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

FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2019

or

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

Commission File Number 000-50549

Oncternal Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**46-4137807**
(State or other jurisdiction of incorporation or organization)	**(IRS Employer Identification No.)**
12230 El Camino Real, Suite 300, San Diego CA	**92130**
(Address of principal executive offices)	**(Zip Code)**

(858) 434-1113
(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, $0.001 par value	ONCT	The 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 and post 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 the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

As of August 6, 2019, the registrant had 15,384,764 shares of common stock outstanding.

Oncternal Therapeutics, Inc.

FORM 10-Q

TABLE OF CONTENTS

PART I - FINANCIAL INFORMATION

Item 1.	Condensed Consolidated Financial Statements (unaudited)	3
	Condensed Consolidated Balance Sheets	3
	Condensed Consolidated Statements of Operations	4
	Condensed Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)	5
	Condensed Consolidated Statement of Cash Flows	7
	Notes to Condensed Consolidated Financial Statements	8
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	22
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	31
Item 4.	Controls and Procedures	32

PART II - OTHER INFORMATION

Item 1.	Legal Proceedings	33
Item 1A.	Risk Factors	33
Item 2.	Unregistered Sales of Equity Securities	80
Item 3.	Defaults Upon Senior Securities	80
Item 4.	Mine Safety Disclosures	80
Item 5.	Other Information	80
Item 6.	Exhibits	81
Signatures		85

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

Oncternal Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except par value)

	June 30, 2019 (Unaudited)	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 28,516	$ 20,645
Prepaid and other assets	1,355	565
Total current assets	29,871	21,210
Right-of-use asset	265	—
Other assets	767	752
Total assets	$ 30,903	$ 21,962
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 2,765	$ 3,440
Accrued liabilities	2,550	891
Deferred grant revenue	2,387	—
Current portion of lease liability	139	—
Total current liabilities	7,841	4,331
Preferred stock warrant liability	—	674
Lease liability	126	—
Commitments and contingencies (Notes 3 and 5)		
Convertible preferred stock, $0.0001 par value; authorized shares - none and 130,100 at June 30, 2019 and December 31, 2018, respectively; issued and outstanding – none and 8,148 at June 30, 2019 and December 31, 2018, respectively; liquidation preference of $0 and $48,954 at June 30, 2019 and December 31, 2018, respectively	—	46,588
Stockholders' equity (deficit):		
Preferred stock, $0.001 par value, authorized shares – 5,000 shares and none at June 30, 2019 and December 31, 2018, respectively; issued and outstanding shares – none	—	—
Common stock, $0.001 par value; authorized shares – 60,000 and 200,000 shares at June 30, 2019 and December 31, 2018, respectively; issued and outstanding shares – 15,370 and 3,762 at June 30, 2019 and December 31, 2018, respectively	15	5
Additional paid-in capital	79,445	1,748
Accumulated deficit	(56,524)	(31,384)
Total stockholders' equity (deficit)	22,936	(29,631)
Total liabilities and stockholders' equity (deficit)	$ 30,903	$ 21,962

See accompanying notes.

Oncternal Therapeutics, Inc.
Condensed Consolidated Statements of Operations
(Unaudited; in thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Grant revenue	$ 674	$ 1,527	$ 1,144	$ 1,715
Operating expenses:				
Research and development	2,587	3,513	4,483	4,802
In-process research and development	18,088	—	18,088	—
General and administrative	1,619	555	2,551	1,136
Total operating expenses	22,294	4,068	25,122	5,938
Loss from operations	(21,620)	(2,541)	(23,978)	(4,223)
Other income (expense):				
Change in fair value of warrant liability	(1,285)	114	(1,268)	77
Other income	—	—	—	216
Interest expense	—	—	—	(1)
Interest income	59	15	106	28
Total other income (expense)	(1,226)	129	(1,162)	320
Net loss	$ (22,846)	$ (2,412)	$ (25,140)	$ (3,903)
Net loss per share, basic and diluted	$ (3.38)	$ (0.68)	$ (4.81)	$ (1.10)
Weighted-average shares outstanding, basic and diluted	6,765	3,573	5,229	3,555

See accompanying notes.

Oncternal Therapeutics, Inc.
Condensed Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(Unaudited; in thousands)

	Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Capital	Deficit	(Deficit)
Balance at December 31, 2018	8,148	$ 46,588	3,762	$ 5	$ 1,748	$ (31,384)	$ (29,631)
Exercise of stock options for cash	—	—	2	—	2	—	2
Vesting related to repurchase liability	—	—	—	—	4	—	4
Stock-based compensation	—	—	—	—	39	—	39
Net loss	—	—	—	—	—	(2,294)	(2,294)
Balance at March 31, 2019	8,148	46,588	3,764	5	1,793	(33,678)	(31,880)
Issuance of common stock to former stockholders of GTx upon Merger	—	—	3,458	2	29,047	—	29,049
Conversion of convertible preferred stock into common stock upon Merger	(8,148)	(46,588)	8,148	8	46,580	—	46,588
Reclassification of convertible preferred stock warrant liability	—	—	—	—	1,942	—	1,942
Vesting related to repurchase liability	—	—	—	—	20	—	20
Stock-based compensation	—	—	—	—	63	—	63
Net loss	—	—	—	—	—	(22,846)	(22,846)
Balance at June 30, 2019	—	$ —	15,370	$ 15	$ 79,445	$ (56,524)	$ 22,936

See accompanying notes.

Oncternal Therapeutics, Inc.
Condensed Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(Unaudited; in thousands)

	Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Capital	Deficit	(Deficit)
Balance at December 31, 2017	5,653	$ 28,715	3,745	$ 5	$ 1,522	$ (24,805)	$ (23,278)
Collection of stock subscription receivable	—	1,100	—	—	—	—	—
Stock-based compensation	—	—	—	—	43	—	43
Net loss	—	—	—	—	—	(1,491)	(1,491)
Balance at March 31, 2018	5,653	29,815	3,745	5	1,565	(26,296)	(24,726)
Issuance of restricted common shares	—	—	15	—	—	—	—
Stock-based compensation	—	—	—	—	41	—	41
Net loss	—	—	—	—	—	(2,412)	(2,412)
Balance at June 30, 2018	5,653	$ 29,815	3,760	$ 5	$ 1,606	$ (28,708)	$ (27,097)

See accompanying notes.

Oncternal Therapeutics, Inc.
Condensed Consolidated Statements of Cash Flows
(Unaudited; in thousands)

	Six Months Ended June 30,	
	2019	**2018**
Cash flows from operating activities		
Net loss	$ (25,140)	$ (3,903)
Adjustments to reconcile net loss to net cash used in operating activities:		
In-process research and development	18,088	—
Noncash lease expense	13	—
Noncash other income	—	(216)
Stock-based compensation	102	84
Noncash compensation expense	24	—
Noncash interest expense	—	1
Change in fair value of preferred stock warrants liability	1,268	(77)
Changes in operating assets and liabilities:	—	—
Prepaid expenses and other assets	(663)	(2,599)
Accounts payable	(4,435)	2,543
Change in operating lease liability	(13)	—
Accrued liabilities	(1,503)	130
Deferred grant revenue	2,387	(1,246)
Net cash used in operating activities	(9,872)	(5,283)
Cash flows from investing activities		
Cash acquired in connection with the Merger	18,292	—
Acquisition related costs paid	(551)	—
Net cash provided by investing activities	17,741	—
Cash flows from financing activities		
Proceeds from exercise of stock options	2	—
Proceeds from convertible preferred stock subscription	—	1,100
Net cash provided by financing activities	2	1,100
Net increase (decrease) in cash and cash equivalents	7,871	(4,183)
Cash and cash equivalents at beginning of period	20,645	10,188
Cash and cash equivalents at end of period	$ 28,516	$ 6,005
Supplemental disclosure of non-cash investing and financing activities:		
Conversion of convertible preferred stock into common stock	$ 46,588	$ —
Issuance of common stock to GTx stockholders	$ 29,049	$ —
Reclassification of preferred stock warrants liability to additional paid-in capital	$ 1,942	$ —
Net liabilities assumed in Merger	$ 5,177	$ —
Acquisition related costs included in accounts payable and accrued liabilities	$ 1,604	$ —

See accompanying notes.

1. Description of Business, Basis of Presentation and Summary of Significant Accounting Policies

Description of Business

Oncternal Therapeutics, Inc. (the "Company," "Oncternal," or the "combined company"), formerly known as GTx, Inc., was incorporated in Tennessee in September 1997 and reincorporated in Delaware in 2003 and is based in San Diego, California. The Company is a clinical-stage biopharmaceutical company focused on developing first-in-class product candidates for cancers with critical unmet medical need. The Company's clinical pipeline consists of its lead program, cirmtuzumab, a humanized monoclonal antibody that binds to ROR1 (Receptor-tyrosine kinase-like Orphan Receptor 1), and TK216, a small molecule inhibiting the biological activity of ETS-family transcription factor oncoproteins targeting patients with Ewing sarcoma. The Company is also developing a CAR-T (chimeric antigen receptor T-cells) product candidate that targets ROR1.

Merger

On March 6, 2019, the Company, then operating as GTx, Inc. ("GTx"), entered into an Agreement and Plan of Merger and Reorganization, as amended (the "Merger Agreement"), with privately-held Oncternal Therapeutics, Inc. ("Private Oncternal") and Grizzly Merger Sub, Inc., a wholly-owned subsidiary of the Company ("Merger Sub"). Under the Merger Agreement, Merger Sub merged with and into Private Oncternal, with Private Oncternal surviving as a wholly-owned subsidiary of the Company (the "Merger"). On June 7, 2019, the Merger was completed. GTx changed its name to Oncternal Therapeutics, Inc., and Private Oncternal, which remains as a wholly-owned subsidiary of the Company, changed its name to Oncternal Oncology, Inc. On June 10, 2019, the combined company's common stock began trading on The Nasdaq Capital Market under the ticker symbol "ONCT."

Except as otherwise indicated, references herein to "Oncternal," "the Company," the "combined company," "we," "us," and "our," refer to Oncternal Therapeutics, Inc. on a post-Merger basis, and the term "Private Oncternal" refers to the business of privately-held Oncternal Therapeutics, Inc., prior to completion of the Merger. References to GTx refer to GTx, Inc. prior to completion of the Merger.

Pursuant to the terms of the Merger Agreement, each outstanding share of Private Oncternal common stock outstanding immediately prior to the closing of the Merger was converted into approximately 0.073386 shares of Company common stock (the "Exchange Ratio"), after taking into account the Reverse Stock Split, as defined below. Immediately prior to the closing of the Merger, all shares of Private Oncternal preferred stock then outstanding were exchanged into shares of common stock of Private Oncternal. In addition, all outstanding options exercisable for common stock of Private Oncternal and warrants exercisable for convertible preferred stock of Private Oncternal became options and warrants exercisable for the same number of shares of common stock of the Company multiplied by the Exchange Ratio. Immediately following the Merger, stockholders of Private Oncternal owned approximately 77.5% of the outstanding common stock of the combined company.

The transaction was accounted for as a reverse asset acquisition in accordance with generally accepted accounting principles in the United States of America ("GAAP"). Under this method of accounting, Private Oncternal was deemed to be the accounting acquirer for financial reporting purposes. This determination was primarily based on the facts that, immediately following the Merger: (i) Private Oncternal's stockholders owned a substantial majority of the voting rights in the combined company, (ii) Private Oncternal designated a majority of the members of the initial board of directors of the combined company, and (iii) Private Oncternal's senior management holds all key positions in the senior management of the combined company. As a result, as of the closing date of the Merger, the net assets of the Company were recorded at their acquisition-date relative fair values in the condensed consolidated financial statements of the Company and the reported operating results prior to the Merger will be those of Private Oncternal.

Reverse Stock Split and Exchange Ratio

On June 7, 2019, in connection with, and prior to the completion of, the Merger, the Company effected a one-for-seven reverse stock split of its then outstanding common stock (the "Reverse Stock Split"). The par value and the authorized shares of the common stock were not adjusted as a result of the Reverse Stock Split. All of the Company's issued and outstanding common stock have been retroactively adjusted to reflect this Reverse Stock Split for all periods presented. All issued and outstanding Private Oncternal common stock, preferred stock, options and warrants prior to the effective date of the Merger have been retroactively adjusted to reflect the Exchange Ratio for all periods presented.

Principles of Consolidation

The condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Oncternal Oncology, Inc. and Oncternal, Inc. All intercompany accounts and transactions have been eliminated in the preparation of the condensed consolidated financial statements.

Liquidity and Going Concern

From its inception through June 30, 2019, the Company has devoted substantially all of its efforts to organizational activities including raising capital, building infrastructure, acquiring assets, developing intellectual property, and conducting preclinical studies, clinical trials and product development activities. The Company has a limited operating history and the sales and income potential of the Company's business and market are unproven. Since inception, the Company has experienced recurring net losses and negative cash flows from operating activities and expects to continue to incur losses into the foreseeable future. At June 30, 2019, the Company had an accumulated deficit of $56.5 million and had cash and cash equivalents of $28.5 million. The Company believes that its existing cash and cash equivalents will be sufficient to fund its operations into the second quarter of 2020. The Company will need to continue to raise a substantial amount of funds until it is able to generate revenues to fund its development activities and operations. The accompanying condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business. However, based on the Company's current working capital, anticipated operating expenses and net losses and the uncertainties surrounding its ability to raise additional capital as needed, as discussed below, the Company believes that there is substantial doubt about its ability to continue as a going concern for one year after the date these condensed consolidated financial statements are issued.

The Company plans to continue to fund its losses from operations and capital funding needs through a combination of equity offerings, debt financings, government funding, or other sources, including, potentially, collaborations, licenses and other similar arrangements. There can be no assurance that the Company will be able to obtain any sources of financing on acceptable terms, or at all. To the extent that the Company can raise additional funds by issuing equity securities, the Company's stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact the Company's ability to conduct its business.

Unaudited Interim Financial Information

The unaudited condensed consolidated financial statements at June 30, 2019, and for the three and six months ended June 30, 2019 and 2018, have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission ("SEC") and with GAAP. These unaudited condensed consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements and include all adjustments, consisting of only normal recurring accruals, which in the opinion of management are necessary to present fairly the Company's financial position as of the interim date and results of operations for the interim periods presented. Interim results are not necessarily indicative of results for a full year or future periods. The preparation of financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures 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 materially from those estimates. These unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements for the year ended December 31, 2018 filed with the SEC on Form S-4/A on May 6, 2019.

Use of Estimates

The Company's condensed consolidated financial statements are prepared in accordance with GAAP. The preparation of the Company's condensed consolidated financial statements and accompanying notes requires it to make estimates and assumptions that impact the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities. Significant estimates consist of those used to determine the fair value of the Company's preferred stock, preferred stock warrant liability and stock-based awards, and those used to determine grant revenue and accruals for research and development costs. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of three months or less when purchased to be cash equivalents. Cash and cash equivalents include cash in readily available checking accounts and money market accounts.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts and believes it is not exposed to significant risk on its cash balances due to the financial position of the depository institution in which those deposits are held. Additionally, the Company established guidelines regarding approved investments and maturities of investments, which are designed to maintain safety and liquidity.

Patent Costs

Costs related to filing and pursuing patent applications are recorded as general and administrative expense and expensed as incurred since recoverability of such expenditures is uncertain.

Research and Development Expenses and Accruals

Research and development expenses consist of costs incurred for the Company's own and for sponsored and collaborative research and development activities. Research and development costs are expensed as incurred and include manufacturing process development costs, manufacturing costs, costs associated with preclinical studies and clinical trials, regulatory and medical affairs activities, quality assurance activities, salaries and benefits, including stock-based compensation, fees paid to third-party consultants, license fees and overhead.

The Company has entered into various research and development contracts with research institutions, clinical research organizations, clinical manufacturing organizations and other companies. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and payments made in advance of performance are reflected in the accompanying condensed consolidated balance sheets as prepaid expenses and other or accrued liabilities. The Company records accruals for estimated costs incurred for ongoing research and development activities. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the services, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates may be made in determining the prepaid or accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates.

Preferred Stock Warrant Liability

Prior to the Merger, Private Oncternal had outstanding freestanding warrants to purchase shares of its Series B-2 convertible preferred stock (the "Series B-2 warrants"). Because the underlying Series B-2 convertible preferred stock was classified as temporary equity, the Series B-2 warrants were classified as a liability in the accompanying condensed consolidated balance sheets. Private Oncternal adjusted the carrying value of such Series B-2 warrants to their estimated fair value at each reporting date, with any related increases or decreases in the fair value recorded as an increase or decrease to other income (expense) in the condensed consolidated statements of operations. Upon the completion of the Merger, the Series B-2 warrants were amended such that they were converted into warrants to purchase the Company's common stock. As amended, warrant liability accounting is no longer required and the fair value of the warrant liability has been reclassified into stockholders' equity.

Fair Value Measurements

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or non-recurring basis. 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. 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 liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets.

Level 2: Inputs, other than the quoted prices in active markets that are observable either directly or indirectly.

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

The carrying amounts of the Company's current financial assets and liabilities are considered to be representative of their respective fair values because of the short-term nature of those instruments. The Company has no financial assets or liabilities, other than the preferred stock warrant liability described below, measured at fair value on a recurring basis. No transfers between levels have occurred during the periods presented.

Liabilities measured at fair value on a recurring basis are as follows (in thousands):

	Total	Fair Value Measurements at Reporting Date Using: Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
At December 31, 2018				
Preferred stock warrant liability	$ 674	$ —	$ —	$ 674

As of December 31, 2018, the preferred stock warrant liability was recorded at fair value utilizing the Black-Scholes option pricing model using significant unobservable inputs consistent with the inputs used for the Company's stock-based compensation expense adjusted for the preferred stock warrants' expected term and the fair value of the underlying preferred stock.

The Company calculated the final remeasurement of the preferred stock warrant liability on June 7, 2019, the Merger closing date, using the closing price of GTx's common stock on that date to determine the fair value of the warrants, and recorded a $1.3 million change in the fair value of the preferred stock warrant liability for the three and six months ended June 30, 2019.

The assumptions used in the Black-Scholes option pricing model to determine the fair value of the preferred stock warrant liability as of December 31, 2018 were as follows:

	December 31, 2018
Fair value of underlying preferred stock	$ 0.29
Risk-free interest rate	2.4% — 2.7%
Expected volatility	75.3% — 76.4%
Expected term (in years)	3.7 — 4.0
Expected dividend yield	—%

The following table provides a reconciliation of the preferred stock warrant liability measured at fair value using Level 3 significant unobservable inputs (in thousands):

	Preferred Stock Warrant Liability
Balance at December 31, 2018	$ 674
Change in fair value	1,268
Reclassification of preferred stock warrant liability to equity	(1,942)
Balance at June 30, 2019	$ —

Revenue Recognition

The Company currently generates revenue from a research subaward agreement from the California Institute for Regenerative Medicine (see Note 4), which provides the Company with payments in return for certain research and development activities over a contractually defined period. Revenue from such subaward is recognized in the period during which the related qualifying services are rendered and costs are incurred, provided that the applicable conditions under the subaward agreement have been met.

The subaward agreement is on a best-effort basis and does not require scientific achievement as a performance obligation. All fees received under the agreement are non-refundable. The costs associated with the agreement are expensed as incurred and reflected as a component of research and development expense in the accompanying condensed consolidated statements of operations.

Funds received from the subaward agreement are recorded as revenue as the Company is the principal participant in the arrangement because the activities under the subaward are part of the Company's development programs. In those instances where the Company first receives consideration in advance of providing underlying services, the Company classifies such consideration as deferred revenue until (or as) the Company provides the underlying services. In those instances where the Company first provides the underlying services prior to its receipt of consideration, the consideration is recorded as a grant receivable. At June 30, 2019, the Company had deferred grant revenue of $2.4 million and at December 31, 2018, the Company had a grant receivable of $0.1 million. The Company considers the grant receivable to be fully collectible; accordingly, no allowance for doubtful amounts has been established.

Stock-Based Compensation

Stock-based compensation expense represents the fair value of equity awards, on the grant date, recognized in the period using the Black- Scholes option pricing model. The Company recognizes expense for awards with graded vested schedules over the requisite service period of the awards (usually the vesting period) on a straight-line basis. For equity awards for which vesting is subject to performance-based milestones, the expense is recorded over the remaining service period after the point when the achievement of the milestone is probable or the performance condition has been achieved.

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company recognizes net deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If management determines that the Company would be able to realize its deferred tax assets in the future in excess of their net recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

Segment Reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business in one operating segment in the United States.

Comprehensive Loss

Comprehensive loss is defined as a change in equity during a period from transactions and other events and circumstances from non-owner sources. Net loss and comprehensive loss were the same for all periods presented.

Net Loss Per Share

Basic net loss per share is computed by dividing the net loss by the weighted-average number of common shares outstanding for the period, without consideration for potentially dilutive securities and adjusted for the weighted-average number of common shares outstanding that are subject to repurchase. The Company has excluded weighted-average shares subject to repurchase of 59,114 shares and 72,997 shares from the weighted-average number of common shares outstanding for the three and six months ended June 30, 2019, respectively, and has excluded weighted-average shares subject to repurchase of 180,724 shares and 194,545 shares from the weighted-average number of common shares outstanding for the three and six months ended June 30, 2018, respectively. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of shares of common stock and dilutive common stock equivalents outstanding for the period determined using the treasury-stock and if-converted methods. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding as inclusion of the potentially dilutive securities would be antidilutive.

Potentially dilutive securities not included in the calculation of diluted net loss per share, because to do so would be anti-dilutive, are as follows (in common stock equivalent shares; in thousands):

	June 30,	
	2019	2018
Redeemable convertible preferred stock	—	5,653
Warrants to purchase convertible preferred stock	—	372
Warrants to purchase common stock	842	—
Common stock options	810	152
Common stock subject to repurchase	45	165
	1,697	6,342

Recently Issued Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies that are adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its consolidated financial position or results of operations upon adoption.

In August 2018, the FASB issued Accounting Standards Update ("ASU") 2018-13, *Fair Value Measurement: Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement,* which modifies the disclosure requirements for fair value measurements. The amendments relate to disclosures regarding unrealized gains and losses, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and the narrative description of measurement uncertainty and are to be applied prospectively for only the most recent interim or annual period presented in the initial fiscal year of adoption. All other amendments should be applied retrospectively to all periods presented upon their effective date. The amendments are effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years, and early adoption is permitted. The Company is currently evaluating the timing and impact of the adoption of this guidance on the Company's condensed consolidated financial statements.

Recently Adopted Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02, *Leases*, which, for operating leases, requires a lessee to recognize a right-of-use asset and a lease liability, initially measured at the present value of the lease payments, in its balance sheet. The standard also requires a lessee to recognize a single lease cost, calculated so that the cost of the lease is allocated over the lease term, generally on a straight-line basis. The Company adopted this standard on January 1, 2019 using the modified retrospective approach. As the Company has elected the practical expedient for short-term leases, the adoption of this standard had no impact on the condensed consolidated financial statements on the date of adoption as the Company's only lease was on a month-to-month basis for a contract period of less than one year and expired in May 2019. Subsequent to its adoption, the Company entered into a new office lease agreement and has applied the provisions of this guidance (See Note 3).

2. Balance Sheet Details

Accrued liabilities consist of the following (in thousands):

	June 30, 2019	December 31, 2018
Research and development	$ 1,488	$ 720
Legal fees	400	20
Unvested share liability	30	54
Compensation	472	85
Other	160	12
	$ 2,550	$ 891

3. Commitments, Contingencies and Related Party Transactions

Rent expense was $24,000 and $1,000 for the three months ended June 30, 2019 and 2018, respectively. Rent expense was $33,000 and $4,000 for the six months ended June 30, 2019 and 2018, respectively. Until May 31, 2019, the Company subleased its office space in San Diego, California on a month-to-month basis.

On May 22, 2019, the Company entered into a sublease agreement for office space of 4,677 square feet in San Diego, California ("San Diego Lease") which expires on March 31, 2021. Base rent is approximately $166,000 annually and the monthly rent expense is being recognized on a straight-line basis over the term of the lease.

The San Diego Lease is included in the accompanying condensed consolidated balance sheet at the present value of the lease payments. As the San Diego Lease does not have an implicit interest rate, the present value reflects a 10.0% discount rate which is the estimated rate of interest that the Company would have to pay in order to borrow an amount equal to the lease payments on a collateralized basis over a similar term and in a similar economic environment. The Company recognized an operating lease right-of-use asset and an aggregate lease liability of $0.3 million as of June 30, 2019, in the accompanying condensed consolidated balance sheet. The weighted average remaining lease term was 1.75 years.

Maturities of lease liabilities due under this lease agreement as of June 30, 2019 are as follows (in thousands):

Maturity of lease liabilities	Operating Leases
2019 (6 months)	$ 83
2020	166
2021	41
Total lease payments	290
Less imputed interest	(25)
Total operating lease liabilities as of June 30, 2019	265
Less current portion of lease liability	(139)
Lease liability	$ 126

In June 2019, the Company engaged Newfront Insurance as its broker to obtain director and officer liability insurance for the Company effective as of the Merger. The son of Richard Vincent, the Company's Chief Financial Officer, acted as the Company's agent at Newfront Insurance. The Company paid a premium of approximately $1.0 million in June 2019, for which the son will derive a commission of approximately $87,000. See Notes 4 and 6.

Between April 10 and May 1, 2019, three putative class action lawsuits and one individual lawsuit were filed in the U.S. District Court for the District of Delaware: Wheby v. GTx, Inc. et al., Miller v. GTx, Inc. et al., Tabb v. GTx, Inc. et al., and Living Seas LLC v. GTx, Inc. et al. (collectively, the "Delaware Actions") On April 11 and 23, 2019, two putative class actions were filed in the U.S. District Court for the Southern District of New York: Kopanic v. GTx, Inc. et al. and Cooper v. GTx, Inc. et al. (collectively, the "New York Actions" and, together with the Delaware Actions, the "Actions"). The Actions name as defendants us and our former board of directors, and, in the case of the Wheby and Miller actions, Private Oncternal and Merger Sub. The Actions allege that defendants violated Sections 14(a) and 20(a) of the Exchange Act, as well as Rule 14a-9 promulgated thereunder, in connection with our filing of the Registration Statement in connection with the Merger. Three of the Delaware Actions have now been voluntarily dismissed with prejudice: the Wheby action on June 12, 2019; the Miller action on July 15, 2019; and the Living Seas action on June 26, 2019. At June 30, 2019, the Company cannot predict the outcome of or estimate the possible loss or range of loss from any of these matters.

4. License, Collaboration and Research Subaward Agreements

Georgetown University ("Georgetown")

In March 2014, the Company entered into an Exclusive License Agreement (the "Georgetown License Agreement") with Georgetown, pursuant to which the Company: (i) licensed the exclusive worldwide right to patents and technologies for the development and commercialization of certain product candidates targeting EWS-FLI1 as an anti-tumor therapy for therapeutic, diagnostics, or research tool purposes, (ii) is solely responsible for all development and commercialization activities and costs, and (iii) is responsible for all costs related to the filing, prosecution and maintenance of the licensed patent rights.

Under the terms of the Georgetown License Agreement, commencing in 2015, the Company: (i) shall pay and has paid an annual license maintenance fee of $10,000 until the first commercial sale occurs, (ii) is required to make up to $0.2 million in aggregate milestone payments upon the achievement of certain regulatory milestones, and (iii) will be required to pay low single digit royalties based on annual net product sales. The Company accounted for the licensed technology as an asset acquisition because it did not meet the definition of a business. All milestone payments under the Georgetown License Agreement will be recognized as research and development expense upon completion of the required events, as the triggering events are not considered to be probable until they are achieved. As of June 30, 2019, the Company had not triggered or made any milestone payments under the Georgetown License Agreement.

The Georgetown License Agreement may be terminated by either party upon material breach or may be terminated by the Company as to one or more countries with 90 days written notice of termination. The term of the Georgetown License Agreement will continue until the expiration of the last valid claim within the patent rights covering the product. Georgetown may terminate the agreement in the event: (i) the Company fails to pay any amount and fails to cure such failure within 30 days after receipt of notice, (ii) the Company defaults in its obligation to obtain and maintain insurance and fails to remedy such breach within 60 days after receipt of notice, or (iii) the Company declares insolvency or bankruptcy. The Company may terminate the Georgetown License Agreement at any time upon at least 60 days' written notice.

In 2017, the Company entered into a research agreement with Georgetown for up to $150,000. The Company recorded research and development expenses of $13,000 and $19,000 for the three months ended June 30, 2019 and 2018, and $32,000 for each of the six months ended June 30, 2019 and 2018.

The University of Texas MD Anderson Cancer Center ("MD Anderson")

In December 2014, the Company entered into a collaboration agreement (as amended, the "Collaboration") with MD Anderson, which provides for the conduct of preclinical and clinical research for TK216 in exchange for certain program payments. If MD Anderson successfully completes all the requirements of the Collaboration in full and the program is successfully commercialized, the Company will be required to pay aggregate milestone payments of $1.0 million based on net product sales. The Company recorded no research and development expense for the three and six months ended June 30, 2019 and 2018.

Agreements with the Regents of the University of California (the "Regents")

In March 2016, and as amended and restated in August 2018 in connection with the spin-off transactions described below, the Company entered into a license agreement (as amended, the "Regents License Agreement") for the development, manufacturing and distribution rights related to the development and commercialization of ROR1 related naked antibodies, antibody fragments or synthetic antibodies, and genetically engineered cellular therapy. The Regents License Agreement was amended on March 25, 2019 and May 15, 2019, to update the patents covered under the agreement. The Regents License Agreement provides for the following: (i) in May 2016, an upfront license fee of $0.5 million was paid and 107,108 shares of common stock were issued, (ii) $25,000 in annual license maintenance fees commencing in 2017, (iii) reimbursement of up to $30,000 in annual patent costs, (iv) certain development and regulatory milestones aggregating from $10.0 million to $12.5 million, on a per product basis, (v) certain worldwide sales milestones based on achievement of tiered revenue levels aggregating $75.0 million, (vi) low single-digit royalties, including potential future minimum annual royalties, on net sales of each target, and (vii) minimum diligence to advance licensed assets consisting of at least $1.0 million in development spend annually through 2021. Under the Regents License Agreement, the Company recorded: (i) no license maintenance fees as research and development expense for the three and six months ended June 30, 2019 and 2018, and (ii) $0.1 million and $23,000 in patent costs as general and administrative expense for the three months ended June 30, 2019 and 2018, respectively, and $0.2 million and $44,000 for the six months ended June 30, 2019 and 2018, respectively. As of June 30, 2019, the Company believes it has met its obligations under the Regents License Agreement.

In July 2016, and as modified by the amended and restated Regents License Agreement in August 2018, the Company entered into a Research Agreement (the "Research Agreement") with the Regents for further research on a ROR1 therapeutic development program. Under this five-year agreement, the Regents will have an aggregate budget of $3.6 million, with $125,000 payable quarterly. The Company recorded research and development expense under this Agreement of $0.1 million for each of the three months ended June 30, 2019 and 2018, and $0.3 million for each of the six months ended June 30, 2019 and 2018. Such costs are includable as part of the Company's annual diligence obligations under the Regents License Agreement.

The Regents License Agreement will expire upon the later of the expiration date of the longest-lived patent rights or the 15th anniversary of the first commercial sale of a licensed product. The Regents may terminate the Regents License Agreement if: (i) a material breach by the Company is not cured within a reasonable time, (ii) the Company files a claim asserting the Regents licensed patent rights are invalid or unenforceable and (iii) the Company files for bankruptcy. The Company may terminate the agreement at any time upon at least 60 days' written notice.

University of Tennessee Research Foundation ("UTRF")

In July 2007, the Company and UTRF entered into a consolidated, amended and restated license agreement (the "SARM License Agreement"), pursuant to which the Company was granted exclusive worldwide rights in all existing selective androgen receptor modulator ("SARM") technologies owned or controlled by UTRF, including all improvements thereto, and exclusive rights to future SARM technology that may be developed by certain scientists at the University of Tennessee or subsequently licensed to UTRF under certain existing inter-institutional agreements with The Ohio State University. Under the SARM License Agreement, the Company is obligated to pay UTRF annual license maintenance fees, low single-digit royalties on net sales of products and mid-single-digit royalties on sublicense revenues.

The Company and UTRF also entered into a license agreement (the "SARD License Agreement") in March 2015 pursuant to which the Company was granted exclusive worldwide rights in all existing selective androgen receptor degrader ("SARD") technologies owned or controlled by UTRF, including all improvements thereto. Under the SARD License Agreement, the Company is obligated to employ active, diligent efforts to conduct preclinical research and development activities for the SARD program to advance one or more lead compounds into clinical development. The Company is also obligated to pay UTRF annual license maintenance fees, low single-digit royalties on net sales of products and additional royalties on sublicense revenues, depending on the state of development of a clinical product candidate at the time it is sublicensed.

