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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2019

or

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

For the transition period from to .

Commission File Number: 001-38905

NextCure, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**04-5231247**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
9000 Virginia Manor Road, Suite 200 **Beltsville, Maryland**	**20705**
(Address of principal executive offices)	(Zip Code)

(240) 399-4900

(Registrant's telephone number, including area code)

(Former name, former address and former fiscal year, if changed since last report)

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 per share	NXTC	Nasdaq Global Select Market

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See 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 November 8, 2019, the registrant had 22,753,960 shares of common stock, par value $0.001 per share, issued and outstanding.

NextCure, Inc.
Form 10-Q
For the Quarter Ended September 30, 2019

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

NEXTCURE, INC.
CONDENSED BALANCE SHEETS
(unaudited, in thousands, except share and per share amounts)

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 9,935	$ 135,173
Marketable securities	174,147	—
Restricted cash	1,289	460
Prepaid expenses and other current assets	3,777	152
Total current assets	189,148	135,785
Property and equipment, net	12,031	11,407
Other assets	3,945	436
Total assets	$ 205,124	$ 147,628
Liabilities, Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 2,576	$ 2,483
Accrued liabilities	2,582	2,411
Deferred rent, current portion	—	28
Term loan, current portion	1,250	387
Deferred revenue, current portion	6,199	4,989
Total current liabilities	12,607	10,298
Deferred rent, net of current portion	434	242
Term loan, net of current portion	3,750	73
Deferred revenue, net of current portion	17,684	21,736
Total liabilities	34,475	32,349
Commitments and contingencies (Note 7)		
Redeemable preferred stock:		
Series A Preferred Stock, par value of $0.001 per share; 0 and 68,181,819 shares authorized, issued and outstanding at September 30, 2019 and December 31, 2018, respectively	—	71,000
Series B Preferred Stock, par value $0.001 per share; 0 and 56,828,852 shares authorized at September 30, 2019 and December 31, 2018, respectively, 0 and 56,828,851 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	—	91,223
Total redeemable preferred stock	—	162,223
Stockholders' equity (deficit):		
Preferred stock, par value of $0.001 per share; 10,000,000 and 0 shares authorized at September 30, 2019 and December 31, 2018. No shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	—	—
Common stock, par value of $0.001 per share; 100,000,000 and 158,745,671 shares authorized at September 30, 2019 and December 31, 2018, respectively, 22,739,345, and 1,374,812 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	23	1
Additional paid-in capital	240,791	352
Accumulated other comprehensive loss	(58)	—
Accumulated deficit	(70,107)	(47,297)
Total stockholders' equity (deficit)	170,649	(46,944)
Total liabilities, preferred stock and stockholders' equity (deficit)	$ 205,124	$ 147,628

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

NEXTCURE, INC.
CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(unaudited, in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenue:				
Revenue from research and development arrangement	$ 1,583	$ —	$ 4,342	$ —
Operating expenses:				
Research and development	8,663	4,895	22,819	13,539
General and administrative	2,622	925	6,995	2,590
Total operating expenses	11,285	5,820	29,814	16,129
Loss from operations	(9,702)	(5,820)	(25,472)	(16,129)
Other income, net	1,268	110	2,662	192
Net loss	(8,434)	(5,710)	(22,810)	(15,937)
Net loss per common share—basic and diluted	$ (0.37)	$ (4.17)	$ (1.81)	$ (11.64)
Weighted average number of common shares —basic and diluted	22,715,567	1,369,212	12,609,219	1,369,212
Comprehensive loss:				
Unrealized loss on marketable securities	(58)	—	(58)	—
Total comprehensive loss	$ (8,492)	$ (5,710)	$ (22,868)	$ (15,937)

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

NEXTCURE, INC.
CONDENSED STATEMENTS OF PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(unaudited, in thousands, except share data)

Nine Months Ended September 30, 2019

	Preferred Stock				Stockholders' Equity (Deficit)					
	Series A		Series B		Common Stock		Additional Paid-in	Accumulated Other Comprehensive Loss	Accumulated	Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Capital		Deficit	(Deficit)
Balance as of December 31, 2018	68,181,819	$ 71,000	56,828,851	$ 91,223	1,374,812	$ 1	$ 352	$ —	$ (47,297)	$ (46,944)
Stock-based compensation	—	—	—	—	—	—	383	—	—	383
Issuance of common stock	—	—	—	—	4,697	—	4	—	—	4
Net loss	—	—	—	—	—	—	—	—	(6,155)	(6,155)
Balance as of March 31, 2019	68,181,819	71,000	56,828,851	91,223	1,379,509	1	739	—	(53,452)	(52,712)
Initial public offering, net of issuance costs of $9.4M	—	—	—	—	5,750,000	6	76,848	—	—	76,854
Conversion of preferred stock to common stock	(68,181,819)	(71,000)	(56,828,851)	(91,223)	15,560,569	15	162,208	—	—	162,223
Stock-based compensation expense	—	—	—	—	—	—	412	—	—	412
Issuance of common stock upon exercise of vested options, $0.001 par value	—	—	—	—	24,687	1	38	—	—	39
Net loss	—	—	—	—	—	—	—	—	(8,221)	(8,221)
Balance as of June 30, 2019	—	—	—	—	22,714,765	23	240,245	—	(61,673)	178,595
Stock-based compensation	—	—	—	—	—	—	524	—	—	524
Issuance of common stock	—	—	—	—	24,580	—	22	—	—	22
Unrealized loss on marketable securities	—	—	—	—	—	—	—	(58)	—	(58)
Net loss	—	—	—	—	—	—	—	—	(8,434)	(8,434)
Balance as of September 30, 2019	—	$ —	—	$ —	22,739,345	$ 23	$ 240,791	$ (58)	$ (70,107)	$ 170,649

Nine Months Ended September 30, 2018

	Preferred Stock				Stockholders' Deficit					
	Series A		Series B		Common Stock		Additional Paid-in	Accumulated Other Comprehensive Loss	Accumulated	Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Capital		Deficit	Deficit
Balance as of December 31, 2017	40,000,000	$ 40,000	—	$ —	1,369,212	$ 1	$ 84	$ —	$ (24,498)	$ (24,413)
Stock-based compensation	—	—	—	—	—	—	24	—	—	24
Net loss	—	—	—	—	—	—	—	—	(4,996)	(4,996)
Balance as of March 31, 2018	40,000,000	40,000	—	—	1,369,212	1	108	—	(29,494)	(29,385)
Issuance of Series A-3 preferred stock, net of issuance costs of $0	28,181,819	31,000	—	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	24	—	—	24
Net loss	—	—	—	—	—	—	—	—	(5,231)	(5,231)
Balance as of June 30, 2018	68,181,819	71,000	—	—	1,369,212	1	132	—	(34,725)	(34,592)
Stock-based compensation	—	—	—	—	—	—	90	—	—	90
Issuance of common stock	—	—	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	(5,710)	(5,710)
Balance as of September 30, 2018	68,181,819	$ 71,000	—	$ —	1,369,212	$ 1	$ 222	$ —	$ (40,435)	$ (40,212)

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

NEXTCURE, INC.
CONDENSED STATEMENTS OF CASH FLOWS
(unaudited, in thousands)

	Nine Months Ended September 30,	
	2019	2018
Cash flows from operating activities:		
Net loss	$ (22,810)	$ (15,937)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,933	1,159
Stock-based compensation	1,319	138
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(3,660)	(89)
Accounts payable	93	776
Accrued liabilities and other current liabilities	335	(526)
Deferred revenue	(2,842)	—
Net cash used in operating activities	(25,632)	(14,479)
Cash flows from investing activities:		
Purchase of property and equipment	(2,557)	(1,159)
Purchase of marketable securities	(174,205)	—
Net cash used in investing activities	(176,762)	(1,159)
Cash flows from financing activities:		
Proceeds from initial public offering, net of issuance costs	77,264	—
Proceeds from issuance of preferred stock, net of issuance costs	—	31,000
Proceeds from issuance of common stock	65	—
Proceeds from the term loan	4,540	—
Deferred financing costs	(134)	(14)
Payments of the term loan	—	(300)
Net cash provided by financing activities	81,735	30,686
Net (decrease) increase in cash, cash equivalents and restricted cash	(120,659)	15,048
Cash, cash equivalents and restricted cash—beginning of year	135,633	9,287
Cash, cash equivalents and restricted cash—end of period	$ 14,974	$ 24,335
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 137	$ 18
Supplemental disclosures of noncash investing and financing activities:		
Purchase of property and equipment included in accrued liabilities	$ 73	$ 76
Deferred financing costs included in accrued liabilities	$ 134	$ —
Conversion of convertible preferred stock into common stock	$ 162,223	$ —

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

NEXTCURE, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
(unaudited)

1. Nature of the Business

Organization

NextCure, Inc. ("NextCure" or the "Company") was incorporated in Delaware in September 2015 and is headquartered in Beltsville, Maryland. The Company is a clinical-stage biopharmaceutical company committed to discovering and developing novel, first-in-class immunomedicines to treat cancer and other immune-related diseases by restoring normal immune function. Through its proprietary Functional, Integrated, NextCure Discovery in Immuno-Oncology ("FIND-IO") platform, the Company studies various immune cells in order to discover and understand targets and structural components of immune cells and their functional impact in order to develop immunomedicines. Since inception, the Company has devoted substantially all of its efforts and financial resources to organizing and staffing the Company, identifying business development opportunities, raising capital, securing intellectual property rights related to the Company's product candidates, building and optimizing the Company's manufacturing capabilities and conducting discovery, research and development activities for the Company's product candidates, discovery programs and its FIND-IO platform.

Initial Public Offering

On May 13, 2019, the Company closed its initial public offering ("IPO"), in which the Company issued and sold 5,750,000 shares of common stock at a public offering price of $15.00 per share, for net proceeds to the Company of approximately $77.0 million after deducting underwriting discounts and commissions of $6.0 million and offering expenses of approximately $3.4 million.

In preparation for the IPO, on May 3, 2019, the Company effected a one-for-8.0338 reverse stock split of its issued and outstanding common stock. The par value and authorized shares of common stock were not adjusted as a result of the reverse stock split. All of the share and per share information presented in the accompanying financial statements has been adjusted to reflect the reverse common stock split on a retroactive basis for all periods and as of all dates presented.

Upon the closing of the IPO, on May 13, 2019, all of the outstanding shares of the Company's convertible preferred stock automatically converted into 15,560,569 shares of common stock at the applicable conversion ratio then in effect. Subsequent to the closing of the IPO, there were no shares of preferred stock outstanding.

Upon the closing of the IPO, on May 13, 2019, the Company's certificate of incorporation was amended and restated to provide for 100,000,000 authorized shares of common stock with a par value of $0.001 per share and 10,000,000 authorized shares of preferred stock with a par value of $0.001 per share.

Liquidity

The Company has not generated any revenue to date from product sales and does not expect to generate any revenues from product sales in the foreseeable future. Through September 2019, the Company has funded its operations primarily with proceeds from the sale of preferred stock and proceeds from the Company's agreement with Eli Lilly and Company (Note 6) and proceeds from the IPO. The Company expects to incur additional operating losses and negative operating cash flows for the foreseeable future.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed financial statements as of September 30, 2019 and for the three and nine months ended September 30, 2019 and 2018 have been prepared by the Company in conformity with accounting principles generally accepted in the United States of America ("GAAP") and pursuant to the rules and regulations of the Securities

NEXTCURE, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
(unaudited)

and Exchange Commission ("SEC") for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. Accordingly, these condensed financial statements should be read in conjunction with the Company's audited financial statements and the notes thereto as of and for the year ended December 31, 2018, which are included in the Company's final prospectus that forms a part of the Company's Registration Statement on Form S-1 (Reg. No. 333-230837) (the "Registration Statement"), as filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, on May 9, 2019.

The unaudited interim condensed financial statements have been prepared on the same basis as the audited financial statements. In the opinion of management, the accompanying unaudited interim condensed financial statements contain all adjustments necessary for a fair statement of the Company's financial position as of September 30, 2019 and condensed results of operations and cash flows for the three and nine months ended September 30, 2019 and 2018. Such adjustments are of a normal and recurring nature. The results of operations for the three and nine months ended September 30, 2019 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2019.

Use of Estimates

The preparation of financial statements in accordance with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, management evaluates its estimates, including those related to accrued expenses, revenue recognition, the valuation of equity-based compensation, including incentive stock options, common stock and restricted common stock, as well as income taxes. The Company bases its estimates on various assumptions that the Company believes to be reasonable under the circumstances. Although actual results could differ from those estimates, management does not believe that such differences would be material.

Restricted Cash

The Company is required, as a condition of its Term Loan (Note 8), to maintain cash collateral on deposit in a segregated money market bank account equal to the principal portion of the Term Loan, as determined on a quarterly basis. The bank may restrict withdrawals or transfers by or on behalf of the Company that would violate this requirement. The required reserve totaled $5.0 million as of September 30, 2019. This amount is presented in part as restricted cash and in part as other assets on the accompanying balance sheet.

The following table reconciles cash and cash equivalents and restricted cash per the balance sheet to the statement of cash flows (in thousands):

	September 30, 2019	December 31, 2018
Cash and cash equivalents	$ 9,935	$ 135,173
Restricted cash (including $3,750 in other assets)	5,039	460
Total	$ 14,974	$ 135,633

Marketable Securities

Our investments primarily consist of government debt securities, corporate bonds and agency bonds. These marketable securities are classified as available-for-sale, and as such, are reported at fair value on our condensed balance sheets. Unrealized holding gains and losses are reported within accumulated other comprehensive income (loss) as a separate component of stockholders' equity. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization, together with interest on securities, are included in other income, net, on our condensed statements of operations.

NEXTCURE, INC.
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If a decline in the fair value of a marketable security below our cost basis is determined to be other than temporary, such marketable security is written down to its estimated fair value as a new cost basis and the amount of the write-down is included in earnings as an impairment charge. The cost of securities sold is based on the specific identification method.

Revenue Recognition

The Company has adopted Accounting Standards Codification Topic 606, Revenue from Contracts with Customers ("ASC 606"). Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine the appropriate amount of revenue to be recognized for arrangements determined to be within the scope of ASC 606, the Company performs the following five steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. The Company only applies the five-step model to contracts when it is probable that the Company will collect consideration to which it is entitled in exchange for the goods or services it transfers to the customer.

The Company evaluates customer options for material rights or options to acquire additional goods or services for free or at a discount. If the customer options are determined to represent a material right, the material right is recognized as a separate performance obligation at the outset of the arrangement.

Performance obligations are promised goods or services in a contract to transfer a distinct good or service to the customer and are considered distinct when (i) the customer can benefit from the good or service on its own or together with other readily available resources and (ii) the promised good or service is separately identifiable from other promises in the contract. In assessing whether promised goods or services are distinct, the Company considers factors such as the stage of development of the underlying intellectual property, the capabilities of the customer to develop the intellectual property on its own or whether the required expertise is readily available and whether the goods or services are integral to or dependent on other goods or services in the contract.

The Company estimates the transaction price based on the amount expected to be received for transferring the promised goods or services in the contract. Consideration generally may include fixed consideration or variable consideration. Should an arrangement include variable consideration, the Company will evaluate the amount of potential payments and the likelihood that the payments will be received. The Company will utilize either the most likely amount method or expected amount method to estimate the amount expected to be received based on which method best predicts the amount expected to be received. The amount of variable consideration that is included in the transaction price may be constrained and will be included in the transaction price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period.

The Company's contracts may include development and regulatory milestone payments which would be assessed under the most likely amount method and constrained if it is probable that a significant revenue reversal would occur. Milestone payments that are not within the Company's control or the licensee's control, such as regulatory approvals, will not be considered probable of being achieved until those approvals are received. At the end of each reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments would be recorded on a cumulative catch-up basis, which would affect collaboration revenues in the period of adjustment.

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company will recognize revenue at the later of (i) when the related sales occur and (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

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The Company allocates the transaction price based on the estimated stand-alone selling price of each of the performance obligations. The Company must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. The Company utilizes key assumptions to determine the stand-alone selling price for service obligations, which may include other comparable transactions, pricing considered in negotiating the transaction and the estimated costs. Additionally, in determining the standalone selling price for material rights, the Company may reference comparable transactions, clinical trial success probabilities and estimates of option exercise likelihood. Variable consideration will be allocated specifically to one or more performance obligations in a contract when the terms of the variable consideration relate to the satisfaction of the performance obligation and the resulting amounts allocated are consistent with the amounts the Company would expect to receive for the satisfaction of each performance obligation.

The consideration allocated to each performance obligation is recognized as revenue when control is transferred for the related goods or services. For performance obligations which consist of licenses and other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Upfront payments and fees are recorded as deferred revenue upon receipt or when due until the Company performs its obligations under these arrangements. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current portion of deferred revenue in the accompanying condensed balance sheets. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, net of current portion. Amounts are recorded as accounts receivable when the Company’s right to consideration is unconditional.

Recently Issued Accounting Pronouncements

The Company qualifies as an emerging growth company (“EGC”) as defined under the Jumpstart Our Business Startups Act (the “JOBS Act”). Using exemptions provided under the JOBS Act provided to EGCs, the Company has elected to defer compliance with new or revised financial accounting standards until it is required to comply with such standards.

In February 2016, the FASB issued ASU No. 2016-02, Leases (“ASU 2016-02”). The new guidance will require lessees to record most leases on their balance sheets and recognize the related expenses on their income statements in a manner similar to current practice. ASU 2016-02 states that a lessee would recognize a lease liability for the obligation to make lease payments and a right-to-use asset for the right to use the underlying asset for the lease term. The standard is effective for the Company January 1, 2020.The Company continues to determine if it will elect to use the practical expedients permitted by the guidance and continues to gather data required to comply with the guidance. Based on the work completed to date, the Company is considering the implications of adopting the new standard, including the discount rate to be used in valuing new and existing leases and all applicable financial statement disclosures required by the new guidance. The Company is continuing to evaluate the effect of adoption and anticipates that it will result in the recognition of additional assets and corresponding liabilities related to the existing leases on its balance sheet. The Company is assessing any potential impacts on its internal controls, business processes, and accounting policies related to both the implementation of, and ongoing compliance with, the new guidance.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments (“ASU 2016-13”). ASU 2016-13 will require credit losses to be reported using an expected losses model rather than the incurred losses model that is currently used, and will require additional disclosures related to credit risks. For available-for-sale debt securities with unrealized losses, this standard will require allowances to be recorded instead of reducing the amortized cost of the investment. ASU 2016-13 will be effective for non-emerging growth companies for fiscal years beginning December 15, 2019 and interim periods within those fiscal years, and will be effective for the Company for fiscal years beginning after December 15, 2020, and interim periods

within fiscal years beginning after December 15, 2021, assuming the Company remains an emerging growth company. Early adoption is permitted. The Company is currently evaluating the effects the adoption of ASU 2016-13 will have on its financial statements.

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement—Disclosure Framework-Changes to the Disclosure Requirement for Fair Value Measurement ("ASU 2018-13"). The amendments in ASU 2018-13 modify the disclosure requirements on fair value measurements in ASC 820, Fair Value Measurement, based on the concepts in the FASB Concepts Statement, including the consideration of costs and benefits. ASU 2018-13 will be effective for all companies for fiscal periods beginning after December 15, 2019 and interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the effects the adoption of ASU 2018-13 will have on its financial statements.

In November 2018, the FASB issued ASU No. 2018-18, Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606 ("ASU 2018-18"). ASU 2018-18 clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer in the context of a unit of account. In those situations, all the guidance in Topic 606 should be applied, including recognition, measurement, presentation and disclosure requirements. The amendment also adds unit of account guidance in Topic 808 to align with the guidance in Topic 606 (that is, a distinct good or service) when an entity is assessing whether the collaborative arrangement or a part of the arrangement is within the scope of Topic 606. Lastly, ASU 2018-18 provides that in a transaction with a collaborative arrangement participant that is not directly related to sales to third parties, presenting the transaction together with revenue recognized under Topic 606 will be precluded if the collaborative arrangement participant is not a customer. ASU 2018-18 will be effective for non-emerging growth companies for fiscal years beginning after December 15, 2019 and interim periods within those fiscal years, and will be effective for the Company for fiscal years beginning after December 15, 2020 and interim periods within fiscal years beginning after December 15, 2021, assuming the Company remains an emerging growth company. Early adoption is permitted. The Company is currently evaluating these clarifications for the accounting and presentation for its collaborative arrangements within the scope of Topic 808, but does not expect that the adoption of ASU 2018-18 will have any impact.

3. Investments

Investments consist of the following (in thousands):

	September 30, 2019			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
U.S. treasury securities	$ 19,982	$ 1	$ —	$ 19,983
Agency bonds	47,178	—	(17)	47,161
Corporate bonds	107,045	20	(62)	107,003
Total	$ 174,205	$ 21	$ (79)	$ 174,147

As of September 30, 2019, no investments are considered to be other-than-temporarily impaired. The Company uses the specific identification method when calculating realized gains and losses. For the three and nine months ended September 30, 2019, the Company recorded no realized gains and losses on available-for-sale securities.

4. Fair Value of Financial Instruments

The Company has certain financial assets recorded at fair value, which have been classified as Level 1, 2 or 3 within the fair value hierarchy as described in the accounting standards for fair value measurements.

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

NEXTCURE, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
(unaudited)

Level 2—Inputs other than Level 1 inputs that are either directly or indirectly observable, such as quoted market prices, interest rates and yield curves.

Level 3—Unobservable inputs developed using estimates of assumptions developed by the Company, which reflect those that a market participant would use.

To the extent the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair values requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized as Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The following tables set forth the fair value of the Company's financial assets by level within the fair value hierarchy (in thousands):

	September 30, 2019				
	Carrying Amount	Fair Value	Level 1	Level 2	Level 3
Cash equivalents:					
Money market	$ 5,465	$ 5,465	$ 5,465	$ —	$ —
Marketable securities:					
U.S. treasury securities	19,982	19,983	—	19,983	—
Agency bonds	47,178	47,161	—	47,161	—
Corporate bonds	107,045	107,003	—	107,003	—
Total	$ 179,670	$ 179,612	$ 5,465	$ 174,147	$ —

	December 31, 2018				
	Carrying Amount	Fair Value	Level 1	Level 2	Level 3
Cash equivalents:					
Money market	$ 5,000	$ 5,000	$ 5,000	—	—

The Company did not transfer any assets measured at fair value on a recurring basis between levels during the three and nine months ended September 30, 2019.

5. Property and Equipment, Net

Property and equipment consist of the following (in thousands):

	September 30, 2019	December 31, 2018
Research equipment	$ 9,746	$ 7,787
Leasehold improvements	5,365	4,825
Computer equipment	441	167
Furniture and fixtures	94	70
Construction in progress	787	1,027
Property and equipment, gross	16,433	13,876
Less: accumulated depreciation and amortization	(4,402)	(2,469)
Property and equipment, net	$ 12,031	$ 11,407

Construction in progress at September 30, 2019 consists of the costs incurred for research equipment and for the build-out of additional lab and office space and at December 31, 2018 consists of the costs incurred for the build-out of a manufacturing suite at the Company's headquarters in Beltsville, Maryland.

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Depreciation and amortization expense was $788,000 and $1,933,000 for the three and nine months ended September 30, 2019, respectively, and $396,000 and $1,159,000 for the three and nine months ended September 30, 2018, respectively.

