Table of Contents

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 March 31, 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 No. 001-38551

NEON THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**46-3915846**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
40 Erie St., Suite 110 Cambridge, MA	**02139**
(Address of principal executive offices)	(Zip Code)

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(617) 337-4701

(Registrant's telephone number, including area code)

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 ☒

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

Title of each class	Trade Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	NTGN	The Nasdaq Global Select Market

As of April 30, 2019, there were 28,331,344 shares of common stock, $0.001 par value per share, outstanding.

Table of Contents

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These statements may be identified by such forward-looking terminology as "may," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continue" or the negative of these terms or other comparable terminology. Our forward-looking statements are based on a series of expectations, assumptions, estimates and projections about our company, are not guarantees of future results or performance and involve substantial risks and uncertainty. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements. Our business and our forward-looking statements involve substantial known and unknown risks and uncertainties, including the risks and uncertainties inherent in our statements regarding:

- the success, cost and timing of our product development activities and clinical trials, 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;
- our ability and the potential to successfully manufacture and supply our product candidates for clinical trials and for commercial use, if approved;
- the potential for our identified research priorities to advance our platform, programs or product candidates;
- the ability and willingness of our third-party research institution collaborators to continue research and development activities relating to our product candidates;
- our ability to obtain and maintain regulatory approval of our lead product candidate, NEO-PV-01, and any other product candidates, and any related restrictions, limitations or warnings in the label of an approved product candidate;
- the ability to license additional intellectual property relating to our product candidates and to comply with our existing license agreements;
- our ability to commercialize our products in light of the intellectual property rights of others;
- our ability to obtain funding for our operations, including funding necessary to complete further development and commercialization of our product candidates;
- our plans to research and develop our product candidates;
- the commercialization of our product candidates, if approved;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- future agreements with third parties in connection with the commercialization of our product candidates and any other approved product;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- the rate and degree of market acceptance of our product candidates;
- regulatory developments in the United States and foreign countries;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- our ability to produce our products or product candidates with advantages in turnaround times or manufacturing cost in an economically viable manner;
- the success of competing therapies that are or may become available;
- our ability to attract and retain key scientific or management personnel;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- the impact of laws and regulations;
- our use of the proceeds from our initial public offering;
- our expectations regarding the time during which we will be an "emerging growth company" under the Jumpstart Our Business Startups Act; and
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates.

All of our forward-looking statements are as of the date of this Quarterly Report on Form 10-Q only. In each case, actual results may differ materially from such forward-looking information. We can give no assurance that such expectations or forward-looking statements will prove to be correct. An occurrence of or any material adverse change in one or more of the risk factors or risks and uncertainties referred to in this Quarterly Report on Form 10-Q or included in our other public disclosures or our other periodic reports or other documents or filings filed with or furnished to the Securities and Exchange Commission, or the SEC, could materially and adversely affect our business, prospects, financial condition and results of operations. Except as required by law, we do not undertake or plan to update or revise any such forward-looking statements to reflect actual results, changes in plans, assumptions, estimates or projections or other circumstances affecting such forward-looking statements occurring after the date of this Quarterly Report on Form 10-Q, even if such results, changes or circumstances make it clear that any forward-looking information will not be realized. Any public statements or disclosures by us following this Quarterly Report on Form 10-Q that modify or impact any of the forward-looking statements contained in this Quarterly Report on Form 10-Q will be deemed to modify or supersede such statements in this Quarterly Report on Form 10-Q.

NOTE REGARDING TRADEMARKS

Neon Therapeutics, Inc. is the owner of the NEON THERAPEUTICS, RECON, and NEO-STIM trademarks, as well as certain other trademarks, including design versions of some of these trademarks. The symbols ™ and ® are not used in connection with the presentation of these trademarks in this report and their absence does not indicate a lack of trademark rights. Certain other trademarks used in this report are the property of third-party trademark owners and may be presented with or without trademark references.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

NEON THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)
(In thousands, except share and per share amounts)