Velos Biopharma Holdings, LLC ("VBH") and VelosBio, Inc. ("VelosBio") Spin-off Transactions

In November 2017, the Company formed VBH and in December 2017, made an in-kind tax-free distribution of 100% of its interest in VBH to the Company's stockholders, option holders and warrant holders of record. On February 6, 2018, the Company licensed and assigned its rights to two preclinical product candidates, previously under the Regents License Agreement, to VBH. In consideration for the license, the Company: (i) received a promissory note receivable from VBH of $0.1 million, with an annual interest rate of 2.64% and a due date of 10 years, and (ii) made a partial assignment of its March 2016 Regents License Agreement. Pursuant to the partial assignment, VBH assumed certain obligations related to the licensed Products under the Regents License Agreement as follows: (i) reimbursement of certain historical and future patent costs related to the Products, (ii) certain development and sales milestones for advancing licensed Products targets, (iii) low single-digit royalties, including potential future minimum annual royalties, on net sales of each licensed Product target are to be allocated between the Company and VBH, (iv) certain third party agreements and related obligations specifically related to the licensed Products, (v) minimum diligence requirements to advance licensed assets consisting of a minimum of $0.5 million in development spend annually through 2021, and (vi) Research Agreement obligations equal to $0.5 million annually commencing January 1, 2018. Due to the high uncertainty of the success of VBH ever repaying the note receivable and associated interest, the Company has provided a full valuation allowance for these amounts as of June 30, 2019.

In December 2017, VelosBio was incorporated with VBH being its sole stockholder. On February 6, 2018, VBH sublicensed and assigned its intellectual property rights to its two preclinical product candidates to VelosBio. In consideration for the license, VelosBio agreed to use commercially reasonable efforts to develop the licensed products as well as the following payment obligations: (i) the assumption of each of the VBH assumed obligations under the partial assignment between the Company and VBH as outlined above, and (ii) certain tiered development milestone and royalty payments to VBH. In August 2018, the Company entered into the amended and restated Regents License Agreement and VelosBio entered into their own license agreement directly with the Regents. There is no common control overlap between the companies.

Also on February 6, 2018, the Company and VelosBio entered into: (i) an asset purchase agreement whereby VelosBio purchased the Company's right, title and interest in the Company's nominal assets related to the two preclinical product candidates and assumed the Company's $0.2 million convertible note payable and related $16,000 of accrued interest which has been recorded as other income, and (ii) a transition services agreement whereby the Company agreed to provide VelosBio with certain transition services, as follows: (a) access to certain common laboratory equipment at the Company's lab facility, (b) certain named employees were to devote up to 80% of their time supporting VelosBio related activities, (c) cirmtuzumab manufacturing, process optimization and ancillary activities until VelosBio was able to establish their own, and (d) agreement to cost share the purchase of certain antibody materials with VelosBio. Such services were to be provided at cost or cost plus. During the three and six months ended June 30, 2018, the Company incurred $2.6 million and $2.7 million, respectively, of costs on behalf of VelosBio that were substantially reimbursed and recorded on a net basis within operating expenses in the accompanying condensed consolidated statements of operations. As of December 31, 2018, there were no ongoing rights or commitments under the asset purchase or transition services agreements.

The California Institute for Regenerative Medicine ("CIRM") Award

In August 2017, CIRM awarded an $18.3 million grant to researchers at the University of California San Diego School of Medicine ("UC San Diego") to advance the Company's Phase 1/2 clinical trial evaluating cirmtuzumab in combination with ibrutinib for the treatment of patients with B-cell lymphoid malignancies, including chronic lymphocytic leukemia and mantle cell lymphoma. The Company: (i) is conducting this study in collaboration with UC San Diego, (ii) estimates it will receive $16.1 million in development milestones under research subaward agreements throughout the award project period, estimated to be from October 1, 2017 to March 31, 2022, (iii) is committed to certain co-funding requirements, (iv) received subaward payments of $2.4 million and $0 in three months ended June 30, 2019 and 2018, respectively, and $3.7 million and $0.5 million the for six months ended June 30, 2019 and 2018, respectively, and (v) is required to provide UC San Diego progress and financial update reports throughout the award period. The subaward does not bear a royalty payment commitment, nor is the subaward otherwise refundable. For the three months ended June 30, 2019 and 2018, the Company recorded revenue of $0.7 million and $1.5 million, respectively, and recorded revenue of $1.1 million and $1.7 million for the six months ended June 30, 2019 and 2018, respectively. Related qualifying subaward costs for the three months ended June 30, 2019 and 2018 was $1.2 million and $2.8 million, respectively, and $2.1 million and $3.1 million for the six months ended June 30, 2019 and 2018, respectively. As of June 30, 2019, the Company believes it has met its obligations under the CIRM award and UC San Diego subawards.

Clinical Trial and Supply Agreement

In April 2018, the Company entered into a Clinical Trial and Supply Agreement with Pharmacyclics, LLC, an AbbVie Company ("Pharmacyclics") to supply ibrutinib for the Company's Phase 1/2 clinical trial evaluating cirmtuzumab in combination with ibrutinib. The Company and Pharmacyclics amended the Clinical Trial and Supply Agreement in August 2019. Such agreement does not bear any upfront costs, inventory purchase costs, milestone or royalty payment commitments or other financial obligations.

License and Development Agreement with Shanghai Pharmaceutical (USA) Inc. ("SPH USA"), a Related Party

In November 2018, the Company entered into a License and Development Agreement ("LDA") with SPH USA for: (i) the territory of the People's Republic of China, Hong Kong, Macau, and Taiwan ("Greater China"), and (ii) rights to manufacture, develop, market, distribute and sell all of the Company's product candidates under the Georgetown License Agreement and the Regents License Agreement (exclusive to Greater China only). Under the LDA, SPH USA is solely responsible for: (a) all preclinical and clinical development activities required in order to obtain regulatory approval in Greater China for such product candidates, (b) any third-party license milestone or royalty payments owed under the Georgetown License Agreement and the Regents License Agreement, and (c) paying the Company a low single digit royalty on net sales in the territory.

The LDA will expire upon the expiration of the last royalty term for the last licensed product. The LDA may be terminated by: (i) SPH USA on a country by country or product by product basis with 180 days written notice, (ii) either party upon material breach that is not cured within 90 days, and (iii) either party in the event the other party declares insolvency or bankruptcy.

5. Merger

The Merger, which closed on June 7, 2019, was accounted for as a reverse asset acquisition pursuant to *Topic 805, Business Combinations*, as substantially all of the fair value of the assets acquired were concentrated in a group of similar non-financial assets, and the acquired assets did not have outputs or employees. Because the assets had not yet received regulatory approval, the fair value attributable to these assets was recorded as in-process research and development ("IPR&D") expenses in the Company's condensed consolidated statement of operations for the three and six months ended June 30, 2019.

Pursuant to the Merger Agreement, on June 7, 2019, the Company, a representative of holders of the contingent value rights ("CVRs"), and Computershare, Inc. as rights agent entered into a Contingent Value Rights Agreement (the "CVR Agreement"). Pursuant to the CVR Agreement, the Company's stockholders of record as of immediately prior to the Merger received one CVR for each share of the Company's common stock held immediately prior to the Merger. CVR holders are entitled to receive 75% of the aggregate amount of any net proceeds received by the combined company during the 15-year period after the closing of the Merger from the grant, sale or transfer of rights to the Company's SARD or SARM technology that occurs during the 10-year period after the closing (or in the 11th year if based on a term sheet approved during the initial 10-year period) and, if applicable, to receive royalties on the sale of any SARD or SARM products by the combined company during the 15-year period after the closing. The CVR Agreement will continue in effect until the payment of all amounts payable thereunder. As of the June 7, 2019 closing date and June 30, 2019, no milestones had been accrued as there were no potential milestones yet considered probable.

The total purchase price paid in the Merger has been allocated to the net assets acquired and liabilities assumed based on their fair values as of the completion of the Merger. The following summarizes the purchase price paid in the Merger (in thousands, except share and per share amounts):

Number of shares of the combined organization owned by the Company's pre-Merger stockholders		3,458,170
Multiplied by the fair value per share of GTx common stock (1)	$	8.40
Fair value of consideration issued to effect the Merger	$	29,049
Transaction costs		2,154
Purchase price	$	31,203

(1) Based on the last reported sale price of the Company's common stock on the Nasdaq Capital Market on June 7, 2019, the closing date of the Merger, and gives effect to the Reverse Stock Split.

The allocation of the purchase price is as follows:

Cash acquired	$	18,292
Net liabilities assumed		(5,177)
IPR&D (2)		18,088
Purchase price	$	31,203

(2) Represents the research and development projects of GTx which were in-process, but not yet completed, and which the Company plans to advance. This consists primarily of GTx's preclinical SARD technology. Current accounting standards require that the fair value of IPR&D projects acquired in an asset acquisition with no alternative future use be allocated a portion of the consideration transferred and charged to expense on the acquisition date. The acquired assets did not have outputs or employees.

6. Stockholders' Equity (Deficit)

Amended and Restated Articles of Incorporation

On June 7, 2019, the Company's certificate of incorporation was amended and restated to authorize 60,000,000 shares of common stock and 5,000,000 shares of undesignated preferred stock, each with a par value of $0.001 per share.

Convertible Preferred Stock

In connection with the Merger, all of the outstanding shares of Private Oncternal's convertible preferred stock were converted into 8,148,268 shares of the Company's common stock. As of December 31, 2018, Private Oncternal's convertible preferred stock is classified as temporary equity on the accompanying condensed consolidated balance sheets in accordance with authoritative guidance for the classification and measurement of potentially redeemable securities whose redemption is based upon certain change in control events outside of Private Oncternal's control, including liquidation, sale or transfer of control of Private Oncternal. Private Oncternal did not adjust the carrying values of the convertible preferred stock to the liquidation preferences of such shares because the occurrence of any such change of control event was not deemed probable.

Sales of Convertible Preferred Stock

In September, November and December 2017, Private Oncternal issued an aggregate of 1,662,494 shares of Series B-2 preferred stock at a per share purchase price of $6.13, raising net cash proceeds of $8.9 million, of which $1.1 million was collected in February 2018 and, as such, was recorded as a stock subscription receivable within mezzanine equity at December 31, 2017.

In November 2018, contemporaneous with entering into the LDA, Private Oncternal issued 2,495,114 shares of Series C preferred stock to SPH USA, at a per share purchase price of $6.81, raising net cash proceeds of $16.8 million. Private Oncternal concluded that the shares were issued at fair value and therefore no value was ascribed to the LDA.

Common Stock Warrants

In September, November and December 2017, as adjusted for the Exchange Ratio, Private Oncternal issued 371,624 Series B-2 warrants, which converted into rights to purchase common stock of the Company at the Merger closing, at an exercise price of $6.13 per share. The warrants expire on various dates in September, November and December 2022.

On September 29, 2017, the Company completed a private placement transaction that included warrants to purchase an aggregate of 469,996 shares of the Company's common stock at an exercise price of $63.14 per share. The five-year warrants expire on September 29, 2022.

The Company assessed whether the above warrants require accounting as derivatives after the Merger closing. The Company determined that the warrants were indexed to the Company's own stock. As such, the Company has concluded the warrants meet the scope exception for determining whether the instruments require accounting as warrant liabilities. As of June 30, 2019, none of the warrants have been exercised.

Common Stock and Unvested Share Liability

The Company has issued restricted common stock subject to vesting and repurchase by the Company. For employee and non-employee awards, the issuance date fair value is recognized over the requisite service period of the award (usually the vesting period) on a straight-line basis. In addition, the Company has outstanding unvested shares related to the early exercise of stock options. The Company has the right, but not the obligation, to repurchase any unvested shares at the original purchase price upon any voluntary or involuntary termination. The consideration received in exchange for unvested shares is recorded as an unvested share liability on the accompanying consolidated balance sheets and is reclassified into common stock and additional paid-in capital as the shares vest. At June 30, 2019 and December 31, 2018, the unvested share liability was $30,000 and $54,000, respectively.

A summary of the Company's unvested shares is as follows (in thousands):

	Number of Shares
Balance at December 31, 2018	100
Vested shares	(55)
Balance at June 30, 2019	45

Equity Incentive Plans

Contemporaneous with the Merger closing: (i) Private Oncternal's 2015 Equity Incentive Plan, as amended (the "2015 Plan") was assumed by the Company, and (ii) the Company adopted the 2019 Incentive Award Plan ("2019 Plan") under which the sum of: (a) 1,678,571 shares of common stock, (b) any shares of common stock which were subject to awards under the GTx 2013 Equity Incentive Plan (the "2013 Plan") as of June 7, 2019 which became available for issuance under the 2019 Plan in a number not to exceed 278,343 shares, and (c) an annual increase on the first day of each calendar year beginning January 1, 2020 and ending on and including January 1, 2029, equal to the lesser of (A) 5% of the aggregate number of shares of common stock outstanding on the final day of the immediately preceding calendar year and (B) such smaller number of shares of common stock as is determined by the Board, are reserved for issuance.

As of June 30, 2019, there were 322,775 outstanding and fully vested options under the 2013 Plan with a weighted average exercise price of $76.58 per share.

In July 2015, Private Oncternal adopted the 2015 Plan which provided for the issuance of up to 631,120 shares of common stock for incentive stock options, non-statutory stock options, restricted stock awards, restricted stock unit awards and other stock awards to its employees, members of its board of directors and consultants. In general, the options issued under the 2015 Plan expire ten years from the date of grant and vest over a four-year period. Certain grants vest based on the achievement of development or regulatory milestones. No further awards will be made under the 2015 Plan, which was terminated in June 2019.

The 2015 Plan allows for the early exercise of all stock option grants if authorized by the board of directors at the time of grant. The Company has the option to repurchase any unvested shares at the original purchase price upon any voluntary or involuntary termination.

A summary of the Company's stock option activity under the 2019 Plan and 2015 Plan is as follows:

	Number of Options	Weighted-Average Exercise Price
Balance at December 31, 2018	504,019	$ 0.81
Granted	10,000	$ 7.92
Cancelled	(25,226)	$ 0.81
Exercised	(1,834)	$ 0.81
Balance at June 30, 2019	486,959	$ 0.81

The aggregate intrinsic value of stock options exercised during the six months ended June 30, 2019 and 2018 and year ended December 31, 2018 was not material. The intrinsic value is calculated as the difference between the fair value of the Company's common stock at the time of the option exercise and the exercise price of that stock option.

Stock-Based Compensation Expense

The weighted-average assumptions used in the Black-Scholes option pricing model to determine the fair value of stock option grants were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Risk-free interest rate	2.1%	—%	2.1%	—%
Expected volatility	82%	—%	82%	—%
Expected term (in years)	10	—%	10	—%
Expected dividend yield	—%	—%	—%	—%

Expected volatility. Prior to the Merger, Private Oncternal did not have a trading history for its common stock. Accordingly, the expected volatility assumption is based on volatilities of a peer group of similar companies whose share prices are publicly available. The peer group was developed based on companies in the life sciences industry. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

Expected term. The expected term represents the period of time that options are expected to be outstanding. Because Private Oncternal did not have historical exercise behavior, it determined the expected life assumption using the simplified method for employees, which is an average of the contractual term of the option and its vesting period. The expected term for nonemployee options is generally the remaining contractual term.

Risk-free interest rate. The risk-free interest rate is based on the implied yield on the U.S. Treasury securities with a maturity date similar to the expected term of the associated stock option award.

Expected dividend yield. The Company bases the expected dividend yield assumption on the fact that it has never paid cash dividends and has no present intention to pay cash dividends and, therefore, used an expected dividend yield of zero.

Stock-based compensation expense recognized for all equity awards has been reported in the statements of operations as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Research and development	$ 41	$ 15	$ 67	$ 31
General and administrative	22	26	35	53
	$ 63	$ 41	$ 102	$ 84

As of the latest balance sheet presented, the total compensation cost related to nonvested awards not yet recognized and the weighted-average period over which it is expected to be recognized was $90,000 and 2.9 years, respectively.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance is as follows (in thousands):

	June 30, 2019
Common stock warrants	842
Common stock options issued and outstanding	810
Common stock available for issuance under the 2019 Plan	1,671
	3,323

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with (i) our unaudited condensed consolidated financial statements and related notes thereto included elsewhere in this Quarterly Report on Form 10-Q for the period ended June 30, 2019 (this "Quarterly Report"), (ii) the unaudited condensed consolidated financial statements and related notes thereto for the period ended March 31, 2019 of privately-held Oncternal Therapeutics, Inc. ("Private Oncternal") prior to the merger described herein ("Merger"), included in our Current Report on Form 8-K/A, filed with the Securities and Exchange Commission ("SEC") on August [8], 2019, and (iii) Private Oncternal's audited consolidated financial statements and notes thereto and management's discussion and analysis of financial condition and results of operations for the year ended December 31, 2018, included in our Amendment No. 1 to Registration Statement on Form S-4, filed with the SEC on May 6, 2019 (Registration No. 333-230758) (the "Registration Statement"). As further described in Note 1 – Description of Business and Note 5 – Merger *of our condensed consolidated financial statements included elsewhere* in this Quarterly Report, Private Oncternal was determined to be the accounting acquirer in the Merger. *Accordingly*, the pre-Merger historical financial information presented in this Quarterly Report reflects the standalone financial statements of Private Oncternal and, therefore, period-over-period comparisons may not be meaningful. *In addition, references to the Company's operating results prior to the Merger will refer to the operating results of Private Oncternal. Except as otherwise indicated herein or as the context otherwise requires, references in this Quarterly Report to "Oncternal" "the Company," "we," "us" and "our" refer to Oncternal Therapeutics, Inc., a Delaware corporation, on a post-Merger basis, and the term "Private Oncternal" refers to the business of privately-held Oncternal Therapeutics, Inc. prior to completion of the Merger.*

Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements other than statements of historical facts contained in this Quarterly Report, including statements regarding our future results of operations and financial position, business strategies and plans, prospective products, product approvals, research and development costs, timing and likelihood of success, plans and objectives of management for future operations and future results of anticipated products, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "could," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continue," or the negative of these terms or other comparable terminology. These forward-looking statements are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Quarterly Report and are subject to a number of risks, uncertainties and assumptions, including those described in Part II, Item 1A, "Risk Factors." The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

Overview

We are a clinical-stage biopharmaceutical company focused on developing first-in-class product candidates for cancers with critical unmet medical need. Our development efforts are focused on promising, yet untreated biological pathways implicated in cancer generation or progression.

Our lead product candidate is cirmtuzumab, a monoclonal antibody that is designed to inhibit the ROR1 receptor, which is being evaluated in a Phase 1/2 clinical trial in combination with ibrutinib for the treatment of chronic lymphocytic leukemia ("CLL") and mantle cell lymphoma ("MCL"), and in a Phase 1b clinical trial in combination with paclitaxel for women with unresectable or metastatic breast cancer. ROR1 is a growth factor receptor that is widely expressed on many tumors and whose overexpression has been correlated with poor prognosis, which activates pathways that lead to increased tumor proliferation, invasiveness and drug resistance. In June 2019, we presented data at the American Society of Clinical Oncology ("ASCO") annual meeting from our CIRRL (Cirmtuzumab and Ibrutinib targeting ROR1 for Leukemia and Lymphoma) clinical trial clinical trial, reporting that results from the first 12 patients with CLL treated in the Part 1 dose finding cohort of the Phase 1 portion of the study our clinical trial demonstrated an observed interim overall objective response rate ("ORR") of 91.7% for the combination of cirmtuzumab plus ibrutinib, including three patients with clinical or confirmed complete responses, and a well-tolerated safety profile consistent with that seen for ibrutinib treatment alone.

In August 2019, we announced that we have opened for enrollment the randomized, Phase 2, randomized portion of the study triggered based on favorable outcomes from the Part 1 dose-finding and Part 2 dose-conforming cohorts of the clinical trial, including an observed interim ORR of 100% for the first nine CLL patients with evaluable data receiving the recommended dosing regimen who have completed 12 weeks of cirmtuzumab plus ibrutinib treatment in Part 2 of the study, and a well-tolerated safety profile consistent with that seen with ibrutinib treatment alone. We anticipate reporting additional data from this study in patients with CLL and MCL at a scientific conference in the fourth quarter of 2019. In addition, at another conference we expect to report data from our Phase 1b study of cirmtuzumab in combination with paclitaxel from patients with breast cancer.

We are also developing TK216, a small molecule that is designed to inhibit E26 Transformation Specific ("ETS") family oncoproteins, which alter gene transcription and RNA processing and lead to increased cell proliferation and invasion. TK216 is being evaluated in a Phase 1 clinical trial, alone and in combination with vincristine, in patients with relapsed or refractory Ewing sarcoma, a rare pediatric cancer. We anticipate completing the dose finding portion of our Phase 1 study of TK216 for patients with Ewing sarcoma and opening the expansion cohort in the third quarter of 2019. We anticipate reporting data from this study at a scientific conference in the fourth quarter of 2019.

In addition, we are developing a CAR-T product candidate that targets ROR1, which is currently in preclinical development as a potential treatment for solid tumors and hematologic cancers. We anticipate selecting a candidate CAR-T construct for studies to support an investigational new drug application in hematologic cancers in the second half of 2019, initiating a Phase 1 clinical trial for hematological cancers in 2020.

On March 6, 2019, we entered into an Agreement and Plan of Merger and Reorganization, as amended (the "Merger Agreement"), with privately-held Oncternal Therapeutics, Inc. ("Private Oncternal") and Grizzly Merger Sub, Inc., a wholly-owned subsidiary of the Company ("Merger Sub"). Under the Merger Agreement, Merger Sub merged with and into Private Oncternal, with Private Oncternal surviving as our wholly-owned subsidiary (the "Merger"). On June 7, 2019, the Merger was completed. We then changed our corporate name from GTx, Inc., to Oncternal Therapeutics, Inc., and Private Oncternal, which remains our wholly-owned subsidiary, changed its name to Oncternal Oncology, Inc. On June 10, 2019, our common stock began trading on The Nasdaq Capital Market under the ticker symbol "ONCT."

Pursuant to the terms of the Merger Agreement, each outstanding share of Private Oncternal common stock outstanding immediately prior to the closing of the Merger was converted into 0.073386 shares of our common stock (the "Exchange Ratio"), after taking into account a one-for-seven reverse stock split. Immediately prior to the closing of the Merger, all shares of Private Oncternal preferred stock then outstanding were exchanged into shares of common stock of Private Oncternal. In addition, all outstanding options exercisable for common stock of Private Oncternal and warrants exercisable for convertible preferred stock of Private Oncternal became options and warrants exercisable for the same number of shares of our common stock multiplied by the Exchange Ratio. Immediately following the Merger, stockholders of Private Oncternal owned approximately 77.5% of our outstanding common stock.

Prior to the Merger, we had been evaluating enobosarm, a selective androgen receptor modulator ("SARM"), for the treatment of post-menopausal women with stress urinary incontinence ("SUI"). However, based on the results of the ASTRID trial, we determined that there was not a sufficient path forward to warrant additional clinical development of enobosarm to treat SUI, and discontinued further development of enobosarm to treat SUI, as well as our SARM technology generally.

Prior to the Merger and since its inception in 2013, Private Oncternal had devoted most of its resources to organizing and staffing, business planning, raising capital, acquiring product candidates and securing related intellectual property rights and advancing its preclinical and clinical development programs. Under our research subaward agreements with the University of California San Diego School of Medicine ("UC San Diego"), we are eligible to receive up to $16.1 million in development milestones throughout the award project period, estimated to be from October 1, 2017 to March 31, 2022. Prior to the Merger, Private Oncternal funded its operations primarily through: (i) gross proceeds of $49.0 million from the issuance and sale of convertible preferred stock, and (ii) receipt of $7.7 million in subaward grant payments received from UC San Diego. As of June 30, 2019, we had cash and cash equivalents of $28.5 million, including cash proceeds of $18.3 million received in connection with the closing of the Merger.

We have incurred net losses in each year since inception. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our current or future product candidates. Our net losses were $25.1 million ($18.1 million related to nonrecurring Merger costs) and $3.9 million for six months ended June 30, 2019 and 2018, respectively. As of June 30, 2019, we had an accumulated deficit of $56.5 million. Substantially all of our net losses have resulted from costs incurred in connection with: (i) advancing our research and development programs, (ii) general and administrative costs associated with our operations, and (iii) in-process research and development costs associated with the Merger. We expect to continue to incur significant and increasing operating losses for at least the next several years. We expect that our expenses and capital funding requirements will increase substantially in connection with our ongoing activities, particularly if and as we:

- conduct our ongoing Phase 1/2 clinical trial of cirmtuzumab and any additional clinical trials for our product candidates;
- continue to develop additional product candidates;
- advance preclinical studies for our CAR-T program;
- acquire or in-license other product candidates and technologies;
- maintain, expand and protect our intellectual property portfolio;
- establish a commercial manufacturing source and secure supply chain capacity sufficient to provide commercial quantities of any product candidates for which we may obtain regulatory approval;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which it may obtain regulatory approval; and
- add operational, financial and management information systems and personnel, including personnel to support our planned product development and future commercialization efforts, as well as to support our operating costs as a public reporting company.

We will not generate product sales revenue unless and until we successfully complete clinical development and obtain regulatory approval for our product candidates. If we obtain regulatory approval for any of our product candidates and do not enter into a commercialization partnership, we expect to incur significant expenses related to developing our internal commercialization capability to support product sales, marketing and distribution. In addition, we expect to incur additional costs associated with operating as a public company.

As a result, we believe we will need substantial additional funding to support our continuing operations and pursue our business strategy. Until such time as we can generate significant revenue product sales, if ever, we expect to finance our operations through a combination of equity offerings, debt financings, government funding, or other sources, including potentially collaborations, licenses and other similar arrangements. We may not be able to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, reduce or eliminate the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

We expect that our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements into the second quarter of 2020. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See "*Liquidity and Going Concern*." Beyond that point, we will need to

raise additional capital to finance our operations, which cannot be assured. Management has concluded that this circumstance raises substantial doubt about our ability to continue as a going concern within one year after the issuance date of our condensed consolidated financial statements as of and for the six months ended June 30, 2019. See Note 1 of our condensed consolidated financial statements included elsewhere in this Quarterly Report.

Components of Results of Operations

Grant Revenue

We have not and do not expect to generate any product sales revenue in the foreseeable future. If our development efforts for our product candidates are successful and result in regulatory approval, we may generate product sales revenue in the future. We cannot predict if, when, or to what extent we will generate revenue from the commercialization and sale of our product candidates. We may never succeed in obtaining regulatory approval for any of our product candidates. Our total revenue to date has been derived from a California Institute for Regenerative Medicine ("CIRM") grant subaward with UC San Diego.

In August 2017, CIRM awarded an $18.3 million grant to researchers at UC San Diego to advance our Phase 1/2 clinical trial evaluating cirmtuzumab in combination with ibrutinib for the treatment of patients with B-cell lymphoid malignancies, including MCL and CLL. Oncternal is conducting this study in collaboration with UC San Diego and estimates it will receive $16.1 million in development milestones under research subaward agreements throughout the award project period, estimated to be from October 1, 2017 to March 31, 2022. In addition, we are committed to certain co-funding requirements and are required to provide UC San Diego progress and financial update reports throughout the award project period. We received subaward payments of $3.7 million and $0.5 million in the six months ended June 30, 2019 and June 30, 2018, respectively. As of June 30, 2019, we have met our obligations under the CIRM award and UC San Diego subawards.

Operating Expenses

Research and Development

Research and development expenses consist primarily of costs incurred for the preclinical and clinical development of our lead product candidate, cirmtuzumab, as well as TK216, which include:

- expenses under agreements with third-party contract organizations, investigative clinical trial sites that conduct research and development activities on our behalf, and consultants;
- costs related to develop and manufacture preclinical study and clinical trial material;
- salaries and employee-related costs, including stock-based compensation;
- costs incurred under our collaboration and third-party licensing agreements; and
- laboratory and vendor expenses related to the execution of preclinical and clinical trials.

We accrue all research and development costs in the period for which they are incurred. Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors, collaborators and third-party service providers. Advance payments for goods or services to be received in future periods for use in research and development activities are deferred and then expensed as the related goods are delivered and as services are performed.

We expect our research and development expenses to increase substantially for the foreseeable future as we: (i) invest in additional operational personnel to support our planned product development efforts, and (ii) continue to invest in developing our product candidates as our product candidates advance into later stages of development, and as we begin to conduct larger clinical trials. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials.

Our direct research and development expenses are tracked by product candidate and consist primarily of external costs, such as fees paid under third-party license agreements and to outside consultants, contract research organizations ("CROs"), contract manufacturing organizations and research laboratories in connection with our preclinical development, process development, manufacturing and clinical development activities. We do not allocate employee costs and costs associated with our discovery efforts, laboratory supplies and facilities, including other indirect costs, to specific product candidates because these costs are deployed across multiple programs and, as such, are not separately classified. We use internal resources primarily to conduct our research as well as for managing our preclinical development, process development, manufacturing and clinical development activities. These employees work across multiple programs and, therefore, we do not track our costs by product candidate unless such costs are includable as subaward costs.

We cannot determine with certainty the timing of initiation, the duration or the completion costs of current or future preclinical studies and clinical trials of our product candidates due to the inherently unpredictable nature of preclinical and clinical development, including any potential expanded dosing beyond the original protocols based in part on ongoing clinical success. Clinical and preclinical development timelines, the probability of success and development costs can differ materially from expectations. We anticipate that we will make determinations as to which product candidates to pursue and how much funding to direct to each product candidate on an ongoing basis in response to the results of ongoing and future preclinical studies and clinical trials, regulatory developments and our ongoing assessments of each product candidate's commercial potential. We will need to raise substantial additional capital in the future. In addition, we cannot forecast which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

General and Administrative

General and administrative expenses consist primarily of personnel-related costs, insurance costs, facility costs and professional fees for legal, patent, consulting, investor and public relations, accounting and audit services. Personnel-related costs consist of salaries, benefits and stock-based compensation. We expect our general and administrative expenses will increase substantially as we: (i) incur additional costs associated with being a public company, including audit, legal, regulatory, and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums, and investor relations costs, (ii) hire additional personnel, and (iii) protect our intellectual property.

Other Income (Expense)

Change in Fair Value of Preferred Stock Warrant Liability

In connection with Private Oncternal's Series B-2 preferred stock financing in 2017, Private Oncternal issued warrants to purchase shares of its Series B-2 preferred stock. We classify these warrants as a liability on our condensed consolidated balance sheets and remeasure them to fair value at each reporting date, and we recognize changes in the fair value of the warrant liability as a component of other income (expense), net in our condensed consolidated statements of operations.

Upon the closing of the Merger, all outstanding warrants to purchase Private Oncternal Series B-2 preferred stock were converted into warrants to purchase our common stock. As a result, such warrants will no longer require liability accounting and the fair value of the warrant liability has been reclassified to stockholders' equity.

Interest Income

Interest income consists of interest earned on our cash equivalents, which consist of money market funds. Our interest income has not been significant due to low interest earned on invested balances.

Results of Operations

Comparison of Three Months Ended June 30, 2019 and 2018

The following table summarizes our results of operations for the three months ended June 30, 2019 and 2018:

	Three Months Ended June 30,		
	2019	2018	Change
	(in thousands)		
Grant revenue	$ 674	$ 1,527	$ (853)
Operating expenses:			
Research and development	2,587	3,513	(926)
In-process research and development	18,088	—	18,088
General and administrative	1,619	555	1,064
Total operating expenses	22,294	4,068	18,226
Loss from operations	(21,620)	(2,541)	(19,079)
Other income (expense):			
Change in fair value of warrant liability	(1,285)	114	(1,399)
Interest income	59	15	44
Total other income (expense)	(1,226)	129	(1,355)
Net loss	$ (22,846)	$ (2,412)	$ (20,434)

Grant Revenue

Grant revenue for the three months ended June 30, 2019 was $0.7 million, compared to $1.5 million for the three months ended June 30, 2018. The decrease was driven by lower research and development subaward related costs in 2019 as compared to 2018.

Research and Development Expenses

The following table summarizes our research and development expenses for the periods indicated:

	Three Months Ended June 30,		Increase/ (Decrease)
	2019	2018	
	(in thousands)		
Cirmtuzumab	$ 1,521	$ 2,846	$ (1,325)
TK216	517	220	297
Unallocated research and development expenses	549	447	102
Total research and development expenses	$ 2,587	$ 3,513	$ (926)

Research and development expenses for the three months ended June 30, 2019 and 2018 were $2.6 million and $3.5 million, respectively, a decrease of $0.9 million. The decrease was due to a $1.0 million decrease in direct product candidate costs, which was partially offset by a $0.1 million increase in unallocated research and development expenses.

Direct expenses for cirmtuzumab decreased $1.3 million for the three months ended June 30, 2019, compared to the three months ended June 30, 2018, due primarily to the following partially offsetting factors: (i) a $1.9 million decrease due primarily to the timing of manufacturing clinical trial materials in the second quarter of 2018, and (ii) a $0.5 million increase in clinical trial activities related to our ongoing Phase 1/2 clinical trial of cirmtuzumab in combination with ibrutinib for the treatment of patients with B-cell lymphoid malignancies, including MCL and CLL, that commenced in the latter part of 2017.

Direct expenses for TK216 increased $0.3 million for the three months ended June 30, 2019, compared to the three months ended June 30, 2018, due primarily to the following: (i) a $0.2 million increase in manufacturing clinical trial material costs, and (ii) a $0.1 million increase in clinical trial activities related to our ongoing Phase 1 clinical trial of TK216 in refractory Ewing sarcoma.

In-Process Research and Development Expenses

In-process research and development expenses increased $18.1 million for three months ended June 30, 2019, compared to the three months ended June 30, 2018, due to the issuance of common stock and transaction costs incurred related to the Merger.

General and Administrative Expenses

General and administrative expenses for the three months ended June 30, 2019 and 2018 were $1.6 million and $0.6 million, respectively, an increase of $1.0 million. The increase is primarily due to higher corporate legal fees of $0.5 million incurred to significantly expand our intellectual property portfolio with respect to the cirmtuzumab product candidate and for additional legal support incurred to become a public company, an increase in personnel related costs of $0.4 million, as well as expenses to operate as a publicly-traded company.