6. Agreement with Eli Lilly and Company

On November 2, 2018, the Company entered into a multi-year research and development collaboration agreement (the "Lilly Agreement") with Eli Lilly and Company ("Lilly"), pursuant to which the Company will use its proprietary FIND-IO platform to identify novel oncology targets for additional collaborative research and drug discovery by the Company and Lilly. Under the Lilly Agreement, Lilly and the Company have granted one another an equal number of exclusive options to research, develop, manufacture and commercialize compounds and products directed to oncology targets identified through the Lilly Agreement. Both Lilly and the Company have all options remaining eligible for exercise. The research collaboration with Lilly will be managed by a joint steering committee formed by an equal number of members from the Company and Lilly and will expire upon the earlier of the exercise of all options granted to Lilly or four years from the date of the agreement, subject to certain extensions. The Company considers Lilly to be a related party based on Lilly's equity investment in the Company as discussed below.

During the research term under the Lilly Agreement, as a part of target discovery, the Company will be responsible for providing Lilly with oncology targets identified using the Company's FIND-IO platform. From the targets provided by the Company, Lilly may select targets to advance to target validation using criteria developed by both parties. Following completion of the agreed upon target validation plan with respect to a given target, either party may propose to advance that target to compound discovery. For each target that has been advanced to compound discovery, Lilly will have the option to obtain an exclusive license with respect to the compounds and products directed to the target. If Lilly does not exercise its option with respect to a given target or has previously exercised all of its options, the Company will have the option to obtain licenses with respect to compounds and products directed to that target. Following option exercise by a party, the development and commercialization of any products directed to the target will be conducted by the exercising party. The exercising party must use commercially reasonable efforts to develop, seek regulatory approval for and commercialize any such products under mutually agreed upon work plans.

In November 2018, the Company received an upfront, non-refundable payment of $25.0 million under the Lilly Agreement and a concurrent $15.0 million equity investment. In addition, the Company will receive quarterly research and development support payments during a portion of the research term as well as option exercise fees upon option exercises by Lilly.

Pursuant to the Lilly Agreement, Lilly may owe an aggregate of up to $1.4 billion in development and regulatory milestones and sales milestones. Additionally, Lilly will pay mid to high single-digit royalties on net sales for all products directed to each target optioned by Lilly. Upon the Company's exercise of an option with respect to a given target, the Company will pay Lilly an option exercise payment and may become obligated to milestone and royalty payments. The company may owe an aggregate of up to $710.0 million in development and regulatory milestones and sales milestones.

Upon the adoption of ASC 606, the Company evaluated the Lilly Agreement under the provisions of ASC 606 and concluded that Lilly is a customer prior to the exercise of its option to obtain an exclusive license with respect to the compounds and products directed to a target that has been advanced to compound discovery. The Company identified the following material promises under the Lilly Agreement: (i) a limited research license to conduct activities under the research collaboration; (ii) research and development services together with the provision of a data package in connection with Lilly's option; (iii) various governance obligations, most notably participation on the joint steering committee; and (iv) rights related to an optional term extension by Lilly. The Company evaluated Lilly's option to obtain an exclusive license with respect to the compounds and products directed to a target that has been advanced to compound discovery and concluded that the option was not issued at a significant and incremental discount, and therefore does not provide material rights. As such, they are excluded as performance obligations at the outset of the arrangement. The Company determined that the research license was not capable of being distinct and the related research and development services and governance activities are not distinct in the context of the contract and, as such, the Company determined that these

promises should be combined into a single performance obligation, resulting in a total of two performance obligations under the Lilly Agreement; one for research and development services and one for the right related to an optional term extension by Lilly.

The transaction price at the outset of the arrangement was determined to be $32.7 million, comprised of the upfront fee received from Lilly, quarterly research and development support payments to be received from Lilly during a portion of the research term and an equity investment premium as determined by the Company with reference to a valuation of the Company's preferred stock prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants Practice Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation.*

The transaction price was allocated to the two performance obligations based on their relative standalone selling price determined with reference to the Company's estimated costs attendant to the obligations. Revenue allocated to the research and development performance obligation is being recognized as the research and development services are provided using an input method according to research and development costs incurred to date compared to estimated total research and development costs. The transfer of control occurs over this time period and, in management's judgment, is the best measure of progress towards satisfying the performance obligation. Revenue allocated to Lilly's right related to an optional term extension is deferred until the right is exercised or lapses, and will subsequently be recognized accordingly.

While the Lilly Agreement was executed in November 2018, the Company's performance initiated in January 2019. Under the Lilly Agreement, the Company recognized revenue of $1.6 million and $4.3 million for the three and nine months ended September 30, 2019, respectively. As of September 30, 2019, deferred revenue included in the Company's balance sheets comprised the following (in thousands):

	September 30, 2019	December 31, 2018
Deferred revenue, beginning of period	$ 26,725	$ —
Up-front payment	—	25,000
Attributed premium on the proceeds from Lilly's investment in the Company	—	1,725
Research and development support billing	1,500	—
Revenue from research and development arrangement recognized	(4,342)	—
Total deferred revenue, end of period	23,883	26,725
Less: Deferred revenue, current portion	(6,199)	(4,989)
Deferred revenue, non-current portion	$ 17,684	$ 21,736

7. Commitments and Contingencies

Operating Leases

On February 9, 2016, the Company entered into a non-cancelable facilities operating sublease (the "2016 Sublease"). On March 15, 2019, the Company amended and restated the 2016 Sublease (as amended, the "Amended 2016 Sublease") to include additional square footage to be used for office space, which the Company took possession of upon entering into the Amended 2016 Sublease. The Amended 2016 Sublease expires in August 2025. The base rent under the Amended 2016 Sublease is currently $32,254 per month plus the Company's prorated share of the sublandlord's operating expense and is subject to annual rent increases of 3%.

On January 30, 2019, the Company entered into a new lease to be used for office and laboratory space (the "New Premises"), which the Company took possession of on June 1, 2019 (the "2019 Lease"). On August 2, 2019, the Company amended the 2019 Lease (as, the "Amended 2019 Lease") to include additional space to be used for office and laboratory

space (the "Expansion Premises"), which the Company expects to take possession of on April 1, 2020. The Amended 2019 Lease expires in March 2030. Upon expiration of the Amended 2016 Sublease, the Amended 2019 Lease will also cover the space the Company is currently subleasing under the Amended 2016 Sublease. Base rent is abated until April 1, 2020 for the New Premises and until seven months after delivery of the Expansion Premises for the Expansion Premises, after which the base rent will be $19,646 per month for the New Premises and $18,178 per month for the Expansion Premises, each subject to annual rent increases of 3%. In connection with this lease, the Company executed a $39,000 letter of credit, which has not been drawn down on. Additionally, there is a base rate adjustment of 8.5% per annum multiplied by the outstanding balance of amounts paid for tenant improvements. The budgeted amounts of tenant improvements are approximately $1,477,000 for the New Premises and $1,517,000 for the Expansion Premises, which are to be fully reimbursed by the landlord.

The future minimum payments for the operating leases are as follows (in thousands):

Remainder of the year	$	97
2020		566
2021		692
2022		742
2023		733
Thereafter		6,088
Total future minimum payments	$	8,918

Rent expense incurred under operating leases was approximately $252,000 and $442,000 for the three and nine months ended September 30, 2019, respectively, and $107,000 and $308,000 for the three and nine months ended September 30, 2018, respectively.

Legal Proceedings

The Company, from time to time, may be party to litigation arising in the ordinary course of business. The Company is not a party to any litigation or legal proceedings, nor is management aware of any pending or threatened litigation that, in the opinion of the Company's management, are likely to have a material adverse effect on the Company's business. At each reporting date, the Company evaluates whether a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses the costs related to its legal proceedings as incurred.

8. Term Loan

In April 2016, the Company entered into a $1.0 million term loan with a commercial bank (the "Term Loan"). On January 25, 2019, the Company amended the Term Loan to increase the Company's borrowing capacity to $5.0 million, which amount remains secured by the Company's certificates of deposit, money market account, investment property and deposit or investment accounts. As amended, the Term Loan bears interest at the greater of the prime rate less 1% and 4.25%. The effective interest rate was 4.33% and 4.44% for the three and nine months ended September 30, 2019, respectively. The effective interest rate was 4.18% and 3.84% for the three and nine months ended September 30, 2018, respectively. Under the Term Loan, the Company is required to make monthly interest-only payments through January 2020 and is required to make 36 equal monthly payments of principal plus accrued interest thereafter through January 2023.

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Future maturities of the Term Loan as of September 30, 2019 are as follows (in thousands):

Remainder of the year	$ —
2020	1,528
2021	1,667
2022	1,667
2023	138
Total	5,000
Less: current portion of term loan	(1,250)
Term loan, net of current portion	$ 3,750

Interest expense under the Term Loan was approximately $56,000 and $155,000 for the three and nine months ended September 30, 2019, respectively, and $7,000 and $20,000 for the three and nine months ended September 30, 2018, respectively.

9. Stock-Based Compensation

Employee Equity Plans

The NextCure, Inc. 2015 Omnibus Incentive Plan (the "2015 Plan") provides for the Company to grant incentive stock options or nonqualified stock options, restricted stock awards, unrestricted stock awards or restricted stock units to employees, consultants and directors of the Company. The 2015 Plan is administered by the board of directors, or at the discretion of the board of directors, by a committee of the board of directors. The exercise prices, vesting and other restrictions are determined at the discretion of the board of directors or its committee if so delegated, except that the exercise price per share of the stock options may not be less than 100% of the fair market value of a share of the Company's common stock on the date of grant and the term of the stock options may not be greater than 10 years.

On May 3, 2019, the Company’s stockholders approved the NextCure, Inc. 2019 Omnibus Incentive Plan (the ‘‘2019 Plan’’), which became effective on May 8, 2019, the date on which the Registration Statement was declared effective (the “Effective Date”). The 2019 Plan replaces the 2015 Plan as the Company’s board of directors (the “Board”) determined not to make additional awards under the 2015 Plan following the effectiveness of the 2019 Plan. The 2019 Plan provides for the grant of awards of options, stock appreciation rights, restricted stock, restricted stock units, deferred stock units, unrestricted stock, dividend equivalent rights, other equity-based awards and cash bonus awards to the Company’s officers, employees, non-employee directors and other key persons (including consultants). The number of shares of common stock reserved for issuance under the 2019 Plan is 2,900,000 plus the number of shares of stock related to awards outstanding under the 2015 Plan that subsequently terminate by expiration or forfeiture, cancellation or otherwise without the issuance of such shares. The number of shares reserved for issuance under the 2019 Plan will automatically increase on January 1, 2020 and each January 1st thereafter during the term of the 2019 Plan by 4% of the number of shares of the Company’s common stock outstanding on December 31st of the preceding calendar year or such lesser number of shares determined by the Board.

As of September 30, 2019, 2,653,969 shares were reserved for future grant under the 2019 Plan.

Stock options granted under the 2015 Plan and 2019 Plan (together, the “Plans”) to employees generally vest over four years and expire after ten years.

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A summary of stock option activity for awards under the Plans is presented below:

	Options Outstanding and Exercisable			
	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value[(1)] (in thousands)
Outstanding as of December 31, 2018	2,056,891	$ 4.74	9.4	$ 5,946
Granted	247,275	$ 18.18	10.0	
Exercised	(53,963)	$ 1.20	8.1	
Forfeitures	(1,250)	$ 7.63	9.5	
Outstanding as of September 30, 2019	2,248,953	$ 6.30	9.1	$ 55,305
Vested and expected to vest as of September 30, 2019	2,248,953	$ 6.30		$ 55,305
Exercisable as of September 30, 2019	450,866	$ 1.15		$ 12,335

(1) The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying options and the estimated fair value of the common stock for the options that were in the money at September 30, 2019 and December 31, 2018.

The weighted-average grant date fair value of stock options granted to employees for the nine months ended September 30, 2019 was $11.48. The aggregate intrinsic value of stock options exercised during the nine months ended September 30, 2019 was $1,600,000.

The Company's potential dilutive securities, which as of September 30, 2019 include common stock options, have been excluded from the computation of diluted net loss per share as the effect would be anti-dilutive. Therefore, the weighted average number of common shares used to calculate both basic and diluted net loss per common share is the same. The Company excluded 2,248,953 potential shares of common stock, presented based on amounts outstanding at three and nine periods ended September 30, 2019, from the computation of diluted net loss per common share for the period indicated because including them would have had an anti-dilutive effect.

On May 3, 2019, the Company's stockholders approved the NextCure, Inc. 2019 Employee Stock Purchase Plan (the "ESPP"), which became effective on the Effective Date. The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423(b) of the Internal Revenue Code. A total of 240,000 shares of common stock were reserved for issuance under this plan. In addition, the number of shares of common stock that may be issued under the ESPP will automatically increase on January 1, 2020 and each January 1st thereafter until expiration of the ESPP, in an amount equal to the lesser of (i) 1% of the number of shares of the Company's common stock outstanding on December 31st of the preceding calendar year, (ii) 480,000 shares of common stock and (iii) a number of shares of common stock determined by the administrator of the ESPP.

Stock-Based Compensation

The Company recorded stock-based compensation expense of $524,000 and $1,319,000 for the three and nine months ended September 30, 2019, respectively, and $90,000 and $138,000 for the three and nine months ended September 30, 2018, respectively.

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Stock-based compensation expense recorded as research and development and general and administrative expenses is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Research and development	$ 182	$ 41	$ 482	$ 62
General and administrative	342	49	837	76
Total stock-based compensation expense	$ 524	$ 90	$ 1,319	$ 138

10. Income Taxes

The Company did not record a provision or benefit for income taxes during the nine months ended September 30, 2019. The Company continues to maintain a full valuation allowance against its deferred tax assets.

The Company has evaluated the positive and negative evidence involving its ability to realize its deferred tax assets. Management has considered the Company's history of cumulative net losses incurred since inception and its lack of any commercially ready products. It has concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets. Management reevaluates the positive and negative evidence at each reporting period.

Under the provisions of Sections 382 and 383 of the Internal Revenue Code, certain substantial changes in the Company's ownership may have limited, or may limit in the future, the amount of net operating loss and research and development credit carryforwards that can be used to reduce future income taxes.

11. Subsequent Events

The Company has evaluated subsequent events through the issuance date of these interim condensed financial statements.

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 the unaudited condensed financial statements and the notes thereto included in this Quarterly Report. Some of the statements contained in this discussion and analysis or set forth elsewhere in this Quarterly Report are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including with respect to our plans, objectives and expectations for our business, operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "aim," "anticipate," "assume," "believe," "continue," "could," "due," "estimate," "expect," "intend," "may," "objective," "plan," "predict," "potential," "positioned," "seek," "should," "target," "will," "would" and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or similar language. Forward-looking statements include, but are not limited to, statements about:

- *our expectations regarding the timing, progress and results of preclinical studies and clinical trials for NC318, NC410 and any other product candidates we develop, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available and our research and development programs;*
- *the timing or likelihood of regulatory filings for NC318, NC410 and any other product candidates we develop and our ability to obtain and maintain regulatory approvals for such product candidates for any indication;*
- *the development of a complimentary diagnostic for NC318;*
- *our manufacturing capabilities and strategy, including the scalability of our manufacturing methods and processes;*
- *our expectations regarding the potential benefits, activity, effectiveness and safety of NC318, NC410 and any other product candidates we develop;*
- *our intentions and ability to successfully commercialize our product candidates;*
- *our expectations regarding the nature of the biological pathways we are targeting;*
- *our expectations for our FIND-IO platform, including our ability to discover and advance product candidates using our FIND-IO platform;*
- *the potential benefits of and our ability to maintain our relationships and collaborations with Yale University, Dr. Lieping Chen and Eli Lilly and Company;*
- *our estimates regarding our expenses, future revenues, capital requirements and our needs for or ability to obtain additional financing and the period over which we expect the proceeds of our initial public offering, together with our current cash, cash equivalents and marketable securities, to be sufficient to fund our operations;*
- *our intended reliance on and the performance of third parties, including collaborators, contract research organizations and third-party manufacturers;*
- *our ability to protect and enforce our intellectual property protection and the scope and duration of such protection;*
- *developments and projections relating to our competitors and our industry, including competing therapies; and*
- *the impact of current and future laws and regulations.*

These statements are based on management's current expectations, estimates, forecasts and projections about our business and industry, are not guarantees of future performance and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control and that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from those anticipated by the forward-looking statements. We discuss many of these risks in greater detail in the section entitled "Risk Factors" included in Part II, Item 1A and elsewhere in this report. While we believe that our internal expectations, estimates, forecasts and projections are reasonable, no independent source has verified such expectations, estimates, forecasts and projections, as a result we cannot assure you that the forward-looking statements in this Quarterly Report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. Accordingly, you should not rely upon forward-looking statements as predictions of future events. These forward-looking statements speak only as of the date of this Quarterly Report, and except as required by law, we are under no duty to update or revise any of the forward-looking statements, whether as a result of new information, future events or otherwise.

Overview

We are a clinical-stage biopharmaceutical company committed to discovering and developing novel, first-in-class immunomedicines to treat cancer and other immune-related diseases by restoring normal immune function. We view the immune system holistically and, rather than target one specific immune cell type, we focus on understanding biological pathways, the interactions of cells and the role each interaction plays in an immune response. Through our proprietary Functional, Integrated, NextCure Discovery in Immuno-Oncology, or FIND-IO, platform, we study various immune cells to discover and understand targets and structural components of immune cells and their functional impact in order to develop immunomedicines. We are focused on patients who do not respond to current therapies, patients whose cancer progresses despite treatment and patients with cancer types not adequately addressed by available therapies. We are committed to discovering and developing first-in-class immunomedicines, which are immunomedicines that use new or unique mechanisms of action to treat a medical condition, for these patients.

Our lead product candidate, NC318, is a first-in-class immunomedicine against a novel immunomodulatory receptor called Siglec-15, or S15. In October 2018, we initiated a Phase 1/2 clinical trial of NC318 in patients with advanced or metastatic solid tumors. We completed enrollment of the Phase 1 portion of this trial in August 2019 and announced preliminary data from the Phase 1 portion at the Society for Immunotherapy of Cancer annual meeting in November 2019. We began enrolling patients in the Phase 2 portion of the trial in October 2019 and expect to announce initial data from the Phase 2 portion by the end of 2020. We expect to initiate an additional Phase 2 clinical trial to evaluate NC318 in combination with standard of care chemotherapies in patients with advanced or metastatic solid tumors in the first half of 2020. Our second product candidate, NC410, is a novel immunomedicine designed to block immune suppression mediated by an immune modulator called Leukocyte-Associated-Immunoglobulin-like Receptor 1, or LAIR-1. We expect to submit an IND for NC410 and initiate a Phase 1/2 clinical trial in patients with advanced or metastatic solid tumors in the first quarter of 2020.

Financial Overview

Since commencing operations in 2015, we have devoted substantially all of our efforts and financial resources to organizing and staffing our company, identifying business development opportunities, raising capital, securing intellectual property rights related to our product candidates, building and optimizing our manufacturing capabilities and conducting discovery, research and development activities for our product candidates, discovery programs and FIND-IO platform.

We have not generated any revenue from product sales and only limited revenue from other sources and, as a result, we have never been profitable and have incurred net losses since the commencement of our operations. Our net losses for the three months ended September 30, 2019 and 2018 were $8.4 million and $5.7 million, respectively, and our net losses for the nine months ended September 30, 2019 and 2018 were $22.8 million and $15.9 million, respectively. As of September 30, 2019, we had an accumulated deficit of $70.1 million, primarily as a result of research and development and general and administrative expenses. We do not expect to generate product revenue unless and until we obtain marketing approval for and commercialize a product candidate, and we cannot assure you that we will ever generate significant revenue or profits.

We have funded our operations to date primarily with proceeds from the sale of preferred stock, proceeds from our multi-year research collaboration and development agreement with Eli Lilly and Company, or Lilly, and proceeds from our initial public offering, or our IPO. From our inception through September 30, 2019, we received gross proceeds of $164.4 million through private placements of preferred stock and an upfront payment of $25.0 million in connection with our agreement with Lilly, or the Lilly Agreement. In April 2018, we received gross proceeds of $31.0 million from the sale and issuance of shares of our Series A-3 Preferred Stock, and in November 2018, we received gross proceeds of $93.4 million from the sale and issuance of shares of our Series B Preferred Stock, including $15.0 million from Lilly as described below.

In November 2018, we entered into a multi-year research and development collaboration agreement with Lilly, or the Lilly Agreement, pursuant to which we will use our FIND-IO platform to identify novel oncology targets for additional collaborative research and drug discovery by us and Lilly. We received an upfront payment of $25.0 million in cash and an equity investment of $15.0 million from Lilly upon entering into the Lilly Agreement, and we are eligible for quarterly research and development support payments during a portion of the term of the Lilly Agreement, option exercise payments and milestone payments in an aggregate of up to $1.4 billion, as well as mid to high single-digit royalty payments on net sales for all products directed to each target optioned by Lilly. We expect to recognize revenue from the Lilly Agreement on a proportional performance basis over the term of the Lilly Agreement.

On May 13, 2019, we closed our IPO, in which we sold 5,750,000 shares of common stock, at a public offering price of $15.00 per share, for aggregate gross proceeds of $86.3 million. The net offering proceeds to us were approximately $77.0 million after deducting underwriting discounts and commissions of $6.0 million and offering expenses of $3.4 million. See Note 1 to our unaudited condensed financial statements included elsewhere in this Quarterly Report for more information.

As of September 30, 2019, we had cash and cash equivalents, excluding restricted cash, of $9.9 million and marketable securities of $174.1 million. We believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our planned operations into the first half of 2022. We have based this estimate on assumptions that may prove to be incorrect, and we could use our available capital resources sooner than we currently expect.

We expect to incur substantial expenditures in the foreseeable future as we advance our product candidates through clinical development, the regulatory approval process and, if approved, commercialization, and as we expand our pipeline through research and development activities related to our FIND-IO platform and discovery programs. Specifically, in the near term, we expect to incur substantial expenses relating to our ongoing Phase 1/2 clinical trial and planned Phase 2 clinical trial of NC318, preclinical studies and our planned Phase 1/2 clinical trial of NC410 and other research and development activities. We expect to incur significantly increased costs as a result of operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company.

We will need substantial additional funding to support our continuing operations and to pursue our development strategy. Until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our operations through a combination of public or private equity offerings, debt financings, marketing and distribution arrangements, other collaborations, strategic alliances and licensing arrangements. Adequate funding may not be available to us on acceptable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials, or other research and development activities or one or more of our development programs.

Components of Our Results of Operations

Revenue

For the three and nine months ended September 30, 2019, we recognized $1.6 million and $4.3 million, respectively, in revenue under the Lilly Agreement. Through September 30, 2019, we have not generated any revenue from product sales.