	March 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 49,264	$ 52,700
Marketable securities	32,000	50,611
Prepaid expenses and other current assets	2,349	2,116
Total current assets	83,613	105,427
Operating lease, right-of-use assets	8,441	—
Property and equipment, net	8,488	8,205
Other long-term assets	498	456
Total assets	$ 101,040	$ 114,088
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,112	$ 4,268
Accrued expenses	6,237	8,422
Operating lease liabilities, current	1,110	—
Total current liabilities	11,459	12,690
Operating lease liabilities, net of current portion	7,488	—
Other liabilities	22	149
Total liabilities	18,969	12,839
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Common stock, $0.001 par value; 150,000,000 shares authorized as of March 31, 2019 and December 31, 2018; 28,331,344 and 28,314,274 shares issued and outstanding as of March 31, 2019 and December 31, 2018, respectively	28	28
Additional paid-in capital	276,837	275,058
Accumulated other comprehensive loss	(8)	(75)
Accumulated deficit	(194,786)	(173,762)
Total stockholders' equity	82,071	101,249
Total liabilities and stockholders' equity	$ 101,040	$ 114,088

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

NEON THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (UNAUDITED)
(In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2019	**2018**
Operating expenses:		
Research and development	$ 16,172	$ 13,158
General and administrative	5,408	3,599
Total operating expenses	21,580	16,757
Loss from operations	(21,580)	(16,757)
Other income (expense), net		
Interest income	556	247
Other expense	—	(10)
Total other income, net	556	237
Net loss	(21,024)	(16,520)
Accretion of redeemable convertible preferred stock to redemption value	—	(3,186)
Net loss attributable to common stockholders	$ (21,024)	$ (19,706)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.76)	$ (9.47)
Weighted average common shares outstanding, basic and diluted	27,651,067	2,080,993
Comprehensive loss:		
Net loss	$ (21,024)	$ (16,520)
Other comprehensive income:		
Unrealized gains on marketable securities	67	5
Total other comprehensive income	67	5
Comprehensive loss	$ (20,957)	$ (16,515)

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

NEON THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK, CONTINGENTLY REDEEMABLE RESTRICTED COMMON STOCK AND STOCKHOLDERS' EQUITY (DEFICIT) (UNAUDITED)
(In thousands, except share amounts)

	Redeemable Convertible Preferred Stock		Contingently Redeemable Restricted Common Stock	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount		Shares	Amount				
Balance at December 31, 2018	—	$ —	$ —	28,314,274	$ 28	$275,058	$ (75)	$ (173,762)	$ 101,249
Stock-based compensation expense	—	—	—	—	—	1,729	—	—	1,729
Exercise of stock options	—	—	—	17,070	—	45	—	—	45
Vesting of restricted common stock	—	—	—	—	—	5	—	—	5
Unrealized gains on marketable securities	—	—	—	—	—	—	67	—	67
Net loss	—	—	—	—	—	—	—	(21,024)	(21,024)
Balance at March 31, 2019	—	$ —	$ —	28,331,344	$ 28	$276,837	$ (8)	$ (194,786)	$ 82,071

Balance at December 31, 2017	93,222,418	$174,895	$ 355	3,302,927	$ 3	$ —	$ (13)	$ (93,562)	$ (93,572)
Stock-based compensation expense	—	—	99	—	—	1,551	—	—	1,551
Accretion of redeemable convertible preferred stock to redemption value	—	3,186	—	—	—	(1,557)	—	(1,629)	(3,186)
Vesting of restricted common stock	—	—	—	—	—	6	—	—	6
Unrealized gains on marketable securities	—	—	—	—	—	—	5	—	5
Net loss	—	—	—	—	—	—	—	(16,520)	(16,520)
Balance at March 31, 2018	93,222,418	$178,081	$ 454	3,302,927	$ 3	$ —	$ (8)	$ (111,711)	$ (111,716)

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

NEON THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)
(In thousands)