Other Income (Expense)

Other expense was $1.2 million for the three months ended June 30, 2019, compared to $0.1 million of income for the three months ended June 30, 2018. The decrease was primarily due to a $1.4 million change in the fair value of the preferred stock warrant liability.

Comparison of Six Months Ended June 30, 2019 and 2018

The following table summarizes our results of operations for the six months ended June 30, 2019 and 2018:

	Six Months Ended June 30,		
	2019	2018	Change
	(in thousands)		
Grant revenue	$ 1,144	$ 1,715	$ (571)
Operating expenses:			
Research and development	4,483	4,802	(319)
In-process research and development	18,088	—	18,088
General and administrative	2,551	1,136	1,415
Total operating expenses	25,122	5,938	19,184
Loss from operations	(23,978)	(4,223)	(19,755)
Other income (expense):			
Change in fair value of warrant liability	(1,268)	77	(1,345)
Other income	—	216	(216)
Interest income	106	28	78
Interest expense	—	(1)	1
Total other income (expense)	(1,162)	320	(1,482)
Net loss	$ (25,140)	$ (3,903)	$ (21,237)

Grant Revenue

Grant revenue for the six months ended June 30, 2019 was $1.1 million, compared to $1.7 million for the six months ended June 30, 2018. The decrease was due to lower research and development subaward related costs incurred in 2019 as compared to 2018.

Research and Development Expenses

The following table summarizes our research and development expenses for the periods indicated:

	Six Months Ended June 30,		Increase/ (Decrease)
	2019	2018	
	(in thousands)		
Cirmtuzumab	$ 2,887	$ 3,417	$ (530)
TK216	790	462	328
Unallocated research and development expenses	806	923	(117)
Total research and development expenses	$ 4,483	$ 4,802	$ (319)

Research and development expenses for the six months ended June 30, 2019 and 2018 were $4.5 million and $4.8 million, respectively, a decrease of $0.3 million. The decrease was due to a $0.2 million decrease in direct product candidate costs and a $0.1 million decrease in unallocated research and development expenses.

Direct expenses for cirmtuzumab decreased $0.5 million for the six months ended June 30, 2019, compared to the six months ended June 30, 2018, due primarily to the following partially offsetting factors: (i) a $1.5 million increase in clinical trial activities related to our ongoing Phase 1/2 clinical trial of cirmtuzumab in combination with ibrutinib for the treatment of patients with B-cell lymphoid malignancies, including MCL and CLL, that commenced in the latter part of 2017, and (ii) a $2.0 million decrease in manufacturing costs, due primarily to the timing of manufacturing clinical trial materials in the second quarter of 2018.

Direct expenses for TK216 increased $0.3 million for the six months ended June 30, 2019, compared to the six months ended June 30, 2018, due primarily to the following partially offsetting factors: (i) a $0.1 million increase in clinical trial activities related to our continuing Phase 1 clinical trial of TK216 in refractory Ewing sarcoma, and (ii) development expenses as we generally reduced our preclinical program activities, and (ii) a $0.2 million increase in manufacturing costs for clinical trial materials.

Unallocated research and development expenses decreased $0.1 million for six months ended June 30, 2019 and 2018 primarily due to lower personnel costs resulting from entering into the VelosBio transition services agreement.

In-Process Research and Development Expenses

In-process research and development expenses increased $18.1 million for six months ended June 30, 2019, compared to the six months ended June 30, 2018, due solely to the Merger.

General and Administrative Expenses

General and administrative expenses for the six months ended June 30, 2019 and 2018 were $2.5 million and $1.1 million, respectively, an increase of $1.4 million. The increase is primarily due to an increase in personnel related costs of $0.6 million, higher corporate legal fees of $0.4 million incurred to expand our intellectual property portfolio on the cirmtuzumab platform and product candidates in 2019 and additional legal support incurred to become a public company, as well as expenses to operate as a publicly-traded company.

Other Income (Expense)

Other expense was $1.2 million for the six months ended June 30, 2019, compared to other income of $0.3 million for the six months ended June 30, 2018, a change of $1.5 million in additional expense. The decrease was primarily due to a: (i) $1.3 million decrease in the fair value of the preferred stock warrant liability, and (ii) gain of $0.2 million related to an asset purchase agreement with VelosBio as further described in Note 4 to our condensed consolidated financial statements included elsewhere in this Quarterly Report.

Liquidity and Going Concern

From our inception through June 30, 2019, we have devoted substantially all of our efforts to organizational activities including raising capital, building infrastructure, acquiring assets, developing intellectual property, and conducting preclinical studies, clinical trials and product development activities. We have a limited operating history and the sales and income potential of our business and market are unproven. We have experienced recurring net losses and negative cash flows from operating activities. At June 30, 2019, we had an accumulated deficit of $56.5 million and had cash and cash equivalents of $28.5 million. We will need to continue to raise a substantial amount of funds until we are able to generate revenues to fund our development and operating activities.

We expect to continue to incur net losses into the foreseeable future. Successful transition to attaining profitable operations is dependent upon achieving a level of revenues adequate to support our cost structure. We have incurred net losses since inception and have relied on our ability to fund our operations through debt and equity financings and grant funding. These conditions raise substantial doubt about our ability to continue as a going concern. The accompanying condensed consolidated financial statements have been prepared assuming that we will continue as a going concern and do not include any adjustments that might result from the outcome of this uncertainty. This basis of accounting contemplates the recovery of our assets and the satisfaction of liabilities in the normal course of business.

We plan to continue to fund our losses from operations and capital funding needs through a combination of equity offerings, debt financings, government funding, or other sources, including potentially collaborations, licenses and other similar arrangements. There can be no assurance that we will be able to obtain any sources of financing on acceptable terms, or at all. To the extent that we can raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact our ability to conduct our business.

Cash Flows

The following table summarizes our sources and uses of cash for each of the periods presented:

	Six Months Ended June 30,	
	2019	2018
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (9,872)	$ (5,283)
Investing activities	17,741	-
Financing activities	2	1,100
Net increase (decrease) in cash and cash equivalents	$ 7,871	$ (4,183)

Operating activities

During the six months ended June 30, 2019, net cash used in operating activities was $9.9 million, resulting from our net loss of $25.1 million, which included non-cash charges of $18.1 million related to the acquisition of in-process research and development, a change in the fair value of the warrant liability of $1.3 million, offset by a $4.2 million change in our operating assets and liabilities.

The $4.2 million change in operating assets and liabilities primarily consisted of a $0.7 million increase in prepaid expenses and other assets, a $2.4 million increase in deferred revenue, and a $5.9 million increase in accounts payable and accrued expenses.

During the six months ended June 30, 2018, net cash used in operating activities was $5.3 million, resulting from our net loss of $3.9 million, which included non-cash charges of other income of $0.2 million, a change in the fair value of warrant liability of $0.1 million, stock-based compensation charges of $0.1 million, and a $1.1 million change in operating assets and liabilities. The $1.1 million change in operating assets and liabilities consisted of a $2.6 million increase in prepaid expenses and other assets, a $1.2 million decrease in deferred revenue, and a $2.7 million increase in accounts payable and accrued expenses.

Investing activities

Net cash provided by investing activities was $17.7 million for the six months ended June 30, 2019, primarily resulting from cash received in connection with the Merger. Net cash provided by investing activities was $0 for the six months ended June 30, 2018.

Financing activities

Net cash provided by financing activities was nominal for the six months ended June 30, 2019. Net cash provided by financing activities was $1.1 million for the six months ended June 30, 2018, which resulted from the collection of $1.1 million of Series B-2 convertible preferred stock subscriptions receivable issued in December 2017.

We believe our existing cash and cash equivalents will be sufficient to meet our anticipated cash requirements into the second quarter of 2020. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we expect. Additionally, the process of testing product candidates in clinical trials is costly, and the timing of progress, potential dose expansions beyond our planned study protocols based in part on our clinical progress, and expenses in these trials is uncertain.

Our future capital requirements will depend on many factors, including:

- the type, number, scope, progress, expansions, results, costs and timing of, our preclinical studies and clinical trials of our product candidates which we are pursuing or may choose to pursue in the future;
- the costs and timing of manufacturing for our product candidates, including commercial manufacturing if any product candidate is approved;
- the costs of obtaining ibrutinib, for which we currently obtain supply at no cost under our clinical supply agreement with Pharmacyclics LLC, and vincristine to conduct our clinical trials of cirmtuzumab and TK216, respectively;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of obtaining, maintaining and enforcing our patents and other intellectual property rights;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal controls over financial reporting;
- the costs associated with hiring additional personnel and consultants as our preclinical and clinical activities increase;
- the costs and timing of establishing or securing sales and marketing capabilities if any product candidate is approved;
- our ability to achieve sufficient market acceptance, adequate coverage and reimbursement from third-party payors and adequate market share and revenue for any approved products;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements; and
- costs associated with any products or technologies that it may in-license or acquire.

Until such time, if ever, as we can generate substantial product revenues to support our cost structure, we expect to finance our losses from operations and capital funding needs through a combination of equity offerings, debt financings, government funding and other sources, including potentially collaborations, licenses and other similar arrangements. To the extent we raise additional capital through the sale of debt or equity securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. 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 funds through collaborations, licenses and other similar 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 and/or may reduce the value of our common stock. If we are unable to raise additional funds through debt or equity 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 our product candidates even if we would otherwise prefer to develop and market such product candidates by ourselves. There can be no assurance that we will be able to obtain any sources of financing on acceptable terms, or at all.

Contractual Obligations and Commitments

We are party to a number of license agreements, pursuant to which we have payment obligations that are contingent upon future events such as our achievement of specified development, regulatory and commercial milestones and are required to make royalty payments in connection with the sale of products developed under those agreements. As of June 30, 2019, we were unable to estimate the timing or likelihood of achieving the milestones or making future product sales and, therefore, any related payments are not included in the table above. See Note 4 to our condensed consolidated financial statements included elsewhere in this Quarterly Report for a description of these agreements.

We enter into contracts in the normal course of business with clinical trial sites and clinical supply manufacturers and with vendors for preclinical studies, research supplies and other services and products for operating purposes. These contracts generally provide for termination after a notice period, and, therefore, are cancelable contracts and not included in the table above.

Government Contracts, Grant Agreements and Incentive Programs

The California Institute for Regenerative Medicine ("CIRM") Award

In August 2017, CIRM awarded an $18.3 million grant to researchers at UC San Diego, to advance our Phase 1/2 clinical trial evaluating cirmtuzumab in combination with ibrutinib for the treatment of patients with B-cell lymphoid malignancies, including MCL and CLL. We: (i) are conducting this study in collaboration with UC San Diego, (ii) estimate we will receive $16.1 million in development milestones under research subaward agreements throughout the award project period, estimated to be from October 1, 2017 to March 31, 2022, (iii) are committed to certain co-funding requirements, (iv) received subaward payments of $0.5 million and $3.6 million in June 2019 and 2018, respectively, and (v) are required to provide UC San Diego progress and financial update reports throughout the award project period. The subaward does not bear a royalty payment commitment, nor is the subaward otherwise refundable. For the six months ended June 30, 2019 and 2018, we recorded revenue of $1.2 million and $1.7 million, respectively. Related qualifying subaward costs during the six months ended June 30, 2019 and 2018 were $2.6 million and $3.4 million, respectively. As of June 30, 2019, we have met our obligations under the CIRM award and UC San Diego subawards to date.

Critical Accounting Policies

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of the financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses incurred during the reporting periods.

Our estimates are based on our historical experience, trends and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We consider our critical accounting policies and estimates to be related to research and development expenses and accruals, the valuation of warrants to purchase convertible preferred stock (which did convert at the Merger closing), and revenue recognition. There have been no material changes to our critical accounting policies and estimates during the six months ended June 30, 2019 from those disclosed in "Oncternal's Management's Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies," included in the Registration Statement.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISKS

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

ITEM 4. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

We maintain "disclosure controls and procedures" as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act that are designed to ensure that information required to be disclosed in the reports we file and submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, who serve as our principal executive officer and principal financial officer, respectively, has evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2019. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of such date.

Changes in Disclosure Controls and Procedures

On June 7, 2019, we completed the Merger as described in above. Otherwise, there were no changes in our internal control over financial reporting during the six months ended June 30, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

Litigation Related to the Merger

Between April 10 and May 1, 2019, three putative class action lawsuits and one individual lawsuit were filed in the U.S. District Court for the District of Delaware: Wheby v. GTx, Inc. et al., *Miller v. GTx, Inc. et al*., Tabb v. GTx, Inc. et al., and Living Seas LLC v. GTx, Inc. et al. (collectively, the "Delaware Actions") On April 11 and 23, 2019, two putative class actions were filed in the U.S. District Court for the Southern District of New York: Kopanic v. GTx, Inc. et al. and Cooper v. GTx, Inc. et al. (collectively, the "New York Actions" and, together with the Delaware Actions, the "Actions"). The Actions name as defendants us and our former board of directors, and, in the case of the Wheby and Miller actions, Private Oncternal and Merger Sub. The Actions allege that defendants violated Sections 14(a) and 20(a) of the Exchange Act, as well as Rule 14a-9 promulgated thereunder, in connection with our filing of the Registration Statement in connection with the Merger. Three of the Delaware Actions have now been voluntarily dismissed with prejudice: the Wheby action on June 12, 2019; the Miller action on July 15, 2019; and the Living Seas action on June 26, 2019. We and our board of directors believe that the remaining lawsuits are without merit and intend to vigorously defend these actions. We cannot predict the outcome of or estimate the possible loss or range of loss from any of these matters. It is possible that additional, similar complaints may be filed or the complaints described above will be amended. If this occurs, we do not intend to announce the filing of each additional, similar complaint or any amended complaint unless it contains allegations that are substantially distinct from those made in the pending actions described above.

ITEM 1A. RISK FACTORS.

You should carefully consider the following risk factors, together with the other information contained in this Quarterly Report, including our condensed consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before making a decision to purchase or sell shares of our common stock. We cannot assure you that any of the events discussed in the risk factors below will not occur. These risks could have a material and adverse impact on our business, results of operations, financial condition and growth prospects. If that were to happen, the trading price of our common stock could decline. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations or financial condition. As a result of the Merger, the following the risks represent material changes from those set forth in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2018.

Risks Related to Our Limited Operating History, Financial Position and Capital Requirements

We have a limited operating history, have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future. We may never generate any revenue or become profitable or, if we achieve profitability, we may not be able to sustain it.

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are a clinical-stage biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. To date, we have focused primarily on organizing and staffing our company, business planning, raising capital, identifying, acquiring and in-licensing our product candidates and conducting preclinical studies and early-stage clinical trials. Cirmtuzumab and TK216 are in clinical development, while our ROR1 CAR-T program is in the preclinical stage. We have not yet demonstrated an ability to successfully obtain regulatory approvals, manufacture a commercial scale product, or arrange for a third-party to do so on our behalf, or embark on sales and marketing activities necessary for successful post regulatory approval product commercialization, and have not developed any companion diagnostic test for our product candidates. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing biopharmaceutical products.

We have incurred significant operating losses since our inception. If our product candidates are not successfully developed and approved, we may never generate any revenue. Our net losses were $25.1 million and $3.9 million for the six months ended June 30, 2019 and 2018, respectively. As of June 30, 2019, we had an accumulated deficit of $56.5 million. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. All of our product candidates will require substantial additional development time and resources before we would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. We expect to continue to incur losses for the foreseeable future, and anticipate these losses will increase substantially as we continue to develop, seek regulatory approval for and potentially commercialize any of our product candidates, and seek to identify, assess, acquire, in-license or develop additional product candidates.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing clinical trials and preclinical studies of our product candidates, obtaining regulatory approval for these product candidates and manufacturing, marketing and selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability. In addition, we 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 industry. Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. 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 our value and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product candidates or even continue our operations. A decline in our company's value could also cause stockholders to lose all or part of their investment.

We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed and on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations.

The development of biopharmaceutical product candidates is capital-intensive. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct our ongoing and planned clinical trials of cirmtuzumab and TK216, continue research and development and initiate clinical trials of our other development programs and seek regulatory approval for our current product candidates and any future product candidates we may develop. In addition, as our product candidates progress through development and toward commercialization, we will need to make milestone payments to the licensors and other third parties from whom we have in-licensed or acquired our product candidates, including cirmtuzumab, TK216 and CAR-T. If we obtain regulatory approval for any of our product candidates, we also expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Because the outcome of any clinical trial or preclinical study is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates. Furthermore, following the completion of the merger, we have incurred additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

We have based our estimates on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our operating plans and other demands on our cash resources may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through a combination of equity financings, debt financings, government funding or other capital sources, including potentially collaborations, licenses and other similar arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop our product candidates.

Our future capital requirements will depend on many factors, including:

- the type, number, scope, progress, expansions, results, costs and timing of, our clinical trials of cirmtuzumab and TK216, and preclinical studies or clinical trials of other product candidates that we may choose to pursue in the future;
- the costs and timing of manufacturing for our product candidates, including commercial manufacturing if any product candidate is approved;
- the costs of obtaining ibrutinib, for which we currently obtain supply at no cost under our clinical supply agreement with Pharmacyclics LLC, and vincristine to conduct our clinical trials of cirmtuzumab and TK216, respectively;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of obtaining, maintaining and enforcing our patents and other intellectual property rights;
- our efforts to evaluate, develop or partner the SARD and/or SARM assets; our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal controls over financial reporting;

- the costs associated with hiring additional personnel and consultants as our clinical and other development activities increase;
- the timing and amount of the milestone or other payments we must make to the licensors and other third parties from whom we have in-licensed or acquired our product candidates or technology;
- the costs and timing of establishing or securing sales and marketing capabilities if any of our product candidates are approved;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements; and
- costs associated with any products or technologies that we may in-license or acquire.

Conducting clinical trials and preclinical studies is a time consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all.

Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through equity offerings, debt financings, government funding or other capital sources, including potentially collaborations, licenses and other similar arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, existing stockholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect stockholders' rights as a common 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 funds through future collaborations, licenses and other similar arrangements, we may have to relinquish valuable rights to our future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us and/or that may reduce the value of our common stock.

Risks Related to the Discovery, Development and Regulatory Approval of Our Product Candidates

We depend heavily on the success of cirmtuzumab and TK216, which are in Phase 1 or Phase 2 clinical trials, as well as our ROR1 CAR-T program, which is in preclinical development. If we are unable to advance our product candidates in clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

Our two clinical-stage product candidates are in Phase 1 or Phase 2 clinical development. In May 2018, we commenced a Phase 1/2 clinical trial evaluating cirmtuzumab in combination with ibrutinib in patients with MCL and CLL. We announced interim results of the study in June 2019, and in August 2019, we announced that we have opened for enrollment the randomized Phase 2, randomized portion of the study of cirmtuzumab in combination with ibrutinib in, for patients with CLL. The decision to open the Phase 2 portion of the study comes from the Part 1 dose-finding and Part 2 dose-confirming cohorts of the clinical trial, including an observed interim objective response rate ("ORR") of 100% for the first nine CLL patients with evaluable data receiving the recommended dosing regimen who have completed 12 weeks of cirmtuzumab plus ibrutinib treatment in Part 2, and a well-tolerated safety profile consistent with that seen with ibrutinib treatment alone. In addition, our TK216 product candidate is currently being evaluated in a Phase 1 clinical trial in patients with relapsed or refractory Ewing sarcoma. We plan to initiate a Phase 1 clinical trial of TK216 in AML, and to commence IND-enabling preclinical studies for TK216 for the treatment of patients with prostate cancer. Additionally, our ROR1 CAR-T program will need further preclinical development and IND-enabling studies prior to commencing clinical development. None of our product candidates have advanced into a pivotal or registrational study for the indications for which we are studying them. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates. The success of our product candidates will depend on various factors, including the following:

- successful completion of preclinical and clinical studies with favorable results;
- acceptance of investigation new drug applications ("INDs") by the U.S. Food and Drug Administration ("FDA") or similar regulatory filing by comparable foreign regulatory authorities for the conduct of clinical trials of our product candidates and our proposed designs for future clinical trials;
- demonstrating safety and efficacy of our product candidates to the satisfaction of applicable regulatory authorities;
- receiving marketing approvals from applicable regulatory authorities, including Biologics License Applications ("BLAs") or new drug applications ("NDAs"), from the FDA and maintaining such approvals;
- making arrangements with our third-party manufacturers for commercial manufacturing capabilities for our product candidates;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;
- establishing and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates;
- the demonstration of an acceptable safety profile of our products following approval, if any;
- developing, in-licensing or acquiring companion diagnostics to our product candidates; and
- maintaining and growing an organization for people who can develop our product candidates and technology.

The success of our business, including our ability to finance the company and generate any revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of our product candidates, which may never occur. We have not yet succeeded and may not succeed in demonstrating efficacy and safety for any of our product candidates in clinical trials or in obtaining marketing approval thereafter. Given our early stage of development, it may be several years, if at all, before we have demonstrated the safety and efficacy of a product candidate sufficient to warrant approval for commercialization. If we are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize our product candidates, we may not be able to generate sufficient revenue to continue our business.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and the results of preclinical studies and early clinical trials are not necessarily predictive of future results. Our product candidates may not have favorable results in clinical trials or receive regulatory approval on a timely basis, if at all.

Clinical drug development is expensive and can take many years to complete, and its outcome is inherently uncertain. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all, and failure can occur at any time during the preclinical study or clinical trial process. Despite promising preclinical or clinical results, any product candidate can unexpectedly fail at any stage of preclinical or clinical development. The historical failure rate for product candidates in our industry is high.

The results from preclinical studies or clinical trials of a product candidate may not predict the results of later clinical trials of the product candidate, and interim results of a clinical trial are not necessarily indicative of final results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy characteristics despite having progressed through preclinical studies and initial clinical trials. In particular, while cirmtuzumab was well tolerated and showed favorable results in the Phase 1 portion of our ongoing Phase 1/2 clinical trial as well as the inhibition of ROR1 signaling in patients with CLL in early clinical trials, we do not know how cirmtuzumab will perform in the Phase 2 portion of the clinical trial and one or more of the reported clinical outcomes may materially change as patient enrollment continues in such trial, and such results may not be replicated in any other future clinical trials, including as a result of any differences in the target population, drug interactions or other differences in our trial design. It is not uncommon to observe results in clinical trials that are unexpected based on preclinical studies and early clinical trials, and many product candidates fail in clinical trials despite very promising early results. Moreover, this and any future preclinical and clinical data may be susceptible to varying interpretations and analyses. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies. Furthermore, we cannot assure you that we will be able to successfully progress our preclinical programs from candidate identification to Phase 1 clinical development.

For the foregoing reasons, we cannot be certain that our ongoing and planned clinical trials and preclinical studies will be successful. Any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications, which could have a material adverse effect on our business, financial condition and results of operations.

Any difficulties or delays in the commencement or completion, or termination or suspension, of our current or planned clinical trials could result in increased costs to us, delay or limit our ability to generate revenue, and adversely affect our commercial prospects.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical studies to demonstrate the safety and efficacy of the product candidates in humans. In August 2019, we opened enrollment for the Phase 2 portion of our ongoing Phase 1/2 trial of cirmtuzumab in combination with ibrutinib in patients with CLL and MCL and are also conducting a dose-escalation Phase 1 trial of TK216 in patients with relapsed or refractory Ewing sarcoma. We will have to follow the same procedure for our other preclinical product candidates that we plan to advance to clinical development, and would also be required to submit regulatory filings to foreign regulatory authorities if we decide to initiate clinical trials outside of the United States.

We do not know whether our planned trials will begin on time or be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- subjects failing to enroll or remain in our trial at the rate we expect, or failing to return for post-treatment follow-up;
- subjects choosing an alternative treatment for the indication for which we are developing our product candidates, or participating in competing clinical trials;
- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical studies;
- difficulties in obtaining regulatory authorizations to commence a trial or reaching a consensus with regulatory authorities on trial design;

- difficulties in recruiting clinical trial investigators with the appropriate competencies and experience;
- failure or delay in reaching an agreement with 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;
- delays in obtaining approval from one or more institutional review boards ("IRBs");
- IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- changes to clinical trial protocols;
- clinical sites deviating from trial protocols or dropping out of a trial;
- challenges in manufacturing sufficient quantities of product candidates or obtaining sufficient quantities of combination therapies for use in clinical trials;
- lack of adequate funding to continue clinical trials;
- subjects experiencing severe or unexpected drug-related adverse effects;
- occurrence of serious adverse events in clinical trials of the same class of agents conducted by other companies;
- selection of clinical endpoints that require prolonged periods of clinical observation or analysis of the resulting data;
- a facility manufacturing our product candidates or any of their components being ordered by the FDA or comparable foreign regulatory authorities to temporarily or permanently shut down due to violations of current Good Manufacturing Practices ("cGMP") regulations or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials in a timely manner or consistent with applicable clinical trial protocols, good clinical practices ("GCP"), or other regulatory requirements; third-party contractors not performing data collection or analysis in a timely or accurate manner; or
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications.

We could also encounter delays if our clinical trials are suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial, or by the FDA or comparable foreign regulatory authorities. Regulatory authorities may suspend or terminate clinical trials due to a number of factors, including failure to conduct clinical trials in accordance with regulatory requirements or the applicable clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Further, if we decide to conduct clinical trials of our product candidates in foreign countries additional risks may arise that may delay completion of those clinical trials. These risks include the failure of enrolled patients in other countries to adhere to clinical protocol as a result of differences in healthcare practices or cultural customs, managing additional administrative burdens associated with the regulatory schemes of other countries, as well as political and economic risks relevant to other countries. Under our license and development agreement with SPH USA, SPH USA has the right to manufacture, develop, market, distribute and sell our cirmtuzumab, ROR1 CAR-T, and TK216 product candidates in the People's Republic of China, Hong Kong, Macau and Taiwan, or Greater China, and the obligation to perform all preclinical and clinical development activities required to obtain regulatory approvals for such product candidates in Greater China. In the event that SPH USA's preclinical studies or clinical trials of our product candidates raise new safety or efficacy concerns, the prospects for obtaining regulatory approval of our product candidates in the United States and other countries, and our business, could be adversely impacted.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

If we experience delays in the completion of, or termination of, clinical trials of our product candidates, the commercial prospects of such product candidates may be harmed, and our ability to generate product revenues from such product candidates may be delayed. Moreover, delays in completing our clinical trials may increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues.

In addition, many of the factors that cause, or lead to, the termination, suspension or delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. If we make formulation or manufacturing changes to our product candidates, we may be required to conduct additional preclinical or clinical studies to bridge our modified product candidates to earlier versions. The need to conduct additional preclinical or clinical studies could result in delays in the approval or commercialization of our product candidates, which could shorten any period during which we may have the exclusive right to commercialize our product candidates and enable our competitors to bring products to market before we do. In such an event, the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects significantly.

We may find it difficult to enroll patients in our clinical trials. If we encounter difficulties enrolling subjects in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to identify 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. Subject 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 and exclusion criteria for the trial, the design of the clinical trial, the availability of competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating as well as any drugs under development. We will be required to identify and enroll a sufficient number of subjects for each of our clinical trials. Potential subjects for any planned clinical trials may not be adequately diagnosed or identified with the diseases which we are targeting or may not meet the entry criteria for such trials. For example, a limited number of patients are affected by CLL, MCL and particularly Ewing sarcoma, which are our initial target indications for cirmtuzumab and TK216. We also may encounter difficulties in identifying and enrolling subjects with a stage of disease appropriate for our planned clinical trials. We may not be able to initiate or continue clinical trials if we are unable to locate a sufficient number of eligible subjects to participate in the clinical trials required by the FDA or comparable foreign regulatory authorities. In addition, the process of finding and diagnosing subjects may prove costly.

The timing of our clinical trials depends, in part, on the speed at which we can recruit patients to participate in our trials, as well as completion of required follow-up periods. For certain of our product candidates, including cirmtuzumab and TK216, the conditions which we currently plan to evaluate are orphan or rare diseases with limited patient pools from which to draw for clinical trials. The eligibility criteria of our clinical trials will further limit the pool of available trial participants. If patients are unwilling to participate in our clinical trials for any reason, including the existence of concurrent clinical trials for similar patient populations or the availability of approved therapies, or if we otherwise have difficulty enrolling a sufficient number of patients, the timeline for recruiting subjects, conducting studies and obtaining regulatory approval of our product candidates may be delayed. Our inability to enroll a sufficient number of subjects for any of our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. In addition, we expect to rely on CROs and clinical trial sites to ensure proper and timely conduct of our future clinical trials and, while we intend to enter into agreements governing their services, we will have limited influence over their actual performance.

We cannot assure stockholders that our assumptions used in determining expected clinical trial timelines are correct or that we will not experience delays in enrollment, which would result in the delay of completion of such trials beyond our expected timelines.

Use of our product candidates could be associated with side effects, adverse events or other properties or safety risks, which could delay or preclude approval, cause us to suspend or discontinue clinical trials, abandon a product candidate, limit the commercial profile of the label for an approved product candidate, or result in other significant negative consequences that could severely harm our business, prospects, operating results and financial condition.

As is the case with oncology drugs generally, it is likely that there may be side effects and adverse events associated with the use of our product candidates. Results of our clinical trials could reveal a high and unacceptable severity and prevalence, or unexpected characteristics of side effects. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials, result in a more restrictive label for the product candidate, or delay or cause the denial of regulatory approval of the product candidate by the FDA or comparable foreign regulatory authorities. The drug-related side effects could also affect patient recruitment for our clinical trials, or the ability of enrolled patients to complete the trials, or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Moreover, if our product candidates are associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may elect to abandon their development or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial prospects for the product candidate if approved. We may also be required to modify our plans for future studies based on findings in our ongoing clinical trials. Many compounds that initially showed promise in early-stage testing have later been found to cause side effects that prevented further development of the compound. In addition, regulatory authorities may draw different conclusions or require additional testing to confirm these determinations.

It is possible that as we test our product candidates in larger, longer and more extensive clinical trials, or as the use of our product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by subjects. If such side effects become known later in development or upon approval, if any, such findings may harm our business, financial condition and prospects significantly. In addition, our ongoing clinical trials of cirmtuzumab in combination with ibrutinib and TK216 in combination with vincristine, and the ongoing investigator-initiated clinical trial of cirmtuzumab in combination with paclitaxel, may reveal adverse events based on the combination therapy that may negatively impact the reported safety profile in such clinical trial.

In addition, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw, suspend or limit approvals of such product;
- we may be required to recall a product or change the way such product is administered to patients;
- regulatory authorities may require additional warnings on the label, such as a “black box” warning or a contraindication;
- we may be required to implement a Risk Evaluation and Mitigation Strategy (“REMS”) or create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way a product is distributed or administered, conduct additional clinical trials or change the labeling of a product or be required to conduct additional post-marketing studies or surveillance;
- we could be sued and held liable for harm caused to patients;
- sales of the product may decrease significantly or the product could become less competitive; and
- our reputation could suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

The regulatory landscape that will apply to development of gene therapy or cell-based therapeutic product candidates by us or by our collaborators is rigorous, complex, uncertain and subject to change, which could result in delays or termination of development of such product candidates or unexpected costs in obtaining regulatory approvals.

Regulatory requirements governing products involving gene therapy treatment have changed frequently and will likely continue to change in the future. Approvals by one regulatory agency may not be indicative of what any other regulatory agency may require for approval, and there is substantial, and sometimes uncoordinated, overlap in those responsible for regulation of gene therapy products, cell therapy products and other products created with genome editing technology. For example, in addition to the submission of an IND to the FDA, before initiation of a clinical trial in the United States, certain human clinical trials for cell therapy products and gene therapy had historically been subject to review by the Recombinant DNA Advisory Committee (the "RAC"), of the National Institutes of Health ("NIH"), Office of Biotechnology Activities ("OBA"), pursuant to the NIH Guidelines for Research Involving Recombinant DNA Molecules ("NIH Guidelines"). Following an initial review, RAC members would make a recommendation as to whether the protocol raises important scientific, safety, medical, ethical or social issues that warrant in-depth discussion at the RAC's quarterly meetings. Even though the FDA decides whether individual cell therapy or gene therapy protocols may proceed under an IND, the RAC's recommendations were shared with the FDA and the RAC public review process, if undertaken, could delay the initiation of a clinical trial, even if the FDA had reviewed the trial design and details and has not objected to its initiation or has notified the sponsor that the study may begin. Conversely, the FDA could have put an IND on clinical hold even if the RAC provided a favorable review or had recommended against an in-depth, public review. On August 17, 2018, the NIH issued a notice in the Federal Register and issued a public statement proposing changes to the oversight framework for gene therapy trials, including changes to the applicable NIH Guidelines to modify the roles and responsibilities of the RAC with respect to human clinical trials of gene therapy products, and requesting public comment on its proposed modifications. The NIH announced that during the public comment period, which closed October 16, 2018, it would no longer accept new human gene transfer protocols for review as part of the protocol registration process under the existing NIH Guidelines or convene the RAC to review individual clinical protocols. These trials remain subject to the FDA's oversight and other clinical trial regulations, and oversight at the local level will continue as otherwise set forth in the NIH Guidelines. Specifically, under the NIH Guidelines, supervision of human gene transfer trials includes evaluation and assessment by an institutional biosafety committee, or IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment, and such review may result in some delay before initiation of a clinical trial. While the NIH Guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them. Even though we may not be required to submit a protocol for our gene therapy product candidates such as a ROR1 targeted CAR-T through the NIH for RAC review, we will still be subject to significant regulatory oversight by the FDA, and in addition to the government regulators, the applicable IBC and IRB of each institution at which we or our collaborators conduct clinical trials of our product candidates, or a central IRB if appropriate, would need to review and approve the proposed clinical trial.