For additional information about our revenue recognition policy, see Note 2 to our unaudited condensed financial statements included elsewhere in this Quarterly Report. For the foreseeable future, we expect all of our revenue will be generated from the Lilly Agreement.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our discovery efforts, research activities, development and testing of our product candidates as well as for clinical trials, including:

- salaries, benefits and other related costs, including stock-based compensation, for personnel engaged in research and development functions;
- expenses incurred under agreements with third parties, including agreements with third parties that conduct research, preclinical activities or clinical trials on our behalf, such as our corporate sponsored research agreement, or the SRA, and our license agreement with Yale University;
- costs of outside consultants, including their fees, stock-based compensation and related travel expenses;
- the costs of laboratory supplies and acquiring, developing and manufacturing preclinical study and clinical trial materials; and
- facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

We expense research and development costs as incurred. Our expenses related to clinical trials are based on actual costs incurred and estimates of other incurred costs. These estimated costs are based on several factors, including patient enrollment and related expenses at clinical investigator sites, contract services received, consulting agreement costs and efforts expended under contracts with research institutions and third-party contract research organizations that conduct and manage clinical trials on our behalf. We generally accrue estimated costs related to clinical trials based on contracted amounts applied to the level of patient enrollment and other activity according to the protocol. If future timelines or contracts are modified based on changes in the clinical trial protocol or scope of work to be performed, we would modify our estimates of accrued expenses accordingly on a prospective basis. Historically, any such modifications have not been material.

Due to the early-stage nature of our programs and the discovery-related nature of our efforts, we do not track costs on a program-by-program basis other than costs incurred for the Lilly Agreement. However, as our current and future product candidates proceed along a development path further in clinical trials, we intend to track the costs of each program. We measure costs incurred under the Lilly Agreement as an input to recording revenue from the Lilly Agreement.

Research and development activities are central to our business model. We expect that our research and development expenses will continue to increase substantially for the foreseeable future as we advance our product candidates through development, including conducting our ongoing Phase 1/2 clinical trial of NC318, our planned Phase 2 clinical trial in combination with standard of care chemotherapies and preclinical studies and a Phase 1/2 clinical trial of NC410, as we develop a complementary diagnostic for NC318 if we determine it is advisable, and as we expand our current good manufacturing practice, or cGMP, manufacturing capacity, including to provide drug supply of NC318 for future clinical trials, and as we expand our pipeline through research and development activities related to our FIND-IO platform and discovery programs.

We cannot determine with certainty the duration and costs of future clinical trials of NC318, NC410 or any other product candidate we may develop or if, when or to what extent we will generate revenue from the commercialization and sale of any product candidate for which we may obtain marketing approval. We may never succeed in obtaining marketing approval for any product candidate. The duration, costs and timing of clinical trials and development of NC318, NC410 and any other product candidate we may develop will depend on a variety of factors, including:

- the scope, progress, results and costs of clinical trials of NC318 and NC410, as well as of any future clinical trials of other product candidates and other research and development activities that we may conduct;
- uncertainties in selection of indications, clinical trial design and patient enrollment rates;
- the probability of success for our product candidates, including safety and efficacy, early clinical data, competition, ease and ability of manufacturing and commercial viability;
- significant and changing government regulation and regulatory guidance;
- the timing and receipt of any development or marketing approvals, including the IND for NC410; and
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

A change in the outcome of any of these variables with respect to the development of a product candidate could lead to a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in our clinical trials due to patient enrollment or other reasons, we would be required to expend significant additional financial resources and time to complete clinical development for any such product candidate.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related costs, including payroll and stock-based compensation, for personnel in executive, finance, human resources, business and corporate development and other administrative functions, professional fees for legal, intellectual property, consulting and accounting services, rent and other facility-related costs, depreciation and other general operating expenses not otherwise classified as research and development expenses. General and administrative expenses also include all patent-related costs incurred in connection with filing and prosecuting patent applications, which are expensed as incurred.

We anticipate that our general and administrative expenses will increase substantially during the next few years as a result of staff expansion and additional occupancy costs, as well as costs associated with being a public company, including higher legal and accounting fees, investor relations costs, higher insurance premiums and other compliance costs associated with being a public company.

Other Income, Net

Other income, net consists primarily of interest income earned on U.S. Treasury obligations and payment of interest on our term loan with a commercial bank, or the Term Loan.

Results of Operations

Comparison of the Three and Nine Months Ended September 30, 2019 and 2018

The following table summarizes our results of operations for the periods indicated (in thousands):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2019	2018	Change	2019	2018	Change
Revenue:						
Revenue from research and development arrangement	$ 1,583	$ —	$ 1,583	$ 4,342	$ —	$ 4,342
Operating expenses:						
Research and development	$ 8,663	$ 4,895	$ 3,768	22,819	13,539	9,280
General and administrative	2,622	925	1,697	6,995	2,590	4,405
Loss from operations	(9,702)	(5,820)	(3,882)	(25,472)	(16,129)	(9,343)
Other income, net	1,268	110	1,158	2,662	192	2,470
Net loss	$(8,434)	$(5,710)	$(2,724)	$(22,810)	$(15,937)	$(6,873)

Revenue from Research and Development Arrangement

Revenue was $1.6 million and $0 million for the three months ended September 30, 2019 and 2018, respectively and $4.3 million and $0 million for the nine months ended September 30, 2019 and 2018, respectively. The increase in revenue is related to the recognition of a portion of the upfront consideration under the Lilly Agreement and the premium on the proceeds from Lilly's investment in shares of our Series B-3 Preferred Stock.

Research and Development Expenses

Research and development expenses for the three months ended September 30, 2019 increased by $3.8 million to $8.7 million compared to $4.9 million for the three months ended September 30, 2018. The increase was driven primarily by $1.5 million in personnel-related costs due to an increase in headcount. Other significant components of the increase in research and development expenses included $1.1 million in lab supplies and services for NC318, NC410, other early-stage programs and discovery activities and $0.5 million in clinical research costs related to advancing NC318.

Research and development expenses for the nine months ended September 30, 2019 increased by $9.3 million to $22.8 million compared to $13.5 million for the nine months ended September 30, 2018. The increase was driven primarily by $2.5 million in personnel-related costs due to an increase in headcount. Other significant components of the increase in research and development expenses included the following: $2.3 million in lab supplies and services for NC318, NC410, other early-stage programs and discovery activities; $1.9 million in clinical research costs related to advancing NC318; a $0.5 million payment to Yale University in connection with the closing of our IPO; and $0.6 million related to depreciation expense.

General and Administrative

General and administrative expenses for the three months ended September 30, 2019 increased by $1.7 million to $2.6 million as compared to $0.9 million for the three months ended September 30, 2018. The increase was driven primarily by increases, in connection with our IPO, of $0.6 million for professional fees related to legal, finance and audit services, public relations, compensation and investor relations support, $0.5 million in insurance expenses and $0.4 million in personnel-related costs due to an increase in headcount.

General and administrative expenses for the nine months ended September 30, 2019 increased by $4.4 million to $7.0 million as compared to $2.6 million for the nine months ended September 30, 2018. The increase was driven primarily by increases, in connection with our IPO, of $2.0 million for professional fees related to legal, finance and audit services,

public relations, compensation and investor relations support, $0.8 million in personnel-related costs due to an increase in headcount and $0.8 million in insurance expenses, in connection with our IPO, as well as $0.5 million for an unrestricted gift to an academic lab.

Other Income, Net

Other income, net for the three months ended September 30, 2019 increased by $1.2 million to $1.3 million from $110,000 for the three months ended September 30, 2018. The increase was driven primarily by interest income earned on higher cash balances, partially offset by interest expense related to the Term Loan.

Other income, net for the nine months ended September 30, 2019 increased by $2.5 million to $2.7 million from $192,000 for the nine months ended September 30, 2018. The increase was driven primarily by interest income earned on higher cash balances, partially offset by interest expense related to the Term Loan.

Liquidity and Capital Resources

We have financed our operations primarily through private placements of preferred stock and proceeds pursuant to the Lilly Agreement and our IPO. On May 13, 2019, we closed our IPO in which we sold 5,750,000 shares of common stock, at a public offering price of $15.00 per share, for aggregate gross proceeds of $86.3 million. The net offering proceeds to us were approximately $77.0 million after deducting underwriting discounts and commissions of $6.0 million and offering expenses of $3.4 million. Since inception, we have received aggregate gross proceeds of $164.4 million from the sale and issuance of shares of our preferred stock. In addition, in November 2018, we received an upfront payment of $25.0 million in cash from Lilly pursuant to the Lilly Agreement. Our cash and cash equivalents are held in money market funds.

As of September 30, 2019, we had cash and cash equivalents, excluding restricted cash, of $9.9 million and marketable securities of $174.1 million. We believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our planned operations into the first half of 2022.

In addition, in April 2016, we entered into the Term Loan to finance laboratory equipment purchases. In January 2019, we amended the Term Loan to increase our borrowing capacity from $1.0 million to $5.0 million. As amended, the Term Loan matures in January 2023. Our obligations under the Term Loan are secured by a security interest in our certificates of deposit, money market accounts, cash, securities, investment property and deposit or investment accounts. The Term Loan bears interest at a rate equal to the greater of (i) the prime rate less 1.0% and (ii) 4.25% and is subject to mandatory prepayment upon the occurrence of specified events, including failure to pay the Term Loan when due, uncured breach, bankruptcy or dissolution. Under the Term Loan, we will make interest-only payments through January 2020 and 36 equal monthly payments of principal plus accrued interest thereafter through January 2023. As of September 30, 2019, our outstanding borrowings under the Term Loan were $5.0 million.

Cash Flows

The following table sets forth the primary sources and uses of cash and cash equivalents for each of the periods presented below (in thousands):

	Nine Months Ended September 30,	
	2019	2018
Net cash provided by (used in):		
Operating activities	$ (25,632)	$ (14,479)
Investing activities	(176,762)	(1,159)
Financing activities	81,735	30,686
Net (decrease) increase in cash and cash equivalents	$ (120,659)	$ 15,048

Cash Used in Operating Activities

Net cash used in operating activities was $25.7 million for the nine months ended September 30, 2019, which was primarily due to our net loss of $22.8 million. Net cash used in operating activities was $14.5 million for the nine months ended September 30, 2018, which was primarily due to our net loss of $15.7 million in connection with our research and development activities, partially offset by timing of cash payments. The amount of cash used in operating activities in any period is influenced by the timing of cash payments for research-related expenses.

Cash Used in Investing Activities

Cash used in investing activities for the nine months ended September 30, 2019 and 2018 was $176.7 million, which was primarily due to the purchase of marketable securities. Cash used in investing activities for the nine months ended September 30, 2018 was $1.2 million, which consisted primarily of purchases of property and equipment.

Cash Provided by Financing Activities

Cash provided by financing activities was $81.7 million for the nine months ended September 30, 2019, which consisted primarily of net proceeds from the Company's public offering. Cash provided by financing activities was $30.7 million for the nine months ended September 30, 2018, which consisted of gross proceeds from the sale and issuance of shares of our Series A-3 preferred stock.

Contractual Obligations and Commitments

There have been no material changes outside the ordinary course of business to our contractual obligations during the nine month period ended September 30, 2019, as compared to those disclosed in the final prospectus that forms a part of our Registration Statement on Form S-1 (Reg. No. 333-230837), as filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, on May 9, 2019, or the Prospectus. See Notes 7 and 8 to our unaudited condensed financial statements included elsewhere in this Quarterly Report for a discussion of our leases and the Term Loan, respectively.

Critical Accounting Policies, Significant Judgments and Use of Estimates

Our financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses incurred during the reporting periods. The most significant assumptions used in the financial statements are the underlying assumptions used in revenue recognition and valuing share-based compensation, including the fair value of our common stock in periods before our IPO. Our estimates are based on our historical experience and on 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. We evaluate our estimates and assumptions on an ongoing basis. Actual results may differ from these estimates under different assumptions or conditions.

During the nine months ended September 30, 2019, there were no material changes to our critical accounting policies as reported in the Prospectus.

Off-Balance Sheet Arrangements

Since our inception, we have not engaged in any off-balance sheet arrangements, as defined in the rules and regulations of the Securities and Exchange Commission.

Recent Accounting Pronouncements

See Note 2 to our unaudited condensed financial statements included elsewhere in this Quarterly Report for a discussion of recent accounting pronouncements that may impact our financial position and results of operations.

Emerging Growth Company Status

As an emerging growth company under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, we are eligible to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. We have elected to take advantage of the extended transition period for adopting new or revised accounting standards that have different effective dates for public and private companies until such time as those standards apply to private companies.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

As a smaller reporting company, we are not required to provide the information requested by this Item.

Item 4. Controls and Procedures.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as of September 30, 2019. 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 its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2019, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, that occurred during the quarter ended September 30, 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in litigation or other legal proceedings as part of our ordinary course of business. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below together with all of the other information in this Quarterly Report, including our financial statements and the related notes and the information described in the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. If any of the events described below actually occurs, our business, results of operations, financial conditions, cash flows or prospects could be harmed. If that were to happen, the trading price of our common stock could decline, and you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

Risks Related to Our Financial Position and Need for Additional Capital

We have a limited operating history and no products approved for commercial sale. We have a history of significant losses, expect to continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

We are a clinical-stage biopharmaceutical company with a limited operating history. Since our founding in 2015, we have incurred significant net losses. Our net losses were $22.8 million for the year ended December 31, 2018 and the nine months ended September 30, 2019. As of September 30, 2019, we had an accumulated deficit of $70.1 million. We have funded our operations to date primarily with proceeds from the sale of preferred stock and upfront fees received in connection with the Lilly agreement and proceeds from our IPO. Since commencing operations, we have devoted substantially all of our efforts and financial resources to organizing and staffing our company, identifying business development opportunities, raising capital, securing intellectual property rights related to our product candidates, building and optimizing our manufacturing capabilities and conducting discovery, research and development activities for our product candidates, our discovery programs and our FIND-IO platform.

We expect that it will be several years, if ever, before we have a commercialized product. We expect to continue to incur significant expenses and operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter. We anticipate that our expenses will increase substantially if, and as, we:

- continue to advance the preclinical and clinical development of our existing product candidates and our research programs;
- leverage our FIND-IO platform to advance additional product candidates into preclinical and clinical development;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- expand our cGMP manufacturing capacity, including to provide drug supply of NC318 for future clinical trials;
- hire additional clinical, quality control, regulatory, scientific and administrative personnel;
- expand our operational, financial and management systems and increase personnel, including to support our clinical development, manufacturing and commercialization efforts and our operations as a public company;
- maintain, expand and protect our intellectual property portfolio;
- establish a marketing, sales, distribution and medical affairs infrastructure to commercialize any products for which we may obtain marketing approval and commercialize, whether on our own or jointly with a partner;
- acquire or in-license other technologies or engage in strategic partnerships; and
- incur additional legal, accounting or other expenses in operating our business, including the additional costs associated with operating as a public company.

To become and remain profitable, we, whether on our own or jointly with Lilly or any potential future collaborator, must develop and eventually commercialize products with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials, obtaining marketing approval for product candidates, manufacturing, marketing and selling products and satisfying any post-marketing requirements. We may never succeed in any or all of these activities and, even if we do, we may never generate revenue that is significant or large enough to achieve profitability. 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 decrease

the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We have never generated revenue from product sales and may never be profitable.

Our ability to generate revenue from product sales and achieve profitability depends on our ability, alone or with our collaboration partners, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, our product candidates. We do not anticipate generating revenue from product sales for the next several years, if ever. Our ability to generate future revenue from product sales depends heavily on our, or our existing or future collaborators', success in:

- completing preclinical studies and clinical trials of our product candidates, including our ongoing Phase 1/2 clinical trial for NC318 and other planned clinical trials for NC318 and NC410;
- seeking and obtaining marketing approvals for any product candidates that we or our collaborators develop;
- receiving acceptance of the INDs for NC410 and future product candidates;
- identifying and developing new product candidates;
- launching and commercializing product candidates for which we obtain marketing approval by establishing a marketing, sales, distribution and medical affairs infrastructure or, alternatively, collaborating with a commercialization partner;
- achieving coverage and adequate reimbursement by hospitals and third-party payors, including governmental authorities, such as Medicare and Medicaid, private insurers and managed care organizations, for product candidates, if approved, that we or our collaborators develop;
- manufacturing cGMP supply of our product candidates for clinical trials and, if approved, commercial sales;
- obtaining market acceptance of product candidates, if approved, that we develop as viable treatment options;
- addressing any competing technological and market developments;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter and performing our obligations under such arrangements;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how;
- defending against third-party interference or infringement claims, if any; and
- attracting, hiring and retaining qualified personnel.

We anticipate incurring significant costs associated with commercializing any product candidate that is approved for commercial sale. Our expenses could increase beyond expectations if we are required by the FDA or other regulatory agencies to perform clinical trials or studies in addition to those that we currently anticipate. Even if we are able to generate revenue from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations.

We will require substantial additional financing to pursue our business objectives, which may not be available on acceptable terms, or at all. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development, commercialization efforts or other operations.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to continue the preclinical and clinical development of our current and future programs. If we receive marketing approval for any product candidates, including NC318 and NC410, we will require significant additional amounts of cash in order to launch and commercialize such product candidates. In addition, other unanticipated costs may arise. Because the designs and outcomes of our planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development of and commercialize any product candidate we develop.

Our future capital requirements depend on many factors, including:

- the scope, progress, timing, results and costs of researching and developing NC318, NC410 and our other product candidates, including targets identified through our FIND-IO platform, and of conducting preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining marketing approval for NC318, NC410 and any future product candidates we develop, if clinical trials are successful;
- the success of our collaboration with Lilly, including whether Lilly exercises its licensing options under its collaboration agreement with us, each of which would trigger additional payments to us;
- the costs of manufacturing NC318, NC410 and any future product candidates for preclinical studies and clinical trials and in preparation for marketing approval and commercialization;
- the costs of commercialization activities, including marketing, sales and distribution costs, for NC318, NC410 and any future product candidates we develop, whether alone or with a collaborator, if any of these product candidates are approved for sale;
- the success of our SRA with Yale University;
- our ability to establish and maintain additional strategic collaborations, licensing or other arrangements on favorable terms, if at all;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of any such litigation;
- our current collaboration and license agreements remaining in effect and our achievement of milestones and the timing and amount of milestone payments we are required to make, or that we may be eligible to receive, under those agreements;
- the timing, receipt and amount of sales of, or royalties on, our future products, if any; and
- the emergence of competing therapies and other adverse developments in the oncology market.

Until we can generate sufficient product and royalty revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, marketing and distribution arrangements, other collaborations, strategic alliances and licensing arrangements. As of September 30, 2019, we had $184.1 million in cash, cash equivalents (excluding restricted cash) and marketable securities. Based on our research and development plans, we expect that our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements into the first half of 2022.

This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we expect. Changes may occur beyond our control that would cause us to consume our available capital before that time, including changes in and progress of our development activities, acquisitions of additional product candidates and changes in regulation.

If we raise additional capital through marketing, sales and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, future revenue streams or research programs, technologies or grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest will be diluted. If we raise additional capital through debt financing, we would be subject to fixed payment obligations and may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

Adequate additional financing may not be available to us on acceptable terms, or at all. If we are unable to obtain additional financing on favorable terms when needed, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials, or other research and development activities or one or more of our development programs.

Risks Related to the Discovery and Development of Our Product Candidates

Our business is dependent on our ability to advance our current and future product candidates through clinical trials, obtain marketing approval and ultimately commercialize them.

We are early in our development efforts. We initiated our first clinical trial for NC318, our lead product candidate, in October 2018, and our second product candidate, NC410, is in preclinical development. Our ability to generate product revenues, which we do not expect will occur for several years, if ever, will depend heavily on the successful development and eventual commercialization of NC318, NC410 and any future product candidates we develop, which may never occur. Our current product candidates, including NC318 and NC410, and any future product candidates we develop will require additional preclinical or clinical development, management of clinical, preclinical and manufacturing activities, marketing approval in the United States and other jurisdictions, demonstration of effectiveness to pricing and reimbursement authorities, sufficient cGMP manufacturing supply for both preclinical and clinical development and commercial production, building of a commercial organization and substantial investment and significant marketing efforts before we generate any revenues from product sales.

The clinical and commercial success of our current and future product candidates will depend on several factors, including the following:

- timely and successful completion of preclinical studies and our clinical trials;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- acceptance of the INDs for NC410 and future product candidates;
- successful enrollment in and completion of clinical trials;
- successful data from our clinical program that supports an acceptable risk-benefit profile of our product candidates in the intended patient populations;
- our ability to consistently manufacture our product candidates on a timely basis or to establish agreements with third-party manufacturers, if needed;

- whether we are required by the FDA or comparable foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned or anticipated to support approval of our product candidates;
- acceptance of our proposed indications and the primary endpoint assessments evaluated in the clinical trials of our product candidates by the FDA and comparable foreign regulatory authorities;
- receipt and maintenance of timely marketing approvals from applicable regulatory authorities;
- successfully launching commercial sales of our product candidates, if approved;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates, if approved;
- entry into collaborations to further the development of our product candidates;
- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates;
- acceptance of the benefits and uses of our product candidates, if approved, by patients, the medical community and third-party payors;
- maintaining a continued acceptable safety, tolerability and efficacy profile of the product candidates following approval;
- our compliance with any post-approval requirements imposed on our products, such as postmarketing studies, a Risk Evaluation and Mitigation Strategy, or REMS, or additional requirements that might limit the promotion, advertising, distribution or sales of our products or make the products cost-prohibitive;
- competing effectively with other therapies;
- obtaining and maintaining healthcare coverage and adequate reimbursement from third-party payors;
- our ability to identify targets and immunomedicines, whether through our FIND-IO platform, through our relationships with Yale or otherwise; and
- enforcing and defending intellectual property rights and claims.

These factors, many of which are beyond our control, could cause us to experience significant delays or an inability to obtain regulatory approvals or commercialize our current or future product candidates, and could otherwise materially harm our business. Successful completion of preclinical studies and clinical trials does not mean that NC318, NC410 or any future product candidates we develop will receive regulatory approval. Even if regulatory approvals are obtained, we could experience significant delays or an inability to successfully commercialize our current and any future product candidates we develop, which would materially harm our business. If we are not able to generate sufficient revenue through the sale of any current or future product candidate, we may not be able to continue our business operations or achieve profitability.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be materially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the

substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate. Neither we nor any future collaborator is permitted to market any biological product in the United States until we or the future collaborator receive regulatory approval of a biologics license application, or BLA, from the FDA. It is possible that none of our current or future product candidates will ever obtain regulatory approval from the FDA or comparable foreign regulatory authorities.

Our current and future product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe, pure and potent for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from clinical trials or preclinical studies;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA to the FDA or regulatory submissions to comparable regulatory authorities to obtain regulatory approval in such jurisdiction; and
- the FDA or comparable foreign regulatory authorities may find deficiencies with or fail to approve our manufacturing processes or facility or the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies.

This lengthy approval process, as well as the unpredictability of clinical trial results, may result in our failing to obtain regulatory approval to market any product candidate we develop, which would significantly harm our business, results of operations and prospects. The FDA and other comparable foreign authorities have substantial discretion in the approval process and in determining when or whether regulatory approval will be granted for any product candidate that we develop. Even if we believe the data collected from future clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA or any other regulatory authority.

In addition, even if we were to obtain approval, the FDA may approve any of our product candidates for fewer or more limited indications, or a more limited patient population, than we request, may grant approval contingent on the performance of costly clinical trials or other postmarketing requirements, or may approve a product candidate with a label that does not include the labeling claims we believe are necessary or desirable for the successful commercialization of such product candidates.

In addition, the FDA or comparable foreign regulatory authorities may change their policies, promulgate additional regulations, revise existing regulations or take other actions that may prevent or delay approval of our future products under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Clinical development involves a lengthy and expensive process with uncertain outcomes. We may incur additional costs and experience delays in developing and commercializing or be unable to develop or commercialize our current and future product candidates.

