risks. The outcome of preclinical development testing and early clinical trials may not be predictive of the outcome of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates. Once a product candidate has displayed sufficient preclinical data to warrant clinical investigation, we will be required to demonstrate through adequate and well-controlled clinical trials that our product candidates are effective with a favorable benefit-risk profile for use in populations for their target indications before we can seek regulatory approvals for their commercial sale. Many drug candidates fail in the early stages of clinical development for safety and tolerability issues or for insufficient clinical activity, despite promising preclinical results. Accordingly, no assurance can be made that a safe and efficacious dose can be found for these compounds or that they will ever enter into advanced clinical trials alone or in combination with other product candidates. Moreover, success in early clinical trials does not mean that later clinical trials will be successful because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety or efficacy despite having progressed through initial clinical testing. Companies frequently experience significant setbacks in advanced clinical trials, even after earlier clinical trials have shown promising results. There is an extremely high rate of failure of pharmaceutical candidates proceeding through clinical trials.

Individually reported outcomes of patients treated in clinical trials may not be representative of the entire population of treated patients in such studies. In addition, registration or larger scale Phase 3 studies, which are often conducted internationally, are inherently subject to increased operational risks compared to earlier stage studies, including the risk that the results could vary on a region to region or country to country basis, which could materially adversely affect the outcome of the study or the opinion of the validity of the study results by applicable regulatory agencies.

From time to time, we may publicly disclose top-line or preliminary data from our clinical trials, which is based on a preliminary analysis of then available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of such data, and we may not have received or had the opportunity to fully and carefully evaluate all data from the particular study or trial, including all endpoints and safety data. As a result, top-line or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the topline, interim, or preliminary data we previously published. When providing top-line results, we may disclose the primary endpoint of a study before all secondary endpoints have been fully analyzed. A positive primary endpoint does not translate to all, or any, secondary endpoints being met. As a result, top-line and preliminary data should be viewed with caution until the final data are available, including data from the full safety analysis and the final analysis of all endpoints.

Further, from time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. For example, many of the results reported in our early clinical trials rely on local investigator-assessed efficacy outcomes which may be subject to greater variability or subjectivity than results assessed in a blinded, independent, centrally reviewed manner, often required of final or later phase, adequate and well-controlled registration-directed clinical trials. If the results from our registration-directed trials are different from the results found in the earlier studies, we may need to terminate or revise our clinical development plan, which could extend the time for conducting our development program and could have a material adverse effect on our business. Also, time-to-event based endpoints such as duration of response and progression-free survival have the potential to change, sometimes drastically, with longer follow-up. In addition, as patients continue on therapy, there can be no assurance given that the final safety data from studies, once fully analyzed, will be consistent with prior safety data presented, will be differentiated from other similar agents in the same class, will support continued development, or will be favorable enough to support regulatory approvals for the indications studied. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. The information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and regulators or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, top-line or preliminary data that we report differ from final results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, or successfully commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or 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 contract research organizations (“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.

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.

Difficulties in the enrollment of patients in clinical trials may prevent or delay receipt of necessary regulatory approvals.

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 may not be able to initiate or continue clinical trials for one or more of our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. Some of our competitors have ongoing clinical trials for product candidates that treat the same indications 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.

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 comparable foreign regulatory authorities outside the United States. Failure to obtain marketing approval for one or more of our product candidates or any future product candidate will prevent us from commercializing the product candidate. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party 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.

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 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.

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.

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 other regulatory authorities, 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 other applicable regulatory authorities, may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates, 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.

Regulatory approval by the FDA, or any similar regulatory authorities 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 other similar regulatory authorities 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 similar regulatory authorities 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 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.

If our competitors develop treatments for any of our product candidates' target indications and those competitor products are approved more quickly, marketed more successfully or demonstrated to be more effective, the commercial opportunity for our product candidate will be reduced or eliminated.

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

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. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. We will also face competition from these third parties in establishing clinical trial sites, in patient registration for clinical trials, and in identifying and in-licensing new product candidates.

Further, 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.

If any of our product candidates are successfully developed but do not achieve broad market acceptance among physicians, patients, healthcare payors and the medical community, the revenues that any such product candidates generate from sales will be limited.