The same applies in the European Union. The European Medicines Agency (the "EMA"), has a Committee for Advanced Therapies ("CAT") that is responsible for assessing the quality, safety and efficacy of advanced therapy medicinal products. Advanced-therapy medical products include gene therapy medicine, somatic-cell therapy medicines and tissue-engineered medicines. The role of the CAT is to prepare a draft opinion on an application for marketing authorization for a gene therapy medicinal candidate that is submitted to the EMA. In the European Union, the development and evaluation of a gene therapy medicinal product must be considered in the context of the relevant European Union guidelines. The EMA may issue new guidelines concerning the development and marketing authorization for gene therapy medicinal products and require that we comply with these new guidelines. Similarly complex regulatory environments exist in other jurisdictions in which we might consider seeking regulatory approvals for our product candidates, further complicating the regulatory landscape. As a result, the procedures and standards applied to gene therapy products and cell therapy products may be applied to any of our gene therapy product candidates such as CAR-T, but that remains uncertain at this point.

The clinical trial requirements of the FDA, the EMA and other regulatory authorities and the criteria these regulators use to evaluate the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for product candidates involving gene therapy can be more lengthy, rigorous and expensive than the process for other better known or more extensively studied product candidates and technologies. Since we are developing novel treatments for diseases in which there is little clinical experience with new endpoints and methodologies, there is heightened risk that the FDA, the EMA or comparable regulatory bodies may not consider the clinical trial endpoints to provide clinically meaningful results, and the resulting clinical data and results may be more difficult to analyze. This may be a particularly significant risk for many of the genetically defined diseases for which we may develop product candidates alone or with collaborators due to small patient populations for those diseases, and designing and executing a rigorous clinical trial with appropriate statistical power is more difficult than with diseases that have larger patient populations. Regulatory agencies administering existing or future regulations or legislation may not allow production and marketing of products utilizing gene therapy in a timely manner or under technically or commercially feasible conditions. Even if our product candidates obtain required regulatory approvals, such approvals may later be withdrawn as a result of changes in regulations or the interpretation of regulations by applicable regulatory agencies.

Changes in applicable regulatory guidelines may lengthen the regulatory review process for our product candidates, require additional studies or trials, increase development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of such product candidates, or lead to significant post-approval limitations or restrictions. Additionally, adverse developments in clinical trials of gene therapy products conducted by others may cause the FDA, the EMA and other regulatory bodies to revise the requirements for approval of any product candidates we may develop or limit the use of products utilizing gene therapy, either of which could materially harm our business. Furthermore, regulatory action or private litigation could result in increased expenses, delays or other impediments to our research programs or the development or commercialization of current or future product candidates.

As we advance our product candidates alone or with collaborators, we will be required to consult with these regulatory and advisory groups and comply with all applicable guidelines, rules and regulations. If we fail to do so, we or our collaborators may be required to delay or terminate development of such product candidates. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a product candidate to market could decrease our ability to generate sufficient product revenue to maintain our business.

As an organization, we have limited experience in the process of enrolling patients in our clinical trials, have never conducted later-stage clinical trials or submitted a BLA or an NDA, and may be unable to do so for any of our product candidates.

We are early in our development efforts for our product candidates, and will need to successfully complete later-stage and pivotal clinical trials in order to obtain FDA or comparable foreign regulatory approval to market cirmtuzumab, TK216, ROR1 CAR-T, or any future product candidates. Carrying out later-stage clinical trials and submitting a successful BLA or NDA is a complicated process. As an organization, we are in the process of conducting a Phase 1/2 clinical trial for cirmtuzumab in combination with ibrutinib and a Phase 1 clinical trial for TK216, alone and in combination with vincristine. We have not yet conducted any clinical trials for our other product candidates. We have not previously conducted any later stage or pivotal clinical trials, have limited experience as a company in preparing, submitting and prosecuting regulatory filings and have not previously submitted a BLA, an NDA or other comparable foreign regulatory submission for any product candidate. In addition, we have had limited interactions with the FDA and cannot be certain how many additional clinical trials of cirmtuzumab, TK216 or any other product candidates will be required or how such trials should be designed. We may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to regulatory submission and approval of any of our product candidates. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop. Failure to commence or complete, or delays in our planned clinical trials could delay or prevent us from submitting BLAs or NDAs for, and commercializing, our product candidates.

Our product candidates are subject to extensive regulation and compliance, which is costly and time consuming, and such regulation may cause unanticipated delays or prevent the receipt of the required approvals to commercialize our product candidates.

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of our product candidates are subject to extensive regulation by the FDA in the United States and by comparable foreign regulatory authorities in foreign markets. In the United States, we are not permitted to market our product candidates until we receive regulatory approval from the FDA. The process of obtaining regulatory approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications and patient population. Approval policies or regulations may change, and the FDA has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed. We are not permitted to market any of our product candidates in the United States until we receive approval of a BLA or an NDA from the FDA.

Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses, and in the case of biological products, that such product candidates are safe, pure and potent. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authorities, as the case may be, may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or post-approval, or may object to elements of our clinical development program.

The FDA or comparable foreign regulatory authorities can delay, limit or deny approval of a product candidate for many reasons, including:

- such authorities may disagree with the design or execution of our clinical trials;
- negative or ambiguous results from our clinical trials or results may not meet the level of statistical significance required by the FDA or comparable foreign regulatory agencies for approval;
- serious and unexpected drug-related side effects may be experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- such authorities may not accept clinical data from trials that are conducted at clinical facilities or in countries where the standard of care is potentially different from that of their own country;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- such authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- such authorities may not agree that the data collected from clinical trials of our product candidates are acceptable or sufficient to support the submission of a BLA, NDA or other submission or to obtain regulatory approval in the United States or elsewhere, and such authorities may impose requirements for additional preclinical studies or clinical trials;
- such authorities may disagree with us regarding the formulation, labeling and/or the product specifications of our product candidates;
- approval may be granted only for indications that are significantly more limited than those sought by us, and/or may include significant restrictions on distribution and use;
- such authorities may find deficiencies in the manufacturing processes or facilities of the third-party manufacturers with which we contract for clinical and commercial supplies; or
- such authorities may not accept a submission due to, among other reasons, the content or formatting of the submission.

With respect to foreign markets, approval procedures vary among countries and, in addition to the foregoing risks, may involve additional product testing, administrative review periods and agreements with pricing authorities. In addition, events raising questions about the safety of certain marketed pharmaceuticals may result in increased cautiousness by the FDA and comparable foreign regulatory authorities in reviewing new drugs based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us or any of our potential future collaborators from commercializing our product candidates.

Of the large number of drugs in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failure to obtain regulatory approval to market our product candidates, which would significantly harm our business, financial condition, results of operations and prospects.

Even if we eventually complete clinical trials and receive approval of a BLA, NDA or comparable foreign marketing application for our product candidates, the FDA or comparable foreign regulatory authority may grant approval contingent on the performance of costly additional clinical trials, including Phase 4 clinical trials, and/or the implementation of a REMS, which may be required because the FDA believes it is necessary to ensure safe use of the drug after approval. The FDA or the comparable foreign regulatory authority also may approve a product candidate for a more limited indication or patient population than we originally requested, and the FDA or comparable foreign regulatory authority may not approve the labeling that we believe is necessary or desirable for the successful commercialization of a product. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of that product candidate and would materially adversely impact our business and prospects.

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

Because we have limited financial and managerial resources, we are focused on specific product candidates, indications and development programs. As a result, we may forgo or delay the pursuit of opportunities with other indications or other product candidates that could have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential for a particular product candidate, we could relinquish valuable rights to that product candidate through collaborations, licenses and other similar arrangements, when it might be more advantageous for us to retain sole development and commercialization rights to such product candidate.

Fast Track designation by the FDA for TK216 or our other product candidates may not actually lead to a faster development or regulatory review or approval process.

We have been granted a Fast Track designation for TK216 in the United States for the treatment of Ewing sarcoma and may seek Fast Track designation for cirmtuzumab or our other product candidates. The Fast Track program is intended to expedite or facilitate the process for reviewing new product candidates that meet certain criteria. Specifically, new drugs are eligible for Fast Track designation if they are intended, alone or in combination with one or more drugs, to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied. With a Fast Track product candidate, the FDA may consider for review sections of the NDA or BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA or BLA, the FDA agrees to accept sections of the NDA or BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA or BLA.

Obtaining a Fast Track designation does not change the standards for product approval, but may expedite the development or approval process. Even though the FDA has granted such designation for TK216, it may not actually result in faster clinical development or regulatory review or approval. Furthermore, such a designation does not increase the likelihood that TK216 or any other product candidate that may be granted Fast Track designation will receive marketing approval in the United States.

We may not be able to obtain or maintain orphan drug designations for certain of our product candidates, and may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the FDA may designate a product as an orphan product if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or a patient population of greater than 200,000 individuals in the United States, but for which there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the European Union, the EMA's, Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union. We have received orphan drug designation in the United States for TK216 for patients with Ewing sarcoma and we may seek orphan drug designation in the European Union for TK216 for patients with Ewing sarcoma, as well as seek orphan drug designation for certain of our other product candidates. There can be no assurance that the FDA or the EMA's Committee for Orphan Medicinal Products will grant orphan designation for any indication for which we apply, or that we will be able to maintain such designation.

In the United States, orphan designation entitles a party to financial incentives such as opportunities for grant funding for clinical trial costs, tax advantages and user-fee waivers. In addition, if a product candidate that has orphan designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including an NDA or BLA, to market the same drug for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity. The applicable exclusivity period is ten years in Europe, but such exclusivity period can be reduced to six years if a product no longer meets the criteria for orphan designation or if the product is sufficiently profitable so that market exclusivity is no longer justified.

Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA or comparable foreign regulatory authority can subsequently approve the same drug for the same condition if such regulatory authority concludes that the later drug is clinically superior if it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

We may conduct certain of or portions of our clinical trials for our product candidates outside of the United States and the FDA may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business.

We may in the future choose to conduct one or more of our clinical trials or a portion of our clinical trials for our product candidates outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with GCP requirements, and, and FDA must be able to validate the data from the study through an onsite inspection, if required. In general, the patient population for any clinical studies conducted outside of the United States must be representative of the population for whom we intend to label the product in the United States. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will be dependent upon its determination that the studies also complied with all applicable U.S. laws and regulations. There can be no assurance the FDA will accept data from trial conducted outside of the United States. If the FDA does not accept the data from our clinical trials of our product candidates, it would likely result in the need for additional trials, which would be costly and time consuming and delay or permanently halt our development of our product candidates.

Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or topline data from our clinical studies, which are based on preliminary analyses of then-available data. Such preliminary results and related findings and conclusions are subject to change following more comprehensive reviews of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline 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. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical studies, such as the positive interim data we announced from our Phase 1/2 clinical trial of cirmtuzumab in combination with ibrutinib. Interim data from this clinical trial and future 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, following more comprehensive reviews of the data, and as more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses of data from preclinical studies or clinical trials of its product candidates, or may interpret or weigh the importance of data differently, which could impact the value of the particular product candidate, the approvability or prospects for commercialization of the product candidate, or our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and stockholders and others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure. Information that we decide not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, product candidate or our business. If the interim, topline or preliminary data that we disclose differ from actual results, or if others, including regulatory authorities, disagree with the conclusions we reach based on our analyses of such data, our ability to obtain approval for, and commercialize our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Any breakthrough therapy designation that we may receive from the FDA for our product candidates may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval.

We may seek breakthrough therapy designation for some of our product candidates, including cirmtuzumab and TK216. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA are also eligible for accelerated approval. Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. The availability of breakthrough therapy designation was established with the passage of the Food and Drug Administration Safety and Innovation Act of 2012. We cannot be sure that any evaluation we may make of our product candidates as qualifying for breakthrough therapy designation will meet the FDA's expectations. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that such product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Risks Related to Our Reliance on Third Parties

We rely on third parties to conduct many of our preclinical studies and clinical trials. Any failure by a third-party to conduct the clinical trials according to good laboratory practices, GCPs and other requirements and in a timely manner may delay or prevent our ability to seek or obtain regulatory approval for or commercialize our product candidates.

We are dependent on third parties to conduct our clinical trials and preclinical studies, including our ongoing clinical trials for cirmtuzumab and TK216 and preclinical studies for ROR1 CAR-T and our other development programs. Specifically, we have used and relied on, and intend to continue to use and rely on, medical institutions, clinical investigators, CROs and consultants to conduct our clinical trials in accordance with our clinical protocols and applicable regulatory requirements. These CROs, investigators and other third parties play a significant role in the conduct and timing of these trials and subsequent collection and analysis of data. While we have agreements governing the activities of our third-party contractors, we have limited influence over their actual performance. Nevertheless, we are responsible for ensuring that each of its clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs or trial sites 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. 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.

There is no guarantee that any such CROs, investigators or other third parties will devote adequate time and resources to such trials or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, or otherwise performs in a substandard manner, our clinical trials may be extended, delayed or terminated. In addition, many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any BLA or NDA we submit to the FDA. Any such delay or rejection could prevent us from commercializing our product candidates.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties or do so on commercially reasonable terms. Switching or adding additional CROs, investigators and other third parties involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, investigators and other third parties, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

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

We do not own or operate manufacturing facilities and have no plans to build our own clinical or commercial scale manufacturing capabilities. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates and related raw materials for clinical and preclinical development, as well as for commercial manufacture if any of our product candidates receive marketing approval. The facilities used by third-party manufacturers to manufacture our product candidates must be approved by the FDA or other regulatory agencies pursuant to inspections that will be conducted after we submit a BLA or an NDA to the FDA or their equivalent to other regulatory agencies. We do not control the manufacturing process of, and are completely dependent on, third-party manufacturers for compliance with cGMP requirements for manufacture of our drug products. If these third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, including requirements related to the manufacturing of high potency and pure compounds or other products, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates, or if regulatory authorities withdraw any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, 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.

Our or a third-party's failure to execute on our manufacturing requirements, to do so on commercially reasonable terms, or to comply with cGMP could adversely affect our business in a number of ways, including:

- an inability to initiate or continue clinical trials of cirmtuzumab, TK216 or any future product candidates under development;
- delay in submitting regulatory applications, or receiving marketing approvals, for our product candidates;
- subjecting third-party manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease development or to recall batches of our product candidates; and
- in the event of approval to market and commercialize our product candidates, an inability to meet commercial demands for our product candidates.

In addition, 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:

- failure of third-party manufacturers to comply with regulatory requirements and maintain quality assurance;
- breach of the manufacturing agreement by the third-party;
- failure to manufacture our product according to our specifications;
- failure to manufacture our product according to our schedule, or at all;

- misappropriation of our proprietary information, including our trade secrets and know-how; and
- termination or nonrenewal of the agreement by the third-party at a time that is costly or inconvenient for us.

Our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval, and any related remedial measures may be costly or time consuming to implement. We do not currently have arrangements in place for redundant supply or a second source for all required raw materials used in the manufacture of our product candidates. If our current third-party manufacturers cannot perform as agreed, we may be required to replace such manufacturers and we may be unable to replace them on a timely basis or at all.

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

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that our trade secrets will be misappropriated or disclosed.

Because we currently rely on third parties to manufacture our product candidates and to perform quality testing, we must, at times, share our proprietary technology and confidential information, including trade secrets, with them. We seek to protect our proprietary technology, in part, by entering into confidentiality agreements, consulting agreements or other similar agreements with our advisors, employees, consultants and contractors prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are intentionally or inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets and despite our efforts to protect our trade secrets, a competitor's discovery of our proprietary technology and confidential information or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business, financial condition, results of operations and prospects.

We have entered into and may seek to enter into additional collaborations, licenses and other similar arrangements, and we may not be successful in doing so, and we may not realize the benefits of such relationships.

We may seek to enter into collaborations, joint ventures, licenses and other similar arrangements for the development or commercialization of our product candidates, due to capital costs required to develop or commercialize the product candidate or manufacturing constraints, in addition to our collaboration with SPH and SPH USA. We may not be successful in our efforts to establish such collaborations for our product candidates because our research and development pipeline may be insufficient, our product candidates may be deemed to be at too early of a stage of development for collaborative effort or third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy or significant commercial opportunity. In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process can be time consuming and complex. Further, any future collaboration agreements may restrict us from entering into additional agreements with potential collaborators. We cannot be certain that, following a strategic transaction or license, we will achieve an economic benefit that justifies such transaction.

Even if we are successful in our efforts to establish such collaborations, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such collaborations if, for example, development or approval of a product candidate is delayed, the safety of a product candidate is questioned or sales of an approved product candidate are unsatisfactory.

In April 2018, we entered into a clinical trial and supply agreement with Pharmacyclics, LLC, an AbbVie Company, in support of our clinical trial to evaluate the combination of cirmtuzumab with ibrutinib. Ibrutinib is an inhibitor of Bruton's tyrosine kinase, a key component of cell signaling in B-cells, and is marketed by Pharmacyclics for treatment in patients with CLL and MCL. We initiated a Phase 1/2 clinical trial in May 2018 to assess cirmtuzumab in combination with ibrutinib in patients with CLL and MCL. Pursuant to the agreement, Pharmacyclics has supplied ibrutinib up to a maximum aggregate amount at no cost to us for part 1 (a dose-finding arm) and part 2 (dose expansion arm) of the ongoing Phase 1/2 clinical trial evaluating cirmtuzumab in combination with ibrutinib. Under the clinical trial and supply agreement with Pharmacyclics, we are required to provide periodic reports to Pharmacyclics, including safety data reports, and to collaborate with Pharmacyclics in relation to any interactions with regulatory authorities regarding ibrutinib. The agreement includes no upfront costs, milestone or royalty payment commitments. In August 2019, Pharmacyclics agreed to provide additional quantities of ibrutinib at no cost to us for part 3 of the clinical trial, and so that patients who participated in parts 1 and 2 of the study may continue to receive ibrutinib in combination with cirmtuzumab for as long as their disease is responding. In the event the clinical supply agreement is terminated, we would likely incur substantial additional costs in order to obtain and purchase ibrutinib from a source other than Pharmacyclics and the Phase 2 part 3 of the Phase 1/2 clinical trial may be delayed.

In addition, any potential future collaborations may be terminable by our strategic partners, and we may not be able to adequately protect our rights under these agreements. Furthermore, strategic partners may negotiate for certain rights to control decisions regarding the development and commercialization of our product candidates, if approved, and may not conduct those activities in the same manner as we would. Any termination of collaborations we enter into in the future, or any delay in entering into collaborations related to our product candidates, could delay the development and commercialization of our product candidates and reduce their competitiveness if they reach the market, which could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Commercialization of Our Product Candidates

Even if we receive regulatory approval for any product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions on marketing or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates, when and if any of them are approved.

Following potential approval of any of our product candidates, the FDA may impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly and time-consuming post-approval studies, post-market surveillance or clinical trials to monitor the safety and efficacy of the product. The FDA may also require a REMS as a condition of approval of our product candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our products will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCP requirements for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with our products, including adverse events of unanticipated type, severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- restrictions on product distribution or use, or requirements to conduct post-marketing studies or clinical trials;
- fines, restitutions, disgorgement of profits or revenues, warning letters, untitled letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications we filed or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of our products; and
- injunctions or the imposition of civil or criminal penalties.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

In addition, if any of our product candidates are approved, our product labeling, advertising and promotion will be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about drug products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

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

We also 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. For example, certain policies of the current U.S. administration may impact our business and industry. Namely, the current U.S. administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these executive actions, including any Executive Orders, will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA and other regulatory agencies to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

The commercial success of our product candidates will depend upon the degree of market acceptance of such product candidates by physicians, patients, healthcare payors and others in the medical community.

Our product candidates may not be commercially successful. Even if any of our product candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors or the medical community. The commercial success of any of our current or future product candidates will depend significantly on the broad adoption and use of the resulting product by physicians and patients for approved indications. The degree of market acceptance of our products will depend on a number of factors, including:

- demonstration of clinical efficacy and safety compared to other more-established products;
- the indications for which our product candidates are approved;
- the limitation of our targeted patient population and other limitations or warnings contained in any FDA-approved labeling;
- acceptance of a new drug for the relevant indication by healthcare providers and their patients;
- the pricing and cost-effectiveness of our products, as well as the cost of treatment with our products in relation to alternative treatments and therapies;
- our ability to obtain and maintain sufficient third-party coverage and adequate reimbursement from government healthcare programs, including Medicare and Medicaid, private health insurers and other third-party payors;
- the willingness of patients to pay all, or a portion of, out-of-pocket costs associated with our products in the absence of sufficient third-party coverage and adequate reimbursement;
- any restrictions on the use of our products, and the prevalence and severity of any adverse effects;
- potential product liability claims;
- the timing of market introduction of our products as well as competitive drugs;
- the effectiveness of our or any of our potential future collaborators' sales and marketing strategies; 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 or patients, we may not generate sufficient revenue from that product and may not become or remain profitable. our efforts to educate the medical community and third-party payors regarding the benefits of our products may require significant resources and may never be successful.

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

Cancer therapies are sometimes characterized as first line, second line or third line, and the FDA often approves new therapies initially only for third line use. When cancer is detected early enough, first line therapy is sometimes adequate to cure the cancer or prolong life without a cure. Whenever first line therapy, including targeted therapy, immunotherapy, chemotherapy, hormone therapy, surgery or a combination of these, proves unsuccessful, second line therapy may be administered. Second line therapies often consist of more chemotherapy, radiation, antibody drugs, tumor targeted small molecules or a combination of these. Third line therapies can include bone marrow transplantation, antibody and small molecule targeted therapies, more invasive forms of surgery and new technologies. In markets with approved therapies, there is no guarantee that our product candidates, even if approved, would be approved for second line or first line therapy. This could limit our potential market opportunity. In addition, we may have to conduct additional clinical trials prior to gaining approval for second line or first line therapy.

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

Any product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

The Affordable Care Act includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty, and any processes adopted by the FDA to implement the BPCIA could have a material adverse effect on the future commercial prospects for our biological products.

We believe that any of our future product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to Congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, could be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products will depend on a number of marketplace and regulatory factors that are still developing.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. If we are found or alleged to have improperly promoted off-label uses, we may become subject to significant liability.

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, as our product candidates would be, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion and avoid off-label promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

The successful commercialization of our product candidates, if approved, will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels and favorable pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our products could limit our ability to market those products and decrease our ability to generate revenue.

The availability of coverage and the adequacy of reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford prescription medications such as our product candidates, if approved. Our ability to achieve coverage and acceptable levels of reimbursement for our products by third-party payors will have an effect on our ability to successfully commercialize those products. Even if we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the European Union or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive therapy is available. It is possible that a third-party payor may consider our products as substitutable and only offer to reimburse patients for the less expensive product. Even if we are successful in demonstrating improved efficacy or improved convenience of administration with our products, pricing of existing drugs may limit the amount we will be able to charge for our products. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our products and may not be able to obtain a satisfactory financial return on products that we may develop.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs will be covered. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our products.

Obtaining and maintaining reimbursement status is time consuming, costly and uncertain. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs. However, no uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely.

Additionally, we or our collaborators may develop companion diagnostic tests for use with our product candidates as we are targeting certain defined populations for our treatments. We, or our collaborators, will be required to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement sought for our product candidates, once approved. While we, or our collaborators, have not yet developed any companion diagnostic test for our product candidates, if we do, there is significant uncertainty regarding our ability to obtain approval, coverage and adequate reimbursement for the same reasons applicable to our product candidates.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries has and will continue to put pressure on the pricing and usage of our products. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our products. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our products. We expect to experience pricing pressures in connection with the sale of any of our products due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

We face significant competition, and if our competitors develop technologies or product candidates more rapidly than we do, or their technologies are more effective, our ability to develop and successfully commercialize products may be adversely affected.

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary and novel products and product candidates. Our competitors have developed, are developing or may develop products, product candidates and processes competitive with our product candidates. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of conditions for which we may attempt to develop product candidates. In particular, there is intense competition in the fields of immunology, inflammation and oncology. Our competitors include larger and better funded pharmaceutical, biopharmaceutical, biotechnological and therapeutics companies. Moreover, we may also compete with universities and other research institutions who may be active in the indications we are targeting and could be in direct competition with us. We also compete with these organizations to recruit management, scientists and clinical development personnel, which could negatively affect our level of expertise and our ability to execute our business plan. We will also face competition in establishing clinical trial sites, enrolling subjects for clinical trials and in identifying and in-licensing new product candidates. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

If any of our product candidates are approved in oncology indications such as CLL or MCL, they will compete with small molecule therapies, biologics, cell-based therapies and vaccines, either approved or under development, that are intended to treat the same cancers that we are targeting, including through approaches that may prove to be more effective, have fewer side effects, be less costly to manufacture, be more convenient to administer or have other advantages over any product candidates we develop. In addition to competing with other therapies targeting similar indications, there are numerous other companies and academic institutions focused on similar targets as our product candidates and/or different scientific approaches to treating the same indications. We face competition from such companies in seeking any future potential collaborations to partner our product candidates, as well as potentially competing commercially for any approved products.

CLL has traditionally been treated with standard cytotoxic agents such as fludarabine, chlorambucil, cyclophosphamide, and bendamustine. Rituximab, marketed as Rituxan by Genentech, which is a monoclonal antibody that specifically recognizes CD20, an antigen on B-cells from which the tumor cells in CLL arise, was approved for use in CLL in 2010, but was previously widely prescribed off-label. Rituximab, which is typically used to treat patients with CLL in combination with cytotoxic agents, remains a treatment option for younger patients who can tolerate the side effects of the associated chemotherapy. Regulatory authorities have also approved other monoclonal antibody products that target CD20, as well as antibodies targeting another surface protein found on CLL tumor cells known as CD52, and three classes of small molecules: ibrutinib, venetoclax, an inhibitor of the protein B-cell lymphoma-2 ("Bcl-2"), which is marketed as Venclexta and Venclyxto by AbbVie and Roche/Genentech, and Zydelig (idelalisib, marketed by Gilead Sciences) and Copiktra (duvelisib, marketed by Verastem), inhibitors of Phosphoinositide 3-kinase ("PI3K"). These agents are approved for use as single agents, but are being investigated in combination with each other and with various monoclonal antibody products. Additionally, clinicians are investigating their potential in earlier stage disease in multiple clinical trials.

There are several therapeutic options available to treat MCL. Newly diagnosed patients are typically treated with rituximab combined with a chemotherapy regimen known as CHOP, comprised of cyclophosphamide, doxorubicin, vincristine, and prednisone. Alternative chemotherapy regimens include bortezomib or bendamustine. Patients with clinical responses to chemotherapy may become candidates for another therapeutic approach, autologous stem cell transplantation, a procedure in which radiation and/or chemotherapy is used to eliminate the patient's immune cells, including residual MCL cells. Recently, ibrutinib was granted accelerated approval by the FDA for the treatment of relapsed MCL.

The current standard therapy for patients with localized Ewing sarcoma in the U.S. is surgery plus local radiation therapy, plus a combination of chemotherapy agents, including vincristine, doxorubicin and cyclophosphamide, with alternating cycles of ifosfamide and etoposide, which is a therapy known as VDC/IE.

Many of our competitors have significantly greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we do. If we successfully obtain approval for any product candidate, we will face competition based on many different factors, including the safety and effectiveness of our products, the ease with which our products can be administered and the extent to which patients accept relatively new routes of administration, the timing and scope of regulatory approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Competing products could present superior treatment alternatives, including by being more effective, safer, more convenient, less expensive or marketed and sold more effectively than any products we may develop. Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our product candidates. If we are unable to compete effectively, our opportunity to generate revenue from the sale of products we may develop, if approved, could be adversely affected.

If the market opportunities for our products are smaller than we believe they are, our revenue may be adversely affected, and our business may suffer.

The precise incidence and prevalence for all the conditions we aim to address with our product candidates are unknown. Our projections of both the number of people who have these diseases, the number who have the specific indicated stage or treatment history we believe will be the approved indication, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new trials may change the estimated incidence or prevalence of these diseases. The total addressable market across all of our product candidates will ultimately depend upon, among other things, the indication approved by regulatory agencies and the diagnostic criteria included in the final label for each of our product candidates approved for sale for these indications, the availability of alternative treatments and the safety, convenience, cost and efficacy of our product candidates relative to such alternative treatments, acceptance by the medical community and patient access, drug pricing and reimbursement. The number of patients in the United States and other major markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our products or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business. Further, even if we obtain significant market share for our product candidates, because some of our potential target populations are very small, we may never achieve profitability despite obtaining such significant market share.

We currently have no marketing and sales organization and have no experience as a company in commercializing products, and we may have to invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our products, we may not be able to generate product revenue.

We have no internal sales, marketing or distribution capabilities, nor have we commercialized a product. If any of our product candidates ultimately receives regulatory approval, we must build a marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize each such product in major markets, which will be expensive and time consuming, or collaborate with third parties that have sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. We have no prior experience as a company in the marketing, sale and distribution of biopharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, our product revenues and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we are not successful in commercializing our products, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future growth may depend, in part, on our ability to develop and commercialize our product candidates in foreign markets. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from applicable regulatory authorities in foreign markets, and we may never receive such regulatory approvals for any of our product candidates. To obtain separate regulatory approval in most other countries, we must comply with numerous and varying regulatory requirements regarding safety and efficacy and governing, among other things, clinical trials, commercial sales, manufacturing, pricing and distribution of our product candidates. If we receive regulatory approval of our product candidates and ultimately commercialize our products in foreign markets, we would be subject to additional risks and uncertainties, including:

- different regulatory requirements for approval of drugs in foreign countries;
- reduced protection for intellectual property rights;
- the existence of additional third-party patent rights of potential relevance to our business;
- unexpected changes in tariffs, trade barriers and regulatory requirements;

- economic weakness, including inflation, or political instability in particular foreign economies and markets; compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- foreign reimbursement, pricing and insurance regimes;
- workforce uncertainty in countries where labor unrest is common;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

Risks Related to Our Business Operations and Industry

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide.

Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to:

- the timing and cost of, and level of investment in, research, development, regulatory approval and commercialization activities relating to our product candidates, which may change from time to time;
- coverage and reimbursement policies with respect to our product candidates, if approved, and potential future drugs that compete with our products;
- the cost of manufacturing our product candidates, which may vary depending on the quantity of production and any manufacturing issues or challenges requiring additional manufacturing activities, and the terms of our agreements with third-party manufacturers;
- the timing and amount of any milestone or other payments we must make to the licensors and other third parties from whom we have in-licensed or acquired our product candidates;
- expenditures that we may incur to acquire, develop or commercialize additional product candidates and technologies;
- the level of demand for any approved products, which may vary significantly;
- future accounting pronouncements or changes in our accounting policies; and
- the timing and success or failure of preclinical studies or clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue or earnings guidance we may provide.

We are dependent on the services of our management and if we are not able to retain these individuals or recruit additional management or other key personnel, our business will suffer.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We are highly dependent upon our senior management, particularly our Chief Executive Officer, as well as other members of our senior management team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, initiation or completion of our planned operations, planned clinical trials or the commercialization of our product candidates. Although we have executed employment agreements or offer letters with each member of our senior management team, these agreements are terminable at will with or without notice and, therefore, we may not be able to retain their services as expected. We do not currently maintain "key person" life insurance on the lives of any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

We will need to expand and effectively manage our managerial, operational, financial and other resources in order to successfully pursue our clinical development and commercialization efforts. We may not be successful in maintaining our unique company culture and continuing to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among pharmaceutical, biotechnology and other businesses, particularly in the San Diego area. Our industry has experienced a high rate of turnover of management personnel in recent years. If we are not able to attract, integrate, retain and motivate 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.

We may encounter difficulties in managing our growth and expanding our operations successfully.

As of June 30, 2019, we had six full-time employees and three part-time employees. As we continue research and development activities and pursue the potential commercialization of our product candidates, as well as function as a public company, we will need to expand our financial, research, development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for the company. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Our future financial performance and our ability to develop and commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively.

We are subject to various foreign, federal, and state healthcare and privacy laws and regulations, and our failure to comply with these laws and regulations could harm our results of operations and financial condition.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors and customers expose us to broadly applicable foreign, federal and state fraud and abuse and other healthcare and privacy laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute any products for which we obtain marketing approval. Such laws include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, in return for, either the referral of an individual or the purchase, lease, or order, or arranging for or recommending the purchase, lease, or order of any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti- Kickback Statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- the federal false claims and civil monetary penalties laws, including the civil False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making or causing to be made 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, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and their implementing regulations, also impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers as well as their business associates that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information;

- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare and Medicaid Services ("CMS"), information related to payments and other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental third-party payors, including private insurers, or by the patients themselves; state 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 and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information or which require tracking gifts and other remuneration and items of value provided to physicians, other healthcare providers and entities; state and local laws that require the registration of pharmaceutical sales representatives; state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA; state and foreign governments that have enacted or proposed requirements regarding the collection, distribution, use, security, and storage of personally identifiable information and other data relating to individuals (including the European Union General Data Protection Regulation 2016/679 ("GDPR"), and the California Consumer Protection Act), and federal and state consumer protection laws are being applied to enforce regulations related to the online collection, use, and dissemination of data, thus complicating compliance efforts.