To obtain the requisite regulatory approvals to commercialize any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe, pure and potent in humans. Clinical testing is expensive and can take many years to complete, and its outcome is highly uncertain. Failure can occur at any time during the clinical trial process and our future clinical trial results may not be successful. We may experience delays in completing our clinical trials or preclinical studies and initiating or completing additional clinical trials. Although we initiated a Phase 1/2 clinical trial of NC318 in October 2018, we may experience delays in initiating or completing our planned clinical trials and development efforts. Additionally, we cannot be certain the ongoing and planned preclinical studies or clinical trials for NC318, NC410 or any future product candidates will begin on time, not require redesign, enroll an adequate number of subjects on time or be completed on schedule, if at all. We may also experience numerous unforeseen events during our clinical trials that could delay or prevent our ability to receive marketing approval or commercialize the product candidates we develop, including:

- results from preclinical studies or clinical trials may not be predictive of results from later clinical trials of any product candidate;
- the FDA or other regulatory authorities, Institutional Review Boards, or IRBs, or independent ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- the FDA or other regulatory authorities may require us to submit additional data such as long-term toxicology studies, or impose other requirements on us, before permitting us to initiate a clinical trial;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations, or CROs, as the terms of these agreements can be subject to extensive negotiation and vary significantly among different CROs and trial sites;
- clinical trials of any product candidate may fail to show safety, purity or potency, or may produce negative or inconclusive results, which may cause us to decide, or regulators to require us, to conduct additional nonclinical studies or clinical trials or which may cause us to decide to abandon product candidate development programs;
- the number of patients required for clinical trials may be larger than we anticipate, or we may have difficulty in recruiting and enrolling patients to participate in clinical trials, including as a result of the size and nature of the patient population, the proximity of patients to clinical trial sites, eligibility criteria for the clinical trial, the nature of the clinical trial protocol, the availability of approved effective treatments for the relevant disease and competition from other clinical trial programs for similar indications and clinical trial subjects;
- it may be difficult to enroll a sufficient number of patients, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials or may fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our CROs and other third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- we may elect to, or regulators, IRBs or ethics committees may require that we or our investigators, suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that participants are being exposed to unacceptable health risks;

- any of our product candidates could cause undesirable side effects that could result in significant negative consequences, including the inability to enter clinical development or receive regulatory approval;

- the cost of preclinical or nonclinical testing and studies and clinical trials of any product candidates may be greater than we anticipate;

- we may face hurdles in addressing subject safety concerns that arise during the course of a trial, causing us or our investigators, regulators, IRBs or ethics committees to suspend or terminate trials, or reports may arise from nonclinical or clinical testing of other cancer therapies that raise safety or efficacy concerns about our product candidates; and

- the supply, quality or timeliness of delivery of materials for product candidates we develop or other materials necessary to conduct clinical trials may be insufficient or inadequate.

We could encounter delays if a clinical trial is suspended or terminated by us, or by the IRBs of the institutions in which such trials are being conducted, ethics committees or the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of marketing approval of our product candidates. Further, the FDA or other regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials.

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 a regulatory authority concludes that the financial relationship may have affected the interpretation of the trial, 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 the marketing application we submit. Any such delay or rejection could prevent or delay us from commercializing our current or future product candidates.

If we experience delays in the completion, or termination, of any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down the development and approval process for our product candidates and jeopardize our ability to commence product sales and generate revenues. Significant clinical trial delays could also allow our competitors to bring products to market before we do or shorten any periods during which we have the exclusive right to commercialize our product candidates. Any such events would impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates or result in the development of our product candidates stopping early.

Preclinical development is uncertain. Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all.

With the exception of NC318, all of our product candidates are still in the preclinical discovery stage, and the risk of failure for such product candidates is high. In order to obtain FDA approval to market a new biologic we must

demonstrate proof of safety, purity and potency, including efficacy, in humans. To meet these requirements, we will have to conduct adequate and well-controlled clinical trials. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our planned clinical trials in humans. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our current or future product candidates. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin.

Conducting preclinical testing is a lengthy, time-consuming and expensive process. The length of time of such testing may vary substantially according to the type, complexity and novelty of the program, and often can be several years or more per program. Delays associated with programs for which we are conducting preclinical testing and studies may cause us to incur additional operating expenses. Moreover, we may be affected by delays associated with the preclinical testing and studies of certain programs that are the responsibility of Lilly or our potential future collaborators over which we have no control. The commencement and rate of completion of preclinical studies and clinical trials for a product candidate may be delayed by many factors, including but not limited to:

- an inability to generate sufficient preclinical or other *in vivo* or *in vitro* data to support the initiation of clinical studies;
- delays in reaching a consensus with regulatory agencies on study design; and
- the FDA not permitting the reliance on preclinical or other data from published scientific literature.

Positive results from preclinical studies and early-stage clinical trials may not be predictive of future results. Initial positive results in any of our clinical trials may not be indicative of results obtained when the trial is completed or in later stage trials.

The results of preclinical studies may not be predictive of the results of clinical trials. Preclinical studies and early-stage clinical trials are primarily designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the side effects of product candidates at various doses and schedules, and the results of any early-stage clinical trials may not be predictive of the results of later-stage, large-scale efficacy clinical trials. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. There can be no assurance that any of our current or future clinical trials will ultimately be successful or support further clinical development of any of our product candidates. There is a high failure rate for drugs and biologics proceeding through clinical trials. 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, and any such setbacks in our clinical development could have a material adverse effect on our business and operating results.

Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval for our product candidates. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, the results of our preclinical studies may not be predictive of the results of outcomes in human clinical trials. For example, our current or future product candidates may demonstrate different chemical, biological and pharmacological properties in patients than they do in laboratory studies or may interact with human biological systems in unforeseen or harmful ways. Product candidates in later stages of clinical trials may fail to show desired pharmacological properties or produce the necessary safety and efficacy results despite having progressed through preclinical studies and initial clinical trials. Even if we are able to initiate and complete clinical trials, the results may not be sufficient to obtain regulatory approval for our product candidates. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy during the period of our product candidate development. Any such delays could negatively impact our business, financial condition, results of operations and prospects.

Interim and preliminary results 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, validation and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim data, including interim top-line results or preliminary results from our clinical trials. Interim data and results from our clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or top-line results also remain subject to audit, validation and verification procedures that may result in the final data being materially different from the interim and preliminary data we previously published. As a result, interim and preliminary data may not be predictive of final results and should be viewed with caution until the final data are available. Differences between preliminary or interim data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly.

Our approach to the discovery and development of product candidates using our FIND-IO platform is unproven and may not result in marketable products.

The success of our business depends in part upon our ability to identify targets based on our proprietary FIND-IO platform and to develop and commercialize immunomedicines. Our approach to the discovery of targets using the FIND-IO platform is novel. We have not yet initiated or completed a clinical trial of any product candidate developed for a target identified from the FIND-IO platform. The platform may fail to accurately identify targets that modulate the immune system and are appropriate for immunomedicines. Even if we are able to identify targets from the FIND-IO platform and to develop corresponding product candidates, we cannot assure that such product candidates will achieve marketing approval to safely and effectively treat cancer or other disease states.

If we uncover any previously unknown risks related to our FIND-IO platform, or if we experience unanticipated problems or delays in developing our FIND-IO product candidates, we may be unable to achieve our strategy of building an oncology pipeline of novel targets for new immunomedicines focused on non-responders, or meet our obligations under the Lilly Agreement.

Our current or future product candidates may cause undesirable side effects or have other properties when used alone or in combination with other approved products or investigational new drugs that could halt their clinical development, delay or prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.

Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are safe, pure and potent for use in each target indication, and failures can occur at any stage of testing. As with most biologics, use of our current or future product candidates could be associated with side effects or adverse events which can vary in severity from minor reactions to death and in frequency from infrequent to prevalent. There have been serious adverse side effects reported in response to immunotherapies in oncology.

The most common treatment-related adverse events reported in Phase 1 of the Phase 1/2 clinical trial of NC318 as of September 26, 2019 have been diarrhea, infusion reactions, fatigue, headaches, elevated amylase and elevated lipase. Most treatment-related adverse events have been easily manageable, asymptomatic or mild or moderate, with the exception of one case of grade 3 episcleritis/uveitis that resolved after steroid therapy and two cases of grade 3 pneumonitis. Immune-related adverse events that represent immune effects on normal tissue and can result from misdirected stimulation of the immune system are a common class of toxicity in immunomedicines such as NC318. Immune-related adverse events reported in the Phase 1 portion of the Phase 1/2 clinical trial of NC318 included diarrhea, elevated amylase and lipase, pruritis, episcleritis/uveitis, pneumonitis and vitiligo.

Possible adverse side effects that could occur with treatment with immunomedicines include an immunologic reaction early after administration which, while not necessarily adverse to the patient’s health, could substantially limit the effectiveness of the treatment. In addition to any potential side effects caused by the product or product candidate, the

administration process or related procedures also can cause adverse side effects. If unacceptable adverse events occur, our clinical trials or any future marketing authorization could be suspended or terminated.

If unacceptable side effects arise in the development of our product candidates, we, the FDA, the IRBs at the institutions in which our studies are conducted or the DSMB could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete any of our clinical trials or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly.

Although our current and future product candidates have undergone and will undergo safety testing to the extent possible and, where applicable, under such conditions discussed with regulatory authorities, not all adverse effects of drugs can be predicted or anticipated. Immunomedicines and their method of action of harnessing the body's immune system are powerful and could lead to serious side effects that we only discover in clinical trials or during commercial marketing. Unforeseen side effects could arise either during clinical development or after our product candidates have been approved by regulatory authorities and the approved product has been marketed, resulting in the exposure of additional patients. So far, we have not demonstrated that NC318, NC410 or any other product candidate is safe in humans, and we cannot predict if ongoing or future clinical trials will do so. If any of our current or future product candidates fail to demonstrate safety and efficacy in clinical trials or do not gain marketing approval, we will not be able to generate revenue and our business will be harmed.

In addition, we intend to pursue NC318 in part in combination with other therapies and may develop NC410 and future product candidates in combination with other therapies, which exposes us to additional risks relating to undesirable side effects or other properties. For example, the other therapies may lead to toxicities that are improperly attributed to our product candidates or the combination of our product candidates with other therapies may result in toxicities that the product candidate or other therapy does not produce when used alone. The other therapies we are using in combination may be removed from the market, or we may not be able to secure adequate quantities of such materials for which we have no guaranteed supply contract, and thus be unavailable for testing or commercial use with any of our approved products. The other therapies we may use in combination with our product candidates may also be supplanted in the market by newer, safer or more efficacious products or combinations of products.

Even if we successfully advance one of our product candidates through clinical trials, such trials will likely only include a limited number of subjects and limited duration of exposure to our product candidates. As a result, we cannot be assured that adverse effects of our product candidates will not be uncovered when a significantly larger number of patients are exposed to the product candidate. Further, any clinical trial may not be sufficient to determine the effect and safety consequences of taking our product candidates over a multi-year period.

If any 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 their approval of the product;
- we may be required to recall a product or change the way such product is administered to patients;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- regulatory authorities may require the addition of labeling statements, such as a "black box" warning or a contraindication;

- we may be required to implement a REMS or create a Medication Guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of the foregoing events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and result in the loss of significant revenues, which would materially harm our business. In addition, if one or more of our product candidates or our immunotherapeutic development approach generally prove to be unsafe, our entire technology platform and pipeline could be affected, which would also materially harm our business.

As an organization, we have limited experience designing and implementing clinical trials and we have never conducted pivotal clinical trials. Failure to adequately design a trial, or incorrect assumptions about the design of the trial, could adversely affect the ability to initiate the trial, enroll patients, complete the trial, or obtain regulatory approval on the basis of the trial results, as well as lead to increased or unexpected costs and in delayed timelines.

The design and implementation of clinical trials is a complex process. We have limited experience designing and implementing clinical trials, and we may not successfully or cost-effectively design and implement clinical trials that achieve our desired clinical endpoints efficiently, or at all. A clinical trial that is not well designed may delay or even prevent initiation of the trial, can lead to increased difficulty in enrolling patients, may make it more difficult to obtain regulatory approval for the product candidate on the basis of the study results, or, even if a product candidate is approved, could make it more difficult to commercialize the product successfully or obtain reimbursement from third-party payors. Additionally, a trial that is not well-designed could be inefficient or more expensive than it otherwise would have been, or we may incorrectly estimate the costs to implement the clinical trial, which could lead to a shortfall in funding. We also expect to continue to rely on third parties to conduct our pivotal clinical trials. See "—Risks Related to Reliance on Third Parties—We rely or will rely on third parties to help conduct our ongoing and planned preclinical studies and clinical trials for NC318, NC410 and any future product candidates we develop. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain marketing approval for or commercialize NC318, NC410 and any future product candidates we develop and our business could be materially harmed." Consequently, we may be unable to successfully and efficiently execute and complete clinical trials that are required for BLA submission and FDA approval of NC318, NC410 or future 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.

If we or our collaborators encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise be adversely affected.

The successful and timely completion of clinical trials in accordance with their protocols depends on, among other things, our ability to enroll a sufficient number of patients who remain in the trial until the trial's conclusion, including any follow-up period. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the nature and size of the patient population required for analysis of the trial's primary endpoints and the process for identifying patients;
- the number and location of participating clinical sites or patients;
- the design of the trial;

- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- 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 products that may be approved for the indications we are investigating;
- the availability of competing commercially available therapies and other competing drug candidates' clinical trials;
- our ability to obtain and maintain patient informed consents for participation in our clinical trials; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion or, because they may be late-stage cancer patients, will not survive the full terms of the clinical trials.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our current and potential future product candidates. This competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such sites. Moreover, because our current and potential future product candidates may represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy, rather than enroll patients in our ongoing or any future clinical trial.

Delays of difficulties in patient enrollment may result in increased costs or may affect the timing, outcome or completion of clinical trials, which would adversely affect our ability to advance the development of the product candidates we develop.

Because the number of subjects in our Phase 1/2 clinical trial of NC318 is small, the results from this trial, once completed, may be less reliable than results achieved in larger clinical trials.

A study design that is considered appropriate includes a sufficiently large sample size with appropriate statistical power, as well as proper control of bias, to allow a meaningful interpretation of the results. The preliminary results of studies with smaller sample sizes, such as our ongoing Phase 1/2 clinical trial of NC318, can be disproportionately influenced by the impact the treatment had on a few individuals, which limits the ability to generalize the results across a broader community, thus making the study results less reliable than studies with a larger number of subjects. As a result, there may be less certainty that NC318 would achieve a statistically significant effect in any future clinical trials. If we conduct any future clinical trials of NC318, we may not achieve a statistically significant result or the same level of statistical significance seen, if any, in our Phase 1/2 clinical trial. Similarly, if we conduct a clinical trial of any other product candidate we develop, including NC410, with a smaller sample size, the results of any such trial may be less reliable than results achieved in larger clinical trials and may provide less certainty of achieving statistically significant effects in any future clinical trials.

We may be required to suspend, repeat or terminate our clinical trials if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive or the trials are not well designed.

Clinical trials must be conducted in accordance with the FDA's current good clinical practices requirements, or cGCP, or analogous requirements of applicable foreign regulatory authorities. Clinical trials are subject to oversight by the FDA, other foreign governmental agencies and IRBs or ethical committees at the study sites where the clinical trials are conducted. In addition, clinical trials must be conducted with product candidates manufactured in accordance with applicable cGMP. Clinical trials may be suspended by the FDA, other foreign regulatory authorities, us, or by an IRB or ethics committee with respect to a particular clinical trial site, for various reasons, including:

- deficiencies in the conduct of the clinical trials, including failure to conduct the clinical trial in accordance with regulatory requirements or study protocols;
- deficiencies in the clinical trial operations or trial sites;
- unforeseen adverse side effects or the emergence of undue risks to study subjects;
- deficiencies in the trial design necessary to demonstrate efficacy;
- the product candidate may not appear to offer benefits over current therapies; or
- the quality or stability of the product candidate may fall below acceptable standards.

We have chosen to prioritize development of NC318 and NC410. We may expend our limited resources on product candidates or indications that do not yield a successful product and fail to capitalize on other candidates or indications for which there may be a greater likelihood of success or may be more profitable.

Because we have limited resources, we have strategically determined to prioritize development of NC318 and NC410 rather than other product candidates based, in part, on the significant resources required for developing and manufacturing immunomedicines. To date, no regulatory authority has granted approval for an immunomedicine targeting S15 or the LAIR pathway. As a result, we may be foregoing other potentially more profitable immunomedicines or therapies or those with a greater likelihood of success. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of any viable commercial product and may divert resources away from better opportunities. Similarly, our potential decisions to delay, terminate or collaborate with third parties with respect to, certain programs may subsequently also prove to be suboptimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the viability or market potential of any of our current or future product candidates or misread trends in the oncology or biopharmaceutical industry, our business, financial condition and results of operations could be materially adversely affected. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases and disease pathways that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain development and commercialization rights.

We may need to develop, or enter into a collaboration or partnership to develop, complementary or companion diagnostics for our current or future product candidates. If we, or our future collaborators, are unable to successfully develop such complementary or companion diagnostics, or experience significant delays in doing so, we may not realize the full commercial potential of our current or future product candidates.

One of the key elements of our product development strategy is to identify cancer patient populations that may derive meaningful benefit from our current or future product candidates. Because predictive biomarkers may be used to identify the right patients for current or future product candidates, we believe that our success may depend, in part, on our ability to develop complementary or companion diagnostics in collaboration with partners.

We have limited experience in the development of diagnostics and, as such, we may rely in part on future collaborators in developing appropriate diagnostics to pair with our current or future product candidates. We have not yet begun substantial discussions with any potential partners with respect to the development of complementary or companion diagnostics and may be unsuccessful in entering into collaborations for the development of any such diagnostics for our current or future product candidates.

Complementary or companion diagnostics are subject to regulation by the FDA and similar comparable foreign regulatory authorities as medical devices and require separate regulatory approval or clearance prior to commercialization. If we, our collaborators, or any third parties that we engage to assist us, are unable to successfully develop complementary or companion diagnostics for our current or future product candidates or experience delays in doing so:

- development of our current or future product candidates may be adversely affected if we are unable to appropriately select patients for enrollment in our clinical trials; and

- we may not realize the commercial potential of our current or future product candidates if, among other reasons, we are unable to appropriately identify, or it takes us longer to identify, patients who are likely to benefit from therapy with our products, if approved. If any of these events were to occur, our business could be materially harmed.

Risks Related to the Regulatory Approval and Commercialization of Product Candidates and Other Legal Compliance Matters

We may be unable to obtain FDA approval of our product candidates under applicable regulatory requirements. The denial or delay of any such approval would prevent or delay commercialization of our product candidates and adversely impact our potential to generate revenue, our business and our results of operations.

To gain approval to market our product candidates in the United States, we must provide the FDA with clinical data that adequately demonstrate the safety, purity and potency, including efficacy, of the product candidate for the proposed indication or indications in a BLA submission. Product development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical development programs. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in clinical trials, even after promising results in earlier preclinical studies or clinical trials. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and the results of clinical trials by other parties may not be indicative of the results in trials we may conduct.

We have not previously submitted a BLA or any other marketing application to the FDA or similar filings to comparable foreign regulatory authorities. A BLA or other similar regulatory filing requesting approval to market a product candidate must include extensive preclinical and clinical data and supporting information to establish that the product candidate is safe, pure and potent for each desired indication. The BLA or other similar regulatory filing must also include significant information regarding the chemistry, manufacturing and controls for the product.

The research, testing, manufacturing, labeling, approval, marketing, sale and distribution of biological products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, and such regulations differ from country to country. We are not permitted to market our product candidates in the United States or in any foreign countries until they receive the requisite approval from the applicable regulatory authorities of such jurisdictions.

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

- our inability to demonstrate to the satisfaction of the FDA or a comparable foreign regulatory authority that our product candidates are safe and effective for the requested indication;

- the FDA or a comparable foreign regulatory authority's disagreement with our trial protocol or the interpretation of data from preclinical studies or clinical trials;
- our inability to demonstrate that the clinical and other benefits of our product candidates outweigh any safety or other perceived risks;
- the FDA or a comparable foreign regulatory authority's requirement for additional preclinical studies or clinical trials;
- the FDA or a comparable foreign regulatory authority's non-approval of the formulation, labeling, or specifications of our product candidates;
- the FDA or a comparable regulatory authority's failure to approve our manufacturing processes and facilities or the manufacturing processes and facilities of third-party manufacturers upon which we rely; or
- potential for approval policies or regulations of the FDA or a comparable foreign regulatory authority to significantly change in a manner rendering our clinical data insufficient for approval.

Even if we eventually complete clinical testing and receive approval from the FDA or comparable foreign regulatory authorities for any of our product candidates, the FDA or comparable foreign regulatory authorities may grant approval contingent on the performance of costly additional clinical trials which may be required after approval. The FDA or comparable foreign regulatory authorities also may approve any of our product candidates for a more limited indication or a narrower patient population than we originally requested, and the FDA or comparable foreign regulatory authorities may not approve any of our product candidates with the labeling that we believe is necessary or desirable for the successful commercialization of any such product candidates.

Of the large number of biopharmaceutical products in development, only a small percentage successfully complete the FDA or other regulatory bodies' approval processes and are commercialized. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of our product candidates and would materially harm our business.

Even if a current or future product candidate receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If any current or future product candidate we develop receives marketing approval, whether as a single agent or in combination with other therapies, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors, and others in the medical community. For example, current approved immunotherapies, and other cancer treatments like chemotherapy and radiation therapy, are well established in the medical community, and doctors may continue to rely on these therapies. Our approach to targeting different components of the tumor microenvironment is novel and unproven. In addition, adverse events in clinical trials testing our product candidates or in clinical trials of others developing similar product candidates and the resulting publicity, as well as any other adverse events in the field of immuno-oncology that may occur in the future, could result in a decrease in demand for our current or future product candidates. If public perception is influenced by claims that the use of cancer immunotherapies is unsafe, whether related to our immunomedicines or our competitors' products, our products may not be accepted by the general public or the medical community. Future adverse events in immuno-oncology or the biopharmaceutical industry could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our products.

If our current and any future product candidates we develop do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of our current and any future product candidates, if approved for commercial sale, will depend on a number of factors, including:

- efficacy and potential advantages compared to alternative treatments, including those that are not yet approved;
- the ability to offer our products, if approved, for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing, sales and distribution support;
- the ability to obtain sufficient third-party coverage and adequate reimbursement, including with respect to the use of the approved product as a combination therapy;
- the regulatory approval and adoption of a companion or complementary diagnostic, if needed; and
- the prevalence and severity of any side effects.

The market opportunities for any current or future product candidate we develop, if approved, may be limited to those patients who are ineligible for established therapies or for whom prior therapies have failed, and may be small.

Any revenue we are able to generate in the future from product sales will be dependent, in part, upon the size of the market in the United States and any other jurisdiction for which we gain regulatory approval and have commercial rights. If the markets or patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, even if approved.

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, usually chemotherapy, hormone therapy, surgery, radiation therapy or a combination of these, is sometimes adequate to cure the cancer or prolong life without a cure. Second- and third-line therapies are administered to patients when prior therapy is not effective. We may initially seek approval for NC318, NC410 and any other product candidates we develop as second- or third-line therapies. If we do so, for those products that prove to be sufficiently beneficial, if any, we would expect potentially to seek approval as a first-line therapy, but there is no guarantee that any product candidate we develop, even if approved, would be approved for first-line therapy, and, prior to any such approvals, we may have to conduct additional clinical trials.