Even if our product candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors and the medical community. Coverage and reimbursement of our product candidates by third-party payors, including government payors, generally would also be necessary for commercial success. The degree of market acceptance of any approved products would depend on a number of factors, including, but not necessarily limited to:

- the efficacy and safety as demonstrated in clinical trials;
- 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 hospitals and clinics and patients of the product as a safe and effective treatment;
- the potential and perceived advantages of product candidates over alternative treatments;
- the safety of product candidates in a broader patient group (i.e. based on actual use);
- the cost of treatment in relation to alternative treatments;
- the availability of adequate reimbursement and pricing by third parties and government authorities;
- changes in regulatory requirements by government authorities for our product candidates
- relative convenience and ease of administration;
- the prevalence and severity of side effects and adverse events;
- the effectiveness of our sales and marketing efforts; and
- unfavorable publicity relating to the product.

If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate sufficient revenue from these products and in turn we may not become or remain profitable.

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 be unsuccessful in commercializing our product candidates, if 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 approved product candidate, we would need to build marketing, sales, distribution, managerial and other non-technical capabilities, or arrange for third parties to perform these services, and we may be unsuccessful in doing so. In the event of successful development and regulatory approval of any of our current or future product candidates, 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.

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. If we obtain marketing approval for one or more of our product candidates in development, we intend to expand our insurance coverage to include the sale of commercial products, 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.

Risks Related to Reliance on Third Parties

We intend to contract with third parties for the manufacture of our approved products, if any. If such contract manufacturer fails to timely produce sufficient product volume or to comply with applicable regulations, the commercialization of our product candidates may be delayed, we may be unable to meet market demand, and we may lose potential revenues.

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

All of our contract manufacturers must comply with strictly enforced federal, state and foreign regulations, including cGMP requirements enforced by the FDA through its 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.

We rely, and expect to continue to rely, on third parties to conduct our preclinical studies and clinical trials. Those third parties may perform unsatisfactorily, fail to meet deadlines for trial completion, or to comply with applicable regulatory requirements.

We rely on third-party CROs and site management organizations to conduct some of our preclinical studies and all 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 ("GLPs") 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 rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical and clinical testing and for the future commercialization of our approved products, if any. Reliance on third parties increases the risk that we will not have sufficient quantities of our products 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.

Risks Relating to Legislation and Regulation Affecting the Biopharmaceutical and Other Industries

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, specifically through rulemaking and guidance, that could impact the pharmaceutical business and industry. A few of the major administrative actions include:

1. On October 9, 2019, the Centers for Medicare & Medicaid Services ("CMS") issued a proposed rule entitled,*Modernizing and Clarifying the Physician Self-Referral Regulations* and on the same day the HHS Office of Inspector General issued a similar rule, entitled*Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary penalty Rules Regarding Beneficiary Inducements*. The proposed rules are an effort to reform regulations dealing with anti-kickback and self-referral laws. The proposals are attempting to allow certain financial arrangements that would otherwise violate anti-kickback and self-referral laws for providers that are participating in value-based payment arrangements. The proposed rule could impact drug purchasing behavior to ensure providers are within their budget and/or restructure existing payment structures between providers and manufacturers.

2. On October 30, 2019, the Administration issued an advanced notice of proposed rulemaking ("ANPRM") entitled,*International Pricing Index Model for Medicare Part B Drugs*. This ANPRM is soliciting feedback on a potential proposal to align United States drug prices in the Medicare Part B program with international prices. It also solicits public feedback on a policy that would allowing private-sector vendors to negotiate prices, take title to drugs, and improve competition for hospital and physician business. Although this is only a notice for a potential rule, it signals the Administration's desire to regulatorily influence the United States drug pricing system that could adversely affect the industry.

3. On November 15, 2019, CMS issued a proposed rule entitled,*Transparency in Coverage* and finalized the *Calendar Year ("CY") 2020 Outpatient Prospective Payment System ("OPPS") & Ambulatory Surgical Center Price Transparency Requirements for Hospitals to Make Standard Charges Rule*. Together the rules would increase price transparency through health plans and in hospitals. The affects may influence consumer purchasing habits in the health care sector as a whole. Although the transparency provisions are not yet in effect and the hospital price transparency requirements are subject to litigation, there could be implications for the industry related to drug pricing if or when it is enacted.