As of May 25, 2018, the GDPR replaced the Data Protection Directive with respect to the processing of personal data in the European Union. The GDPR imposes many requirements for controllers and processors of personal data, including, for example, higher standards for obtaining consent from individuals to process their personal data, more robust disclosures to individuals and a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention and secondary use of information, increased requirements pertaining to health data and pseudonymised (i.e., key-coded) data and additional obligations when we contract third-party processors in connection with the processing of the personal data. The GDPR allows European Union member states to make additional laws and regulations further limiting the processing of genetic, biometric or health data. Failure to comply with the requirements of GDPR and the applicable national data protection laws of the European Union member states may result in fines of up to €20 million or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties.

Ensuring that our internal operations and business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including our consulting arrangements with physicians and other healthcare providers, some of whom received stock options as compensation for services provided, do not comply with current or future statutes, regulations, agency guidance 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 the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, disgorgement, individual imprisonment, contractual damages, reputational harm, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, diminished profits and the curtailment or restructuring of our operations. Further, defending against any such actions can be costly, time consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusion from government funded healthcare programs and imprisonment. If any of the above occur, it could adversely affect our ability to operate our business and our results of operations.

Recently enacted legislation, future legislation and healthcare reform measures may increase the difficulty and cost for us to obtain marketing approval for and commercialize our product candidates and may affect the prices we may set.

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system, including cost-containment measures that may reduce or limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell any product candidates for which we obtain marketing approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare.

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "Affordable Care Act") was enacted in the United States. Among the provisions of the Affordable Care Act of importance to our potential product candidates, the Affordable Care Act: establishes an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; extends manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; expands eligibility criteria for Medicaid programs; expands the entities eligible for discounts under the Public Health program; increases the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program; creates a new Medicare Part D coverage gap discount program; establishes a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and establishes a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

At this time, we are unsure of the full impact that the Affordable Care Act will have on our business. There have been judicial and political challenges to certain aspects of the Affordable Care Act. For example, since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements of the Affordable Care Act. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the Affordable Care Act have been signed into law. The Tax Cuts and Jobs Act ("Tax Act") includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain Affordable Care Act-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share. The Bipartisan Budget Act of 2018 (the "BBA"), among other things, amends the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole," by increasing from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. In July 2018, CMS published a final rule permitting further collections and payments to and from certain Affordable Care Act qualified health plans and health insurance issuers under the Affordable Care Act risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or Texas District Court Judge, ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. While the Texas District Court Judge, as well as the Trump Administration and CMS, have stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, resulted in reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2027 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products.

At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid and to eliminate cost sharing for generic drugs for low-income patients. Additionally, the Trump administration released a "Blueprint" to lower drug prices through proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services has begun the process of soliciting feedback on some of these measures and, at the same time, is implementing others under our existing authority. Although some of these, and other, proposals will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 ("Right to Try Act"), was signed into law. The law, among other things, provides a federal framework for certain patients with life-threatening diseases or conditions to access certain investigational new drug products that have completed a Phase 1 clinical trial. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA approval under the FDA expanded access program. There is no obligation for a drug manufacturer to make our drug products available to eligible patients as a result of the Right to Try Act.

We expect that the Affordable Care Act, these new laws and other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates, if approved.

We and any of our third-party manufacturers or suppliers may use potent chemical agents and hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time consuming or costly.

We and any of our third-party manufacturers or suppliers will use biological materials, potent chemical agents and may use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety of the environment. Our historical operations and the operations of our third-party manufacturers and suppliers also produce hazardous waste products. Federal, state and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development efforts. In addition, we cannot eliminate the risk of accidental injury or contamination from these materials or wastes. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. In the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended.

Although we maintain workers' compensation insurance for certain costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for toxic tort claims that may be asserted against us in connection with our storage or disposal of biologic, 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, which have tended to become more stringent over time. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions or liabilities, which could materially adversely affect our business, financial condition, results of operations and prospects.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our products.

We face an inherent risk of product liability as a result of the clinical trials of our product candidates and will face an even greater risk if we commercialize our product candidates. For example, we may be sued if our product candidates allegedly cause injury or are found to be otherwise unsuitable during product 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 candidate, negligence, strict liability and a breach of warranties. Claims may be brought against us by clinical trial participants, patients or others using, administering or selling products that may be approved in the future. Claims could also be asserted under state consumer protection acts.

If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or cease the commercialization of our products. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- significant negative financial impact;
- the inability to commercialize our product candidates; and
- a decline in our stock price.

We currently hold approximately $10.0 million in product liability insurance coverage in the aggregate. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of our product candidates. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies will also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

We and any of our potential future collaborators will be required to report to regulatory authorities if any of our approved products cause or contribute to adverse medical events, and any failure to do so would result in sanctions that would materially harm our business.

If we and any of our potential future collaborators are successful in commercializing our products, the FDA and foreign regulatory authorities would require that we and any of our potential future collaborators report certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We and any of our potential future collaborators or CROs may fail to report adverse events within the prescribed timeframe. If we or any of our potential future collaborators or CROs fail to comply with such reporting obligations, the FDA or a foreign regulatory authority could take action, including criminal prosecution, the imposition of civil monetary penalties, seizure of our products or delay in approval or clearance of future products.

Our internal computer systems, or those of any of our CROs, manufacturers, other contractors or consultants or potential future collaborators, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

The United States federal and various state and foreign governments have adopted or proposed requirements regarding the collection, distribution, use, security, and storage of personally identifiable information and other data relating to individuals, and federal and state consumer protection laws are being applied to enforce regulations related to the online collection, use, and dissemination of data. Despite the implementation of security measures, our internal computer systems and those of our current and any future CROs and other contractors, consultants and collaborators are vulnerable to damage from computer viruses, cybersecurity threats, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations or result in the unauthorized disclosure of or access to personally identifiable information or individually identifiable health information (violating certain privacy laws such as GDPR), it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other similar disruptions. Some of the federal, state and foreign government requirements include obligations of companies to notify individuals of security breaches involving particular personally identifiable information, which could result from breaches experienced by us or by our vendors, contractors, or organizations with which we have formed strategic relationships. Even though we may have contractual protections with such vendors, contractors, or other organizations, notifications and follow-up actions related to a security breach could impact our reputation, cause us to incur significant costs, including legal expenses, harm customer confidence, hurt our expansion into new markets, cause us to incur remediation costs, or cause us to lose existing customers. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. We also rely on third parties to manufacture our product candidates, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, the further development and commercialization of our product candidates could be delayed, and we could be subject to significant fines, penalties or liabilities for any noncompliance to certain privacy and security laws.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. We rely on third- party manufacturers to produce our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers were affected by a man-made or natural disaster or other business interruption. In addition, our corporate headquarters is located in San Diego, California near major earthquake faults and fire zones, and the ultimate impact on us of being located near major earthquake faults and fire zones and being consolidated in a certain geographical area is unknown. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

Our employees and independent contractors, including principal investigators, CROs, consultants and vendors, may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees and independent contractors, including principal investigators, CROs, consultants and vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate: (1) the laws and regulations of the FDA and other similar regulatory requirements, including those laws that require the reporting of true, complete and accurate information to such authorities, (2) manufacturing standards, including cGMP requirements, (3) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad or (4) laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our preclinical studies or clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and 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. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. 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 financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, individual imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We could face criminal liability and other serious consequences for violations, which could harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, and anti-corruption and anti-money laundering laws and regulations, including the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, clinical research organizations, contractors and other collaborators and partners from authorizing, promising, offering, providing, soliciting or receiving, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase, and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, clinical research organizations, contractors and other collaborators and partners, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time, we may consider strategic transactions, such as acquisitions of companies, asset purchases and out-licensing or in-licensing of intellectual property, products or technologies, similar to our approach in in-licensing and acquiring our current product candidates. Any future transactions could increase our near and long-term expenditures, result in potentially dilutive issuances of our equity securities, including our common stock, or the incurrence of debt, contingent liabilities, amortization expenses or acquired in-process research and development expenses, any of which could affect our financial condition, liquidity and results of operations. Additional potential transactions that we may consider in the future include a variety of business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Future acquisitions may also require us to obtain additional financing, which may not be available on favorable terms or at all. These transactions may never be successful and may require significant time and attention of management. In addition, the integration of any business that we may acquire in the future may disrupt our existing business and may be a complex, risky and costly endeavor for which we may never realize the full benefits of the acquisition. Accordingly, although there can be no assurance that we will undertake or successfully complete any additional transactions of the nature described above, any additional transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects.

Risks Related to Our Intellectual Property

Our success depends on our ability to protect our intellectual property and our proprietary technologies.

Our commercial success depends in part on our ability to obtain and maintain patent protection and trade secret protection for our product candidates, proprietary technologies and their uses as well as our ability to operate without infringing upon the proprietary rights of others. If we are unable to protect our intellectual property rights or if our intellectual property rights are inadequate for our technology or our product candidates, our competitive position could be harmed. We generally seek to protect our proprietary position by licensing or filing patent applications in the United States and abroad related to our product candidates, proprietary technologies and their uses that are important to our business. Our or our licensor's patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. There can be no assurance that our or our licensor's patent applications will result in patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents if issued will not be infringed, designed around or invalidated by third parties. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. These uncertainties and/or limitations in our ability to properly protect the intellectual property rights relating to our product candidates could have a material adverse effect on our financial condition and results of operations.

Although we own and license issued patents in the United States and foreign countries, we cannot be certain that the claims in our or our licensor's other U.S. pending patent applications, corresponding international patent applications and patent applications in certain foreign countries will be considered patentable by the United States Patent and Trademark Office ("USPTO"), courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in our or our licensor's issued patents will not be found invalid or unenforceable if challenged.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we, our licensors or any of our potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;

- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or block our ability to make, use and sell our product candidates;

- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and

- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing products.

The patent prosecution process is also expensive and time consuming, and we and our licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we or our licensors will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, directed to technology that we license from third parties. We may also require the cooperation of our licensor in order to enforce the licensed patent rights, and such cooperation may not be provided. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. We cannot be certain that patent prosecution and maintenance activities by our licensors have been or will be conducted in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such applications. If they fail to do so, this could cause us to lose rights in any applicable intellectual property that we in-license, and as a result our ability to develop and commercialize products or product candidates may be adversely affected and we may be unable to prevent competitors from making, using and selling competing products.

In addition, although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors, licensees, collaboration partners, and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties, including with respect to cirmtuzumab and TK216, or otherwise experiences disruptions in our business relationships with our licensors, we could lose license rights that are important to our business.

We are a party to several license agreements under which we are granted rights to intellectual property that are important to our business and we may enter into additional license agreements in the future. For example, in March 2014, we entered into an exclusive license agreement with Georgetown University, or Georgetown, to obtain an exclusive license to certain intellectual property rights to develop and commercialize compounds targeting EWS-FLI1. In March 2016, we entered into an exclusive license agreement with the Regents of the University of California to obtain an exclusive license to certain intellectual property rights to develop and commercialize cirmtuzumab and other ROR1 related naked antibodies.

These license agreements impose, and we expect that any future license agreements where we in-license intellectual property, will impose on us, various development, regulatory and/or commercial diligence obligations, payment of milestones and/or royalties and other obligations. If we fail to comply with our obligations under these agreements, or we are subject to bankruptcy-related proceedings, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license.

We may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we cannot provide any assurances that third-party patents do not exist which might be enforced against our product candidates in the absence of such a license. We may fail to obtain any of these licenses on commercially reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;

- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- our right to transfer or assign the license; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may not be able to successfully develop and commercialize the affected product candidates, which would have a material adverse effect on our business.

If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our and our licensor's patent rights are highly uncertain. Our and our licensor's pending and future patent applications may not result in patents being issued which protect our product candidates or which effectively prevent others from commercializing competitive product candidates.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we own or license currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own or license may be challenged or circumvented by third parties or may be narrowed or invalidated as a result of challenges by third parties. Consequently, we do not know whether our product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our or our licensor's patents by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our and our licensor's patents may not cover our product candidates or may be challenged in the courts or patent offices in the United States and abroad. Our and our licensor's patents may be subject to a third-party pre-issuance submission of prior art to the USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant review ("PGR"), and inter partes review ("IPR"), or other similar proceedings in the USPTO or foreign patent offices challenging our or our licensor's patent rights. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we or our predecessors or our licensor and the patent examiner were unaware during prosecution. There is no assurance that all potentially relevant prior art relating to our patents and patent applications or those of our licensors has been found. There is also no assurance that there is not prior art of which we, our predecessors or licensors are aware, but which we do not believe affects the validity or enforceability of a claim in our patents and patent applications or those of our licensors, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our or our licensor's patent rights, allow third parties to commercialize our product candidates and compete directly with us, without payment to us. Such loss of patent rights, loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable 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 product candidates. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. In addition, if the breadth or strength of protection provided by our or our licensor's patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

The patent protection and patent prosecution for some of our product candidates may be dependent on third parties.

We or our licensors may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we or our licensors may miss potential opportunities to strengthen our patent position. It is possible that defects of form in the preparation or filing of our or our licensor's patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If there are material defects in the form, preparation, prosecution, or enforcement of our or our licensor's patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. If we or our licensors, whether current or future, fail to establish, maintain or protect our patents and other intellectual property rights, such rights may be reduced or eliminated. If our licensors are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

As a licensee of third parties, we rely on third parties to file and prosecute patent applications and maintain patents and otherwise protect the licensed intellectual property under some of our license agreements. We have not had and do not have primary control over these activities for certain of our patents or patent applications and other intellectual property rights. We cannot be certain that such activities by third parties have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. Pursuant to the terms of the license agreements with some of our licensors, the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents and even if we are permitted to pursue such enforcement or defense, we will require the cooperation of our licensors. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business. If any of our licensors or any of our future licensors or future collaborators fail to appropriately prosecute and maintain patent protection for patents covering any of our product candidates, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products.

In addition, even where we have the right to control patent prosecution of patents and patent applications we have acquired or licensed from third parties, we may still be adversely affected or prejudiced by actions or inactions of our predecessors or licensors and their counsel that took place prior to our assuming control over patent prosecution.

Our technology acquired or licensed from various third parties may be subject to retained rights. Our predecessors or licensors often retain certain rights under their agreements with us, including the right to use the underlying technology for noncommercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our predecessors or licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse.

If we are limited in our ability to utilize acquired or licensed technologies, or if we lose our rights to critical in-licensed technology, we may be unable to successfully develop, out-license, market and sell our products, which could prevent or delay new product introductions. Our business strategy depends on the successful development of licensed and acquired technologies into commercial products. Therefore, any limitations on our ability to utilize these technologies may impair our ability to develop, out-license or market and sell our product candidates.

Some of our intellectual property has been discovered through government funded programs and thus may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights, and limit our ability to contract with non-U.S. manufacturers.

Some of the intellectual property rights we have acquired or licensed or may acquire or license in the future may have been generated through the use of U.S. government funding and may therefore be subject to certain federal regulations. For example, some of the research and development work on cirmtuzumab and TK216 was funded by government research grants. As a result, the U.S. government may have certain rights to intellectual property embodied in our product candidates pursuant to the Bayh-Dole Act of 1980, or Bayh-Dole Act. These U.S. government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third-party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to

as “march-in rights”). The U.S. government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. industry may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. To the extent any of our future intellectual property is also generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to develop products that are similar to our product candidates but that are not covered by the claims of the patents that we own or license;
- we or our licensors or predecessors might not have been the first to make the inventions covered by the issued patents or patent applications that we own or license;
- we or our licensors or predecessors might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our or our licensor’s pending patent applications will not lead to issued patents;
- issued patents that we own or license may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, it could significantly harm our business, results of operations and prospects.

We rely on licensee relationships, and any disputes or litigation with our partners or termination or breach of any of the related agreements could reduce the financial resources available to us, including milestone payments and future royalty revenues.

Our existing collaborations may not continue or be successful, and we may be unable to enter into future collaborative arrangements to develop and commercialize our unpartnered assets. If any of our collaborative partners breach or terminate their agreements with us or otherwise fail to conduct their collaborative activities successfully, our product development under these agreements will be delayed or terminated. Disputes or litigation may also arise with our collaborators (with us and/or with one or more third parties), including those over ownership rights to intellectual property, know-how or technologies developed with our collaborators. Such disputes or litigation could adversely affect our rights to one or more of our product candidates and could delay, interrupt or terminate the collaborative research, development and commercialization of certain potential products, create uncertainty as to ownership rights of intellectual property, or could result in litigation or arbitration. In addition, a significant downturn or deterioration in the business or financial condition of our collaborators or partners could result in a loss of expected revenue and our expected returns on investment. The occurrence of any of these problems could be time-consuming and expensive and could adversely affect our business.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Claims by third parties that we infringe their proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts.

Our commercial success depends in part on avoiding infringement of the patents and proprietary rights of third parties. However, our or our licensee's research, development and commercialization activities may be subject to claims that we or our licensee infringes or otherwise violates patents or other intellectual property rights owned or controlled by third parties. Other entities may have or obtain patents or proprietary rights that could limit our or our licensee's ability to make, use, sell, offer for sale or import our product candidates and products that may be approved in the future, or impair our competitive position. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biopharmaceutical industry, including patent infringement lawsuits, oppositions, reexaminations, IPR proceedings and PGR proceedings before the USPTO and/or foreign patent offices. Numerous third-party U.S. and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidates. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates.

As the biopharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. Because patent applications are maintained as confidential for a certain period of time, until the relevant application is published we may be unaware of third-party patents that may be infringed by commercialization of any of our product candidates, and we cannot be certain that we were the first to file a patent application related to a product candidate or technology. Moreover, because patent applications can take many years to issue, there may be currently-pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Any claims of patent infringement asserted by third parties would be time consuming and could:

- result in costly litigation that may cause negative publicity;
- divert the time and attention of our technical personnel and management;
- cause development delays;
- subject us to an injunction preventing us from making, using, selling, offering for sale, or importing our products;
- prevent us from commercializing any of our product candidates until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- subject us to significant liability to third parties; or
- require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all, or which might be non-exclusive, which could result in our competitors gaining access to the same technology.

Although no third-party has asserted a claim of patent infringement against us as of the date of this prospectus, others may hold proprietary rights that could prevent our product candidates from being marketed. Any patent-related legal action against us claiming damages and seeking to enjoin activities relating to our product candidates or processes could subject us to potential liability for damages, including treble damages if we were determined to willfully infringe, and require us to obtain a license to manufacture or develop our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially reasonable terms, if at all. Moreover, even if we or our future strategic partners were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. In addition, we cannot be certain that we could redesign our product candidates or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing our product candidates, which could harm our business, financial condition and operating results.

Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful. Further, our issued patents could be found invalid or unenforceable if challenged in court.

Competitors may infringe our intellectual property rights or those of our licensors. To prevent infringement or unauthorized use, we and/or our licensors may be required to file infringement claims, which can be expensive and time consuming. In addition, in a patent infringement proceeding, a court may decide that a patent we own or license is not valid, is unenforceable and/or is not infringed. If we or any of our licensors or potential future collaborators were to initiate legal proceedings against a third-party to enforce a patent directed at one of our product candidates, the defendant could counterclaim that our or our licensor's patent is invalid and/or unenforceable in whole or in part. In patent litigation, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, lack of written description or non-enablement. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution.

If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on such product candidate. In addition, if the breadth or strength of protection provided by our patents and patent applications or those of our licensors is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Such a loss of patent protection would have a material adverse impact on our business.

Even if resolved in our favor, litigation or other legal proceedings relating to our or our licensor's intellectual property rights may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. 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 or our licensor may not have sufficient financial or other resources to conduct or participate in 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 or our licensor 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.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings.

Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our common shares to decline.

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing products, programs or intellectual property could be diminished. Accordingly, the market price of shares of our common stock may decline. Such announcements could also harm our reputation or the market for our future products, which could have a material adverse effect on our business.

Derivation or interference proceedings may be necessary to determine priority of inventions, and an unfavorable outcome may require us to cease using the related technology or to attempt to license rights from the prevailing party.

Derivation or interference proceedings provoked by third parties or brought by us or our licensors or declared by the USPTO or similar proceedings in foreign patent offices may be necessary to determine the priority of inventions with respect to our or our licensor's patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our or our licensor's defense of such proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with such proceedings could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us bring our product candidates to market.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

On September 16, 2011, the Leahy-Smith America Invents Act ("Leahy-Smith Act") was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a "first inventor to file" system in which, assuming that other requirements of patentability are met, the first inventor to file a patent application will be entitled to the patent regardless of whether a third-party was first to invent the claimed invention. A third-party that files a patent application in the USPTO after March 2013 but before we could therefore be awarded a patent covering an invention of our even if we had made the invention before it was made by such third-party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensor was the first to either (1) file any patent application related to our product candidates or (2) invent any of the inventions claimed in our or our licensor's patents or patent applications.

The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including PGR, IPR, and derivation proceedings. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position.

Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third-party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third-party may attempt to use the USPTO procedures to invalidate our or our licensor's patent claims that would not have been invalidated if first challenged by the third-party as a defendant in a district court action. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensor's patent applications and the enforcement or defense of our or our licensor's issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Changes in U.S. patent law, or laws in other countries, could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves a high degree of technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time consuming and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property rights and may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in our or our licensor's patents or in third-party patents. In addition, Congress or other foreign legislative bodies may pass patent reform legislation that is unfavorable to us.

For example, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our and our licensor's ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our or our licensor's ability to obtain new patents or to enforce our existing patents and patents we might obtain in the future.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may also be subject to claims that former employees or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of product candidates, patents protecting our product candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to our product candidates.

If we do not obtain patent term extension for our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, one or more of our or our licensor's U.S. patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Amendments"). The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. A maximum of one patent may be extended per FDA approved product as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign countries upon regulatory approval of our product candidates. However, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our or our licensor's patent expiration, and our revenue could be reduced, possibly materially. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

We may not be able to protect our intellectual property rights throughout the world.

Although we and our licensors have issued patents and pending patent applications in the United States and certain other countries, filing, prosecuting and defending patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we or our licensor has not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our and our licensor's patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many foreign countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We or our licensor may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our or our licensor's efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or our licensor is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our and our licensors' patents and/or applications. We have systems in place to remind us to pay these fees, and we rely on third parties to pay these fees when due. Additionally, the USPTO and various foreign patent office's require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If such an event were to occur, it could have a material adverse effect on our business.

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

In addition, we rely on the protection of our trade secrets, including unpatented know-how, technology and other proprietary information to maintain our competitive position. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisors, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and 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, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced and our competitive position would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

As is common in the biopharmaceutical industry, in addition to our employees, we engage the services of consultants to assist us in the development of our product candidates. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other biopharmaceutical companies including our competitors or potential competitors. We may become subject to claims that we, our employees or a consultant inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

Risks Related to Our Common Stock

An active, liquid and orderly market for our common stock may not be maintained.

Although our common stock is listed on the Nasdaq Capital Market ("Nasdaq"), an active trading market for our common stock may never develop or, if it develops, many not be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses or technologies using our shares as consideration, which, in turn, could materially adversely affect our business.

The trading price of the shares of our common stock may be highly volatile, and purchasers of our common stock may incur substantial losses.

Our stock price is likely to be volatile. The stock market in general and the market for stock of biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above their purchase price. The market price for our common stock may be influenced by those factors discussed in this "Risk Factors" section and many others, including:

- our ability to enroll subjects in our ongoing and planned clinical trials;
- results of our clinical trials and preclinical studies, and the results of the trials of our competitors or those of other companies in our market sector;
- regulatory approval of our product candidates, or limitations to specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- regulatory developments in the United States and foreign countries;
- changes in the structure of healthcare payment systems, especially in light of current reforms to the U.S. healthcare system;
- the success or failure of our efforts to acquire, license or develop additional product candidates;
- innovations or new products developed by us or our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- manufacturing, supply or distribution delays or shortages;
- any changes to our relationship with any manufacturers, suppliers, licensors, future collaborators or other strategic partners;
- achievement of expected product sales and profitability;
- variations in our financial results or those of companies that are perceived to be similar to us;
- market conditions in the biopharmaceutical sector and issuance of securities analysts' reports or recommendations;
- trading volume of our common stock;
- an inability to obtain additional funding;
- sales of our stock by insiders and stockholders;
- general economic, industry and market conditions or other events or factors, many of which are beyond our control;
- additions or departures of key personnel; and
- intellectual property, product liability or other litigation against us.

In addition, in the past, stockholders have initiated class action lawsuits against biopharmaceutical companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources, which could have a material adverse effect on our business, financial condition and results of operations.

Our failure to meet the continued listing requirements of Nasdaq could result in a delisting of our common stock.

If we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we can provide no assurance that any action we take to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with Nasdaq's listing requirements.

Our executive officers, directors and principal stockholders, if they choose to act together, will continue to control or significantly influence all matters submitted to stockholders for approval. Furthermore, two of our directors have been appointed by one of our principal stockholders.

Our executive officers, directors and greater than 5% stockholders, in the aggregate, own approximately 29.0% of our outstanding common stock (assuming no exercise of outstanding options). Furthermore, two of our directors have been appointed by our largest stockholder, SPH USA. As a result, such persons or their appointees to our board of directors, acting together, will have the ability to control or significantly influence all matters submitted to our board of directors or stockholders for approval, including the appointment of our management, the election and removal of directors and approval of any significant transaction, as well as our management and business affairs. This concentration of ownership may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquiror from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders.

We do not currently intend to pay dividends on our common stock, and, consequently, your ability to achieve a return on your investment will depend on appreciation, if any, in the price of our common stock.

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, the terms of any future debt agreements may preclude us from paying dividends. Any return to stockholders will therefore be limited to the appreciation of their stock. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which stockholders have purchased their shares.

Sales of a substantial number of shares of our common stock by our stockholders in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur could significantly reduce the market price of our common stock and impair our ability to raise adequate capital through the sale of additional equity securities. As of June 30, 2019, 6,402,834 shares of our outstanding common stock are freely tradable, without restriction, in the public market, unless they are purchased by one of our affiliates.

Holders of approximately 58.3% of our outstanding securities, including our directors and executive officers, entered into lock-up agreements in connection with the Merger pursuant to which they may not, with limited exceptions, for a period of 180 days from the date of the effective time of the Merger, offer, sell or otherwise transfer or dispose of any of our securities, without our prior written consent, subject to certain exceptions. Sales of these shares, or perceptions that they will be sold, could cause the trading price of our common stock to decline. After the lock-up agreements expire, up to an additional 8,967,006 shares of common stock will be eligible for sale in the public market.

In addition, as of June 30, 2019, up to 2,505,818 shares of common stock that are either subject to outstanding warrants, options or reserved for future issuance under our equity incentive plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act of 1933, as amended ("Securities Act"). If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of the combined company's common stock could decline.

We incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Exchange Act, which will require, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, Sarbanes-Oxley, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of Sarbanes-Oxley, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the SEC has adopted additional rules and regulations in these areas, such as mandatory "say on pay" voting requirements that apply to us. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will increase our net loss and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

If securities or industry analysts do not publish research or reports or publish unfavorable research or reports about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. We do not currently have and may never obtain research coverage by securities and industry analysts. If no securities or industry analysts commence coverage of our company, the trading price for our common stock would be negatively impacted. In the event we obtain securities or industry analyst coverage, if one or more of the analysts who covers us downgrades our stock, our stock price would likely decline. If one or more of these analysts ceases to cover us or fails to regularly publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline.

If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

Pursuant to Section 404 of Sarbanes-Oxley, we are required to report upon the effectiveness of our internal control over financial reporting. Additionally, our independent registered public accounting firm is required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we have been required to upgrade our information technology systems; implement additional financial and management controls, reporting systems and procedures; and hire additional accounting and finance staff. If we or, if required, our auditors are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could significantly reduce the value of our shares to a potential acquiror or delay or prevent changes in control or changes in our management without the consent of our board of directors. The provisions in our charter documents include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors, unless the board of directors' grants such right to the stockholders, to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- the prohibition on removal of directors without cause due to the classified board of directors;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;
- the ability of our board of directors to alter our amended and restated bylaws without obtaining stockholder approval;
- the required approval of at least 66-2/3% of the shares entitled to vote to adopt, amend or repeal our amended and restated bylaws or repeal certain provisions of our amended and restated certificate of incorporation;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- an exclusive forum provision providing that the Court of Chancery of the State of Delaware will be the exclusive forum for certain actions and proceedings;
- the requirement that a special meeting of stockholders may be called only by the chairman of the board of directors, the chief executive officer or the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

We are also subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine. These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. By agreeing to this provision, however, stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. If a court were to find the choice of forum provisions in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

If the Merger does not qualify as a "reorganization" for U.S. federal income tax purposes, U.S. Holders of our common stock will be required to recognize gain or loss for U.S. federal income tax purposes upon the exchange of their Private Oncternal common stock for our common stock in the Merger.

The U.S. federal income tax consequences of the Merger to U.S. Holders will depend on whether the merger qualifies as a "reorganization" for U.S. federal income tax purposes. Our and Private Oncternal's obligations to effect the Merger were subject to the satisfaction, or waiver, at or prior to the effective time of the Merger, of the condition that each company receive an opinion of counsel, dated as of the closing date of the merger, to the effect that the merger will qualify as a "reorganization" within the meaning of Section 368(a) of the Code. If, contrary to the opinions from counsel, the Merger fails to qualify as a reorganization within the meaning of Section 368(a) of the Code, a U.S. Holder of Private Oncternal common stock would recognize gain or loss for U.S. federal income tax purposes on each share of Private Oncternal common stock surrendered in the merger for our common stock and any cash received in lieu of a fractional share. For purposes of this discussion, a U.S. Holder is a beneficial owner of Oncternal common stock that, for U.S. federal income tax purposes, is or is treated as: an individual who is a citizen or resident of the United States; a corporation created or organized under the laws of the United States, any state thereof, or the District of Columbia; an estate, the income of which is subject to U.S. federal income tax regardless of its source; or a trust that (i) is subject to the primary supervision of a U.S. court and the control of one or more "United States persons" (within the meaning of Section 7701(a)(30) of the Code) over all of its substantial decisions or (ii) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

Our ability to use net operating loss ("NOL") carryforwards and other tax attributes may be limited.

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire (if at all). At December 31, 2018, we had federal and state NOL carryforwards of approximately $29.7 million. As of June 30, 2019 and as a result of the Merger, for federal income tax purposes, in accordance with Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), we are planning on making an election to forego approximately $430.0 million of NOLs that are estimated to expire unutilized, leaving us with approximately $72.0 million of NOLs. Approximately $22.0 million of NOLs do not expire and the remaining federal and state NOL carryforward will begin to expire in 2033, unless previously utilized. At December 31, 2018, we had federal and state research and development credit carryforwards of approximately $0.9 million and $0.5 million, respectively. The federal research and development credit carryforwards will begin expiring in 2034, unless previously utilized. The state research and development credits do not expire.

Under the Tax Act, federal NOLs generated in taxable years ending after December 31, 2017, may be carried forward indefinitely but federal NOLs generated in taxable years beginning after December 31, 2017 may only be used to offset 80% of our taxable income annually. Our NOL carryforwards are subject to review and possible adjustment by the Internal Revenue Service (the "IRS") and state tax authorities. Under Sections 382 and 383 of the Code, our federal NOL and research and development tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50 percentage points. Our ability to utilize our NOL carryforwards and other tax attributes to offset future taxable income or tax liabilities may be limited as a result of ownership changes, including in connection with the Merger. Similar rules may apply under state tax laws. We have not yet determined the amount of the cumulative change in our ownership resulting from the Merger or other transactions, or any resulting limitations on our ability to utilize our NOL carryforwards and other tax attributes. If we earn taxable income, such limitations could result in increased future tax liability to us and our future cash flows could be adversely affected. We have recorded a full valuation allowance related to our NOLs and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets.

U.S. tax legislation may materially adversely affect our financial condition, results of operations and cash flows.

The Tax Act has significantly changed the U.S. federal income taxation of U.S. corporations, including by reducing the U.S. corporate income tax rate and revising the rules governing NOLs. Many of these changes became effective beginning in 2018, without any transition periods or grandfathering for existing transactions. The legislation is unclear in many respects and could be subject to potential amendments and technical corrections, as well as interpretations and implementing regulations by the U.S. Treasury Department and the IRS, any of which could lessen or increase certain adverse impacts of the legislation. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation, which often uses federal taxable income as a starting point for computing state and local tax liabilities. There may be other material adverse effects resulting from the legislation that we have not yet identified. While some of the changes made by the tax legislation may adversely affect us in one or more reporting periods and prospectively, other changes may be beneficial on a going forward basis. We continue to work with our tax advisors to determine the full impact that the recent tax legislation as a whole will have on us. We urge our investors to consult with their legal and tax advisors with respect to such legislation.

We are currently involved, and may become involved in the future, in securities class action litigation that could divert management's attention, adversely affect our business and subject us to significant liabilities.

Between April 10, 2019 and May 7, 2019, six purported stockholder class action lawsuits were filed, naming us and our board of directors as defendants. See Part II, Item 1 "Legal Proceedings" in this Quarterly Report on Form 10-Q for more information about the lawsuits related to the Merger that have been filed. In addition, stock markets have experienced significant price and volume fluctuations that have affected the market prices for the common stock of pharmaceutical companies. These broad market fluctuations as well a broad range of other factors, including the realization of any of the risks described in these "Risk Factors," may cause the market price of our common 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 pharmaceutical companies have experienced significant stock price volatility in recent years. Any current or future litigation we face could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

Our stockholders prior to the Merger who hold CVRs may not receive any payment on the CVRs and the CVRs may otherwise expire valueless.