The number of patients who have the types of cancer we are targeting may turn out to be lower than expected. Additionally, the potentially addressable patient population for our current or future product candidates may be limited, if and when approved. Even if we obtain significant market share for any product candidate, if and when approved, if the potential target populations are small, we may never achieve profitability without obtaining marketing approval for additional indications, including to be used as first- or second-line therapy.

We intend to develop NC318 in part in combination with other therapies and may develop NC410 and future product candidates in combination with other therapies, which exposes us to additional regulatory risks.

We intend to develop NC318 in part in combination with other therapies and may develop NC410 and future product candidates in combination with one or more currently approved cancer therapies. These combinations have not been tested before and may, among other things, fail to demonstrate synergistic activity, may fail to achieve superior

outcomes relative to the use of single agents or other combination therapies, or may fail to demonstrate sufficient safety or efficacy traits in clinical trials to enable us to complete those clinical trials or obtain marketing approval for the combination therapy.

In addition, we did not develop or obtain regulatory approval for, and we do not manufacture or sell, any of these approved therapeutics. Therefore, even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risk that the FDA or comparable foreign regulatory authorities could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. This could result in our own products being removed from the market or being less successful commercially. Combination therapies are commonly used for the treatment of cancer, and we would be subject to similar risks if we develop any of our product candidates for use in combination with other drugs or for indications other than cancer.

We may also evaluate NC318, NC410, or any future product candidate in combination with one or more other cancer therapies that have not yet been approved for marketing by the FDA or comparable foreign regulatory authorities. We will not be able to market and sell NC318, NC410 or any product candidate we develop in combination with any such unapproved cancer therapies that do not ultimately obtain marketing approval.

If the FDA or comparable foreign regulatory authorities do not approve these other biological products or revoke their approval of, or if safety, efficacy, manufacturing or supply issues arise with, the biologics we choose to evaluate in combination with NC318, NC410 or any product candidate we develop, we may be unable to obtain approval of or market any such product candidate.

Even if we receive marketing approval of a product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. If we fail to comply or experience unanticipated problems with our products, we may be subject to administrative and judicial enforcement, including monetary penalties, for non-compliance and our approved products, if any, could be deemed misbranded or adulterated and prohibited from continued distribution.

Any marketing approvals that we receive for any current or future product candidate may be subject to limitations on the approved indicated uses for which the product may be marketed or the conditions of approval, or contain requirements for potentially costly post-market testing and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require implementation of a REMS as a condition of approval of any product candidate, 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 a product candidate, the manufacturing processes, labeling, packaging, distribution, adverse event and deviation reporting, storage, advertising, promotion, import and export and record keeping for the product candidate 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 cGMP and cGCP, for any clinical trials that we may conduct post-approval. Later discovery of previously unknown problems with any approved candidate, including adverse events of unanticipated severity or frequency, or with our or our third-party manufacturers' manufacturing processes or facilities, or failure to comply with regulatory requirements, may result in, among other things:

- suspension of, or imposition of restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or product recalls;
- Warning Letters or Untitled Letters, or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications we file, or suspension or revocation of approved biologics licenses;
- product seizure or detention, monetary penalties, refusal to permit the import or export of the product, or placement on Import Alert; and

- permanent injunctions and consent decrees including the imposition of civil or criminal penalties.

Given the nature of biologics manufacturing, there is a risk of contamination. Any contamination could materially adversely affect our ability to produce product candidates on schedule and could, therefore, harm our results of operations and cause reputational damage. Some of the raw materials and other components required in our manufacturing process are derived from biologic sources. Such raw materials are difficult to procure and may be subject to contamination or recall. A material shortage, contamination, recall or restriction on the use of biologically derived substances in the manufacture of our product or product candidates could adversely impact or disrupt the commercial manufacturing or the production of clinical material, which could materially and adversely affect our development and commercialization timelines and our business, financial condition, results of operations and prospects and could adversely affect our ability to meet our supply obligations.

Moreover, the FDA strictly regulates the promotional claims that may be made about drug and biological products. In particular, an approved product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling, or off-label uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. The FDA has issued guidance on the factors that it will consider in determining whether a firm's product communication is consistent with the FDA-required labeling for that product, and those factors contain complexity and potential for overlap and misinterpretation. A company that is found to have improperly promoted off-label uses of their products may be subject to significant civil, criminal and administrative penalties.

The FDA and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay marketing approval of a product. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. 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.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

Certain policies of the Trump Administration may impact our business and industry. President Trump 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 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 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 restrictions on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

In addition, 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.

Obtaining and maintaining marketing approval of our current and future product candidates in one jurisdiction does not mean that we will be successful in obtaining and maintaining marketing approval of our current and future product candidates in other jurisdictions.

Obtaining and maintaining marketing approval of our current and future product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain marketing approval in any other jurisdiction, while a failure or delay in obtaining marketing approval in one jurisdiction may have a negative effect on the marketing approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate

in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign marketing approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

We depend on our information technology systems, and any failure of these systems could harm our business. Security breaches, loss of data, and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business, results of operations and financial condition.

We collect and maintain information in digital form that is necessary to conduct our business, and we are dependent on our information technology systems and those of third parties to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information, and data to comply with cGMP and data integrity requirements. It is critical that we do so in a secure manner to maintain data security and data integrity of such information. We have established physical, electronic and organizational measures to safeguard and secure our systems to prevent a data compromise. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information. Our internal information technology systems and infrastructure, and those of our current and any future collaborators, contractors and consultants and other third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions, phishing, persons inside our organization or persons with access to systems inside our organization.

The risk of a security breach or disruption or data loss, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information or other intellectual property. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. Moreover, if a computer security breach affects our systems or results in the unauthorized release of personally identifiable information, our reputation could be materially damaged. In addition, such a breach may require notification to governmental agencies, the media or individuals pursuant to various federal and state privacy and security laws, if applicable, including the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended, and its implementing rules and regulations, as well as regulations promulgated by the Federal Trade Commission and state breach notification laws. We would also be exposed to a risk of loss or litigation and potential liability, which could materially adversely affect our business, results of operations and financial condition.

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

The availability of coverage and adequacy of reimbursement by third-party payors, including managed care plans, governmental healthcare programs, such as Medicare and Medicaid and private health insurers is essential for most patients to be able to afford medical services and pharmaceutical products such as our product candidates that receive FDA approval. Our ability to achieve acceptable levels of coverage and reimbursement for our products or procedures using our products by third-party payors will have an effect on our ability to successfully commercialize our product candidates. Obtaining coverage and adequate reimbursement for our products may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. Separate reimbursement for the product itself or the treatment or procedure in which our product is used may not be available. A decision by a third-party payor not to cover or not to separately reimburse for our products or procedures using our products could reduce physician utilization of our products once approved. Assuming there is coverage for our product candidates, or procedures using our product candidates 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 our current or future product candidates, or for any procedures using such product candidates, and any reimbursement that may become available may not be adequate or may be decreased or eliminated in the future.

Our ability to successfully commercialize any product candidate, whether as a single agent or combination therapy, will also depend in part on the extent to which coverage and reimbursement for these product candidates and related treatments will be available from third-party payors. Third-party payors decide which medications they will pay for and establish reimbursement levels. It is difficult to predict at this time what government authorities and third-party payors will decide with respect to coverage and reimbursement for our current and future product candidates.

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

There is significant uncertainty related to the insurance coverage and reimbursement of newly-approved products, especially novel products like our immunomedicines. To date, no regulatory authority has granted approval for an immunomedicine targeting S15 or the LAIR pathway. The Medicare and Medicaid programs are increasingly used as models in the United States for how private third-party payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. 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. We cannot predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

No uniform policy for coverage and reimbursement for products exist 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 may require us to provide scientific and clinical support for the use of our product candidates 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 on short notice, and we believe that changes in these rules and regulations are likely.

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

Moreover, increasing efforts by 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 product candidates. We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and biologics and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products.

Enacted healthcare legislation, changes in healthcare law and implementation of regulations, as well as changes in healthcare policy, may increase the difficulty and cost for us to commercialize our product candidates, may impact our business in ways that we cannot currently predict, could affect the prices we may set, and could have a material adverse effect on our business and financial condition.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. 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 of 2010, or collectively, the ACA, was passed, which substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, subjects biological products to potential competition by lower-cost biosimilars, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs and creates a new Medicare Part D coverage gap discount program in which, as a condition of coverage of its products under Medicare Part D, manufacturers must now agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period.

Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges, as well as efforts by President Trump’s administration to repeal or replace certain aspects of the ACA, and to alter the implementation of the ACA and related laws. For example, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or the Tax Act, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA 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, the President signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called “Cadillac” tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share and the medical device excise tax on non-exempt medical devices. The Bipartisan Budget Act of 2018, among other things, amended the ACA, effective January 1, 2019, to reduce the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole.” Also, in 2018, the Centers for Medicare and Medicaid Services, or CMS, issued final rules permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district

court litigation regarding the method CMS uses to determine this risk adjustment. In December 2018, a United States District Court Judge for the Northern District of Texas ruled that the entire ACA is unconstitutional because the tax penalty associated with the "individual mandate" was repealed by Congress as part of the Tax Act. This ruling is under appeal and stayed pending appeal. While the United States District Court Judge for the Northern District of Texas, as well as the Trump Administration and CMS, have stated that the ruling will have no effect while this appeal is pending, it is unclear how this decision, subsequent appeals and other efforts to invalidate the ACA, regulations promulgated under the ACA and related laws, or portions thereof will impact the ACA, its implementation and our business.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, 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, further reduced Medicare payments to several types of providers.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, effective January 1, 2014, CMS began bundling into the hospital outpatient prospective payment rate the Medicare payments for most laboratory tests ordered while a patient received services in a hospital outpatient setting. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for any product candidate we develop or complementary or companion diagnostics or additional pricing pressures.

CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation that legislators intend to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs, and review the relationship between pricing and manufacturer patient programs. The Trump Administration's budget proposals for fiscal 2019 and 2020 contain drug price control measures, including 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. For example, the Trump Administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional 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 started soliciting feedback on some of these measures and, at the same, is implementing others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. Although a number of these and other proposed measures may require additional authorization to become effective, Congress and the Trump Administration have each indicated that they will continue to seek new legislative and/or administrative measures to control drug costs. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the extent to which the U.S. federal government covers particular healthcare products and services and could limit the amounts that the U.S. federal government will pay for healthcare products and services. This could result in reduced demand for our product candidates or additional pricing pressures.

Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement limitations, 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 on coverage or access 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 that we successfully commercialize or put pressure on our product pricing.

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

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Our relationships with customers, third-party payors and others may be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare providers, third-party payors, customers, and others may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, which may constrain the business or financial arrangements and relationships through which we research, as well as sell, market and distribute any products for which we obtain marketing approval. The applicable federal and state healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- The federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under the Medicare and Medicaid programs or other federal healthcare programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exceptions and regulatory safe harbors to the federal Anti-Kickback Statute protecting certain common business arrangements and activities from prosecution or regulatory sanctions, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration to those who prescribe, purchase, or recommend pharmaceutical and biological products, including certain discounts, or engaging such individuals as speakers or consultants, may be subject to scrutiny if they do not fit squarely within an exception or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability. Moreover, there are no safe harbors for many common practices, such as educational and research grants or patient or product assistance programs.

- The federal civil and criminal false claims laws and civil monetary penalty laws, including the civil False Claims Act, or FCA, which prohibits, among other things, knowingly presenting, or causing to be presented, claims for payment of government funds that are false or fraudulent, or knowingly making, or using or causing to be made or used, a false record or statement material to a false or fraudulent claim to avoid, decrease, or conceal an obligation to pay money to the federal government. Private individuals, commonly known as “whistleblowers,” can bring FCA qui tam actions, on behalf of the government and such individuals and may share in amounts paid by the entity to the government in recovery or settlement. In addition, 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 FCA. FCA liability is potentially significant in the healthcare industry because the statute provides for treble damages and significant mandatory penalties per false claim or statement for violations. Criminal penalties, including imprisonment and criminal fines, are also possible for making or presenting a false, fictitious or fraudulent claim to the federal government.

- The HIPAA fraud provisions, which prohibit knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors, and prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false fictitious or fraudulent statement or entry 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 can be found guilty of violating the HIPAA fraud provisions without actual knowledge of the statutes or specific intent to violate them.

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, also impose specified requirements relating to the privacy, security and transmission of individually identifiable health information held by covered entities, which include health plans, healthcare clearinghouses and certain healthcare providers, and their business associates, individuals or entities that perform certain services on behalf of a covered entity that involve the use or disclosure of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions;

- The federal Physician Payments Sunshine Act, being implemented as the Open Payments Program, which requires 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 CMS information related to direct or indirect payments and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held in a company by physicians and their immediate family members. Beginning in 2022, applicable manufacturers will also be required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists and certified nurse-midwives; and

- Analogous U.S. state and local laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state laws that restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs; state laws that require drug manufacturers to report information related to clinical trials, or information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state laws that require drug manufacturers to report information on the pricing of certain drugs; state laws and local ordinances that require identification or licensing of sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our business activities could be subject to challenge under one or more of such laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare

providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring that our business arrangements with third parties comply with applicable healthcare laws, as well as responding to investigations by government authorities, can be time and resource consuming and can divert management's attention from the business.

If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Further, if the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to criminal, civil and administrative sanctions, including exclusion from government funded healthcare programs. In addition, the approval and commercialization of any product candidate we develop outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws. All of these could harm our ability to operate our business and our financial results.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations. We can face serious consequences for violations.

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

Our business is heavily regulated and therefore involves significant interaction with public officials. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We also expect our non-U.S. activities to increase in time. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA. We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities. In particular, our operations will be subject to FCPA, which prohibits, among other things, U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government-owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof. Recently, the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents, suppliers, manufacturers, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of facilities, including those of our suppliers and manufacturers, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs and prohibitions on the conduct of our business. Any such violations could also result in prohibitions on our ability to offer our products in one or more countries, as well as difficulties in manufacturing or continuing to develop our products, and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees and our business, prospects, operating results and financial condition.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

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

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

Risks Related to Manufacturing

Given our limited operating history, our manufacturing experience as an organization and with our manufacturing facility is limited.

Manufacturing is a critical component of our approach to developing immunomedicines and we have invested significantly in our manufacturing facility. We currently manufacture our product candidates for preclinical and clinical trials.

The manufacture of drugs for clinical trials and for commercial sale is subject to oversight by the FDA to ensure compliance with cGMP and by other regulatory authorities under other laws, regulations and standards. We cannot assure you that we can successfully manufacture our products in compliance with cGMP and with any other applicable laws, regulations and standards in sufficient quantities for clinical trials or for commercial sale, or in a timely or economical manner.

Our manufacturing facility requires specialized personnel and is expensive to operate and maintain. Validation is an ongoing process that must be maintained to allow us to manufacture under cGMP guidelines. We cannot guarantee that our facility will remain in compliance with cGMP.

The manufacture of pharmaceutical products is a highly complex process in which a variety of difficulties may arise from time to time. We are currently the sole manufacturer of NC318 and NC410 and if anything were to interfere with our continuing manufacturing operations in our facility, it could materially adversely affect our business and financial condition.

If we fail to develop sufficient manufacturing capacity and experience, whether internally or with a third party, or fail to manufacture our product candidates economically or on reasonable scale or volumes, or in accordance with cGMP, our development programs and commercialization of any approved products will be materially adversely affected. This may result in delays in commencing or continuing our clinical trials for NC318 or filing our IND for NC410. Any such delays could materially adversely affect our business and financial condition.

We may be unable to successfully scale-up manufacturing of our product candidates in sufficient quality and quantity, which would delay or prevent us from developing and, if approved, commercializing our product candidates.

In order to conduct clinical trials of our product candidates, we will need to manufacture them in large quantities. Currently, our product candidates are manufactured in small quantities for use in various preclinical studies and our ongoing Phase 1/2 clinical trial of NC318. We intend to expand our manufacturing capacity, including to provide drug supply of NC318 for future clinical trials, which will require us to incur significant expenses. If one or more of our product

candidates progress to late-stage development, we may incur additional significant expenses in the further expansion and/or construction of manufacturing facilities and increases in personnel in order to manufacture product candidates. We cannot assure you that we will be able to successfully manufacture additional product candidates at a larger scale in a timely or economical manner, or at all. If we are unable to successfully increase our manufacturing scale or capacity, the development, testing, and clinical trials of our current or future product candidates may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business.

The loss of our third-party manufacturing partners or our, or our partners', failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect our business.

Although we currently manufacture our product candidates for preclinical and clinical trials, certain elements of manufacturing, including Master Cell Bank manufacturing and fill-finish services, take place at qualified third-party contract manufacturing organizations, or CMOs. If approved, commercial supply of NC318, NC410 and any future product candidates may be manufactured at a CMO or CMOs.

The facilities used by our CMOs to manufacture our product candidates are subject to various regulatory requirements and may be subject to the inspection of the FDA or other regulatory authorities. We do not control the manufacturing process at our CMOs, and are completely dependent on them for compliance with current regulatory requirements. If we or our CMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable regulatory authorities in foreign jurisdictions, we may not be able to rely on their manufacturing facilities for the manufacture of elements of our product candidates. In addition, we have limited control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority finds our facilities or those of our CMOs inadequate for the manufacture of our product candidates or if such facilities are subject to enforcement action in the future or are otherwise inadequate, 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.

Additionally, our CMOs may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our CMOs were to encounter any of these difficulties, our ability to provide our product candidate to patients in clinical trials, or to provide product for the treatment of patients once approved, would be jeopardized.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates proceed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, FDA notification or FDA approval. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence sales and generate revenue.

We are subject to multiple manufacturing risks, any of which could substantially increase our costs and limit supply of our product candidates.

The process of manufacturing immunomedicines, including our product candidates, is complex, time-consuming, highly regulated and subject to several risks, including:

- product loss during the manufacturing process, including loss caused by contamination, equipment failure or improper installation or operation of equipment, or operator error. Even minor deviations from normal

manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our products or in the manufacturing facilities in which our products are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination;

- the manufacturing facilities in which our products are made could be adversely affected by equipment failures, labor and raw material shortages, natural disasters, power failures and numerous other factors; and

- any adverse developments affecting manufacturing operations for our products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our products. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives.

We may also make changes to our manufacturing processes at various points during development, for a number of reasons, such as controlling costs, achieving scale, decreasing processing time, increasing manufacturing success rate or other reasons. Such changes carry the risk that they will not achieve their intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of our ongoing or future clinical trials. In some circumstances, changes in the manufacturing process may require us to perform ex vivo comparability studies and to collect additional data from patients prior to undertaking more advanced clinical trials. For instance, changes in our process during the course of clinical development may require us to show the comparability of the product used in earlier clinical phases or at earlier portions of a trial to the product used in later clinical phases or later portions of the trial.

We depend on third-party suppliers for key materials used in our manufacturing processes, and the loss of these third-party suppliers or their inability to supply us with adequate materials could harm our business.

We rely on third-party suppliers for certain materials and components required for the production of our product candidates. Our dependence on these third-party suppliers and the challenges we may face in obtaining adequate supplies of materials involve several risks, including limited control over pricing, availability, and quality and delivery schedules. As a small company, our negotiation leverage is limited, and we are likely to get lower priority than our competitors that are larger than we are. We cannot be certain that our suppliers will continue to provide us with the quantities of these raw materials that we require or satisfy our anticipated specifications and quality requirements. Any supply interruption in limited or sole sourced raw materials could materially harm our ability to manufacture our product candidates until a new source of supply, if any, could be identified and qualified. We may be unable to find a sufficient alternative supply channel in a reasonable time or on commercially reasonable terms. Any performance failure on the part of our suppliers could delay the development and potential commercialization of our product candidates, including limiting supplies necessary for clinical trials and regulatory approvals, which would have a material adverse effect on our business.

Risks Related to Intellectual Property

We have filed patent applications for our lead product candidates, but no patent has yet issued from these applications. If we are unable to obtain and maintain patent protection for our product candidates, or if the scope of the patent protection obtained is not sufficiently broad or robust, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our product candidates may be adversely affected.

Our success depends, in large part, on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates. We and our licensors have sought, and intend to seek, to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates and technology that are important to our business. No patent has yet issued from our patent applications.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has, in recent years, been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future

patent applications may not result in patents being issued that protect our technology or product candidates or that effectively prevent others from commercializing competitive technologies and product candidates. Because patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our licensors were the first to file a patent application relating to any particular aspect of a product candidate. Furthermore, if third parties have filed such patent applications, we may challenge their ownership, for example in a derivation proceeding before the U.S. Patent and Trademark Office, or USPTO, to determine who has the right to the claimed subject matter in the applications. Similarly, if our patent applications are challenged in a derivation proceeding, the USPTO may hold that a third-party is entitled to certain patent ownership rights instead of us. We may then be forced to seek a license from the third party that may not be available on commercially favorable terms, or at all.

The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

Even if the patent applications we license or own do 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. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products that do not infringe our patents.

We are party to a license agreement with Yale University under which we acquired rights to intellectual property related to certain of our product candidates. If we breach our obligations under this agreement, the agreement could be terminated, which would adversely affect our business and prospects.

We are a party to a license agreement with Yale pursuant to which we in-license patents and technology for certain of our product candidates. This license imposes various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these and other obligations or otherwise materially breach this license agreement, Yale may have the right to terminate the license. If this agreement is terminated, we may not be able to develop, manufacture, market or sell the product candidates or products covered by the agreement, or we would have to negotiate a new or reinstated agreement, which may not be available to us on equally favorable terms, or at all.

Our intellectual property agreements with third parties may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations to our licensors.

Certain provisions in our intellectual property agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or technology, or affect financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government 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 government fees on patents and/or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our licensed patents and/or applications and any patent rights we own or may own in the future. We rely, in part, on our outside counsel or our licensing partners to pay these fees due to the USPTO and to non-U.S. patent agencies. The USPTO and various non-U.S. government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent

lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance 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. In such an event, potential competitors might be able to enter the market and this circumstance could have a material adverse effect on our business.

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

Filing, prosecuting and enforcing patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States are and could remain 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 be less likely to be able to prevent third parties from infringing our patents in all countries outside the United States, or from selling or importing products that infringe our patents in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have 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 products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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 any of our licensors 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.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The America Invents Act also includes a number of significant changes that affect the way patent applications are 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 or ownership of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review and derivation proceedings. The America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent rulings from the U.S. Court of Appeals for the Federal Circuit and the U.S. Supreme Court have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

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

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

In addition, many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to biotechnology products, 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 generally. 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 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 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 own, develop or license.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court. We may not be able to protect our trade secrets in court.

If we or one of our licensing partners initiate legal proceedings against a third party to enforce any patent that is issued covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description or non-enablement. In addition, patent validity challenges may, under certain circumstances, be based upon non-statutory obviousness-type double patenting, which, if successful, could result in a finding that the claims are invalid for obviousness-type double patenting or the loss of patent term, including a patent term adjustment granted by the USPTO, if a terminal disclaimer is filed to obviate a finding of obviousness-type double patenting. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld information material to patentability from the USPTO, or made a misleading statement, during prosecution. Third parties also may raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, *inter partes* review and equivalent proceedings in foreign jurisdictions. Such proceedings could result in the revocation or cancellation of or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art of which the patent examiner and we or our licensing partners were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we could lose part, and perhaps all, of the patent protection on one or more of our product candidates. Such a loss of patent protection could have a material adverse impact on our business.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult

to enforce and any other elements of our product candidate discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents, including portions of our FIND-IO platform. However, trade secrets can be difficult to protect, and some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business and financial condition.