4. On November 18, 2019, CMS issued a proposed rule entitled,*Medicaid Fiscal Accountability Regulation ("MFAR")*. The proposed rule would significantly impact states' ability to finance their Medicaid programs. If finalized, the MFAR could force states to restructure their Medicaid financing that could disincentivize or change state prescription drug purchasing behavior that would adversely impact the industry.

5. On December 18, 2019, the FDA issued a proposed rule entitled,*Importation of Prescription Drugs.* The proposed rule would allow the importation of certain prescription drugs from Canada. If finalized, states or other non-federal government entities would be able to submit importation program proposals to FDA for review and authorization. This proposed rule could also influence pricing practices in the United States.

6. On January 30, 2020, CMS issued a state waiver option entitled *Health Adult Opportunity ("HAO")*. The HAO would allow states to restructure benefits and coverage policies for their Medicaid programs. The HAO will provide states administrative flexibilities in exchange for a capped federal share. The cap on the federal share is commonly referred to as a "block grant." Importantly, the HAO allows states to set formularies that align with Essential Health Benefit requirements while still requiring manufacturers to participate in the Medicaid Rebate Program. Depending on utilization of the HAO by states, it could impact the industry – especially if states elect to use a formulary.

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.

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, 2018, a Texas federal district court judge issued a ruling declaring that the ACA in its entirety is unconstitutional. Upon appeal, the Fifth Circuit upheld the district court's ruling that the individual mandate is unconstitutional. However, the Fifth Circuit remanded the case back to the district court to conduct a more thorough assessment of the constitutionality of the entire ACA despite the individual mandate being unconstitutional. The Supreme Court agreed to hear the case on appeal from the Fifth Circuit on March 2, 2020 and held oral arguments on November 10, 2020. While this lawsuit has no immediate legal effect on the ACA and its provisions, this lawsuit is ongoing and the outcome may have a significant impact on our business.

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

The 116th Congress 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), 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. The 117th Congress convened on January 3, 2021, and could reintroduce many of the bills targeting drug prices. While we cannot predict what proposals may ultimately become law, the elements under consideration could significantly change the landscape in which the pharmaceutical market operates.

The Senate Committee on Health, Education, Labor, and Pensions (HELP) advanced the Lower Health Care Costs Act of 2019. Among other things, the bill is intended to reduce costs in the United States health sector. The bill revises certain requirements to expedite the approval of generics and biosimilars. It also limits prices that pharmacy benefit managers may charge health insurers or enrollees for prescription drugs. Although this bill still needs to pass the full Senate and House of Representatives, it is worth noting the wide-ranging effects it could have on the health care sector.

On December 12, 2019, the House of Representatives passed broad legislation (H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act) that would, among other provisions, require HHS to negotiate drug prices and impose price caps and restructure the Medicare Part D benefit, imposing more financial responsibility on certain drug manufacturers. Failure by a manufacturer to reach an agreement with HHS on the negotiated price could result in significant penalties for prescription drug manufacturers. In addition, S. 2543, the Prescription Drug Pricing Reduction Act would also, among other provisions, restructure the Medicare Part D benefit, but it would not authorize direct negotiation by the federal government. While we cannot predict what proposals may ultimately become law, the elements under consideration could significantly change the landscape in which the pharmaceutical market operates.

The Trump Administration took several regulatory steps to redirect ACA implementation. The HHS finalized a Medicare hospital payment reduction for Part B drugs acquired through the 340B Drug Pricing Program.

Under the Trump Administration, HHS finalized several proposals aimed at lowering drug prices for Medicare beneficiaries and increasing price transparency. For example, the Trump Administration issued an interim final rule on November 27, 2020 implementing a "Most Favored Nation" payment model for Part B drugs that applies international reference pricing to determine reimbursement for certain drugs paid by Medicare Part B. The interim final rule was enjoined by federal courts prior to its implementation date of January 1, 2021, and the lawsuit is ongoing. In addition, HHS, in conjunction with the FDA, finalized four pharmaceutical importation pathways in September 2020: (1) regulations establishing importation of pharmaceuticals from Canada by wholesalers and pharmacists; (2) FDA guidance permitting manufacturers to import their own pharmaceuticals that were originally intended for marketing in other countries; (3) a request for proposals from private sector entities to import prescription drugs for personal use under existing statutory authority; and (4) a request for proposals from private sector entities to reimport insulin under existing statutory authority. Further, on November 11, 2020, the Trump Administration issued a final rule that changes the permissible structure of drug rebates and discounts between drug manufacturers and third-party payors (including pharmacy benefit managers that negotiate drug prices on behalf of such third-party payors). This final rule, often referred to as the "Rebate Rule," could have significant direct and indirect impacts on drug pricing in both government and commercial markets. With respect to price transparency, the Trump Administration promulgated regulations that require hospitals and third-party payors to disclose prices of items and services, which may impact negotiated rates in the commercial market.