We and certain other parties have entered into the CVR Agreement pursuant to which, for each share of GTx common stock held, stockholders of record as of immediately prior to the Merger received one CVR entitling such holders to receive in the aggregate 75% of any net proceeds received during the 15-year period after the closing of the Merger from the grant, sale or transfer of rights to our SARD or SARM technology that occurs during the 10-year period after the closing of the Merger (or in the 11th year if based on a term sheet approved during the initial 10-year period) and, if applicable, to receive royalties on the sale of any SARD products or SARM products by us during the 15-year period after the closing of the Merger. In light of the results of the ASTRID trial, we have no current intent to develop the SARM program. The CVRs are not transferable, will not have any voting or dividend rights, and interest will not accrue on any amounts potentially payable on the CVRs. Accordingly, the right of any stockholder of record as of immediately prior to the Merger to receive any future payment on or derive any value from the CVRs will be contingent solely upon the achievement of the foregoing events within the time periods specified in the CVR Agreement and if these events are not achieved for any reason within the time periods specified in the CVR Agreement, no payments will be made under the CVRs, and the CVRs will expire valueless. In addition, we (as successor in interest to GTx) have agreed only to use commercially reasonable efforts to develop SARD products and to divest our SARM technology, subject to certain limitations, which allows for the consideration of a variety of factors in determining the efforts that the combined company is required to use to develop SARD products and to divest the SARM technology, and we are not required to take all possible actions to continue efforts to develop SARD products and to divest the SARM technology. Accordingly, under certain circumstances we may not be required to continue efforts to develop SARD products and to divest the SARM technology, or may allocate resources to other projects, which would have an adverse effect on the value, if any, of the CVRs. Furthermore, the CVRs will be unsecured obligations of our company and all payments under the CVRs, all other obligations under the CVR Agreement and the CVRs and any rights or claims relating thereto will be subordinated in right of payment to the prior payment in full of all of our current or future senior obligations. Finally, the U.S. federal income tax treatment of the CVRs is unclear. There is no legal authority directly addressing the U.S. federal income tax treatment of the receipt of, and payments on, the CVRs, and there can be no assurance that the Internal Revenue Service (the "IRS"), would not assert, or that a court would not sustain, a position that could result in adverse U.S. federal income tax consequences to holders of the CVRs.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

Unregistered Sales of Equity Securities

None.

Use of Proceeds

Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

ITEM 5. OTHER INFORMATION.

On August 7, 2019, our Compensation Committee approved the Oncternal Therapeutics, Inc. Annual Incentive Plan (the "Annual Incentive Plan"), which is intended to provide an incentive for eligible employees and certain consultants to perform to the best of their abilities and achieve our corporate objectives, to further our growth, development and financial success, and to enable us to attract and retain highly qualified employees and consultants. The Annual Incentive Plan sets forth the annual target bonuses for our executive officers as well as the weighting of the portions of cash bonus payments that are based on corporate performance goals and individual performance objectives. Annual bonuses under the Annual Incentive Plan will not exceed 150% of target unless otherwise specifically approved by our Compensation Committee. Our Compensation Committee will establish the performance objectives for each fiscal year under the Annual Incentive Plan, which are expected to generally relate to clinical achievements, corporate transactions and financing objectives and operational achievements.

The initial target bonus percentages under the Bonus Plan for our executive officers are as follows:

Position	Target Award Percentage (% of base salary)
Chief Executive Officer	50%
EVP/C-Level	35%
Senior Vice President / Vice President	30%

The initial weightings for purposes of the Bonus Plan between corporate and individual performance for our executive officers will be as follows:

Position	Corporate Performance	Individual Performance
Chief Executive Officer	100%	0%
Other C-level	80%	20%
Senior Vice President / Vice President	70%	30%

The Company expects to adopt an annual incentive program under the Annual Incentive Plan for future fiscal years, which will reward achievement at specified levels of corporate and individual performance and will contain target bonuses consistent with those disclosed above.

The foregoing description of the Bonus Plan does not purport to be complete and is qualified in its entirety by the Annual Incentive Plan, a copy of which the Company intends to file with its Quarterly Report on Form 10-Q for the quarter ending September 30, 2019.

Item 6. Exhibits.

EXHIBIT INDEX

Exhibit Number	Description of Exhibit	Incorporated by Reference				Filed Herewith
		Form	File Number	Date of Filing	Exhibit Number	
2.1	Agreement and Plan of Merger and Reorganization, dated March 6, 2019, by and among GTx, Inc., Oncternal Therapeutics, Inc. and Grizzly Merger Sub, Inc.	8-K	000-50549	March 7, 2019	2.1	
2.2	Amendment No. 1 to Agreement and Plan of Merger and Reorganization, dated April 30, 2019, by and among GTx, Inc., Oncternal Therapeutics, Inc. and Grizzly Merger Sub, Inc.	8-K	000-50549	April 30, 2019	2.1	
2.3	CVR Agreement, dated as of June 7, 2019, by and between the Registrant, Marc S. Hanover, as the Holders' Representative, and Computershare Investor Services, as Rights Agent	8-K	000-50549	June 10, 2019	10.1	
2.4	Form of Lock-Up Agreement, dated March 6, 2019, by each of the parties named in each agreement therein	8-K	000-50549	March 7, 2019	2.5	
3.1	Restated Certificate of Incorporation of the Registrant	S-3	333-127175	August 4, 2005	4.1	
3.2	Certificate of Amendment of Restated Certificate of Incorporation of the Registrant	8-K	000-50549	May 6, 2011	3.2	
3.3	Certificate of Amendment of Restated Certificate of Incorporation of the Registrant	8-K	000-50549	May 9, 2014	3.3	
3.4	Certificate of Amendment of Restated Certificate of Incorporation of the Registrant	10-Q	000-50549	May 11, 2015	3.4	
3.5	Certificate of Amendment of Restated Certificate of Incorporation of the Registrant	8-K	000-50549	December 5, 2016	3.1	
3.6	Certificate of Amendment of Restated Certificate of Incorporation of the Registrant	8-K	000-50549	June 10, 2019	3.1	
3.7	Certificate of Amendment of Restated Certificate of Incorporation of the Registrant	8-K	000-50549	June 10, 2019	3.2	
3.8	Amended and Restated Bylaws of the Registrant	8-K	000-50549	June 10, 2019	3.3	
4.1	Form of Amendment to Warrant to Purchase shares of Series B-2 Preferred Stock of Oncternal Therapeutics, Inc.					X
4.2	Specimen of Common Stock Certificate					X
10.1†	Commercial License Agreement between Selexis SA (predecessor to Oncternal Therapeutics, Inc.) and ROAR Therapeutics, LLC, dated May 19, 2014	S-4	333-230758	April 8, 2019	10.46	

10.2†	Exclusive License Agreement between Georgetown University and Oncternal Therapeutics, Inc., dated March 26, 2014	S-4	333-230758	April 8, 2019	10.47
10.3	Amendment to Exclusive License Agreement between Georgetown University and Oncternal Therapeutics, Inc., dated March 17, 2016	S-4	333-230758	April 8, 2019	10.48
10.4†	Collaboration Agreement between Oncternal Therapeutics, Inc. and The University of Texas M.D. Anderson Cancer Center, dated December 15, 2014	S-4	333-230758	April 8, 2019	10.49
10.5†	Amendment #1 to Collaboration Agreement between Oncternal Therapeutics, Inc. and The University of Texas M.D. Anderson Cancer Center, dated January 24, 2016	S-4	333-230758	April 8, 2019	10.50
10.6†	Amendment #2 to Collaboration Agreement between Oncternal Therapeutics, Inc. and The University of Texas M.D. Anderson Cancer Center, dated May 1, 2016	S-4	333-230758	April 8, 2019	10.51
10.7†	Amendment #3 to Collaboration Agreement between Oncternal Therapeutics, Inc. and The University of Texas M.D. Anderson Cancer Center, dated September 17, 2018	S-4	333-230758	April 8, 2019	10.52
10.8†	Research agreement between Oncternal Therapeutics, Inc. and the Regents of the University of California, on behalf of its San Diego Campus, dated November 3, 2016	S-4	333-230758	April 8, 2019	10.53
10.9†	License Agreement between Oncternal Therapeutics, Inc. and Velos Biopharma Holdings, LLC, dated February 6, 2018	S-4	333-230758	April 8, 2019	10.54
10.10†	Amended and Restated License Agreement between Oncternal Therapeutics, Inc. and The Regents of the University of California, dated August 31, 2018	S-4	333-230758	April 8, 2019	10.55
10.11†	Amendment #1 to Amended and Restated License Agreement between Oncternal Therapeutics, Inc. and the Regents of the University of California, dated March 25, 2019	S-4	333-230758	April 8, 2019	10.56
10.12#	Oncternal Therapeutics, Inc. 2015 Equity Incentive Plan, as amended	S-4	333-230758	April 8, 2019	10.57
10.13#	Form of Stock Option Agreement under the Oncternal Therapeutics, Inc. 2015 Equity Incentive Plan, as amended	S-4	333-230758	April 8, 2019	10.58
10.14#	Form of Early Exercise Stock Option Agreement under the Oncternal Therapeutics, Inc. 2015 Equity Incentive Plan, as amended	S-4	333-230758	April 8, 2019	10.59
10.15#	Restricted Stock Purchase Agreement dated May 22, 2017, between Oncternal Therapeutics, Inc. and Richard G. Vincent	S-4	333-230758	April 8, 2019	10.60

10.16#	Restricted Stock Purchase Agreement dated December 14, 2017, between Oncternal Therapeutics, Inc. and Richard G. Vincent	S-4	333-230758	April 8, 2019	10.61	
10.17#	Restricted Stock Purchase Agreement dated December 14, 2017, between Oncternal Therapeutics, Inc. and William R. LaRue	S-4	333-230758	April 8, 2019	10.62	
10.18#	Restricted Stock Purchase Agreement dated May 9, 2018, between Oncternal Therapeutics, Inc. and Charles Theuer, M.D., Ph.D.	S-4	333-230758	April 8, 2019	10.63	
10.19#	Employment Letter dated May 31, 2017, between Oncternal Therapeutics, Inc. and James B. Breitmeyer, M.D., Ph.D.	S-4	333-230758	April 8, 2019	10.64	
10.20#	Employment Letter dated January 1, 2019, between Oncternal Therapeutics, Inc. and Richard G. Vincent	S-4	333-230758	April 8, 2019	10.65	
10.21#	Consulting Agreement dated April 3, 2017, between Oncternal Therapeutics, Inc. and Richard G. Vincent	S-4	333-230758	April 8, 2019	10.66	
10.22#	Registrant's 2019 Incentive Award Plan effective June 7, 2019	8-K	000-50549	June 10, 2019	10.2	
10.23	Sublease by and between Oncternal Therapeutics, Inc. and Host Hotels & Resorts, L.P., dated May 22, 2019					X
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					X
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					X
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					X
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					X
101.INS	XBRL Instance Document					X
101.SCH	XBRL Taxonomy Extension Schema Document					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					X

101.LAB	XBRL Taxonomy Extension Label Linkbase Document	X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	X

† Portions of this exhibit have been omitted for confidentiality purposes.

Management compensatory plan or arrangement.

* These certifications are being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are not subject to the liability of that section. These certifications are not to be incorporated by reference into any filing of Oncternal Therapeutics, Inc., whether made before or after the date hereof, regardless of any general incorporation language in such filing.

SIGNATURES

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

Company Name

Date: August 9, 2019

By: /s/ James B. Breitmeyer

Name: James B. Breitmeyer

Title: President and Chief Executive Officer

Date: August 9, 2019

By: /s/ Richard G. Vincent

Name: Richard G. Vincent

Title: Chief Financial Officer

Exhibit 4.1

ONCTERNAL THERAPEUTICS, INC.
AMENDMENT TO
WARRANT TO PURCHASE SHARES OF
SERIES B-2 PREFERRED STOCK

This Amendment to Warrant to Purchase Shares of Series B-2 Preferred Stock (this "**Amendment**"), dated as of June 7, 2019 (the "**Effective Date**"), is being entered into by and between Oncternal Therapeutics, Inc., a Delaware corporation (the "**Company**") and the holders of certain warrants to purchase shares of Series B-2 Preferred Stock issued in connection with that certain Series B-2 Preferred Stock and Warrant Purchase Agreement dated September 12, 2017 by and among the Company and the entities and persons listed on the Schedule of Investors thereto (each, a "**Holder**").

WHEREAS, each Holder is the record and beneficial owner of certain warrants (the "**Outstanding Warrants**") to purchase shares of the Company's common stock, par value $0.001 per share ("**Common Stock**"), set forth on Exhibit A hereto;

WHEREAS, the Company has announced entering into that certain Agreement and Plan of Merger and Reorganization, dated as of March 6, 2019 (as amended, the "**Merger Agreement**"), by and among GTx, Inc., a Delaware corporation ("**Parent**"), Grizzly Merger Sub, Inc., a Delaware corporation ("**Merger Sub**") and the Company, whereby Parent and the Company intend to effect a merger of Merger Sub with and into the Company (the "**Merger**") and stockholders of the Company will receive the right to receive shares of Parent common stock as consideration in the Merger;

WHEREAS, Section 5.5 of the Merger Agreement contemplates that the Outstanding Warrants shall be converted into and become warrants to purchase Parent common stock and Parent shall assume each Outstanding Warrant as a result of the Merger;

WHEREAS, Section 6.2 of the Outstanding Warrants provides that the Outstanding Warrants shall terminate upon the merger of the Company;

WHEREAS, Section 6.7 of the Outstanding Warrants provides that the Outstanding Warrants may be amended and the observance of any other term of the Outstanding Warrants may be waived, with the written consent of the Company and the Holders of at least a majority in interest of the shares issuable upon the exercise of all Outstanding Warrants; and

WHEREAS, the Company and the Holders of at least a majority in interest of the shares issuable upon the exercise of all Outstanding Warrants have agreed to amend the Outstanding Warrants in the manner provided in this Amendment.

NOW, THEREFORE, in consideration of the mutual covenants and agreements set forth herein below and other good and valuable consideration, the receipt and legal sufficiency of which are hereby mutually acknowledged, the Holders and the Company hereby agree as follows:

1. Capitalized Terms. Unless otherwise specified in this Amendment, all terms herein shall have the same meanings ascribed to them in the Outstanding Warrants.

2. Amendments.

2.1. A new Section 2.8 is added to the Outstanding Warrants to read in its entirety as follows:

2.7 No Cash Settlement. Notwithstanding anything herein to the contrary, the Company shall not be required to make any cash payments or net cash settlement to the Holder in lieu of issuance of any shares of Series B-2 Preferred Stock.

2.2 Section 3.4 of the Outstanding Warrants is amended and replaced in its entirety with the following:

3.4 Reclassification or Reorganization. If the shares of Series B-2 Preferred Stock shall be changed into the same or different number of shares of any class or classes of stock, whether by capital reorganization, reclassification or otherwise (other than a subdivision, conversion or combination of shares or stock dividend provided for in Sections 3.1, 3.2 and 3.3 above), then, and in each such event, Holder shall be entitled to receive upon the exercise of this Warrant the kind and amount of shares of stock and other securities and property receivable upon such reorganization, reclassification or other change, to which a holder of the number of shares of Series B-2 Preferred Stock (or any shares of stock or other securities which may be) issuable upon the exercise of this Warrant would have received if this Warrant had been exercised immediately prior to such reorganization, reclassification or other change, all subject to further adjustment as provided herein (such kind and amount of shares of stock and other securities and property, the "***Reclassified Shares***"). At the request of Holder, this Warrant will thereupon be cancelled and upon its surrender to the Company, the Company will execute and deliver at its expense a new Warrant reflecting the foregoing adjustment, but otherwise identical to the replaced Warrant. Notwithstanding the foregoing, in any such case, the aggregate purchase price payable by Holder for the Reclassified Shares pursuant to this Warrant shall remain the same.

2.3 Section 6.2 of the Outstanding Warrants is amended and replaced in its entirety with the following:

6.2 Early Termination. In the event of, at any time during the Exercise Period, any capital reorganization, or any reclassification of the capital stock of the Company (other than a change in par value or from par value to no par value or no par value to par value or as a result of a stock dividend or subdivision, split-up or combination of shares), or the consolidation or merger of the Company with or into another corporation (other than a merger solely to effect a reincorporation of the Company into another state), or the sale or other disposition of all or substantially all the properties and assets of the Company in its entirety to any other person, the Company shall provide to Holder ten (10) days advance written notice of such reorganization, reclassification, consolidation, merger or sale or other disposition of the Company's assets, and this Warrant shall terminate (subject to the provisions of Section 6.3) unless exercised prior to the occurrence of such reorganization, reclassification, consolidation, merger or sale or other disposition of the Company's assets. This section 6.2 shall not apply to the transactions contemplated by that certain Agreement and Plan of Merger and Reorganization, dated as of March 6, 2019 (the "***Merger Agreement***"), by and among GTx, Inc., a Delaware corporation,Grizzly Merger Sub, Inc., a Delaware corporation and the Company, including the Merger (as defined in the Merger Agreement) or any of the Contemplated Transactions (as defined in the Merger Agreement).

3. No Other Amendment. Except for the matters set forth in this Amendment, all other terms of the Outstanding Warrants shall remain unchanged and in full force and effect.

4. Governing Law. This Amendment shall be governed by and construed and enforced in accordance with the laws of the State of California, without giving effect to its conflicts of laws principles.

5. Counterparts. This Amendment may be executed in the original or by facsimile in two or more counterparts, each of which shall be deemed an original and all of which, taken together, shall constitute but one and the same instrument.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

ONCTERNAL THERAPEUTICS, INC.

By: /s/Richard G. Vincent
Name: Richard G. Vincent
Title: Chief Financial Officer

Address: 12230 El Camino Real, Ste 300
San Diego, CA 92130

[Amendment to Warrants to Purchase Shares of Series B-2 Pre ferred Stock Signature Page]

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Alexander Moore

By: /s/Alexander Moore
Name:
Title:

Address:

1442 Kearny st

San Francisco, ca 94133

Holder Signature Page to Amendment to Warrants to Purchase Shares of Series B-2 Preferred Stock

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Alexandria Venture Investments, LLC
By: Alexandria Real Estate Equities, Inc., its managing member

By: /s/ Aaron Jacobson
Name: **Aaron Jacobson**
Title: **SVP-Venture Counsel**

Address: 385 E. Colorado Blvd., Suite 299, Pasadena, CA 91101

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Alma Life Sciences LLC

By: _____

Name: Francois Ferre Magda Marquet

Title: Co-President Co CEO

Address:

8540 Avenida de las Ondas

La Jolla ÇA 92037

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Amanda Miller

By: /s/Amanda Miller
Name:
Title:

Address:

334 12th St.

Seal Beach, CA 90740

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Andrew Tyler Dixon

By: /s/Andrew Tyler Dixon
Name:
Title:

Address:

353 W 200 S #207

Salt Lake City, UT 84101

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Benjamin Verschuere

By: /s/Benjamin Verschuere
Name:
Title:

Address:

2195 beach street apt 301 san francisco

ca94123

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Berge K. Hagopian and Mary Ann Hagopian, Co Trustees, Hagopian Family Trust UA DTD 03/25/88

By:	/s/Berge K. Hagopian	Mary Ann Hagopian
Name:	Berge K. Hagopian	Mary Ann Hagopian
Title:	Managing Partner	Managing Partner

Address:

11150 Santa Monica Blvd, suite 1200

Los Angeles, Calif 90025

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Beta Operator Fund, LP

By: /s/Parag Saxena
Name: Parag Saxena
Title: Director

Address:

250 West 55th St Suite 13D

New York, NY 10019

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Blackcomb Advisors LLC

By: /s/Frank Stonebanks
Name: Frank Stonebanks
Title: Mr

Address:

440 Stevens Ave Suite 200

Solana Beach, CA 92075

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Breede 2013 FLP LLC

By: /s/ Michael Edward Breede
Name: Michael Edward Breede
Title: member

Address:

35 golf lane

Ridgefield, ct 06877

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Brian I Pidgeon Trust

By: /s/ Brian I. Pidgeon
Name: Brian I. Pidgeon
Title: Trustee

Address:

4619 Rancho Verde Trail

San Diego, Ca 92130

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: PENSCO Trust Company LLC Custodian FBO Bruce A. Bastian IRA

By:	/s/ Bruce A. Bastian	/s/ Francis Novella
Name:	Bruce A. Bastian	Francis Novella
Title:	N/A	PENSCO Trust Company Authorize Authorized Signatory
Address:		
675 Enfield Ct		PO BOX 173859
Delray Beach, FL 33444		Denver, CO 80217

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Bruce and Kerry Goodfield

By: /s/ Bruce Goodfield /s/ Kerry Goodfield
Name:
Title:

Address:

14 Doheny

Laguna Niguel, CA 92677

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Carl F. Edman and Xiaofan Dong (JTWRS)

By:	/s/ Carl F. Edman	/s/ Xiaofan Dong
Name:	Carl F. Edman	Xiaofan Dong
Title:		

Address:

1502 Monmouth Drive

San Diego, CA 92109

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Cheston J. Larson

By: /s/ Cheston J. Larson
Name:
Title:

Address:

c/o Latham & Watkins LLP

12670 High Bluff Drive

San Diego, CA 92130

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Conlin Living Trust Dated February 1, 2012

By: /s/ Therese Conlin
Name: Therese Conlin
Title: Trustee

Address:

435 Winsome Place

Encinitas CA 92024

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Cove Partners II

By: /s/ Richard Chan
Name: Richard Chan
Title: General Partner

Address:

1515 Crespo Drive

La Jolla, CA 92037

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Craig Gallagher

By: /s/ Craig Gallagher
Name:
Title:

Address:

13385 Highlands Place #1236

San Diego. CA 92130

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Darcy Thompson

By: /s/ Darcy Thompson
Name:
Title:

Address:

2010 Trumar Lane

Gilroy, CA 95020

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: DAVID ISCAR DE HOYOS NIF: 51411105X

By: /s/ David
Name:
Title:

Address:

DAVID ISCAR DE HOYOS

51411105X

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: David Johnson

By: /s/ David Johnson
Name:
Title:

Address:

11900 NE Country Club Rd

Bainbridge Island, WA 98110

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: David M. Rudolf

By: /s/ David M. Rudolf
Name:
Title:

Address:

2360 Francisco street

San Francisco cA 94123

Holder Signature Page to Amendment to Warrants to Purchase Shares of Series B-2 Preferred Stock

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Derek M. Evjenth

By: /s/ Derek M. Evjenth
Name:
Title:

Address:

17265 Clara st

Monte Sereno, ca 95030

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Dixon Family Trust

By: /s/ Craig Dixon
Name: Craig Dixon
Title: Owner

Address:

6344 Cardeno Dr.

La Jolla, ca. 92037

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Donald R. Rady Trust dated November 26, 1992,
Donald R. Rady, Trustor and Trustee

By: /s/ Donald Rady
Name:
Title:

Address:

don rady

trustee

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Donald W. Peitz Revocable Trust

By: /s/ Donald W. Peitz
Name: Donald W. Peitz
Title: Trustee

Address:

10226 Carmer Road

Fenton, MI 48430

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Emerald Isle Capital

By: /s/ Henry O'Halloran
Name: Henry O'Halloranitz
Title: MD

Address:

Henry I' Halloran

MD

Holder Signature Page to Amendment to Warrants to Purchase Shares of Series B-2 Preferred Stock

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Erik Hemmi

By: /s/ Erik Hemmi
Name:
Title:

Address:

578 Gage Lane

San Diego CA 92106

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Equity Trust Company Custodian FBO Craig L. Dixon IRA

By: /s/ Craig Dixon
Name: Craig Dixon
Title: Owner

Address:

6344 Cardeno Drive

La Jolla, Ca. 92037

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Finney Family 2002 Trust, U/D/T dated October 16 2002

By: /s/ Kevin Finney
Name: Kevin Finney
Title: Mr

Address:

2859 Via Conquistador

Carlsbad, CA 92009

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Frederic R. Gross

By: /s/ Frederic R. Gross
Name:
Title:

Address:

45 Manor Drive

Marlboro NJ 07746

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Friedman-Bioventure Fund I, LP

By: /s/ Jeff Friedman
Name: Jeff Friedman
Title: Managing Partner, Friedman Bioventure Fund LP

Address:

1431 Pacific Highway #615

San Diego, CA 92101

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Garner Investments, LLC

By: /s/ Cam L. Garner
Name: Cam L. Garner
Title: Managing Member

Address:

P.O.Box 675866

Rancho Santa Fe, CA 92067

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: George and Traci Stuart 2009 Revocable Trust dated 2/4/09

By: /s/ George Stuart
Name: George Stuart
Title: Trustee

Address:

520 Del Corro Court

Chula Vista, CA 91910

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Glenn Holdings, L.P.

By: /s/ Scott L. Glenn
Name: Scott L. Glenn
Title: General Partner

Address:

451 Curtis Ave PO Box 1865

Telluride, CO 81435

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Growth Ventures, Inc. Roth 401K

By: /s/ Gary J. McAdam
Name: Gary J. McAdam
Title: Trustee

Address:

14 Red Tail Drive

Highlands Ranch, CO 80126

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Hale BioPharma Ventures, LLC

By: /s/ David F. Hale
Name: David F. Hale
Title: Chairman & CEO

Address:

PO Box 8925

Rancho Santa Fe, Ca 92067

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Hanover-Oncternal, LLC

By: /s/ Reed A. Miller
Name: Reed A. Miller
Title: Reed A. Miller, Managing Member

Address:

19 Benedict Place

Greenwich, CT 06830

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Hines Haus, LLC

By: /s/ Merrill O. Hines III
Name: Merrill O. Hines III
Title: Partner

Address:

933 Columbia st

Houston TX 77008

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Jack Breard

By: /s/ Jack Breard
Name:
Title:

Address:

3615 Centenary

Dallas, TX 75225

Holder Signature Page to Amendment to Warrants to Purchase Shares of Series B-2 Preferred Stock

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: The James and Mary Breitmeyer Trust

By: /s/ James Breitmeyer
Name: James Breitmeyer
Title: Trustee

Address:

7572 Northern Lights

San Diego, CA 92127

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: James C. Blair, Ph.D.

By: /s/ James C. Blair
Name:
Title:

Address:

202 Carnegie Center, Suite 104

Princeton, NJ 08540

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: James A. Weil

By: /s/ James Weil
Name:
Title:

Address:

4 Dolma Rd

Scarsdale N.Y. 10583

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: James Engelman 401K Plan

By: /s/ James C. Engelman
Name: James C. Engelman
Title: Plan Administrator

Address:

5001 February St.

San Diego, CA 92110

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Weil Family II, LLC

By: /s/ James Weil
Name: James Weil
Title: MANAGING MEMBER

Address:

4 Dolma Rd

Scarsdale N.Y.10583

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: J3NS2 Capital, LLC

By: /s/ Joel B. Braunstein
Name: Joel B. Braunstein
Title: Managing Member

Address:

27 Aberdeen Ct.

Bannockburn, IL 60015

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Jason Hemmi

By: /s/Jason Hemmi
Name:
Title:

Address:

3625 Dudley Street

San Diego, CA 92106

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Pensco Trust Co Custodian FBO Jason Hemmi, IRA

By: /s/Jason Hemmi
Name: Jason Hemmi
Title: Fbo jason hemmi

Address:

3625 Dudley Street

San Diego, CA 92106

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Jole Blon LLC

By: /s/Michael Aquino
Name: Michael Aquino
Title: owner

Address:

19 Worthington Avenue Spring Lake

NJ 07762

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Jonathan and Rachael Cohen Living Trust

By:	/s/Jonathan Cohen	/s/Rocki Cohen
Name:	Michael Aquino	Rocki Cohen
Title:	Dr.	Mrs

Address:

413 Crawford rd
Modesto, CA 95356

413 Crawford Rd
Modesto, CA 95356

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: KCK Investors, G.P.

By: /s/Joseph S. Cantie
Name: Joseph S. Cantie
Title: Partner, KCK Investors G.P.

Address:

18026 Stonebrook Drive

Northville, MI 48168

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Kenneth F. Buechler Trust

By: /s/Kenneth
Name: Kenneth F. Buechler
Title: trustee

Address:

Po box 49

Rancho Santa Fe CA 92067

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Kenneth Markstein

By: /s/Kenneth Markstein
Name: Kenneth F. Buechler
Title:

Address:

po box 354

rancho santa fe ca 92067

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Kevin Haddad

By: /s/Kevin Haddad
Name:
Title:

Address:

3223 marlton drive

San Diego Ca 92104

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Laine Shakerdge

By: /s/Laine Shakerdge
Name:
Title:

Address:

3230 Highland Place, NW

Washington DC 20008

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Lance Torrey

By: /s/Lance Torrey
Name:
Title:

Address:

3005 Sacramento St., #5

San Francisco, CA 94115

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Make-A-Wish Foundation of America

By: /s/ Maureen Musselman
Name: Maureen Musselman
Title: VP, CFO

Address:

1702 E. Highland Ave Suite 400

Phoenix, AZ 85016

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Marc Fleischman Living Trust

By: /s/ Marc W. Fleischman
Name: Marc W. Fleischman
Title: Individual

Address:

310 7th Street

Del Mar, CA 92014

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: IRA Services Trust Company CFBO: Mark IRA Erlander, 462287

By: /s/Mark Erlander
Name: Mark Erlander
Title:

Address:

3087 Cranbrook Ct

San Diego CA 92037

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Marc A. Offit Revocable Trust

By: /s/Marc A. Offit
Name: Marc A. Offit
Title: Trustee

Address:

324 Ramsay Rd

Deerfield, IL 60015

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Maryanne K. Sorge Revocable Trust (Dated: 4/6/2005)
By: /s/Maryanne K. Sorge
Name: Maryanne K. Sorge
Title: K Sorge

Address:

box 8678

RSF, Ca. 92067

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Mesa Verde Venture Partners II, L.P.

By: /s/Carey Ng
Name: Carey Ng
Title: Managing Director

Address:

4225 Executive Square Suite 600

La Jolla, CA 92037

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Michael Caggiano

By: /s/Michael Caggiano
Name:
Title:

Address:

1513 Hampton Hill Cir

McLean, VA

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Michael Foster

By: /s/ Michael Foster
Name:
Title:

Address:

6462 e Oberlin way

Scottsdale az 85266

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Michael John Pollock TR FBO Michael J Pollock Revocable Trust
By: /s/ Michael J. Pollock
Name: Michael J. Pollock
Title: trustee

Address:

7355 N St Rte 48

Springboro Ohio 45066

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Pamela Dixon

By: /s/ Pamela Dixon
Name:
Title:

Address:

3223 Marlton Drive

San Diego, CA 92104

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Patrick Verschuere

By: /s/ PV
Name:
Title:

Address:

30 rue de l'elevage 1340 Orrignies

Belgium

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Paul Ecke III and Julie Hampton, Joint Tenants

By: /s/ Paul Ecke III /s/ Julie Hampton
Name:
Title:

Address:

7220 Avenida Encinas Suite 204

Carlsbad, CA. 92011

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Perry Krallis

By: /s/ Perry Krallis
Name:
Title:

Address:

11035 130th AVe NE

Kirkland, WA 98033

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Piccadilly Holdings, LLC

By: /s/ Samuel H. Chamberlain
Name: Samuel H. Chamberlain
Title: Managing Partner

Address:

320 S. Fairfax Street

Alexandria, VA 22314

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Gillon Family Trust

By: /s/ Peter Gillon
Name: Peter Gillon
Title: Trustee

Address:

3020 Chain Bridge Rd, NW

Washington, DC 20016

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Peter N. Reikes

By: /s/ Peter N. Reikes
Name:
Title:

Address:

151 E. 79th Street, Apt. 3

New York, NY 10075

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Phillip David Mervis and Sheryl A Facktor
JTWROS

By:	/s/ Phillip David Mervis	/s/ Sheryl A Facktor
Name:	Phillip David Mervis	Sheryl A Facktor
Title:		
Address:		
4265 N. pennsylvania		4265 N. pennsylvania
indianapolis, IN. 46205		indianapolis, IN. 46205

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Piccadilly Holdings, LLC

By: /s/ Samuel H. Chamberlain
Name: Samuel H. Chamberlain
Title: Managing Partner

Address:

320 S. Fairfax Street

Alexandria, VA 22314

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Rana Prasad

By: /s/ Rana Prasad
Name:
Title:

Address:

8920 WEST RUSSELL ROAD, UNIT 2028

LAS VEGAS, NV 89148

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Ray E. Kiefhaber

By: /s/ Ray E. Kiefhaber
Name:
Title:

Address:

505 curryer rd.

Middletown, ohio

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Re: Align, Inc. Defined Benefit Plan DTD 01-01-15 Theodore and Jennifer Rolf, Trustees

By: /s/ Theodore D. Rolf
Name: Theodore D. Rolf
Title: Trustee

Address:

1345 Pine Avenue

Carlsbad, CA 92008

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: The Richard G. Vincent and Stacy K. Vincent Trust, U.T.D. April 4, 2008

By: /s/ Richard G. Vincent
Name: Richard G. Vincent
Title: Trustee

Address:

4732 Finchley Terrace

San Diego, CA 92130

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Ronald L. Graham

By: /s/ Ronald L. Graham
Name:
Title:

Address:

9017 Shearwater Rd

Blaine WA 98230

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Schuh Ventures, LLC

By: /s/ Antonius Schuh, Ph.D.
Name: Antonius Schuh, Ph.D.
Title: Manager

Address:

5028 Seachase Way

San Diego, CA 92130

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Scott Nader Afshar

By: /s/ Scott Nader Afshar
Name:
Title:

Address:

5630 Circle Drive

El Sobrante, CA 94803

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Scott N. Wolfe

By: /s/ Scott N. Wolfe
Name:
Title:

Address:

12670 High Bluff Dr

San Diego, CA 92130

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: SDL Ventures, LLC

By: /s/ Donald R. Scifres
Name: Donald R. Scifres
Title: Managing Director

Address:

4984 El Camino Real, Suite 200

Los Altos, Ca 94022

IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its duly authorized representatives.