Our commercial success depends upon our ability and the ability of any collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights and intellectual property of third parties. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current manufacturing methods, product candidates or future methods or products, resulting in either an injunction prohibiting our manufacture or sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates and technology, including post grant review and *inter partes* review before the USPTO. The risks of being involved in such litigation and proceedings may also increase as our product candidates approach commercialization and as we gain greater visibility as a public company. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could materially and adversely affect our ability to commercialize any of our product candidates or technologies covered by the asserted third-party patents.

If we are found to infringe a third party's valid and enforceable intellectual property rights, we could be required to obtain a license from such third party to continue developing, manufacturing and marketing our product candidates and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or product candidates. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. A finding of infringement could prevent us from manufacturing and commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects.

Others may claim an ownership interest in our intellectual property and our product candidates, which could expose us to litigation and have a significant adverse effect on our prospects.

While we are presently unaware of any claims or assertions by third parties with respect to our patents or other intellectual property, we cannot guarantee that a third party will not assert a claim or an interest in any of such patents or intellectual property. For example, a third party may claim an ownership interest in one or more of our, or our licensors', patents or other proprietary or intellectual property rights. A third party could bring legal actions against us to seek monetary damages or enjoin clinical testing, manufacturing or marketing of the affected product candidate or product. If we become involved in any litigation, it could consume a substantial portion of our resources and cause a significant diversion of effort by our technical and management personnel. If any such action is successful, in addition to any potential liability for damages, we could be required to obtain a license to continue to manufacture or market the affected product candidate or product, in which case we could be required to pay substantial royalties or grant cross-licenses to patents. We cannot, however, assure you that any such license would be available on acceptable terms, if at all. Ultimately, we could

be prevented from commercializing a product, or forced to cease some aspect of our business operations as a result of claims of patent infringement or violation of other intellectual property rights. Further, the outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of any adverse party. This is especially true in intellectual property cases, which may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations or prospects.

If we are unable to protect the confidentiality of our proprietary information, the value of our technology and products could be adversely affected.

Trade secrets and know-how can be difficult to protect. To maintain the confidentiality of trade secrets and proprietary information, we enter into confidentiality agreements with our employees, consultants, collaborators and others upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. Our agreements with employees and our personnel policies also provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes, and individuals with whom we have these agreements may not comply with their terms. Thus, despite such agreement, there can be no assurance that such inventions will not be assigned to third parties. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our employees, consultants or contractors use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions. To the extent that an individual who is not obligated to assign rights in intellectual property to us is rightfully an inventor of intellectual property, we may need to obtain an assignment or a license to that intellectual property from that individual, or a third party or from that individual's assignee. Such assignment or license may not be available on commercially reasonable terms or at all. We also seek to preserve the integrity and confidentiality of our trade secrets by other means, including maintaining physical security of our premises and physical and electronic security of our information technology systems. However, these security measures may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property.

Adequate remedies may not exist in the event of unauthorized use or disclosure of our proprietary information. The disclosure of our trade secrets would impair our competitive position and may materially harm our business, financial condition and results of operations. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to maintain trade secret protection could adversely affect our competitive business position. In addition, others may independently discover or develop our trade secrets and proprietary information, and the existence of our own trade secrets affords no protection against such independent discovery. For example, a public presentation in the scientific or popular press on the properties of our product candidates could motivate a third party, despite any perceived difficulty, to assemble a team of scientists having backgrounds similar to those of our employees to attempt to independently reverse engineer or otherwise duplicate our antibody technologies to replicate our success.

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

Many of our employees, consultants or advisors are currently, or were previously, employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals, or we, have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer, or that patents and applications we have filed to protect inventions of these employees, even those related to one or more of our product candidates, are rightfully owned by their former or current employer. 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. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Any registered trademarks or trade names may be challenged, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

Intellectual property rights do not necessarily address all potential threats.

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 make products that are similar to our product candidates but that are not covered by the claims of the patents that we own or license or may own in the future;
- we, or any partners or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future;
- we, or any partners or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- it is possible that our pending licensed patent applications or those that we may own in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including 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;
- the patents of others may have an adverse effect on our business; and
- we may choose not to file a patent for certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

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

Risks Related to Reliance on Third Parties

We rely or will rely on third parties to help conduct our ongoing and planned preclinical studies and clinical trials for NC318, NC410 and any future product candidates we develop. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain marketing approval for or commercialize NC318, NC410 and any future product candidates we develop and our business could be materially harmed.

We currently do not have the ability to independently conduct preclinical studies that comply with the regulatory requirements known as current good laboratory practice, or GLP, requirements. We also do not currently have the ability to independently conduct any clinical trials. The FDA and regulatory authorities in other jurisdictions require us to comply with regulations and standards, including cGCP, or requirements for conducting, monitoring, recording and reporting the results of clinical trials, in order to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. We rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct GLP-compliant preclinical studies and cGCP-compliant clinical trials on our product candidates properly and on time. While we have agreements governing their activities, we control only certain aspects of their activities and have limited influence over their actual performance. The third parties with whom we contract for execution of our GLP-compliant preclinical studies and our cGCP-compliant clinical trials play a significant role in the conduct of these studies and trials and the subsequent collection and analysis of data. These third parties are not our employees and, except for restrictions imposed by our contracts with such third parties, we have limited ability to control the amount or timing of resources that they devote to our current or future product candidates. Although we rely on these third parties to conduct our GLP-compliant preclinical studies and cGCP-compliant clinical trials, we remain responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with its investigational plan and protocol and applicable laws and regulations, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

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. Further, under certain circumstances, these third parties may terminate their agreements with us upon as little as 10 days' prior written notice. Some of these agreements may also be terminated by such third parties under certain other circumstances. If the third parties conducting our preclinical studies or our clinical trials do not adequately perform their contractual duties or obligations, experience significant business challenges, disruptions or failures, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our protocols or to GLP and cGCP, or for any other reason, we may need to enter into new arrangements with alternative third parties. This could be difficult, costly or impossible, and our preclinical studies or clinical trials may need to be extended, delayed, terminated or repeated. As a result, we may not be able to obtain regulatory approval in a timely fashion, or at all, for the applicable product candidate, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

We may depend on Lilly, Yale or other third-party collaborators for the discovery, development and commercialization of certain of our current and future product candidates. If our collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

In November 2018, we entered into the Lilly Agreement, which is focused on using our FIND-IO platform to identify novel oncology targets for additional research and drug discovery by ourselves and Lilly. Pursuant to the Lilly Agreement, we granted Lilly the exclusive right to obtain worldwide exclusive licenses to research, develop, manufacture and commercialize compounds and products directed to oncology targets identified through our research collaboration. Lilly will have the exclusive ability to control the development and commercialization of any targets it chooses to license on a global basis. Our lack of control over the clinical development of certain programs under the Lilly Agreement could result in delays or other difficulties in the development and commercialization of product candidates. Our right to receive

certain milestone and royalty payments may be subsequently delayed, if we receive any at all. In the event Lilly terminates the Lilly Agreement, we would be prevented from receiving any milestone payments, royalty payments and other benefits under that agreement, which would have a materially adverse effect on our results of operations. Furthermore, in the event Lilly does not purchase and exercise any of its options, we will not be eligible to receive any future milestone payments under the Lilly Agreement, which could require us to seek additional funding in order to avoid delaying, reducing the scope of, or suspending, one or more of our research and development programs or clinical trials.

We have also entered into the SRA with Yale in which we agreed to provide funding for a research program aimed at discovering new targets for immunomedicines. We have and would expect to have limited control over the amount and timing of resources that are employed in the research program. The research program may not be successful, and as a result, we may not be able to identify, develop and commercialize products from this collaboration.

In the future, we may form or seek other strategic alliances, joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to product candidates we develop.

Our collaborations pose, and potential future collaborations involving our product candidates may pose, the following risks to us:

- collaborators may have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- collaborators may not properly enforce, maintain or defend our intellectual property rights or may use our proprietary information in a way that gives rise to actual or threatened litigation or that could jeopardize or invalidate our intellectual property or proprietary information, exposing us to potential litigation or other intellectual property proceedings;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- disputes may arise between a collaborator and us that cause the delay or termination of the research, development or commercialization of the product candidate, or that result in costly litigation or arbitration that diverts management attention and resources;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such products;
- if a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated; and
- collaboration agreements may restrict our right to independently pursue new product candidates.

If we enter into additional collaboration agreements and strategic partnerships or license our intellectual property, products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or net income that justifies such transaction. Any of the factors set forth above and any delays in entering into new collaborations or strategic partnership agreements related to any product candidate we develop could delay the development and commercialization of our product candidates, which would harm our business prospects, financial condition and results of operations.

We may seek to establish additional collaborations, and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

The advancement of our product candidates and development programs and the potential commercialization of our current and future product candidates will require substantial additional cash to fund expenses. For some of our current or future product candidates, we may decide to collaborate with additional pharmaceutical and biotechnology companies with respect to development and potential commercialization. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business.

We face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Whether we reach a definitive agreement for other collaborations will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the progress of our clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate.

Further, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for future product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view them as having the requisite potential to demonstrate safety and efficacy.

We may also be restricted under existing collaboration agreements from entering into future agreements on certain terms with potential collaborators. Such exclusivity could limit our ability to enter into strategic collaborations with future collaborators. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any marketing or sales activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Risks Related to Our Business

We are highly dependent on our key personnel, and if we are not successful in attracting, motivating and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

We are highly dependent on members of our executive team. The loss of the services of any of them may adversely impact the achievement of our objectives. Any of our executive officers could leave our employment at any time, as all of our employees are "at-will" employees. We currently only have "key person" insurance on Michael Richman, our President and Chief Executive Officer, and on Dr. Lieping Chen, our scientific founder, in his role as consultant to us. The loss of the services of Mr. Richman, Dr. Chen or one or more of our other executive officers could impede the achievement of our research, development and commercialization objectives.

We continue to work with Dr. Chen on discovering novel immunomedicines through his consulting agreement and our SRA with Yale. If we are no longer able to leverage our relationships with Dr. Chen and Yale, our ability to

discover additional targets for immunomedicines may be impeded, which may adversely impact the achievement of our objectives.

Recruiting and retaining qualified employees, consultants and advisors for our business, including scientific and technical personnel, will also be critical to our success. Competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies and academic institutions for skilled individuals. In addition, failure to succeed in preclinical studies, clinical trials or applications for marketing approval may make it more challenging to recruit and retain qualified personnel. The inability to recruit, or the loss of services of certain executives, key employees, consultants or advisors, may impede the progress of our research, development and commercialization objectives and have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biotechnology industry is intensely competitive and subject to rapid and significant technological change. Our current or future product candidates may face competition from major pharmaceutical companies, specialty pharmaceutical companies, universities and other research institutions and from products and therapies that currently exist or are being developed, some of which products and therapies we may not currently know about. Many of our competitors have significantly greater financial, manufacturing, marketing, product development, technical and human resources than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining marketing approvals, recruiting patients and manufacturing pharmaceutical products, and they may also have products that have been approved or are in late stages of development, and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. As a result of all of these factors, our competitors may succeed in obtaining patent protection and/or FDA or other regulatory approval or discovering, developing and commercializing products in our field before we do, which could result in our competitors establishing a strong market position before we are able to enter the market.

Our competitors may obtain FDA or other regulatory approval of their product candidates more rapidly than we may or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates or platform technologies. Our competitors may also develop drugs or discovery platforms that are more effective, more convenient, more widely used or less costly than our product candidates or our FIND-IO platform or, in the case of drugs, have a better safety profile than our product candidates. These competitors may also be more successful than us in manufacturing and marketing their products, and have significantly greater financial resources and expertise in research and development.

There are a large number of companies developing or marketing treatments for cancer, including many major pharmaceutical and biotechnology companies. Currently marketed oncology drugs and therapeutics range from traditional cancer therapies, including chemotherapy, to antibody-drug conjugates, such as Genentech's Kadcyla, to immune checkpoint inhibitors targeting CTLA-4, such as BMS' Yervoy, and PD-1/PD-L1, such as BMS' Opdivo, Merck & Co.'s Keytruda and Genentech's Tecentriq, to T cell-engager immunotherapies, such as Amgen's Blincyto. In addition, numerous compounds are in clinical development for cancer treatment. In addition, numerous compounds are in clinical development for cancer treatment. Many of these companies are well-capitalized and have significant clinical experience.

Smaller and other early stage companies may also prove to be significant competitors. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our current and future product candidates. In addition, the biopharmaceutical industry is characterized by rapid technological change. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our product candidates obsolete, less competitive or not economical.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, have a broader label, are marketed more effectively, are reimbursed or are less expensive than any products that we may develop. Our competitors may also obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates or platform technologies. Even if our product candidates achieve marketing approval, they may be priced at a significant premium over competitive products if any have been approved by then, resulting in reduced competitiveness. If we do not compete successfully, we may not generate or derive sufficient revenue from any product candidate for which we obtain marketing approval and may not become or remain profitable.

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As our development plans and strategies develop, and as we transition into operating as a public company, we expect to need additional managerial, operational, marketing, sales, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA review process for NC318, NC410 and any future product candidates we develop, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to advance development of and, if approved, commercialize NC318, NC410 and any future product candidates we develop will depend, in part, on our ability to effectively manage any future growth, and our management may have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of any current or future product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize NC318, NC410 and any future product candidates we develop and, accordingly, may not achieve our research, development and commercialization goals.

If we are unable to establish marketing, sales and distribution capabilities for NC318, NC410 or any other product candidate that may receive regulatory approval, we may not be successful in commercializing those product candidates if and when they are approved.

We do not have sales or marketing infrastructure. To achieve commercial success for NC318, NC410 and any other product candidate for which we may obtain marketing approval, we will need to establish a sales and marketing organization. In the future, we expect to build a focused sales and marketing infrastructure to market some of our product candidates in the United States, if and when they are approved. There are risks involved with establishing our own marketing, sales and distribution capabilities. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely

or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

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

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians in order to educate physicians about our product candidates, once approved;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are unable to establish our own marketing, sales and distribution capabilities and are forced to enter into arrangements with, and rely on, third parties to perform these services, our revenue and our profitability, if any, are likely to be lower than if we had developed such capabilities ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. 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 do not establish marketing, sales and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of our product candidates.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human trials and may face greater risk if we commercialize any products that we develop. Product liability claims may be brought against us by subjects enrolled in our trials, patients, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against such claims, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidate we may develop;
- withdrawal of trial participants;
- termination of clinical trial sites or entire trial programs;
- injury to our reputation and significant negative media attention;
- initiation of investigations by regulators;
- significant time and costs to defend the related litigation;
- substantial monetary awards to trial subjects or patients;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize any product candidates that we may develop.

While we currently hold trial liability insurance coverage consistent with industry standards, the amount of coverage may not adequately cover all liabilities that we may incur. We may not be able to maintain insurance coverage

at a reasonable cost or in an amount adequate to satisfy any liability that may arise. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain marketing approval for our product candidates, but we may be unable to obtain commercially reasonable product liability insurance. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business and financial condition.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple errors or mistakes. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Our ability to use our net operating loss carryforwards to offset future taxable income may be subject to certain limitations.

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. As of September 30, 2019, we had federal and state net operating loss carryforwards of $43.5 million and $43 million, respectively. The federal and state net operating loss carryforwards will begin to expire, if not utilized, by 2036. Limitations imposed by the applicable jurisdictions on our ability to utilize net operating loss carryforwards could cause income taxes to be paid earlier than would be paid if such limitations were not in effect and could cause such net operating loss carryforwards to expire unused, in each case reducing or eliminating the benefit of such net operating loss carryforwards. Furthermore, we may not be able to generate sufficient taxable income to utilize our net operating loss carryforwards before they expire. If any of these events occur, we may not derive some or all of the expected benefits from our net operating loss carryforwards. In addition, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. As a result, even if we earn net taxable income, our ability to use our net operating loss and tax credit carryforwards may be materially limited, which could harm our future operating results by effectively increasing our future tax obligations.

Risks Related to Our Common Stock

An active trading market for our common stock may not be sustained, and you may not be able to sell your shares at or above a recently reported market price, or at all.

Prior to our IPO, there was no public market for shares of our common stock. Although our common stock is listed on the Nasdaq Global Select Market, or Nasdaq, an active, liquid trading market for our shares may not be sustained. In the absence of an active trading market for our common stock, you may not be able to sell your common stock at or above a recently reported market price or at the time that you would like to sell.

The price of our common stock may be volatile and fluctuate substantially.

Our stock price is likely to be volatile. The stock market in general, and the market for 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, you may not be able to sell your common stock at or above a recently reported price, or at all. The market price for our common stock may be influenced by many factors, including:

- the commencement, enrollment or results of our ongoing or future clinical trials, or changes in the development status of our product candidates;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- adverse results or delays in clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- our failure to commercialize our product candidates;
- unanticipated serious safety concerns related to the use of our product candidates;
- the size and growth of our target markets;
- the success of competitive products or technologies;
- regulatory actions with respect to our product candidates or our competitors' products or product candidates;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- regulatory or legal developments in the United States and other countries applicable to our product candidates, including but not limited to clinical trial requirements for approvals;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license product candidates;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts or publications of research reports about us or our industry;
- variations in our annual or quarterly financial results or those of companies that are perceived by investors to be similar to us;

- our cash position;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our directors, officers or their affiliated funds or our other stockholders;
- changes in the structure of healthcare payment systems;
- significant lawsuits, including patent or stockholder litigation;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and Nasdaq and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this “Risk Factors” section, could have a dramatic and material adverse impact on the market price of our common stock.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock relies, in part, on the research and reports that industry or financial analysts publish about us or our business. As a newly public company, we have only limited coverage by equity research analysts. If additional analysts do not commence coverage of us, the trading price of our stock could decrease. In addition, if one or more of the analysts covering our business issue adverse reports about us or downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock or fail to publish reports on us regularly, we could lose visibility in the market for our stock, which, in turn, could cause our stock price to decline.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall, even if our business is doing well.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline. As of September 30, 2019, we had outstanding a total of 22,739,345 shares of common stock.

We have registered on Registration Statements on Form S-8 5,167,502 shares of common stock that were either subject to outstanding options or reserved for future issuance under our existing equity incentive plans as of May 13, 2019, and as a result these shares will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and the lock-up agreements. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

In addition, the holders of 15,560,569 shares, or approximately 68.5%, of our common stock outstanding as of September 30, 2019 are entitled to rights with respect to the registration of their shares under the Securities Act, subject to

the lock-up agreements described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates. Any sales of securities by these stockholders could have a material adverse effect on the market price of our common stock.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may delay or prevent an acquisition of us or a change in our management. For example, our board of directors has the authority to issue up to 10,000,000 shares of preferred stock. The board of directors can fix the price, rights, preferences, privileges and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change of control transaction. As a result, the market price of our common stock and the voting and other rights of our stockholders may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders.

These provisions also include a classified board of directors, a prohibition on actions by written consent of our stockholders and the ability of our board of directors to issue preferred stock without stockholder approval. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us. Although we believe these provisions collectively provide for an opportunity to obtain greater value for stockholders by requiring potential acquirers to negotiate with our board of directors, they would apply even if an offer rejected by our board were considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

Our executive officers, directors and current beneficial owners of 5% or more of our common stock and their respective affiliates exercise significant influence over our company, which limits your ability to influence corporate matters and could delay or prevent a change in corporate control.

Our executive officers, directors and current beneficial owners of 5% or more of our common stock and their respective affiliates beneficially own, in the aggregate, a majority of our outstanding common stock. As a result, these stockholders, if they act together, will be able to influence our management and affairs and the outcome of matters submitted to our stockholders for approval, including the election of directors and any sale, merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership might adversely affect the market price of our common stock by:

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

We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We will remain an emerging growth company until the earliest of (i) December 31, 2024, (ii) the last day of the

first fiscal year in which we have total annual gross revenues of at least $1.07 billion, (iii) the last day of the first fiscal year in which the market value of our common stock that is held by non-affiliates exceeds $700.0 million on June 30th and (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to take advantage of this extended transition period to enable us to comply with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS act. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

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 the Sarbanes-Oxley Act, our management will be required to report upon the effectiveness of our internal control over financial reporting beginning with the annual report for our fiscal year ending December 31, 2020. When we lose our status as an “emerging growth company,” our independent registered public accounting firm will be 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 will need to implement additional financial and management controls, reporting systems and procedures and hire additional accounting and finance staff.

We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Our independent registered public accounting firm will not be required to provide an attestation report on the effectiveness of our internal control over financial reporting so long as we qualify as an “emerging growth company,” which may increase the risk that material weaknesses or significant deficiencies in our internal control over financial reporting go undetected. 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.

We do not intend to pay dividends on our common stock, so any returns will be limited to the value of our 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. Any return to stockholders will therefore be limited to the appreciation of their stock.

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

As a public company, and particularly after we are no longer an emerging growth company, we have incurred and expect to continue to incur significant legal, accounting, investor relations and other expenses that we did not incur as a private company, which we anticipate could be between $2.5 million and $4.5 million annually. The Sarbanes-Oxley

Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time consuming and costly. For example, we expect that these rules and regulations may 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 sufficient 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. Moreover, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock may be volatile, and in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

Our amended and restated bylaws designate the Court of Chancery of the State of Delaware or the United States District Court for the District of Delaware as the exclusive forum for certain types of actions and proceedings that may be initiated by 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, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware or, if subject matter jurisdiction over the matter that is the subject of such action is vested exclusively in the federal courts, the United States District Court for the District of Delaware will, to the fullest extent permitted by law, be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers and employees, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws, (iv) any action or proceeding to interpret, apply, enforce or determine the validity of our certificate of incorporation or the bylaws or (v) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery or the United States District Court for the District of Delaware, as applicable, having personal jurisdiction over the indispensable parties named as defendants therein. In addition, any person holding, owning or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and to have consented to this provision of our bylaws. The choice of forum provision does not apply to any actions arising under the Securities Act or the Exchange Act. The choice of forum provision 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 employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. Stockholders who do bring a claim in the Court of Chancery or the United States District Court for the District of Delaware could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near the jurisdiction. The Court of Chancery or the United States District Court for the District of Delaware may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments or results may be more favorable to us than to our stockholders. Alternatively, if a court were to find this provision of our amended and restated bylaws inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs, which could have a material adverse effect on our business, financial condition or results of operations.

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

On May 13, 2019, we closed our IPO pursuant to which we issued and sold 5,750,000 shares of common stock at a public offering price of $15.00 per share for aggregate gross proceeds of $86.3 million. The offer and sale of the shares was made pursuant to a registration statement on Form S-1 (File No. 333-230837) that the SEC declared effective on May 9, 2019. Morgan Stanley & Co. LLC, Merrill Lynch, Pierce, Fenner & Smith Incorporated and Piper Jaffray & Co. acted as joint book-running managers of our IPO. The net offering proceeds to us were approximately $77.0 million after deducting underwriting discounts and commissions of $6.0 million and offering expenses of approximately $3.4 million. During the period from the closing of our IPO on May 13, 2019 through September 30, 2019, $0.5 million of the net proceeds from our IPO have been used for payment to Yale University in connection with the closing of our IPO, and the reminder has been invested in temporary investments pending other uses.