On January 20, 2021, Joe Biden was inaugurated as the 46th president of the United States. As a presidential candidate, Mr. Biden indicated support for several policies aimed at lowering drug prices, including government price negotiation, drug importation, international reference pricing, and price increase controls. The incoming Biden Administration may continue, modify, or repeal many of the drug pricing policies proposed and finalized by the Trump Administration. While we cannot predict which policies the Biden Administration may support and enforce, the policies finalized in the months prior to the beginning of Mr. Biden's term, if continued, could significantly change the landscape in which the pharmaceutical market operates and significantly impact our ability to effectively market and sell our products.

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:

- 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;
- our ability to generate revenues and achieve or maintain profitability;
- 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. In January 2020, President Trump signed into law the U.S.-Mexico-Canada (USMCA) trade deal into law. As enacted, there are no commitments with respect to biological product intellectual property rights or data protection, which may create an unfavorable environment across these three countries.

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.

Risks Related to Intellectual Property and Potential Disputes with Licensors Thereof

If we are unable to obtain and maintain sufficient patent protection for our technology and products, 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.

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 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.

We depend on our licensors to maintain and enforce the intellectual property covering certain of our product candidates. We have limited, if any, control over the resources that our licensors can or will devote to securing, maintaining, and enforcing patents protecting 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.

Protecting our proprietary rights is difficult and costly, and we may be unable 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, and an unfavorable outcome in any litigation would harm our business.

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.

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.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expense 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.

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.

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

We have in-licensed the rights to all of our product candidates from third parties. Any disputes between us and any of our licensors regarding our rights under our license agreements may impact our ability to develop and commercialize these product candidates. 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 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 Relating to Our Control by Fortress Biotech Inc.

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.

Risks Related to Conflicts of Interest

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. 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.

General Risks

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 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.

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.

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, which may be impacted by economic or other crises or external factors, including the effects of the COVID-19 pandemic on the global economy;
- 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.

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
3.1	Certificate of Amendment to the Amended and Restated Certificate of Incorporate of Checkpoint Therapeutics, Inc., filed as Exhibit 3.1 to the Form 8-K filed on June 11, 2021 and incorporated herein by reference.
31.1	Certification of Principal Executive Officer of Checkpoint Therapeutics, Inc. pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated August 6, 2021.
31.2	Certification of Principal Financial Officer of Checkpoint Therapeutics, Inc. pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated August 6, 2021.
32.1	Certification of Principal Executive Officer of Checkpoint Therapeutics, Inc. pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated August 6, 2021.
32.2	Certification of Principal Financial Officer of Checkpoint Therapeutics, Inc. pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated August 6, 2021.
101	The following financial information from the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2021, 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).
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

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: August 6, 2021

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

Exhibit 31.1

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

I, James F. Oliviero, certify that:

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

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

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

/s/ James F. Oliviero

James F. Oliviero
President and Chief Executive Officer
(Principal Executive Officer)
August 6, 2021

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
Chief Financial Officer
(Principal Financial Officer)
August 6, 2021

Exhibit 32.1

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

I, James F. Oliviero, Chief Executive Officer of Checkpoint Therapeutics, Inc. (the "Company"), in compliance with 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, hereby certify that, to the best of my knowledge, the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2021 (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
President and Chief Executive Officer
James F. Oliviero
(Principal Executive Officer)
August 6, 2021

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, Chief Financial Officer of Checkpoint Therapeutics, Inc. (the "Company"), in compliance with 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, hereby certify that, to the best of my knowledge, the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2021 (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
Chief Financial Officer
(Principal Financial Officer)
August 6, 2021