Holder: Stephen F. Gallagher, Trustee

By: /s/ Stephen F. Gallagher
Name: Stephen F. Gallagher
Title: trustee

Address:

1428 Baytowne Cir E

Miramar Beach, FL 32550

Exhibit A

Outstanding Warrants to be Amended

Warrant Holder	Shares Underlying Warrants	Issuance Date
600 Mile Challenge Fund 1, LLC	83,907	9/12/2017
Alexander Moore	3,834	9/12/2017
Alexandria Venture Investments, LLC	333,333	12/4/2017
Alma Life Sciences LLC	26,077	9/12/2017
Amanda Miller	3,834	9/12/2017
Andrew Tyler Dixon	1,380	9/12/2017
Benjamin Verschuere	16,666	9/12/2017
Berge K. Hagopian and Mary Ann Hagopian, Co Trustees, Hagopian Family Trust UA DTD 03/25/88	27,611	9/12/2017
Beta Operator Fund, LP	38,349	9/12/2017
Blackcomb Advisors LLC	16,666	12/6/2017
Braydore Partners	7,669	9/12/2017
Breede 2013 FLP LLC	16,666	12/18/2017
Breede 2013 FLP LLC	11,504	9/12/2017
Brian I Pidgeon Trust	16,666	9/12/2017
Bruce and Kerry Goodfield	16,666	11/6/2017
Cam Gallagher	16,666	9/12/2017
Carl F. Edman and Xiaofan Dong (JTWRS)	25,000	9/12/2017
Chad K. Miller & Kathleen L. Miller	3,000	9/12/2017
Cheston J. Larson	7,363	9/12/2017
Christopher J. Twomey and Rebecca J. Twomey Family Trust U.T.D. September 20, 2002	8,333	9/12/2017
Conlin Living Trust Dated February 1, 2012	5,752	11/7/2017
Cove Partners II	24,997	9/12/2017
Craig Gallagher	3,834	9/12/2017
Darcy Thompson	3,834	9/12/2017
David Dare	16,666	9/12/2017
DAVID ISCAR DE HOYOS NIF: 51411105X	8,333	9/12/2017
David Johnson	23,570	9/12/2017
David M. Rudolf	7,669	9/12/2017
Derek M. Evjenth	3,834	9/12/2017
Dixon Family Trust	8,333	9/12/2017
Donald R. Rady Trust dated November 26, 1992, Donald R. Rady, Trustor and Trustee	3,834	9/12/2017
Donald W. Peitz Revocable Trust	16,666	9/12/2017
Emerald Isle Capital	33,333	9/12/2017
Equity Trust Company Custodian FBO Craig L. Dixon IRA	13,805	9/12/2017
Erik Hemmi	12,832	9/12/2017
Finney Family 2002 Trust, U/D/T dated October 16 2002	1,917	9/12/2017
Frederic R. Gross	3,834	9/12/2017
Friedman-Bioventure Fund I, LP	33,333	9/12/2017
Garner Investments, LLC	35,281	9/12/2017
George and Traci Stuart 2009 Revocable Trust dated 2/4/09	3,834	9/12/2017
Gillon Family Trust	13,621	9/12/2017
Glenn Holdings, L.P.	44,485	9/12/2017
Growth Ventures, Inc. Roth 401K	7,669	9/12/2017
Hale BioPharma Ventures, LLC	44,869	9/12/2017
Hanover-Oncternal, LLC	68,107	9/12/2017
Hines Haus, LLC	33,333	11/21/2017
IRA Services Trust Company CFBO: Mark Erlander, IRA 462287	13,333	9/12/2017
IRA Services Trust Company FBO Chad Miller IRA 492425	1,333	9/12/2017

Warrant Holder	Shares Underlying Warrants	Issuance Date
IRA Services Trust Company FBO Kathleen Miller IRA 492413	1,358	9/12/2017
J3NS2 Capital, LLC	50,000	12/13/2017
J3NS2 Capital, LLC	25,000	9/12/2017
Jack Breard	16,666	12/12/2017
James A. Weil	26,844	9/12/2017
James C. Blair, Ph.D.	25,000	9/12/2017
James Engelman 401K Plan	3,834	9/12/2017
Jason Hemmi	7,833	9/12/2017
Jeffrey T. Haux and Evi A. Haux, Trustees, Haux Family Trust dated October 3, 2013	10,000	9/12/2017
Jeffrey T. Haux and Evi A. Haux, Trustees, Haux Family Trust dated October 3, 2013	8,333	12/11/2017
Jole Blon LLC	11,467	9/12/2017
Jonathan and Rachael Cohen Living Trust	3,834	9/12/2017
KCK Investors, G.P.	8,333	9/12/2017
Kenneth F. Buechler Trust	7,669	9/12/2017
Kenneth Markstein	18,407	9/12/2017
Kevin Haddad	25,002	9/12/2017
Laine Shakerdge	1,917	9/12/2017
Lance Torrey	16,666	12/11/2017
Larry T. Aker and Hazel M. Aker, Trustees of The Aker Family Trust Dated July 21, 2014	1,917	9/12/2017
MagnaSci Co-Investments, L.L.C.	748,334	9/12/2017
MagnaSci Fund II, L.P.	366,666	12/30/2017
MagnaSci Fund, L.P.	918,333	9/12/2017
MagnaSci Fund, L.P.	500,000	9/12/2017
Make-A-Wish Foundation of America	8,333	9/12/2017
Marc A. Offit Revocable Trust	50,000	12/8/2017
Marc A. Offit Revocable Trust	16,666	9/12/2017
Marc Fleischman Living Trust	5,000	9/12/2017
Maryanne K. Sorge Revocable Trust (Dated: 4/6/2005)	16,666	9/12/2017
Mesa Verde Venture Partners II, L.P.	33,333	9/12/2017
Michael Caggiano	1,725	9/12/2017
Michael Foster	10,000	9/12/2017
Michael Foster	8,333	12/11/2017
Michael John Pollock TR FBO Michael J Pollock Revocable Trust	5,752	9/12/2017
Nathaniel Dixon	2,531	9/12/2017
Pamela Dixon	6,667	9/12/2017
Patrick Verschuere	5,333	9/12/2017
Paul Ecke III and Julie Hampton, Joint Tenants	6,903	9/12/2017
Pensco Trust Co Custodian FBO Jason Hemmi, IRA	8,332	9/12/2017
PENSCO Trust Company LLC Custodian FBO Bruce A. Bastian IRA	33,333	9/12/2017
Perry Krallis	6,810	9/12/2017
Peter N. Reikes	5,862	9/12/2017
Phillip David Mervis and Sheryl A Facktor JTWROS	38,140	9/12/2017
Piccadilly Holdings, LLC	7,669	9/12/2017
Polar Circus LLC	83,333	9/12/2017
Rana Prasad	7,669	9/12/2017
Ray E. Kiefhaber	1,917	9/12/2017
Re: Align, Inc. Defined Benefit Plan DTD 01-01-15 Theodore and Jennifer Rolf, Trustees	1,957	9/12/2017
Revolutions Advisors Defined Benefit Plan DTD 1/1/2011	100,000	12/15/2017
Ronald L. Graham	33,333	9/12/2017
Schuh Ventures, LLC	19,174	9/12/2017
Scott N. Wolfe	5,522	9/12/2017
Scott Nader Afshar	25,000	9/12/2017
SDL Ventures	19,174	9/12/2017

Warrant Holder	Shares Underlying Warrants	Issuance Date
SDL Ventures, LLC	14,878	11/17/2017
Sean Ainsworth	1,999	9/12/2017
Stephen F. Gallagher, Trustee	5,752	9/12/2017
Steven Koltai	2,684	9/12/2017
Steven Rea	8,333	12/13/2017
Sween-OT Investment, LLC	16,666	9/12/2017
The Greene Family Trust	9,203	9/12/2017
The James and Mary Breitmeyer Trust	10,000	9/12/2017
The Mohsen Zaki Fahmi and Maria Gabriella Fahmi Living Trust Dated August 17, 2016	66,666	9/12/2017
The Mohsen Zaki Fahmi and Maria Gabriella Fahmi Living Trust Dated August 17, 2016	66,666	12/5/2017
The Richard G. Vincent and Stacy K. Vincent Trust, U.T.D. April 4, 2008	3,834	9/12/2017
The Sunroad 2011 Trust	36,815	9/12/2017
The Weeks Family Trust	8,333	9/12/2017
Timothy M. Pennington and Melissa J. Pennington as Trustees of the Pennington Family Revocable Trust UA Dated May 23, 1984	27,611	9/12/2017
TKMB LLC	25,000	9/12/2017
TNKRGK Family Trust dated 12/23/76, Trustees Tawfiq N. Khoury and Richel G. Khoury, Trustee	16,666	9/12/2017
Tom Falk	20,831	9/12/2017
Tristan Peitz	10,666	9/12/2017
Twomey Family Investments, LLC	8,333	9/12/2017
Virani 2012 Trust	76,699	9/12/2017
VP Company Investments 2016, LLC	12,885	9/12/2017
Weil Family II, LLC	3,834	9/12/2017
Weinstein Family Trust	16,666	9/12/2017
Wilkie Trust dated 2/27/04	5,752	9/12/2017
William R. and Joyce E. LaRue Family Trust Dated November 4, 1991	3,834	9/12/2017
WS Investment Company, LLC (2017A)	13,621	9/12/2017
Zaniboni Ventures, LLC	19,174	9/12/2017

ZQ|CERT#|COY|CLS|RGSTRY|ACCT#|TRANSTYPE|RUN#|TRANS#

COMMON STOCK

PAR VALUE $0.001

COMMON STOCK

ONCTERNAL therapeutics™

Certificate Number

ZQ00000000

Shares

ONCTERNAL THERAPEUTICS, INC.

INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE

THIS CERTIFIES THAT

MR. SAMPLE & MRS. SAMPLE & MR. SAMPLE & MRS. SAMPLE

SEE REVERSE FOR CERTAIN DEFINITIONS

CUSIP 68236P 10 7

is the owner of

ZERO HUNDRED THOUSAND ZERO HUNDRED AND ZERO

THIS CERTIFICATE IS TRANSFERABLE IN CITIES DESIGNATED BY THE TRANSFER AGENT, AVAILABLE ONLINE AT www.computershare.com

FULLY PAID AND NON-ASSESSABLE SHARES WITH A PAR VALUE OF $.001 EACH OF THE COMMON STOCK OF

Oncternal Therapeutics, Inc.

transferable on the books of the Corporation by the holder hereof in person or by duly authorized Attorney, upon surrender of this Certificate properly endorsed. This Certificate is not valid until countersigned and registered by the Transfer Agent and Registrar.

WITNESS the facsimile signatures of its duly authorized officers.

President and Chief Executive Officer

Chief Financial Officer and Secretary

ONCTERNAL THERAPEUTICS, INC. SEAL September 4, 2003 DELAWARE

DATED DD-MMM-YYYY

COUNTERSIGNED AND REGISTERED:
COMPUTERSHARE TRUST COMPANY, N.A.
TRANSFER AGENT AND REGISTRAR,

By _____
AUTHORIZED SIGNATURE

1234567

ONCTERNAL therapeutics™

PO BOX 43004, Providence, RI 02940-3004

MR A SAMPLE
DESIGNATION (IF ANY)
ADD 1
ADD 2
ADD 3
ADD 4

CUSIP/IDENTIFIER XXXXXX XX X
Holder ID XXXXXXXXXX
Insurance Value 1,000,000.00
Number of Shares 123456
DTC 12345678 12345678912345

Certificate Numbers	Num	No. Denom.	Total
12345678901234567890	1	1	1
12345678901234567890	2	2	2
12345678901234567890	3	3	3
12345678901234567890	4	4	4
12345678901234567890	5	5	5
12345678901234567890	6	6	6
Total Transaction			7

ONCTERNAL THERAPEUTICS, INC.

THE CORPORATION WILL FURNISH WITHOUT CHARGE TO EACH STOCKHOLDER WHO SO REQUESTS THE POWERS, DESIGNATIONS, PREFERENCES AND RELATIVE, PARTICIPATING, OPTIONAL OR OTHER SPECIAL RIGHTS OF EACH CLASS OF STOCK OR SERIES THEREOF OF THE CORPORATION, AND THE QUALIFICATIONS, LIMITATIONS OR RESTRICTIONS OF SUCH PREFERENCES AND/OR RIGHTS. SUCH REQUEST MAY BE MADE TO THE CORPORATION OR ITS TRANSFER AGENT.

The following abbreviations, when used in the inscription on the face of this certificate, shall be construed as though they were written out in full according to applicable laws or regulations:

TEN COM - as tenants in common	UNIF GIFT MIN ACT - .....(Cust).....Custodian.....(Minor).....
TEN ENT - as tenants by the entireties	under Uniform Gifts to Minors Act .....(State).....
JT TEN - as joint tenants with right of survivorship and not as tenants in common	UNIF TRF MIN ACT - .....(Cust).....Custodian (until age.....)
	.....(Minor).....under Uniform Transfers to Minors Act .....(State).....

Additional abbreviations may also be used though not in the above list.

For value received, _____ hereby sell, assign and transfer unto

PLEASE INSERT SOCIAL SECURITY OR OTHER IDENTIFYING NUMBER OF ASSIGNEE

_____

(PLEASE PRINT OR TYPEWRITE NAME AND ADDRESS, INCLUDING POSTAL ZIP CODE, OF ASSIGNEE)

_____

_____

_____ Shares

of the capital stock represented by the within Certificate, and do hereby irrevocably constitute and appoint

_____ Attorney

to transfer the said stock on the books of the within-named Corporation with full power of substitution in the premises.

Dated: _____ 20 _____

Signature: _____

Signature: _____

Notice: The signature to this assignment must correspond with the name as written upon the face of the certificate, in every particular, without alteration or enlargement, or any change whatever.

Signature(s) Guaranteed: Medallion Guarantee Stamp

THE SIGNATURE(S) SHOULD BE GUARANTEED BY AN ELIGIBLE GUARANTOR INSTITUTION (Banks, Stockbrokers, Savings and Loan Associations and Credit Unions) WITH MEMBERSHIP IN AN APPROVED SIGNATURE GUARANTEE MEDALLION PROGRAM, PURSUANT TO S.E.C. RULE 17Ad-15.

SECURITY INSTRUCTIONS

THIS IS WATERMARKED PAPER. DO NOT ACCEPT WITHOUT NOTING WATERMARK. HOLD TO LIGHT TO VERIFY WATERMARK.

The IRS requires that the named transfer agent ("we") report the cost basis of certain shares or units acquired after January 1, 2011. If your shares or units are covered by the legislation, and you requested to sell or transfer the shares or units using a specific cost basis calculation method, then we have processed as you requested. If you did not specify a cost basis calculation method, then we have defaulted to the first in, first out (FIFO) method. Please consult your tax advisor if you need additional information about cost basis.

If you do not keep in contact with the issuer or do not have any activity in your account for the time period specified by state law, your property may become subject to state unclaimed property laws and transferred to the appropriate state.

153427

Exhibit 10.23

SUBLEASE

Sublandlord:	HOST HOTELS & RESORTS, L.P.
Subtenant:	OCTERNAL THERAPEUTICS, INC.
Premises:	Suite 300
Building:	12230 El Camino Real San Diego, California

SUBLEASE

THIS SUBLEASE (this "**Sublease**") is entered into as of May 22, 2019 by and between Host Hotels & Resorts, L.P., a Delaware limited partnership ("**Sublandlord**"), and Oncternal Therapeutics, Inc., a Delaware corporation ("**Subtenant**").

WITNESSETH:

WHEREAS, pursuant to an Office Lease dated September 1, 2015, by and between Cognac Del Mar Owner II, LLC, a Delaware limited liability company ("**Landlord**"), and Sublandlord (the "**Prime Lease**") covering approximately 4,677 rentable square feet on the third floor known as Suite 300, as further described in the Prime Lease (the "**Prime Lease Premises**"), of the building located at 12230 El Camino Real, San Diego, California (the "**Building**");

WHEREAS, the Prime Lease expires as of May 31, 2021 ("**Prime Lease Expiration Date**"), subject to extension or earlier termination; and

WHEREAS, Sublandlord desires to sublease to Subtenant, and Subtenant desires to sublease from Sublandlord, all of the Prime Lease Premises on the terms and conditions hereinafter set forth.

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

1. Subleasing of the Premises. Sublandlord hereby does sublease to Subtenant, and Subtenant does hereby sublease from Sublandlord, upon and subject to the provisions of this Sublease, the entire Prime Lease Premises as outlined on Exhibit A attached hereto and further described in the Prime Lease (also known herein as the "**Premises**"). Such rentable square footage of the Premises is hereby stipulated by Sublandlord and Subtenant and shall not be subject to any re-measurement.

2. Term.

a. Subject to the other provisions of this Sublease (including, but not limited to, Paragraph 23), this Sublease shall be and continue in full force and effect for a term ("**Term**") commencing on the later of (i) the date Sublandlord delivers to Subtenant possession of the Premises in the Delivery Condition (defined below), or (ii) the date Landlord delivers the Consent (as defined below) to this Sublease ("**Commencement Date**") and expiring at 11:59 p.m. on March 31, 2021 ("**Expiration Date**"), unless sooner terminated as hereinafter provided. Notwithstanding the foregoing, if Subtenant occupies the Premises for the actual day-to-day operation of its business prior to the Commencement Date described above, then the Commencement Date shall be moved earlier to such date Subtenant commences such occupation.

b. The taking of possession of the Premises by Subtenant on the Commencement Date shall constitute an acknowledgement by Subtenant that the Premises are in good condition and Sublandlord has provided the Premises in Delivery Condition.

c. Within ten (10) days of the request of either party, Sublandlord and Subtenant hereby agree to execute a Declaration, substantially in the form attached hereto and incorporated herein as Exhibit B, to confirm the Commencement Date and other matters set forth thereon. Failure to execute such Declaration shall not affect the commencement or expiration of the Term or the other matters described thereon.

3. Base Rent.

a. Subtenant, in consideration for the subleasing of the Premises, agrees to pay to Sublandlord the sum of One Hundred Sixty Five Thousand Seven Hundred Fifty- Six and 48/100 Dollars ($165,756.48) as annual base rent ("**Base Rent**"), payable in equal fixed monthly installments of Thirteen Thousand Eight Hundred Thirteen and 04/100 Dollars ($13,813.04) in advance on the first day of each month ("**Monthly Base Rent**").

b. Subtenant shall pay the first month's Monthly Base Rent to Sublandlord upon execution of this Sublease, being Thirteen Thousand Eight Hundred Thirteen and 04/100 Dollars ($13,813.04) ("**Rent Payment**"). Sublandlord shall apply such Rent Payment to the Monthly Base Rent due on the first full month following the Commencement Date. All such monthly installments shall be payable in advance and without demand, notice or (except as expressly provided in this Sublease) offset, on the first day of each calendar month during the Term at the address for Sublandlord stated in Paragraph 20, or at such other places as Sublandlord may from time to time designate in writing to Subtenant. If the Commencement Date is other than the first day of a month, or if this Sublease terminates or expires with respect to all or any part of the Premises on a date other than the end of a month, then the Monthly Base Rent shall be prorated to reflect such partial month. All of Subtenant's obligations to pay all rental or monies due in or under this Sublease shall survive the expiration or earlier termination of this Sublease.

4. Security Deposit. Subtenant shall pay Sublandlord the sum of Thirteen Thousand Eight Hundred Thirteen and 04/100 Dollars ($13,813.04) at the time of the execution of the Sublease ("**Security Deposit**") as security for Subtenant's full and faithful performance of all covenants and conditions contained in the Sublease. Sublandlord shall have no obligation to maintain the Security Deposit in a separate account. If Subtenant defaults in respect of any of the terms, provisions, covenants and conditions of this Sublease, subject to applicable notice and cure periods, Sublandlord may use, apply, or retain the whole or any part of the Security Deposit for the payment of any Base Rent or other Rent (as defined herein) in default, or for any other sum which the Sublandlord may expend or be required to expend by reason of Subtenant's default, including, without limitation, any damages or deficiency which shall have been incurred by Sublandlord before or after re-entry by Sublandlord. The Security Deposit may not be used or applied by Subtenant as a substitute for any Rent due, but may be so applied by Sublandlord at any time at Sublandlord's sole option. The use, application or retention of the Security Deposit, or any portion thereof, by Sublandlord shall not prevent Sublandlord from exercising any other right or remedy provided by this Sublease or by law (it being intended that the Sublandlord shall not first be required to proceed against the Security Deposit) and shall not operate as a limitation on any recovery to which Sublandlord may otherwise be entitled. If any of the Security Deposit shall be so used, applied or retained by Sublandlord at any time or from time to time, Subtenant shall promptly, in each such instance, on written demand therefor by Sublandlord, pay the Sublandlord such additional sum in cash as may be necessary to restore the Security Deposit to the original amount set forth in the first sentence of this paragraph. To the extent such Security Deposit is not applied as set forth in this paragraph, Sublandlord shall return the

Security Deposit, or any balance thereof, to Subtenant after the later of thirty (30) days after: (a) the Expiration Date or earlier termination of the Term of this Sublease or (b) the date by which Subtenant has vacated the Premises in accordance with the terms hereof ("**Outside Deposit Expiration Date**"). Except as otherwise required by law, Subtenant shall not be entitled to any interest on the Security Deposit. In the event of a transfer of Sublandlord's interest in the Prime Lease, Sublandlord shall transfer the Security Deposit to the transferee, whereupon Sublandlord shall be released from all liability for the return of the Security Deposit. Subtenant waives the provisions of California Civil Code Section 1950.7, and all other provisions of law now in force or that become in force after the date of execution of this Sublease, that restrict Sublandlord's use or application of the Security Deposit or that provide specific time periods for return of the Security Deposit.

5. Additional Rent. Subtenant shall have no obligation to pay to Sublandlord any amount for "Excess Expenses" (as defined in Section 4.3 of the Prime Lease). Within thirty (30) days after receipt of an invoice from Sublandlord accompanied by reasonable supporting written documentation, Subtenant shall reimburse Sublandlord for any additional rent or charges incurred by Sublandlord in accordance with the terms of the Prime Lease (excluding Sublandlord's obligation to pay Monthly Basic Rent [as defined in Section 3.1 of the Prime Lease] to Landlord and Sublandlord's obligation to pay the Excess Expenses), which rent or charges were incurred at the request of Subtenant in connection with this Sublease or the Premises, or as a result of Subtenant's actions or inactions with respect to the Premises. The foregoing includes without limitation rent or charges for nonstandard janitorial services and overtime HVAC. All electricity used by Subtenant in the Premises shall be paid by Subtenant by separate charge billed by the applicable utility company and payable directly by Subtenant prior to delinquency.

6. Services. Notwithstanding anything contained in this Sublease, Subtenant agrees and acknowledges that Sublandlord shall have no obligation or responsibility whatsoever to provide or perform any service, repair, restoration, maintenance, alteration or other similar obligation which is the obligation of Landlord to provide or perform pursuant to the provisions and terms of the Prime Lease, except that Sublandlord covenants to use its commercially reasonable efforts to require Landlord to perform and provide all such service, repair, restoration, maintenance, alteration, and other obligations pursuant to the provisions of the Prime Lease at Subtenant's request, which commercially reasonable efforts shall not include commencing litigation against Landlord. Subtenant shall not make any claim against Sublandlord for any damage which may arise, nor shall Subtenant's obligations hereunder be diminished, by reason of: (i) the failure of Landlord to keep, observe or perform any of its obligations pursuant to the Prime Lease; or (ii) the acts or omissions of Landlord or its agents, contractors, subcontractors, servants, employees, tenants (except Sublandlord), invitees or licensees or other third parties. Subtenant hereby releases Sublandlord from the performance or observance of any agreement or obligation of Landlord under the Prime Lease and agrees that if Landlord shall default in the performance or observance of any such agreement or obligation under the Prime Lease, either for the furnishing of utilities or services or otherwise, Sublandlord shall not be liable therefor to Subtenant. Any condition resulting from such default by Landlord shall not constitute an eviction, actual or constructive, and Subtenant shall not be entitled to cancel this Sublease or to otherwise modify, release or alter its obligations hereunder. The provisions of this Paragraph shall survive the expiration or earlier termination of the Term hereof. Notwithstanding anything in this Paragraph to the contrary, if Sublandlord is entitled to any recovery from Landlord or to offset rental payments or other amounts, as a result of Landlord's failure to perform any of its obligations under the Prime Lease, Subtenant shall, in the event of such failure, be entitled to the same proportionate recovery or offset from Sublandlord as Sublandlord has in fact received from Landlord to the extent such failure or interruption relates directly to the Premises, Subtenant's use or occupancy thereof or other rights of Subtenant hereunder. Subtenant, at its cost, shall obtain and maintain pest control for the Premises to the extent not provided by the Landlord as a service under the Prime Lease.

7. Condition of Premises; Alterations; Maintenance; and Restoration.

a. On or prior to the Commencement Date, Sublandlord shall deliver sole and exclusive possession of the Premises to Subtenant broom clean, vacant, free of all personal property other than the FF&E (defined below), and otherwise in its "as is" "where is" condition as of the date of execution of this Sublease ("**Delivery Condition**"), and Subtenant agrees to accept the Premises in such condition. Sublandlord is not obligated to perform any improvements or alterations to the Premises or to provide to Subtenant any tenant improvements or allowances. Sublandlord makes no representations or warranties concerning the Premises except as specifically set forth in this Sublease. Notwithstanding anything to the contrary herein, Sublandlord shall not be deemed to be providing to Subtenant any of the representations or warranties provided by Landlord to Sublandlord under the Prime Lease. Subtenant hereby waives the provisions of Sections 1932, 1941 and 1942 of California Civil Code and of any similar law, statute or ordinance now or hereafter in effect, as well as any other waivers of applicable laws, statutes or ordinances set forth in the Prime Lease.

b. Any alterations or improvements that Subtenant desires to make to the Premises shall be subject to the terms of the Prime Lease with respect to alterations and improvements, with such terms and requirements benefiting both Landlord as well as the Sublandlord. Subtenant shall pay for all fees charged by Landlord in connection with any alterations being performed by, through, under or on behalf of Subtenant in or about the Premises. Sublandlord, at no expense to Sublandlord, shall reasonably cooperate with any requests by Subtenant for obtaining the approval of Landlord to any improvements or alterations Subtenant desires to make to the Premises.

c. Subtenant shall maintain the Premises in as good order and condition as when the Premises were delivered to it by Sublandlord, shall not commit or allow any waste or damage to be committed on any portion of the Premises, and shall comply with all obligations, laws, orders and regulations which are imposed on the Sublandlord, as Tenant under the Prime Lease and which are applicable to the Premises or Subtenant's use thereof. At the termination of this Sublease, by lapse of time or otherwise, Subtenant shall deliver the Premises to Sublandlord in as good order and condition as when the Premises were delivered to Subtenant by Sublandlord (subject to the terms of Paragraph 7.d below), vacant and broom clean with reasonable wear and tear excepted, subject to the other provisions of this Sublease.

d. On or before the Expiration Date, or earlier termination of this Sublease, Subtenant shall remove from the Premises, at its expense, all of its personal property (including, without limitation, the FF&E, defined below, to the extent the same is deemed Subtenant's personal property as set forth below). All fixtures, equipment, improvements, and installations which Subtenant attached to, or built into, the Premises as Subtenant's alterations are deemed to be the property of Sublandlord (or Landlord if required by the Prime Lease), and upon termination or expiration of this Sublease, shall remain part of the Premises. Notwithstanding the foregoing, Subtenant shall remove all alterations made by or on behalf of Subtenant or anyone claiming by, through or under Subtenant upon the termination or expiration of the Term to the extent Landlord (or the Prime Lease) requires Subtenant (or Sublandlord) to remove the same in accordance with the terms of the Prime Lease. In no event shall Subtenant be required to remove or restore alterations at the end of the Term made by, through or on behalf of Sublandlord prior to the

Commencement Date. If Subtenant is required to remove its alterations, Subtenant shall promptly repair any damage caused by such removal. If Subtenant fails to so remove such alterations and/or repair and restore the Premises as a result of Subtenant's removal by the end of the Term, Subtenant agrees promptly to reimburse Sublandlord for the reasonable cost of such removal and/or repairs and restoration required as the result of damage from such removal done to the Premises or the Building by Subtenant so as to restore the Premises or the Building to the condition required under Paragraph 7.c above. All property permitted or required to be removed by Subtenant upon the Expiration Date or earlier termination of this Sublease which remains on the Premises after the Expiration Date or sooner termination shall be deemed abandoned and may, at the election of the Sublandlord, either be retained as Sublandlord's property or may be removed from the Premises by Sublandlord at Subtenant's expense. Subtenant shall pay any such expenses to Sublandlord within thirty (30) days after written demand accompanied by reasonably supporting written documentation as additional rent hereunder.

8. Assignment and Subletting. The terms and provisions of the Prime Lease with respect to assignment and subletting shall apply as between Sublandlord and Subtenant as if Sublandlord were "Landlord" and Subtenant were "Tenant". Landlord shall retain all rights, and Subtenant shall comply with all obligations and conditions, with respect to any assignment and subletting hereunder as set forth in the Prime Lease.

9. Limitation on Liability. The obligations of Sublandlord and Subtenant under this Sublease do not constitute personal obligations of the individual officers, directors, employees, shareholders, partners, members, shareholders or other owners of interests in Sublandlord and Subtenant, and neither party shall seek recourse against any of the same or any of their personal assets for satisfaction of any liability of a party under this Sublease.

10. Default. This Sublease is subject to the limitation that if at any time during the Term any one or more of the following events ("**Default**") shall occur:

a. Subtenant fails to pay any item of Base Rent and/or additional rent, or any other charge or sum required to be paid by Subtenant under this Sublease (collectively, "**Rent**") when due and payable hereunder, which failure is not cured within three (3) business days after written notice from Sublandlord that such amount was not paid when due, provided that if Subtenant has previously received one (1) or more notices from Sublandlord during the immediately preceding twelve (12) month period stating that Subtenant failed to pay any amount required to be paid by Subtenant under this Sublease when due, then Sublandlord shall not be required to deliver any notice to Subtenant and a default shall immediately occur upon any failure by Subtenant to pay any rent or any other charge required to be paid under the Sublease when due; or

b. Except where a specific time period is otherwise set forth for Subtenant's performance in this Sublease or Sublandlord's performance under the Prime Lease, in which event the failure to perform by Subtenant within such time period shall be a default under this Paragraph 10.b, Subtenant fails to perform or observe any of its other requirements under this Sublease and such failure shall continue for a period of thirty (30) days after written notice thereof from Sublandlord to Subtenant, or such longer period as may be reasonably required to cure such violation or failure if the same is not able to be cured within such thirty (30) day period, provided

Subtenant is diligently pursuing such cure and provided further that the continuance of which will not subject Sublandlord or Landlord to the risk of criminal liability, cause a termination of the Sublease or the Prime Lease, or cause a default by Sublandlord under the Prime Lease; or

c. Subtenant becomes insolvent, fails to pay its debts as they fall due, files a petition under any chapter of the U.S. Bankruptcy Code, 11 U.S.C. et seq., as it may be amended (or similar petition under any insolvency law of any jurisdiction), or if such petition is filed against Subtenant and such proceeding is not dismissed within ninety (90) days after the filing thereof; or

d. If there is, with respect to Subtenant, any dissolution, liquidation, composition, financial reorganization or recapitalization with creditors, Subtenant makes an assignment for the benefit of creditors, or if a receiver, trustee or similar agent is appointed or takes possession with respect to any property of the Subtenant; or

e. The leasehold hereby created is taken on execution or other process of law in any action against Subtenant; then, and in any such case, Sublandlord shall have the right to exercise all remedies set forth in Section 23.2 of the Prime Lease and other applicable sections of the Prime Lease as if Sublandlord were "Landlord" (as defined in the Prime Lease), Subtenant were "Tenant" (as defined in the Prime Lease), the Premises were the "Premises" (as defined in the Prime Lease), the Term were the "Term" (as defined in the Prime Lease), all monies due by Subtenant to Sublandlord under this Sublease were the "Rent" (as defined in the Prime Lease) and the Base Rent were the "Monthly Basic Rent" (as defined in the Prime Lease). The rights and remedies granted to Sublandlord herein are cumulative and in addition to any others Sublandlord may be entitled to at law or in equity.

11. Insurance Obligations. Subtenant shall obtain, deliver and maintain the insurance required to be carried by Sublandlord as Tenant under the terms of the Prime Lease and provide indemnities and waivers of claims as set forth therein. Such provisions of the Prime Lease shall inure to the benefit of Sublandlord and Landlord, including, without limitation, making Sublandlord an additional insured as required thereunder. Notwithstanding anything to the contrary herein, Sublandlord shall not be required to carry the insurance required to be carried by Landlord.