None of the offering expenses or net proceeds were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates. There has been no material change in the planned use of proceeds from our IPO from those disclosed in the Prospectus.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

The exhibits filed or furnished as part of this Quarterly Report are set forth on the Exhibit Index, below.

EXHIBIT INDEX

Exhibit No.	Exhibit Description
10.1†	First Amendment to Lease Agreement, dated August 2, 2019, by and between the Company and ARE-8000/9000/10000 Virginia Manor, LLC.
31.1	Certification of Michael Richman pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Steven P. Cobourn pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Michael Richman and Steven P. Cobourn pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
EX-101.INS	XBRL Instance Document
EX-101.SCH	XBRL Taxonomy Extension Schema Document
EX-101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
EX-101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
EX-101.LAB	XBRL Taxonomy Extension Label Linkbase Document
EX-101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

† Portions of this exhibit have been omitted in compliance with Item 601 of Regulation S-K.

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.

NEXTCURE, INC.

Date: November 12, 2019

By: /s/ Michael Richman
Name: Michael Richman
President and Chief Executive Officer

Date: November 12, 2019

By: /s/ Steven P. Cobourn
Name: Steven P. Cobourn
Chief Financial Officer

Exhibit 10.1

Portions of this exhibit indicated by bracketed asterisks have been omitted because they are not material and would likely cause competitive harm to NextCure, Inc. if publicly disclosed.

FIRST AMENDMENT TO LEASE AGREEMENT

THIS FIRST AMENDMENT TO LEASE AGREEMENT ("**this First Amendment**") is dated as of August 2, 2019 ("**Effective Date**"), by and between **ARE-8000/9000/10000 VIRGINIA MANOR, LLC**, a Delaware limited liability company, having an address at 385 E. Colorado Boulevard, Suite 299, Pasadena, California 91101 ("**Landlord**"), and **NEXTCURE, INC.**, a Delaware corporation, having an address at Suite 140, 8000 Virginia Manor Road, Beltsville, Maryland 20705 ("**Tenant**").

RECITALS

A. Landlord and Tenant have entered into that certain Lease Agreement ("**Lease**") dated as of January 30, 2019, wherein Landlord leased to Tenant approximately 14,075 rentable square feet ("**Existing Premises**") located at Suite 140, 8000 Virginia Manor Road, Beltsville, Maryland 20705, as more particularly described in the Lease.

B. Landlord and Tenant desire to amend the Lease, among other things, to expand the Existing Premises by an additional 14,446 rentable square feet located adjacent to the Existing Premises ("**Expansion Premises**").

AGREEMENT

Now, therefore, the parties hereto agree that the Lease is amended as follows:

1. **Definitions; Recitals.** Terms used in this First Amendment but not otherwise defined shall have the meanings set forth in the Lease. The Recitals form an integral part of this First Amendment and are hereby incorporated by reference.

2. **Expansion Premises.** Effective as of the Expansion Premises Commencement Date (as defined below), (a) the Existing Premises shall be expanded to include the Expansion Premises, and (b) **Exhibit A** to this First Amendment, which depicts the Expansion Premises as the hatched area, is hereby added to **Exhibit A** to the Lease.

3. **Changes to Defined Terms.** Effective as of the Expansion Premises Commencement Date, the following amendments are hereby made to the definitions contained on pages 1 and 2 of the Lease in the Basic Lease Provisions.

a. The defined term "**Premises (before 9000 VMR Effective Date)**" shall be deleted in its entirety and replaced with the following:

> "**Premises (before 9000 VMR Effective Date):** That portion of the Project, containing approximately 28,521 rentable square feet, which consists of the following: (a) approximately 14,075 rentable square feet, as shown as the hatched area on **Exhibit A** attached to this Lease ("**Existing Premises**"), and (b) approximately 14,446 rentable square feet of space shown as the hatched area on **Exhibit A** attached to the First Amendment to Lease Agreement between Landlord and Tenant ("**Expansion Premises**"). The Expansion

Premises consists of (i) approximately 10,069 rentable square feet ("**Expansion Premises #1**") identified as "Suite 110" on **Exhibit A** attached to the First Amendment to Lease Agreement between Landlord and Tenant, and (ii) approximately 4,377 rentable square feet ("**Expansion Premises #2**") identified as "Suite 170" on **Exhibit A** attached to the First Amendment to Lease Agreement between Landlord and Tenant. Gaudreau, Inc., Landlord's architect, has measured the area of the Premises pursuant to the BOMA 2017 for Office Buildings: Standard Methods of Measurement as adopted by the Building Owners and Managers Association International (ANSI/BOMA Z65.1-2017). Tenant acknowledges receipt of such measurement and confirms that (A) Tenant has had an opportunity to confirm such measurement with an architect of its selection before the Commencement Date (with respect to the Existing Premises) and the Expansion Premises Commencement Date (with respect to the Expansion Premises), and (B) such measurement shall be conclusive as to the area of the Premises."

b. The defined term "**Premises (from and after 9000 VMR Effective Date)**" shall be deleted in its entirety and replaced with the following:

"**Premises (from and after 9000 VMR Effective Date):** That portion of the Project, containing approximately 63,576 rentable square feet, which consists of the following: (a) approximately 28,521 rentable square feet ("**8000 VMR Premises**") located in the 8000 VMR Building (as defined below) as shown as the hatched areas on **Exhibit A** attached to this Lease, and (b) approximately 35,055 rentable square feet ("**9000 VMR Premises**") located in the 9000 VMR Building (as defined below) as shown as the hatched areas on **Exhibits A-1** and **A-2** attached to this Lease. Gaudreau, Inc., Landlord's architect, has measured the area of the Premises pursuant to the BOMA 2017 for Office Buildings: Standard Methods of Measurement as adopted by the Building Owners and Managers Association International (ANSI/BOMA Z65.1-2017). Tenant acknowledges receipt of such measurement and confirms that (i) Tenant has had an opportunity to confirm such measurement with an architect of its selection before the Commencement Date (with respect to the Existing Premises and the 9000 VMR Premises) and the Expansion Premises Commencement Date (with respect to the Expansion Premises), and (ii) such measurement shall be conclusive as to the area of the Premises."

c. The defined term "**Rentable Area of Premises (before 9000 VMR Effective Date)**" shall mean approximately 28,521 rentable square feet.

d. The defined term "**Rentable Area of Premises (from and after 9000 VMR Effective Date)**" shall mean approximately 63,576 rentable square feet.

e. The defined term "**Base Rent (Commencement Date)**" shall mean (i) as of the Commencement Date, $[***], per month with respect to the Existing Premises, and (ii) as of the Expansion Premises Commencement Date, $[***], per month with respect to the Expansion Premises.

f. The defined term "**Base Rent (effective as of September 1, 2025)**" shall mean the following:

$[***], per month (8000 VMR Premises)

$[***], per month (9000 VMR Premises)†

† If the 9000 VMR Effective Date occurs before September 1, 2025, the Base Rent for the 9000 VMR Premises shall be amount (based on an annual per rentable square foot basis) that is then being paid by Tenant for the 8000 VMR Premises as of the 9000 VMR Effective Date, and the Base Rent for the 9000 VMR Premises shall be increased in the same manner and amount, and at the same time, as the Base Rent for the 8000 VMR Premises.

g. The defined term "**Tenant's Share of Operating Expenses (before 9000 VMR Effective Date)**" shall mean (i) with respect to the Existing Premises, [***]%, and (ii) with respect to the Expansion Premises, [***]%. From the Expansion Premises Commencement Date to the day before the 9000 VMR Effective Date, the aggregate amount of Tenant's Share of Operating Expenses shall be [***]%.

h. The defined term "**Tenant's Share of Operating Expenses (from and after 9000 VMR Effective Date)**" shall mean [***]%.

i. The defined term "**Base Term**" shall mean June 1, 2019 and the expiration date of the Base Term of the Lease shall be midnight on March 31, 2030.

4. **Delivery of Expansion Premises.** Landlord shall use reasonable efforts to deliver the Expansion Premises to Tenant on April 1, 2020 in their vacant, "as is" (but broom clean) condition ("**Delivery**" or "**Deliver**"). The date on which Landlord Delivers the Expansion Premises to Tenant is referred to as the "**Expansion Premises Commencement Date.**" Upon request of Landlord, Tenant shall execute and deliver a written acknowledgement of the Expansion Premises Commencement Date when it is established in the form attached hereto as **Exhibit B;** provided, however, that Tenant's failure to execute and deliver such acknowledgement shall not affect Landlord's rights under this First Amendment or the Lease, If Landlord fails to Deliver timely the Expansion Premises, Landlord shall not be liable to Tenant

for any loss or damage resulting therefrom, and this First Amendment and the Lease with respect to the Expansion Premises shall not be void or voidable.

a. Except as set forth in this First Amendment, if applicable: (i) Tenant shall accept the Expansion Premises in their broom clean condition as of the Expansion Premises Commencement Date, which condition shall be substantially similar in all material respects to the condition of the Expansion Premises as of the Effective Date; (ii) Landlord shall have no obligation for any defects in the Expansion Premises, and (iii) Tenant's taking possession of the Expansion Premises shall be conclusive evidence that Tenant accepts the Expansion Premises and that the Expansion Premises were in good condition at the time possession was taken. Notwithstanding the provisions of this Section, Tenant shall have a period of 90 days after Landlord's Delivery of the Expansion Premises to Tenant to reasonably identify in writing any (A) all or any part of the HVAC and life safety systems serving the Expansion Premises that are not in good working order, and (B) latent defects in the mechanical, electrical, and plumbing systems and the structural components serving the Expansion Premises. For purposes of this paragraph, "**latent defects**" means those material defects in such systems and/or components that could not have been identified or discovered through a reasonable inspection of such systems or components conducted by a qualified technician. Landlord will promptly repair the items described in clauses (A) and (B) above (subject to Landlord's reasonable confirmation that such items described in clause (A) are not in good working order, and the defects described in clause (B) are, in fact, latent defects).

b. Neither Landlord nor any of its agents has made any representation or warranty with respect to the condition of all or any portion of the Expansion Premises, and/or the suitability of the Expansion Premises for the conduct of Tenant's business, and Tenant waives any implied warranty that the Expansion Premises are suitable for the Permitted Use. Tenant shall use the Expansion Premises only for the Permitted Use under the Lease in compliance with the provisions of Section 7 of the Lease.

c. Landlord shall have no obligation to perform any work at the Building in connection with Tenant's occupancy of the Expansion Premises or obtain any permits, approvals, or entitlements related to Tenant's specific use of the Expansion Premises or Tenant's business operations therein.

d. As of the Effective Date, Landlord is leasing (i) Expansion Premises #1 to [***], and the lease agreement ("[*******] **Lease**") between Landlord and [***] is scheduled to expire on February 29, 2020, and (ii) Expansion Premises #2 to [***], and the lease agreement ("[*******] **Lease**") between Landlord and [***] is scheduled to expire on March 31, 2020. Tenant understands, acknowledges, and agrees that Landlord makes no

guaranty, representation, or assurance that Landlord will be able to Deliver the Expansion Premises to Tenant by the Expansion Premises Commencement Date and that Landlord shall have no obligation or duty to seek the vacation or removal of [***] and [***] from Expansion Premises #1 and Expansion Premises #2, respectively. If Landlord is unable to Deliver the Expansion Premises to Tenant on April 1, 2020 by reason of the failure of [***] and [***] to vacate Expansion Premises #1 and Expansion Premises #2, respectively, by March 31, 2020, the Expansion Premises Commencement Date shall be extended for one day for each day after April 1, 2020 until the date on which the Expansion Premises Commencement Date occurs. To illustrate the operation of this paragraph, assume that Landlord Delivers the Expansion Premises to Tenant on April 10, 2020 because [***] or [***], or both, did not vacate the Expansion Premises until April 9, 2020. Based on that assumption, the Expansion Premises Commencement Date would be extended by 10 calendar days. In addition, if Landlord is unable to Deliver both Expansion Premises #1 and Expansion Premises #2 on or before July 31, 2020, Tenant shall have the right to terminate this First Amendment by sending written notice thereof to Landlord by no later than August 31, 2020, whereupon neither Landlord nor Tenant shall have any further rights, duties, or obligations under this First Amendment. If Tenant does not elect to so terminate this First Amendment by August 31, 2020, such right to terminate this First Amendment shall be waived.

Notwithstanding any contrary provision in this First Amendment, if Landlord Delivers to Tenant before April 1, 2020 either or both of Expansion Premises #1 and Expansion Premises #2, Tenant shall have immediate access to such premises without an obligation to pay Base Rent during such access before April 1, 2020. Tenant, however, shall pay, as Additional Rent, the cost of any utilities consumed therein for the period before April 1, 2020. Before any such access, Tenant shall provide to Landlord the required proof of insurance coverage as set forth in the Lease.

e. Tenant, at its sole expense, shall make any alterations or modifications to the interior of the Expansion Premises that are required by Legal Requirements (including, without limitation, compliance of the Expansion Premises with the ADA; provided, however, that Landlord shall, at no cost or expense to Tenant, make alterations or modifications to the interior of the Expansion Premises to the extent that (i) the Expansion Premises do not comply with the ADA as of the Expansion Premises Commencement Date, and (ii) Tenant notifies Landlord of such non-compliance within 90 days after the Expansion Premises Commencement Date (which notification shall be based on a written report obtained by Tenant and prepared by Tenant’s architect licensed by the State of Maryland, which report Tenant shall provide to Landlord along with such notification).

5. **Base Rent for Expansion Premises.** (a) Tenant shall continue to pay Base Rent with respect to the Existing Premises at the rates set forth in the Lease, (b) commencing on the Expansion Premises Commencement Date (but subject to the Expansion Premises Base Rent Abatement [as defined below]), Base Rent for the Expansion Premises shall be payable at the rate of $[***] per month, and (c) commencing on the Expansion Premises Commencement Date, Base Rent for the Expansion Premises shall be increased as of the date or dates on which Tenant uses the Additional Expansion Premises TI Allowance (as defined in the Expansion Premises Work Letter attached hereto as a part hereof as **Exhibit C**) (such increase to be calculated based on the amount of the Additional Expansion Premises TI Allowance used by Tenant, such amount to be amortized over the Base Term based on an interest rate of [***]% per annum; the resulting amount so amortized shall be added to the monthly installments of Base Rent for the Expansion Premises). Notwithstanding any contrary provision contained in the Lease, the Base Rent for the Expansion Premises shall thereafter be increased on each anniversary of the Expansion Premises Commencement Date (which, solely for purposes of determining such increase, shall be April 1, 2020 if the Expansion Premises Commencement Date occurs before such date) by multiplying the Base Rent payable for the Expansion Premises immediately before such date by the Rent Adjustment Percentage and adding the resulting amount to the Base Rent payable for the Expansion Premises immediately before such date; provided, however, that as more fully set forth in Section 5(b)2 of the Work Letter, the Rent Adjustment Percentage shall not apply to the Additional Expansion Premises TI Allowance. Base Rent for the Expansion Premises, as so adjusted, shall thereafter be due as provided in the Lease.

a. **Expansion Premises Base Rent Abatement.** Notwithstanding anything to the contrary contained in this First Amendment, but provided Tenant is not in Default hereunder or under the Lease, Landlord hereby grants Tenant an abatement of the Base Rent payable with respect to the Expansion Premises during the period beginning on the Expansion Premises Commencement Date and ending 7 months after the Expansion Premises Commencement Date ("**Expansion Premises Base Rent Abatement**"). For the avoidance of doubt, if the Expansion Premises Commencement Date occurs on the first day of a month, the Expansion Premises Base Rent Abatement will be measured from that date. If the Expansion Premises Commencement Date occurs on a day other than the first day of a month, the Expansion Premises Base Rent Abatement will be measured from the first day of the following month. Except as provided in the preceding sentences, Tenant shall pay the full amount of Base Rent due with respect to the Expansion Premises in accordance with the provisions of this First Amendment and the Lease. The administration rent set forth in Section 5 of the Lease shall not be abated and shall be based on the amount of Base Rent with respect to the Expansion Premises that would have been payable but for the Expansion Premises Base Rent Abatement. Notwithstanding anything to the contrary in this Section 5(a) the adjustment in the Base Rent as set forth in this Section 5 shall be based on the full and unabated amount of Base Rent payable with respect to the Expansion Premises for the first 12 month period from and after the Expansion Premises Commencement Date (which, solely for purposes of determining the commencement date of the Expansion Premises Base Rent

Abatement, shall be April 1, 2020 if the Expansion Premises Commencement Date occurs before such date). To illustrate the operation of the foregoing parenthetical, assume that the Expansion Premises Commencement Date is March 27, 2020. Based on that assumption, the Expansion Premises Commencement Date would be assumed to have commenced on April 1, 2020 for purposes of determining the commencement of the Expansion Premises Base Rent Abatement and the date for increasing the Base Rent for the Expansion Premises.

6. **Extension Right.** The Extension Right set forth in Section 40 of the Lease applies to, and shall be exercised (if at all) only with respect to, the entire Premises. The Extension Term shall be for the period beginning on April 1, 2030 and ending, unless earlier terminated in accordance with the terms and conditions of the Lease, on March 31, 2035. For the avoidance of doubt, the Market Rate shall not include the adjustments for the TI Allowance as described in Section 4 of the Lease and the Expansion Premises TI Allowance as described in Section 5 of this First Amendment, but may include build-out allowances to the extent they are then provided as market concessions in the Market Area.

7. **Expansion Right.** As of the Expansion Premises Commencement Date, the Available Space will no longer include (a) Suite 110 (8000 VMR Building) as shown in the table in Section 39(a) of the Lease since that area constitutes Expansion Premises #1, and (b) Suite 170 (8000 VMR Building) as shown in the table in Section 39(a) of the Lease since that area constitutes Expansion Premises #2. Accordingly, the table set forth in Section 39(a) of the Lease is hereby deleted and replaced with the table below:

Suite	Lease Expiration Date[†]
207 (9000 VMR Building)	May 31, 2022
210 (9000 VMR Building)	May 31, 2020
230 (9000 VMR Building)	January 31, 2021

[†] The table above identifies the expiration date for the lease agreement with the existing tenant, subject to rights of renewal or extension In favor of the existing tenants.

8. **Amendment to Section 20(h).** Section 20(h) of the Lease, captioned "Work Letter and 9000 VMR Work Letter," is hereby deleted and replaced with the following new Section 20(h):

(h) **Work Letter, Expansion Premises Work Letter, and 9000 VMR Work Letter.** Tenant fails to perform any obligation imposed on it under the terms and conditions of the Work Letter, the Expansion Premises Work Letter, or the 9000 VMR Work Letter (as applicable), which failure is not cured within any applicable notice and cure period specifically set forth in the Work Letter, the Expansion Premises Work Letter, or the 9000 VMR Work Letter, as applicable.

9. **Amendment to Section 21(f).** Section 21(f) of the Lease, captioned "Suspension of Funding," is hereby deleted and replaced with the following new Section 21(f):

(f) **Suspension of Funding.** Upon a Default by Tenant hereunder and during the continuance thereof, Landlord shall have the right to suspend funding of any TI Allowance and Expansion Premises TI Allowance.

10. **Amendment to Section 30(a).** Section 30(a) of the Lease, captioned "Prohibition/Compliance/Indemnity," is hereby amended by deleting the proviso and replacing it with the following new proviso:

; provided, however, that Tenant shall have no indemnification, remediation, or other obligation or responsibility under this Section 30 for any contamination or Environmental Claim if Tenant proves by a preponderance of the evidence that such contamination or Environmental Claim arises from any Hazardous Materials brought into, kept, used, stored, handled, treated, generated in or about, or released or disposed of from the Premises by Landlord or another tenant unrelated or unaffiliated with Tenant or that existed in the Existing Premises as of the Commencement Date or in the Expansion Premises as of the Expansion Premises Commencement Date and were not brought into, kept, used, stored, handled, treated, generated in or about, or released or disposed of from the Premises by Tenant or any Tenant Party.

11. **Amendment to Section 38(a).** Section 38(a) of the Lease, captioned "Identification Sign," is hereby amended by deleting that provision in its entirety and replacing it with the following new Section 38(a):

(a) **Identification Sign.** Tenant shall have the right, at its sole cost and expense and in compliance with all applicable Legal Requirements, to install and affix to the façade of the 8000 VMR Building at the entrance to the Existing Premises and the Expansion Premises (and, effective as of the 9000 VMR Effective Date, to the façade of the 9000 VMR Building at the entrance to the 9000 VMR Premises) a sign bearing Tenant's name and its then current corporate logo (individually and collectively, an "**Identification Sign**"). Landlord shall have the right to approve the place, size, and design of the Identification Sign, which approval shall not be unreasonably withheld, delayed, or conditioned and shall in all cases comply with building standard signage requirements (except as to font and logo). On the expiration or earlier termination of this Lease, Tenant shall at its sole cost and expense (i) remove the Identification Sign and in accordance with all applicable Legal Requirements and (ii) repair and restore the area from which the Identification Sign was removed (including, but not limited to, repairing any holes and repainting such area) to Landlord's reasonable satisfaction.

12. **Miscellaneous.**

12.1 **Entire Agreement.** The Lease, as amended by this First Amendment, is the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior and contemporaneous oral and written agreements and discussions. The

Lease, as so amended by this First Amendment, may be amended only by an agreement in writing, signed by the parties hereto.

12.2 **Binding Effect.** This First Amendment is binding upon and shall inure to the benefit of the parties hereto, their respective agents, employees, members, representatives, officers, directors, divisions, subsidiaries, affiliates, assigns, heirs, successors in interest and shareholders.

12.3 **Broker.** Landlord and Tenant each represents and warrants that it has not dealt with any broker, agent or other person (collectively, "**Broker**") in connection with this First Amendment and that no Broker brought about this First Amendment, other than [***]. **[*****] shall be paid by Landlord pursuant to a separate agreement between Landlord and [***]. Landlord and Tenant each hereby agree to indemnify and hold the other harmless from and against any claims by any Broker, other than the brokers named in this Section, claiming a commission or other form of compensation by virtue of having dealt with Tenant or Landlord, as applicable, with regard to this First Amendment.

12.4 **Counterparts.** This First Amendment may be executed in 2 or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature process complying with the U.S. federal ESIGN Act of 2000) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes. Electronic signatures shall be deemed original signatures for purposes of this First Amendment and all matters related thereto, with such electronic signatures having the same legal effect as original signatures.

12.5 **Ratification; Conflicts.** Except as amended and/or modified by this First Amendment, the Lease is hereby ratified and confirmed and all other terms of the Lease shall remain in full force and effect, unaltered and unchanged by this First Amendment. In the event of any conflict between the provisions of this First Amendment and the provisions of the Lease, the provisions of this First Amendment shall prevail. Regardless of whether specifically amended by this First Amendment, all of the terms and provisions of the Lease are hereby amended to the extent necessary to give effect to the purpose and intent of this First Amendment.

[SIGNATURES APPEAR ON NEXT PAGE]

IN WITNESS WHEREOF, the parties hereto have executed this First Amendment under seal as of the day and year first above written.

TENANT:

NEXTCURE, INC.,
a Delaware corporation

By: /s/ Michael Richman (SEAL)
Its: President & CEO

LANDLORD:

ARE-8000/9000/10000 VIRGINIA MANOR, LLC, a Delaware limited liability company
By: Alexandria Real Estate Equities, L.P.,
a Delaware limited partnership,
managing member

By: ARE-QRS CORP.,
a Maryland corporation,
general partner

By: /s/ Jennifer Banks (SEAL)
Name: Jennifer Banks
Title: Co-Chief Operating Officer
& General Counsel

EXHIBIT A
EXPANSION PREMISES

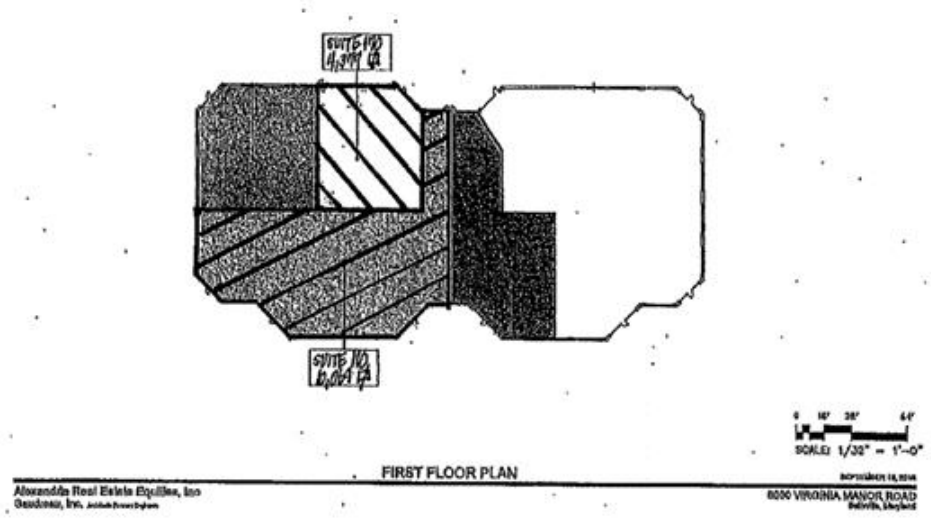

EXHIBIT B
ACKNOWLEDGMENT OF EXPANSION PREMISES COMMENCEMENT DATE

THIS ACKNOWLEDGMENT OF EXPANSION PREMISES COMMENCEMENT DATE is made as of this _____ day of_____, 2020, between **ARE-8000/9000/10000 VIRGINIA MANOR, LLC,** a Delaware limited liability company ("**Landlord**"), and **NEXTCURE, INC.**, a Delaware corporation ("**Tenant**"), and is attached to and made a part of the First Amendment to Lease Agreement dated as of August_, 2019, which amends the Lease Agreement dated January 30, 2019 between Landlord and Tenant (collectively, the "**Lease**"), by and between Landlord and Tenant. Any initially capitalized terms used but not defined herein shall have the meanings given them in the Lease.

Landlord and Tenant hereby acknowledge and agree that the Expansion Premises Commencement Date of the Base Term of the Lease is _____, 2020 (subject to the Expansion Premises Base Rent Abatement), and the expiration date of the Base Term of the Lease shall be midnight on March 31, 2030. In case of a conflict between the terms of the Lease and the terms of this Acknowledgement of Expansion Premises Commencement Date, this Acknowledgement of Expansion Premises Commencement Date shall control for all purposes.

IN WITNESS WHEREOF, Landlord and Tenant have executed this ACKNOWLEDGMENT OF EXPANSION PREMISES COMMENCEMENT DATE to be effective on the date first above written.

NEXTCURE, INC.,
a Delaware corporation

By: _____(SEAL)
Name: _____
Title: _____

LANDLORD:
ARE-8000/9000/10000 VIRGINIA MANOR, LLC,
a Delaware limited liability company
By: ALEXANDRIA REAL ESTATE EQUITIES, L.P.,
a Delaware limited partnership,
managing member
By: ARE-QRS CORP.,
a Maryland corporation,
general partner
By: _____ (SEAL)
Name: _____
Title: _____

EXHIBIT C
EXPANSION PREMISES WORK LETTER

THIS EXPANSION PREMISES WORK LETTER ("**this Expansion Premises Work Letter**") is incorporated into that certain Lease Agreement dated as of January 30, 2019 ("**Original Lease**"), as amended by that certain First Amendment of Lease Agreement dated as of August ___, 2019 ("**First Amendment**"; together with the Original Lease, the "**Lease**"), by and between **ARE-8000/9000/10000 VIRGINIA MANOR, LLC,** a Delaware limited liability company ("**Landlord**"), and **NEXTCURE, INC.,** a Delaware corporation ("**Tenant**"). Any initially capitalized terms used but not defined herein shall have the meanings given them in the Lease.

1. General Requirements.

(a) **Tenant's Authorized Representative.** Tenant designates Jim Bingham ("**Tenant's Representative**") as the only person authorized to act for Tenant pursuant to this Expansion Premises Work Letter, Landlord shall not be obligated to respond to or act upon any request, approval, inquiry or other communication ("**Communication**") from or on behalf of Tenant in connection with this Expansion Premises Work Letter unless such Communication is in writing from Tenant's Representative. Tenant may change Tenant's Representative at any time upon not less than 5 business days advance written notice to Landlord.

(b) **Landlord's Authorized Representative.** Landlord designates Lawrence J. Diamond and Edward J. Rose (any such individual acting alone, "**Landlord's Representative**") as the only persons authorized to act for Landlord pursuant to this Expansion Premises Work Letter. Tenant shall not be obligated to respond to or act upon any request, approval, inquiry or other Communication from or on behalf of Landlord in connection with this Expansion Premises Work Letter unless such Communication is in writing from Landlord's Representative. Landlord may change any of Landlord's Representative at any time upon not less than 5 business days advance written notice to Tenant.

(c) **Architects, Consultants and Contractors.** Landlord and Tenant hereby acknowledge and agree that the architect ("**TI Architect**") for the Expansion Premises Tenant Improvements (as defined in Section 2(a) below), the general contractor and any subcontractors for the Expansion Premises Tenant Improvements shall be selected by Tenant, subject to Landlord's approval, which approval shall not be unreasonably withheld, conditioned or delayed. Landlord hereby pre-approves Gaudreau, Inc. as the TI Architect and Greatstar, Inc. as Tenant's general contractor. Landlord shall be named as a third party beneficiary of contracts entered into with the TI Architect and the general contractor and any warranties issued in connection with such contracts.

2. Expansion Premises Tenant Improvements.

(a) **Expansion Premises Tenant Improvements Defined.** As used herein, "**Expansion Premises Tenant Improvements**" shall mean all improvements to the Expansion Premises desired by Tenant of a fixed and permanent nature. Other than funding the Expansion Premises TI Allowance (as defined below) as provided herein, Landlord shall not have any obligation whatsoever with respect to the finishing of the Expansion Premises for Tenant's use and occupancy.

(b) **Tenant's Space Plans.** Tenant shall deliver to Landlord schematic drawings and outline specifications ("**TI Design Drawings**") detailing Tenant's requirements for the Expansion Premises Tenant Improvements. Not more than 10 days after such delivery, Landlord shall deliver to Tenant the written objections, questions, or comments of Landlord and the TI Architect with regard to the TI Design Drawings. Tenant shall cause the TI Design Drawings to be revised to address such written comments and shall resubmit the drawings to Landlord for approval. Landlord shall deliver to Tenant any comments thereto within 5 days after such delivery. Such process shall continue until Landlord has approved the TI Design Drawings.

(c) **Working Drawings.** Tenant shall cause the TI Architect to prepare and deliver to Landlord for review and comment construction plans, specifications, and drawings for the Expansion Premises Tenant Improvements **("TI Construction Drawings**"), which TI Construction Drawings shall be prepared substantially in accordance with the TI Design Drawings. Tenant shall be solely responsible for ensuring that the TI Construction Drawings reflect Tenant's requirements for the Expansion Premises Tenant Improvements. Landlord shall deliver its written comments on the TI Construction Drawings to Tenant not later than 10 business days after Landlord's receipt of the same; provided, however, that Landlord may not disapprove any matter that is consistent with the TI Design Drawings. Tenant and the TI Architect shall consider all such comments in good faith and shall, within 10 business days after receipt, notify Landlord how Tenant proposes to respond to such comments. Any disputes in connection with such comments shall be resolved in accordance with Section 2(d) hereof. Provided that the design reflected in the TI Construction Drawings is consistent with the TI Design Drawings, Landlord shall approve the TI Construction Drawings submitted by Tenant. Once approved by Landlord, subject to the provisions of Section 4 below, Tenant shall not materially modify the TI Construction Drawings except as may be reasonably required in connection with the issuance of the TI Permit (as defined in Section 3(a) below).

(d) **Approval and Completion.** If any dispute regarding the design or construction of the Expansion Premises Tenant Improvements is not settled within 10 business days after notice of such dispute is delivered by one party to the other, Tenant may make the final decision regarding the design or construction of the Expansion Premises Tenant Improvements, provided (i) Tenant acts reasonably and such final decision (A) is either consistent with or a compromise between Landlord's and Tenant's positions with respect to such dispute or (B) reflects Tenant's obligation to act in compliance with federal regulatory requirements, (ii) that all

costs and expenses resulting from any such decision by Tenant shall be payable out of the Expansion Premises Allowance, and (iii) Tenant's decision will not affect the base Building, structural components of the Building or any Building systems (in which case Landlord shall make the final decision). Any changes to the TI Construction Drawings after Landlord's and Tenant's approval of same requested by Tenant shall be processed as provided in Section 4 hereof.

3. Performance of the Expansion Premises Tenant Improvements.

(a) Commencement and Permitting of the Expansion Premises Tenant Improvements. Tenant shall commence construction of the Expansion Premises Tenant Improvements upon obtaining and delivering to Landlord a building permit ("**TI Permit**") authorizing the construction of the Expansion Premises Tenant Improvements consistent with the TI Construction Drawings approved by Landlord. The cost of obtaining the TI Permit shall be payable from the Expansion Premises TI Allowance. Landlord shall assist Tenant in obtaining the TI Permit. Prior to the commencement of the Expansion Premises Tenant Improvements, Tenant shall deliver to Landlord a copy of any contract with Tenant's contractors (including the TI Architect), and certificates of insurance from any contractor performing any part of the Expansion Premises Tenant Improvements evidencing industry standard commercial general liability, automotive liability, 'builder's risk", and workers' compensation insurance. Tenant shall cause the general contractor to provide a certificate of insurance naming Landlord, Alexandria Real Estate Equities, Inc., and Landlord's lender (if any) as additional insureds for the general contractor's liability coverages required above. Within 10 days after Landlord's request (but in no event prior to 22 weeks after the date of this Work Letter), Tenant shall at its expense complete and submit any documentation required by the applicable Governmental Authority (including, but not limited to, the Washington Suburban Sanitary Commission ("**WSSC**")) for the issuance of a plumbing authority (or comparable) permit relating to laboratory water and wastewater usage at the Expansion Premises. Such documentation includes, but is not limited to, an Industrial Wastewater Survey on the form specified by WSSC's Regulatory Services Division, Industrial Discharge Control Section. At Landlord's request, Tenant shall also meet with Landlord and WSSC personnel at the Project to review cooperatively matters relating to water and wastewater usage, including, but not limited to, laboratory processes.

(b) Selection of Materials, Etc. Where more than one type of material or structure is indicated on the TI Construction Drawings approved by Tenant and Landlord, the option will be within Tenant's reasonable discretion if the matter concerns the Expansion Premises Tenant Improvements, and within Landlord's sole and absolute subjective discretion if the matter concerns the structural components of the Building or any Building system.

(c) Tenant Liability. Tenant shall be responsible for correcting any deficiencies or defects in the Expansion Premises Tenant Improvements.

(d) **Substantial Completion.** Tenant shall substantially complete or cause to be substantially completed the Expansion Premises Tenant Improvements in a good and workmanlike manner, in accordance with the TI Permit subject, in each case, to Minor Variations and normal "punch list" items of a non-material nature that do not interfere with the use of the Expansion Premises ("**Substantial Completion**" or "**Substantially Complete**"). Upon Substantial Completion of the Expansion Premises Tenant Improvements, Tenant shall require the TI Architect and the general contractor to execute and deliver, for the benefit of Tenant and Landlord, a Certificate of Substantial Completion in the form of the American Institute of Architects ("**AIA**") document G704. For purposes of this Expansion Premises Work Letter, "**Minor Variations**" shall mean any modifications reasonably required: (i) to comply with all applicable Legal Requirements and/or to obtain or to comply with any required permit (including the TI Permit); (ii) to comport with good design, engineering, and construction practices which are not material; or (iii) to make reasonable adjustments for field deviations or conditions encountered during the construction of the Expansion Premises Tenant Improvements.

4. **Changes.** Any changes requested by Tenant to the Expansion Premises Tenant Improvements after the delivery and approval by Landlord of the TI Design Drawings, shall be requested and instituted in accordance with the provisions of this Section 4 and shall be subject to the written approval of Landlord, which approval shall not be unreasonably withheld, conditioned or delayed.

(a) **Tenant's Right to Request Changes.** If Tenant shall request changes ("**Changes**"), Tenant shall request such Changes by notifying Landlord in writing in substantially the same form as the AIA standard change order form (a "**Change Request**"), which Change Request shall detail the nature and extent of any such Change. Such Change Request must be signed by Tenant's Representative. Landlord shall review and approve or disapprove such Change Request within 7 business days thereafter, provided that Landlord's approval shall not be unreasonably withheld, conditioned or delayed.

(b) **Implementation of Changes.** If Landlord approves such Change and Tenant deposits with Landlord any Excess Expansion Premises TI Costs (as defined in Section 5(d) below) required in connection with such Change, Tenant may cause the approved Change to be instituted. If any TI Permit modification or change is required as a result of such Change, Tenant shall promptly provide Landlord with a copy of such TI Permit modification or change.

5. **Costs.**

(a) **Budget For Expansion Premises Tenant Improvements.** Before the commencement of construction of the Expansion Premises Tenant Improvements, Tenant shall obtain a detailed breakdown, by trade, of the costs incurred or that will be incurred, in connection with the design and construction of the Expansion Premises Tenant Improvements ("**Budget**"), and deliver a copy of the Budget to

Landlord for Landlord's approval, which shall not be unreasonably withheld or delayed. The Budget shall be based upon the TI Construction Drawings approved by Landlord and shall include a payment to Landlord of administrative rent ("**Administrative Rent**") equal to [***]% of the Expansion Premises TI Costs (as defined below) for monitoring and inspecting the construction of the Expansion Premises Tenant Improvements, which sum shall be payable from the Expansion Premises TI Allowance. Such Administrative Rent shall include, without limitation, all third party, out-of-pocket costs, expenses, and fees incurred by or on behalf of Landlord arising from, out of, or in connection with, such monitoring of the construction of the Expansion Premises Tenant Improvements, and shall be payable out of the Expansion Premises TI Allowance. If the Budget is greater than the Expansion Premises TI Allowance, Tenant shall deposit with Landlord the difference, in cash, prior to the commencement of construction of the Expansion Premises Tenant Improvements, for disbursement by Landlord as described in Section 5(d).

(b) **Expansion Premises TI Allowance.** Landlord shall provide to Tenant a tenant improvement allowance (collectively, "**Expansion Premises TI Allowance**") as follows:

1. first, Landlord shall provide and disburse a "**Base Expansion Premises TI Allowance**" in the maximum amount of **$**[*******] per rentable square foot in the Expansion Premises, or **$**[*******] in the aggregate (i.e., $[***] x 14,446 rsf), which is included in the Base Rent set forth in the First Amendment; and

2. *then*, upon full disbursement of the Base Expansion Premises TI Allowance, Landlord shall provide and disburse an "**Additional Expansion Premises TI Allowance**" in the maximum amount of **$**[*******] per rentable square foot in the Expansion Premises, or **$**[*******] in the aggregate (i.e., $[***] x 14,446 rsf), which shall, to the extent used, result in adjustments to the Base Rent for the Expansion Premises as set forth in the First Amendment but shall not be included in Base Rent for the purposes of calculating the annual Base Rent increase described in Section 5 of this First Amendment. Notwithstanding any contrary provision set forth in this First Amendment, Tenant shall be permitted to use the Additional Expansion Premises TI Allowance for the Expansion Premises Tenant Improvements (with respect to the Expansion Premises) or the Tenant Improvements (with respect to the Existing Premises).

Before commencing the Expansion Premises Tenant Improvements, Tenant shall notify Landlord how much Additional Expansion Premises TI Allowance Tenant has elected to receive from Landlord **(**"**Elected Amount**"). Such election shall be final and binding on Tenant, and may not thereafter be modified without Landlord's consent, which may be granted or withheld in Landlord's sole and absolute subjective discretion. The Expansion Premises TI Allowance shall be disbursed in accordance with this Expansion Premises Work Letter.

Tenant shall have no right to the use or benefit (including any reduction to Base Rent for the Expansion Premises) of any portion of the Expansion Premises TI Allowance not

required for (i) the design and construction of the Expansion Premises Tenant Improvements described in the TI Construction Drawings approved pursuant to Section 2(d), (ii) the design and construction of any Changes pursuant to Section 4, (iii) assessment of vapor/moisture for any portion of the Premises, including without limitation the Expansion Premises, (iv) the reasonable costs of space planning, architectural, engineering, and construction management fees, and (v) with respect to the Additional Expansion Premises TI Allowance, (A) the design and construction of the Existing Premises Tenant Improvements, (B) the design and construction of any Changes regarding the Existing Premises, (C) the reasonable costs of space planning, architectural, engineering, and construction management fees regarding the Existing Premises. Regardless of the timing incident to the approval of the TI Design Drawings and the TI Construction Drawings as set forth in Sections 2(b) and 2(c) above, respectively, in no event whatsoever shall Tenant have any right to any portion of the Expansion Premises TI Allowance that is not disbursed before the last day of the month that is 18 months after the Expansion Premises Commencement Date ("**Disbursement Deadline**"). If all or any portion of the Additional Expansion Premises TI Allowance is not disbursed by the Disbursement Deadline, for purpose of calculating the Base Rent for the Expansion Premises and adjustments thereto under the First Amendment, Tenant shall be deemed to have been disbursed the entire Elected Amount of the Additional Expansion Premises TI Allowance by the Disbursement Deadline. As a result, the Base Rent for the Expansion Premises shall be adjusted as though Tenant had been disbursed the entire Elected Amount of the Expansion Premises TI Allowance by the Disbursement Deadline.

(c) **Costs Includable in Expansion Premises TI Allowance.** The Expansion Premises TI Allowance shall be used solely for the payment of design, permits, and construction costs in connection with the construction of the Expansion Premises Tenant Improvements (and such additional items as described in Section 5(b)2(v) above), including, without limitation, the cost of electrical power and other utilities used in connection with the construction of the Expansion Premises Tenant Improvements, the cost of preparing the space plans/test fits, TI Design Drawings, and the TI Construction Drawings, all costs set forth in the Budget, including Landlord's Administrative Rent, the cost of Changes, demolition costs, "soft" costs for fees of architects and other professionals engaged in connection with the performance of the Expansion Premises Tenant Improvements, and equipment installed within the Expansion Premises (which equipment shall be surrendered to Landlord at the expiration or earlier termination of the Term except for such equipment that Tenant has to the right to remove in accordance with the terms and conditions of Section 12 of the Lease), and built-in lockers and built-in file cabinets (collectively, "**Expansion Premises TI Costs**"). Notwithstanding anything to the contrary contained herein but subject to the terms of the preceding sentence, the Expansion Premises TI Allowance shall not be used to purchase any furniture, personal property or other non-Building system materials or equipment, including, but not be limited to, Tenant's voice or data cabling, non-ducted biological safety cabinets and other scientific equipment not incorporated into the Expansion Premises Tenant Improvements.

1. Landlord and Tenant shall promptly document, from time to time, in writing in such format as Landlord shall reasonably require the precise identifying information (including, but not limited to, name of manufacturer or supplier, serial number, and other distinguishing information) for all Installations purchased with any of the TI Allowance so as to enable the parties to identify immediately such purchased Installations. If and when any such Installation is replaced, Tenant shall promptly notify Landlord in writing of the precise identifying information for such replacement Installation.

(d) **Excess Expansion Premises TI Costs.** Landlord shall have no obligation to bear any portion of the cost of any of the Expansion Premises Tenant Improvements except to the extent of the Expansion Premises TI Allowance. Notwithstanding anything to the contrary set forth in this Section 5(d), Tenant shall be fully and solely liable for Expansion Premises TI Costs and the cost of Minor Variations in excess of the Expansion Premises TI Allowance.

(e) **Payment for Expansion Premises TI Costs.** During the course of design and construction of the Expansion Premises Tenant Improvements, Landlord shall pay Expansion Premises TI Costs once a month against a draw request in Landlord's standard form (which form shall be the AIA standard requisition form or other form reasonably acceptable to Landlord and Tenant) containing such certifications, lien waivers (including a conditional lien release for each progress payment and unconditional lien releases for the prior month's progress payments), inspection reports and other matters as Landlord customarily obtains, no later than 30 days following receipt of such draw request. Upon completion of the Expansion Premises Tenant Improvements (and prior to any final disbursement of the Expansion Premises TI Allowance), Tenant shall deliver to Landlord: (i) sworn statements setting forth the names of all contractors and first tier subcontractors who did the work and final, unconditional lien waivers from all such contractors and first tier subcontractors; (ii) as-built plans (one copy in print format and two copies in electronic CAD format) for the Expansion Premises Tenant Improvements; (iii) a certification of substantial completion in Form AIA G704, (iv) a certificate of occupancy for the Expansion Premises; and (v) copies of all operation and maintenance manuals and warranties affecting the Expansion Premises.

6. Miscellaneous.

(a) **Consents.** Whenever consent or approval of either party is required under this Expansion Premises Work Letter, that party shall not unreasonably withhold, condition or delay such consent or approval, except as may be expressly set forth herein to the contrary.

(b) **Modification.** No modification, waiver or amendment of this Expansion Premises Work Letter or of any of its conditions or provisions shall be binding upon Landlord or Tenant unless in writing signed by Landlord and Tenant.

(c) **Choice of Law.** Construction and interpretation of this Expansion Premises Work Letter shall be governed by the internal laws of the state in which the Expansion Premises are located, excluding any principles of conflicts of laws.

(d) **Loading Dock.** Tenant shall have reasonable non-exclusive access to the loading docks at 8000 VMR and 9000 VMR without charge.

EXHIBIT 31.1

Certification of Principal Executive Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Michael Richman, certify that:

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

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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) 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

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

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

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

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

Date: November 12, 2019

/s/ Michael Richman
Name: Michael Richman
Title: President and Chief Executive Officer

EXHIBIT 31.2

Certification of Principal Financial Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Steven P. Cobourn, certify that:

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

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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) 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

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

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

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

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

Date: November 12, 2019

/s/ Steven P. Cobourn
Name: Steven P. Cobourn
Title: Chief Financial Officer

EXHIBIT 32.1

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

In connection with the Quarterly Report on Form 10-Q of NextCure, Inc. (the "Company") for the quarter ended September 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned each hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge, on the date hereof:

(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.

Dated: November 12, 2019

/s/ Michael Richman
Name: Michael Richman
Title: President and Chief Executive Officer

Dated: November 12, 2019

/s/ Steven P. Cobourn
Name: Steven P. Cobourn
Title: Chief Financial Officer