12. FF&E. Sublandlord shall make available to Subtenant, at no cost to Subtenant, for its exclusive use during the Term the furniture, fixtures and equipment, artwork, and AV equipment listed on Exhibit C ("**FF&E**"); provided, however that the FF&E shall not include, and Subtenant shall not have the use of, the security system serving the Premises. Subtenant accepts such FF&E in their "as is" condition, and Sublandlord makes no representation or warranty with respect to their condition. Subtenant acknowledges that such FF&E has been used and/or refurbished prior to the Commencement Date. Subtenant shall be liable for any damage to the FF&E, other than ordinary wear and tear, and shall be solely responsible for all costs associated with the insurance, maintenance, cleaning and repair of the FF&E and any taxes related thereto. All FF&E shall remain the property of Sublandlord and shall be surrendered to Sublandlord with the Premises upon the expiration of the Term in substantially the same condition they were in upon the Commencement Date, ordinary wear and tear excepted, subject to the following provisions. Notwithstanding the foregoing, at Sublandlord's option, Subtenant shall be deemed to have acquired the FF&E for the sum of $1.00 (which amount will be deducted from the Security Deposit) as of the Expiration Date (or earlier termination date) from Sublandlord free and clear of all liens and shall remove the FF&E as part of Subtenant's obligations to remove Subtenant's

personal property from the Premises at the end of the Term. Upon the request of either Sublandlord or Subtenant, subject to the foregoing, the parties shall execute a bill of sale confirming the foregoing transfer of title.

13. Landlord Provisions. Except to the extent stated specifically to the contrary herein, whenever under the Prime Lease Sublandlord must comply with particular requirements (such as obtaining insurance) or act or perform (such as to indemnify, hold harmless or reimburse) for the benefit of Landlord, Subtenant shall also comply or act for the benefit of Sublandlord and Landlord. If Subtenant desires to take an action which, under the applicable provisions of the Prime Lease, requires the approval or consent of Landlord, Subtenant shall not take such action until Landlord has provided its approval or consent in connection therewith.

14. Prime Lease.

a. This Sublease is and shall be subject and subordinate to the Prime Lease, any and all ground or underlying leases affecting the Building or the land underlying the Building, and any and all mortgages or deeds of trust which may now or hereafter encumber or affect such leases, land, and Building and to all renewals, modifications, consolidations, replacements and extensions of any such leases, mortgages and deeds of trust (collectively, the "**Documents**"). The provisions of this paragraph shall be self-operative and shall require no further consent or agreement by Subtenant. Subtenant agrees, however, to execute within five (5) days after delivery any consent or agreement to confirm that this Sublease is and shall be subject and subordinate to the Documents, which is reasonably requested by Sublandlord or Landlord or any applicable lessor, mortgagee or beneficiary in connection with this paragraph. Sublandlord shall have no obligation to obtain any non-disturbance agreements from Landlord or any mortgagees, beneficiaries or lessors. If the Prime Lease or any ground lease terminates prior to the Expiration Date, this Sublease shall also terminate on the date that the Prime Lease or any such ground lease terminates.

b. Subtenant acknowledges that it has received and reviewed the Prime Lease (redacted to remove certain information). Subtenant's rights pursuant to this Sublease are subject and subordinate at all times to the Prime Lease and to all of the terms, covenants, and agreements of the Prime Lease. Subtenant shall not do or permit anything to be done in, or in connection with Subtenant's use or occupancy of, the Premises, which would violate any of the terms, covenants, or agreements of the Prime Lease. Except as modified hereby, except for any provisions of this Sublease which conflict with the Prime Lease (in which case the provisions of this Sublease shall control as between Sublandlord and Subtenant) and except as provided in Paragraph 14.c below, Sublandlord shall have the same obligations to Subtenant and rights against Subtenant with respect to this Sublease, as the "Landlord" has with respect to and against the "Tenant" pursuant to the Prime Lease, and Subtenant shall have the same obligations to Sublandlord and rights against Sublandlord with respect to this Sublease as the "Tenant" has with respect to and against the "Landlord" pursuant to the Prime Lease. In furtherance thereof, for purposes of this Sublease, references to the "Premises" in the Prime Lease shall be construed to mean the "Premises"; references to "Landlord" in the Prime Lease shall be construed to mean "Sublandlord"; references to "Tenant" in the Prime Lease shall be construed to mean "Subtenant", and references to "Monthly Basic Rent" in the Prime Lease shall be construed to mean "Base Rent". Sublandlord may enforce directly against Subtenant any of the rights and remedies granted to Landlord pursuant to the Prime Lease. Nothing in this Sublease shall be construed or interpreted to grant any greater rights than the Sublandlord has received as Tenant from Landlord pursuant to the Prime Lease.

c. In the event of a conflict between the terms of the Prime Lease and the terms of this Sublease, as between Sublandlord and Subtenant, the terms of the Sublease shall control to the extent they are inconsistent with the terms of the Prime Lease and their respective counterpart provisions in the Prime Lease shall be excluded to such extent. In addition, the following sections and exhibits of the Prime Lease shall not apply to this Sublease as between Sublandlord and Subtenant: Section 2.2 ("Option to Extend"), Section 8 ("Brokers"), and Exhibit "C" ("Work Letter").

d. Subtenant also acknowledges and has read the provision of Section 11.4 ("Accessibility Disclosure") of the Prime Lease. A Certified Access Specialist (CASp) can inspect the subject premises and determine whether the subject premises comply with all of the applicable construction-related accessibility standards under state law. Although state law does not require a CASp inspection of the subject premises, the commercial property owner or lessor may not prohibit the lessee or tenant from obtaining a CASp inspection of the subject premises for the occupancy or potential occupancy of the lessee or tenant, if requested by the lessee or tenant. The parties shall mutually agree on the arrangements for the time and manner of the CASp inspection, the payment of the fee for the CASp inspection, and the cost of making any repairs necessary to correct violations of construction-related accessibility standards within the premises.

e. This Sublease, together with the exhibits attached hereto and the Prime Lease, contains the entire agreement between the parties regarding the subject matter contained herein and all prior negotiations and agreements are merged herein. If any provisions of this Sublease are held to be invalid or unenforceable in any respect, the validity, legality, or enforceability of the remaining provisions of this Sublease shall remain unaffected. This Sublease may not be modified or amended in any manner other than by a written agreement signed by the party to be charged.

f. Subtenant acknowledges that, under the Prime Lease, Sublandlord has expressly waived certain rights and remedies that might otherwise be available to tenants under California statutory and common law. Subtenant agrees that its rights under the Sublease are expressly subject to such waivers and that Subtenant is hereby making each of those waivers in favor of Sublandlord.

15. Sublandlord's Covenants, Representations and Warranties.

a. Sublandlord represents and warrants, as of the date hereof, to Subtenant as follows: (a) Sublandlord has delivered to Subtenant true and correct copies of the Prime Lease and has not been further modified, amended, or supplemented except as expressly set out herein (which may have been redacted to eliminate certain economic provisions which have no bearing upon this Sublease); (b) to Sublandlord's actual knowledge, the Prime Lease is in full force and effect; and (c) to Sublandlord's actual knowledge, neither Sublandlord nor Landlord are in default of the Prime Lease.

b. Sublandlord covenants to Subtenant that, so long as Subtenant is not in default of this Sublease: (a) Sublandlord shall, during the Term, timely perform each of its material obligations under the Prime Lease, unless performance is prevented or impaired by the act or omission of Subtenant; and (b) without first receiving the prior written consent of Subtenant (which will not be unreasonably withheld, conditioned or delayed), Sublandlord shall not terminate, amend or modify the Prime Lease in a manner which would materially adversely affect Subtenant's rights under this Sublease.

16. Broker. Sublandlord and Subtenant represent to each other that they have not dealt with any brokers in connection with this Sublease other than JLL, as "**Sublandlord's Broker**", and Re:Align, Inc., as "**Subtenant's Broker**," and the parties shall indemnify and hold each other harmless from and against any and all liability, loss, damage, expense, claim, action, demand, suit, or obligation, including but not limited to reasonable attorneys' fees, arising out of or relating to a respective breach of this representation. Sublandlord shall pay Sublandlord's Broker and cause Sublandlord's Broker to pay Subtenant's Broker any fee or commission due them in connection with this Sublease in accordance with a separate agreement or agreements.

17. Signage. Any suite, directional and lobby directory signage ("**Signage**") for Subtenant shall be subject to the approval of Landlord pursuant to the Prime Lease and shall be at Subtenant's expense. Sublandlord shall use reasonable efforts to obtain Landlord's approval of Subtenant's desired Signage. In the event Landlord does not approve any or all of such Signage, Sublandlord shall not be liable to Subtenant therefor.

18. Parking. Subtenant shall have the right, but not the obligation, to obtain from either the Landlord or the applicable parking facility operator, on a month-to-month basis, all or part of the number of parking passes to which Sublandlord is entitled under the Prime Lease (as further described in Section 6.2 to the Prime Lease), all subject to the terms (including the rental therefor) and conditions set forth in the Prime Lease.

19. Holding Over. Sublandlord and Subtenant recognize and agree that the damage to Sublandlord resulting from any failure by Subtenant to timely surrender possession of the Premises upon the Expiration Date will be substantial, will exceed the amount of the monthly installments of Base Rent payable hereunder, and will be impossible to accurately measure. In the event that Subtenant shall not immediately surrender the Premises on the Expiration Date or earlier termination of the Term, Subtenant shall be required to pay each month of such hold-over tenancy one hundred fifty percent (150%) the Rent in effect during the last month of the Term of this Lease. In addition to any other rights and remedies Sublandlord may have hereunder or at law, Subtenant agrees that if possession of the Premises is not surrendered to Sublandlord in the condition required herein on or before the Prime Lease Expiration Date, then Subtenant shall pay to Sublandlord for each month and for any portion of each month during which Subtenant holds over in the Premises after the Prime Lease Expiration Date Sublandlord's holdover damages under the Prime Lease with respect to the Prime Lease Premises. Subtenant agrees to indemnify and save Sublandlord harmless from and against any and all loss, cost, expense or liability resulting from a third party claim arising from the failure of, or the delay by, Subtenant in so surrendering the Premises on or before the Expiration Date, including, without limitation, any claims made by Landlord or any succeeding tenant founded on such failure. Nothing herein contained shall be deemed to permit Subtenant to retain possession of the Premises after the expiration or earlier termination date of the Term, and no acceptance by Sublandlord of payments from Subtenant shall be deemed to be other than on account of the amount to be paid by Subtenant in accordance with the provisions of this Paragraph 19, which provisions shall survive the Expiration Date.

20. Notice. Any notice, consent, approval, agreement, certification, request, invoice, bill, demand, statement, acceptance, or other communication required hereunder ("**Notice**") shall be in writing and shall have been duly given or furnished if delivered personally upon receipt, or refusal to receive, or sent by recognized overnight courier upon receipt, or refusal to receive, or after being mailed in a postpaid envelope (certified mail, return receipt requested, only) upon

receipt, or refusal to receive, addressed (i) to Sublandlord at 6903 Rockledge Drive, Suite 1500, Bethesda, Maryland 20817, Attention: General Counsel, with a copy to Attention: Managing Director of Global Development, Design and Construction at the same address, or (ii) to Subtenant at the Premises, or to such other address or addresses in the United States of America as either party may designate by a Notice given pursuant thereto.

21. Jury Trial. TO THE EXTENT PERMITTED UNDER APPLICABLE LAW, THE PARTIES DO HEREBY EXPRESSLY WAIVE ALL RIGHTS TO TRIAL BY JURY ON ANY CAUSE OF ACTION DIRECTLY OR INDIRECTLY INVOLVING THE TERMS, COVENANTS, OR CONDITIONS OF THIS SUBLEASE OR ANY MATTERS WHATSOEVER ARISING OUT OF OR IN ANY WAY CONNECTED WITH THIS SUBLEASE.

22. Interpretation and Meaning. All terms used in this Sublease shall have the same meaning as the terms used in the Prime Lease, unless specifically defined to the contrary in this Sublease.

23. Condition Precedent. Notwithstanding anything herein to the contrary, this Sublease is expressly conditioned on, and shall not become effective unless and until Landlord has consented to this Sublease by providing written notice of its consent to Sublandlord (which Sublandlord then shares with Subtenant) (the "**Consent**"). Both Sublandlord and Subtenant agree to cooperate and to use reasonable efforts to obtain the Consent from Landlord. Notwithstanding the foregoing, Sublandlord or Subtenant may terminate this Sublease if Landlord has not provided the Consent on or before the date which is forty-five (45) days after the date of the full execution of this Sublease by Sublandlord and Subtenant. Either party may exercise such termination option by providing written notice to the other party by 5:00 p.m. on the tenth (10th) day following the end of such forty-five (45) day period, provided Landlord shall not have provided its Consent prior to the date of such exercise of the termination option. In the event of such termination, Sublandlord and Subtenant shall be released and discharged from any obligation or liability arising hereunder and Sublandlord shall promptly return any Security Deposit and Rent Payment paid by the Subtenant to Subtenant.

24. Authority. Each party represents and warrants to the other that it has the power and authority to enter into this Sublease, and that this Sublease is the valid and binding obligation of such party and is enforceable against it in accordance with its terms, subject to general equitable principles and creditors' rights.

25. Counterparts. This Sublease may be executed in multiple counterparts, all of which together shall constitute and be one and the same instrument. Execution and delivery of this Sublease by facsimile or pdf shall be sufficient for all purposes and shall be binding on any person or entity who so executes, subject to any conditions set forth herein.

26. Governing Law. This Sublease shall be construed and enforced in accordance with the laws of the State of California, without regard to any conflict of interest laws.

[Signatures follow on next page]

IN WITNESS WHEREOF, Sublandlord and Subtenant have executed this Sublease as of the dates set forth below.

SUBLANDLORD:

HOST HOTELS & RESORTS, L.P., a Delaware limited partnership

By: _____
Name: _____
Title: _____
Date: _____,2019

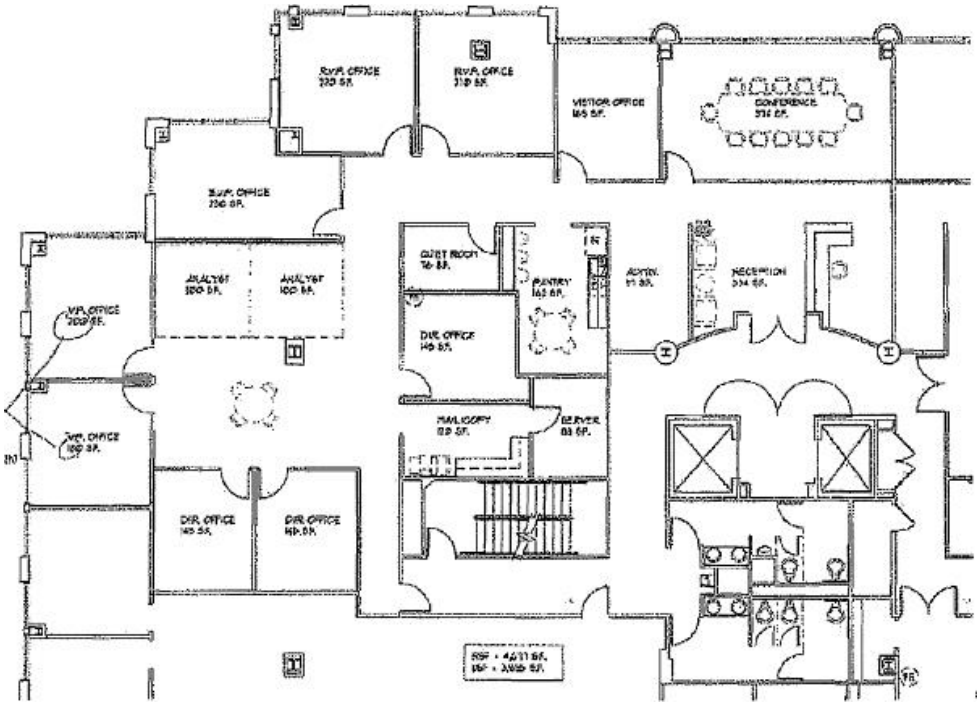
SUBTENANT:

ONCTERNAL THERAPEUTICS, INC., a Delaware corporation

By: /s/ Richard Vincent
Name: **Richard Vincent**
Title: **CFO**
Date: _____,2019

Exhibit A

Premises



(The attached drawing is included merely to show the delineation of the Premises and not for identifying interior walls, furniture or possible uses of spaces.)

IN WITNESS WHEREOF, Sublandlord and Subtenant have executed this Sublease as of the dates set forth below.

SUBLANDLORD:

HOST HOTELS & RESORTS, L.P., a Delaware limited partnership

By: Host Hotels & Resorts, Inc., a Maryland Corporation, its general partner

By: **/s/ Nathan S. Tyrrell**
Name: Nathan S. Tyrrell
Title: Executive Vice President
Date: May 2, 2019

SUBTENANT:

ONCTERNAL THERAPEUTICS, INC., a Delaware corporation

By: _____
Name: _____
Title: _____
Date: _____,2019

Exhibit B

Declaration

Attached to and made part of the Sublease dated as of the _____ day of _____, 2019, entered into by and between **Host Hotels & Resorts, L.P.,** a Delaware limited partnership, as Sublandlord, and **Oncternal Therapeutics, Inc.,** a Delaware corporation, as Subtenant.

Sublandlord and Subtenant do hereby declare that (a) the Commencement Date is hereby established to be _____, (b) the Expiration Date is hereby established to be March 31, 2021, and (c) there are 4,677 rentable square feet in the Premises. The Sublease is in full force and effect as of the date hereof, sublandlord has fulfilled all of its obligations under the Sublease required to be fulfilled by Sublandlord on or prior to the execution of this Declaration by Subtenant, and Subtenant has no right of set-off against any rentals as of the Date Subtenant has executed this Declaration.

SUBLANDLORD:

HOST HOTELS & RESORTS, L.P., a Delaware limited liability partnership

By: _____
Name: _____
Title: _____
Date: _____

SUBTENANT:

ONCTERNAL THERAPEUTICS, INC., a Delaware corporation

By: **/s/ Richard Vincent**
Name: **Richard Vincent**
Title: **CFO**
Date: _____

Exhibit C

FF&E

Furniture listed below and shown on the plan attached hereto as Schedule 1:

(1) Haworth Compose Admin Station

(3) Haworth Compose Standard Stations

(10) Tuohy Xpect, Prato and Spyda Private offices; each office includes a desk, freestanding lateral with stack on bookcase, Workwall, overhead with task light and white back painted glass board, and storage tower

(2) Offices with 36" Round Table

(1) Office with 30 x 60 Oval Table

(26) Haworth Zody Guest Chairs

(3) Haworth Zody Task Chair

(2) Bernhardt Edge Lounge Chairs

(2) Bernhardt Linc Occasional Table

(18) Haworth Zody Conference Chairs

(1) Nucraft Flow 180 x 54 Conference Table

(2) Nucraft Flow 54" wide credenzas

(1) Tuohy 48" Round Table

(3) Humanscale Double Monitor Arms

(10) Humanscale Horizon Task Lights

(3) Humanscale Element Task Light with Tech Base

(1) Bernhardt Blaine Sofa

(3) Haworth Mini Mobile Chairs

(1) Refrigerator

(1) Dishwasher

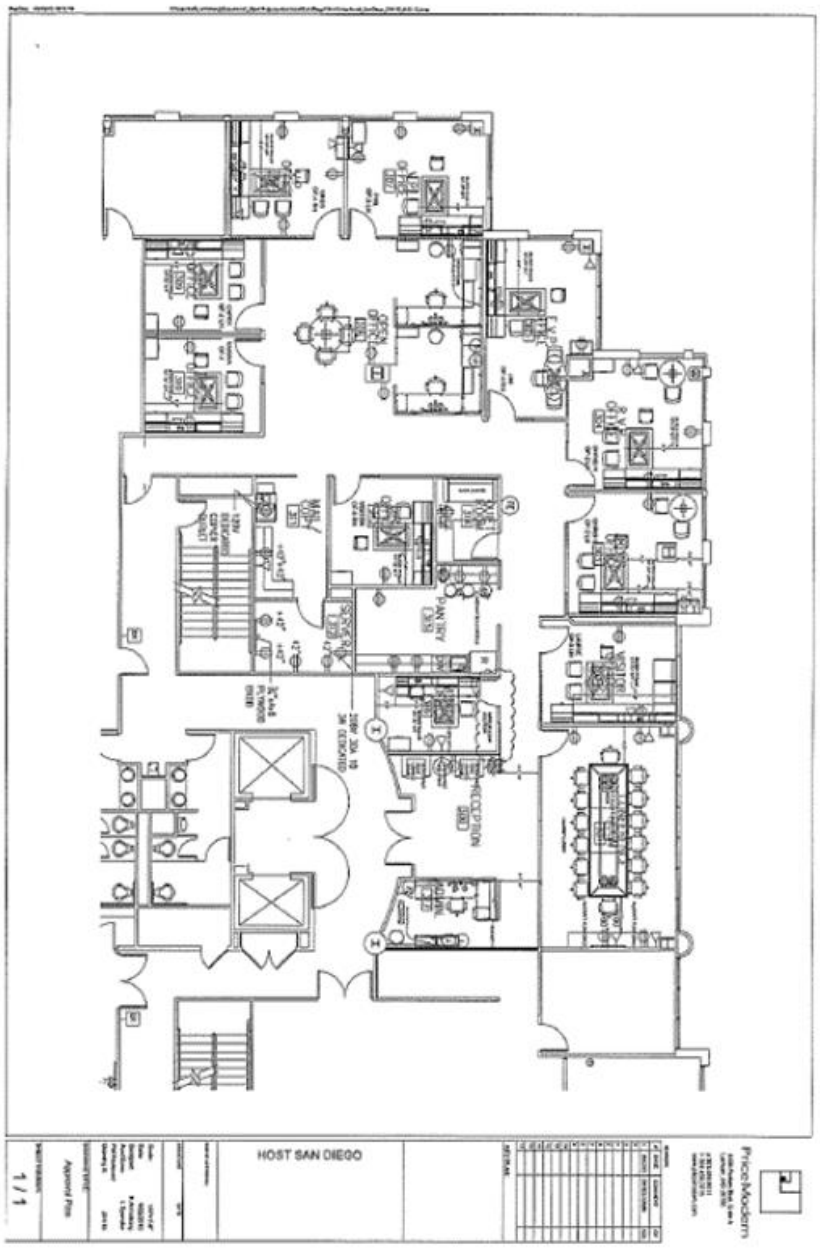
(1) Microwave

(1) Tall table with 3 stools

Artwork listed on Schedule 2 attached hereto

AV and other equipment listed on Schedule 3 attached hereto

Schedule 2



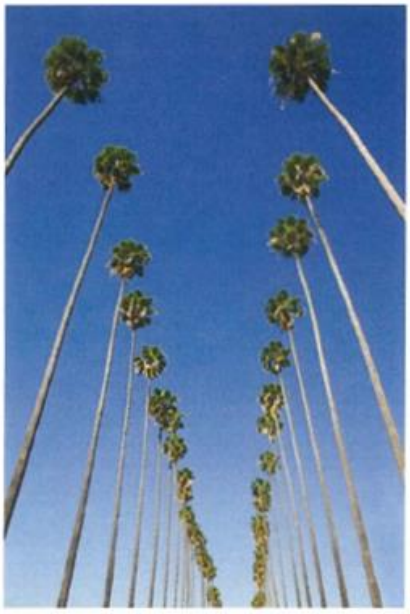
Schedule 2

KEVIN BARRY
FINE ART ASSOCIATES

Qty: 1
Medium: print on paper
Image size: 30"w x 20"h
Matte: 3" white
Moulding: 2" Matte White
Face: Plexi glass
OD size: 40"w x 30"h
Hardware: D-ring
SM: Los Angeles [redacted]

[redacted]

2525 MICHIGAN AVENUE, SUITE A8
SANTA MONICA, CA 90404
310.264.7777
kevinbarryfineart.com



Qty: 1
Medium: print on paper
Image size: 20"w x 30"h
Matte: 3" white
Moulding: 2" Matte White
Face: Plexi glass
OD size: 30"w x 40"h
Hardware: D-ring
SM: Los Angeles [redacted]

[redacted]

2525 MICHIGAN AVENUE, SUITE A8
SANTA MONICA, CA 90404
310.264.7777
kevinbarryfineart.com

KEVIN BARRY
FINE ART ASSOCIATES

Qty: 1
Medium: print on paper
Image size: 22"w x 26"h
Matte: 3" white
Moulding: 2" Matte White
Face: Plexi glass
OD size: 32"w x 36"h
Hardware: D-ring
SM: Del Mar [redacted]

[redacted]

2525 MICHIGAN AVENUE, SUITE A8
SANTA MONICA, CA 90404
310.264.7777
kevinbarryfineart.com

Qty: 1
Medium: print on paper
Image size: 17"w x 17"h
Matte: 3" white
Moulding: 2" Matte White
Face: Plexi glass
OD size: 27"w x 27"h
Hardware: D-ring
SM: San Diego [redacted]

[redacted]

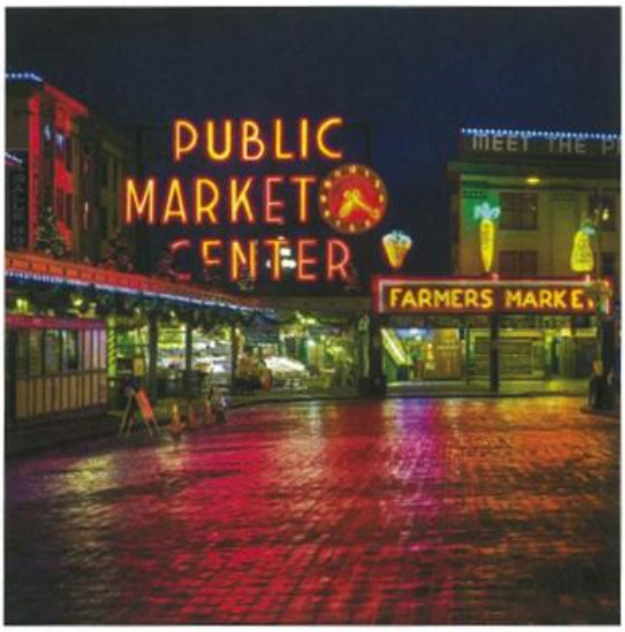
2525 MICHIGAN AVENUE, SUITE A8
SANTA MONICA, CA 90404
310.264.7777
kevinbarryfineart.com

KEVIN BARRY
FINE ART ASSOCIATES

Qty: 1
Medium: print on paper
Image size: 30"w x 20"h
Matte: 3" white
Moulding: 2" Matte White
Face: Plexi glass
OD size: 40"w x 30"h
Hardware: D-ring
SM: Hawaii [redacted]

[redacted]

2525 MICHIGAN AVENUE, SUITE A8
SANTA MONICA, CA 90404
310.264.7777
kevinbarryfineart.com



Qty: 1
Medium: print on paper
Image size: 17"w x 17"h
Matte: 3" white
Moulding: 2" Matte White
Face: Plexi glass
OD size: 27"w x 27"h
Hardware: D-ring
SM: Seattle [redacted]

[redacted]

2525 MICHIGAN AVENUE, SUITE A8
SANTA MONICA, CA 90404
310.264.7777
kevinbarryfineart.com

Qty: 1
Medium: print on paper
Image size: 20"w x 30"h
Matte: 3" white
Moulding: 2" Matte White
Face: Plexi glass
OD size: 30"w x 40"h
Hardware: D-ring
SM: Denver [redacted]

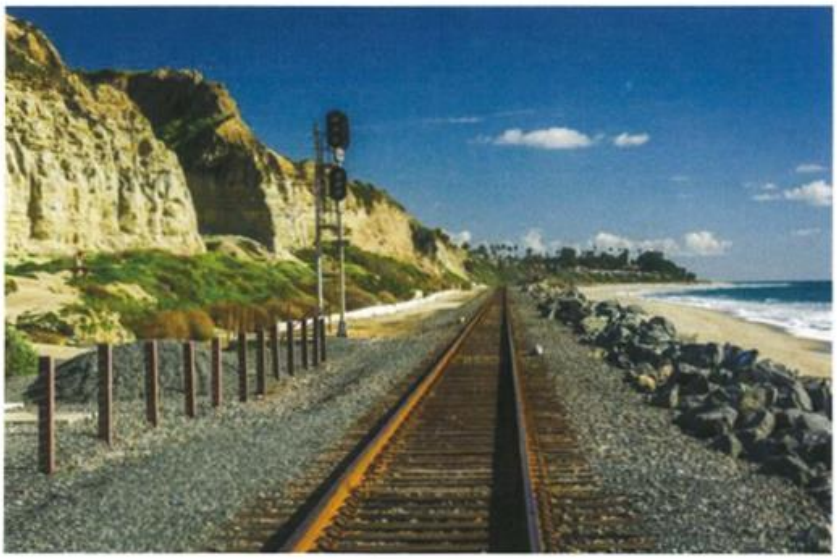
[redacted]

2525 MICHIGAN AVENUE, SUITE A8
SANTA MONICA, CA 90404
310.264.7777
kevinbarryfineart.com

Qty: 1
Medium: print on paper
Image size: 30"w x 20"h
Matte: 3" white
Moulding: 2" Matte White
Face: Plexi glass
OD size: 40"w x 30"h
Hardware: D-ring
SM: Phoenix [redacted]

[redacted]

2525 MICHIGAN AVENUE, SUITE A8
SANTA MONICA, CA 90404
310.264.7777
kevinbarryfineart.com



Qty: 1
Medium: print on paper
Image size: 30"w x 20"h
Matte: 3" white
Moulding: 2" Matte White
Face: Plexi glass
OD size: 40"w x 30"h
Hardware: D-ring
SM: Orange County [redacted]

[redacted]

2525 MICHIGAN AVENUE, SUITE A8
SANTA MONICA, CA 90404
310.264.7777
kevinbarryfineart.com

Qty: 1
Medium: print on paper
Image size: 20"w x 30"h
Matte: 3" white
Moulding: 2" Matte White
Face: Plexi glass
OD size: 30"w x 40"h
Hardware: D-ring
SM: Donkey [redacted]

[redacted]

2525 MICHIGAN AVENUE, SUITE A8
SANTA MONICA, CA 90404
310.264.7777
kevinbarryfineart.com

KEVIN BARRY
FINE ART ASSOCIATES

Qty: 1
Medium: print on paper (artwork provided by client)
Image size: 38"w x 30"h
Matte: 3" white
Moulding: 2" Matte White
Face: Plexi glass
OD size: 48"w x 40"h
Hardware: D-ring
SM: GOLF[redacted]

[redacted]

2525 MICHIGAN AVENUE, SUITE A8
SANTA MONICA, CA 90404
310.264.7777
kevinbarryfineart.com

KEVIN BARRY
FINE ART ASSOCIATES

Qty: 1
Title: Last Wave
Artist: Hobbs
Medium: Giclee on stretched canvas
Image size: 60"w x 48"h
Moulding: 7/16" black floater frame
OD size: 61 ½"w x 49 ½"h
Hardware: Security
SM: Lobby waiting area

[redacted]

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310.264.7777
kevinbarryfineart.com

KEVIN BARRY
FINE ART ASSOCIATES

Qty: 1
Title: Stratosphere
Artist: Ridgers
Medium: giclee on stretched canvas
Image size: 24"w x 60"h
Moulding: 7/16" black floater frame
OD size: 25 ½"w x 61 ½"h
Hardware: Security
SM: End of Hallway

[redacted]

2525 MICHIGAN AVENUE, SUITE A8
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310.264.7777
kevinbarryfineart.com

KEVIN BARRY
FINE ART ASSOCIATES

Qty: 1
Title: Away we go I
Artist: Stockstill
Material: Giclee on stretched canvas
Image size: 48"w x 48"h
Moulding: 7/16" black floater frame
OD size: 49 ½"w x 49 ½"h
Hardware: Security
SM: Conference room

[redacted]

2525 MICHIGAN AVENUE, SUITE A8
SANTA MONICA, CA 90404
310.264.7777
kevinbarryfineart.com

Schedule 3

AV and Other Equipment

Equipment	**Count**
Cisco 3650	1
Meraki MR34 APs	2
AudioCode Unit (for Phones)	1
PolyCom Lync Phones	15
Juniper Firewall	1
RoboShot 30 Camera (conference room)	1
Polycom CX8000 (conference room)	1
80” Touch Screen Display (conference room)	1
Presentation System 300 (conference room)	1
Supporting modules and hardware (conference room)	n/a

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, James B. Breitmeyer, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Oncternal 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 condensed consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

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

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

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

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

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

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

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

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

/s/ James B. Breitmeyer
President and Chief Executive Officer
(Principal Executive Officer)

Dated: August 9, 2019

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Richard G. Vincent, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Oncternal 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 condensed consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

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

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

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

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

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

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

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

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

/s/ Richard G. Vincent
Chief Financial Officer
(Principal Financial Officer)

Dated: August 9, 2019

Exhibit 32.1

CERTIFICATION
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

In connection with the Quarterly Report on Form 10-Q of Oncternal Therapeutics, Inc. (the "Company") for the period ended June 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, James B. Breitmeyer, as Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ James B. Breitmeyer
President and Chief Executive Officer
(Principal Executive Officer)

Dated: August 9, 2019

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

In connection with the Quarterly Report on Form 10-Q of Oncternal Therapeutics, Inc. (the "Company") for the period ended June 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Richard G. Vincent, as Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Richard G. Vincent
Chief Financial Officer
(Principal Financial Officer)

Dated: August 9, 2019

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.