	Three Months Ended March 31,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (21,024)	$ (16,520)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	415	330
Non-cash lease expense	287	—
Net amortization of premiums and discounts on marketable securities	(21)	159
Stock-based compensation expense	1,729	1,650
Loss on disposal of property and equipment	—	9
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(233)	(78)
Other long-term assets	(42)	125
Accounts payable	—	(92)
Accrued expenses and other liabilities	(2,012)	(512)
Lease liabilities	(254)	—
Net cash used in operating activities	(21,155)	(14,929)
Cash flows from investing activities:		
Purchases of marketable securities	—	(11,990)
Sales and maturities of marketable securities	18,700	15,650
Purchases of property and equipment	(1,026)	(1,458)
Net cash provided by investing activities	17,674	2,202
Cash flows from financing activities:		
Payment of initial public offering costs	—	(1,091)
Proceeds from exercise of stock options	45	—
Net cash provided by (used in) financing activities	45	(1,091)
Net decrease in cash, cash equivalents and restricted cash	(3,436)	(13,818)
Cash, cash equivalents and restricted cash, beginning of period	53,156	58,857
Cash, cash equivalents and restricted cash, end of period	$ 49,720	$ 45,039
Supplemental disclosure of non-cash items:		
Accretion of redeemable convertible preferred stock to redemption value	$ —	$ 3,186
Purchases of property and equipment included in accounts payable and accrued expenses	$ 168	$ 419
Deferred offering costs included in accounts payable and accrued expenses	$ —	$ 1,003

The following table provides a reconciliation of the cash, cash equivalents and restricted cash balances as of each of the periods shown above:

	March 31,	
	2019	**2018**
Cash and cash equivalents	$ 49,264	$ 44,432
Restricted cash included in other long-term assets	456	607
Total cash, cash equivalents and restricted cash	$ 49,720	$ 45,039

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

NEON THERAPEUTICS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

1. Nature of the Business

Neon Therapeutics, Inc. (the "Company") is a clinical-stage immuno-oncology company and a leader in the field of neoantigen-targeted therapies, dedicated to transforming the treatment of cancer by directing the immune system towards neoantigens. The Company is leveraging its neoantigen platform and over a decade of insights from its founders to develop neoantigen-targeted therapies that use two distinct approaches, NEON / ONE and NEON / SELECT. These approaches focus on targeting a prioritized set of what the Company believes are the most therapeutically-relevant neoantigens. In NEON / ONE, these neoantigens are specific to each individual. In NEON / SELECT, these neoantigens are shared across subsets of patients or tumor types. The Company is applying these two approaches to develop neoantigen-targeted product candidates using multiple treatment modalities.

NEO-PV-01, the Company's most advanced product candidate, is a personal neoantigen vaccine that is custom-designed and manufactured based on the unique mutational fingerprint of each individual patient. The neoantigen-targeted peptides in NEO-PV-01 are intended to generate an immune response that trains each patient's immune system to target his or her individual tumor's particular neoantigens and kill the cancer cells. NEO-PV-01 is currently being evaluated in multiple Phase 1b clinical trials.

NEO-PTC-01, the Company's personal neoantigen T cell therapy, consists of multiple T cell populations targeting what we predict to be the most therapeutically-relevant neoantigens from each patient’s tumor. NEO-PTC-01 is currently in preclinical development, and the Company expects to file a clinical trial application in Europe in the second half of 2019 to evaluate NEO-PTC-01 in solid tumors in patients who are refractory to checkpoint inhibitors.

NEON / SELECT is the Company's precision medicine approach to neoantigen-targeted therapies. The Company's first product candidate using this approach, NEO-SV-01, is a neoantigen vaccine for the treatment of a genetically defined subset of hormone-receptor-positive breast cancer, for which the Company expects to file an Investigational New Drug application in the second quarter of 2019.

The Company is subject to risks common to early-stage companies in the biotechnology industry including, but not limited to, development by competitors of new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations and the ability to obtain additional financing to fund operations. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance-reporting capabilities. Even if the Company's development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

Initial Public Offering

On June 29, 2018, the Company completed an initial public offering (“IPO”) of its common stock and issued and sold 6,250,000 shares of common stock at a public offering price of $16.00 per share, resulting in net proceeds of $89.9 million after deducting underwriting discounts, commissions and other offering costs. Upon the closing of the IPO in June 2018, all shares of the Company’s outstanding redeemable convertible preferred stock converted into an aggregate of 18,644,462 shares of common stock (see Note 9). In advance of the IPO, the board of directors and the stockholders of the Company approved a one-for-five reverse split of the Company’s issued and outstanding common stock that became effective on June 13, 2018. All common share and per share amounts in these condensed consolidated financial statements have been retroactively adjusted for all periods presented to give effect to the reverse stock split.

Liquidity

In accordance with Accounting Standards Update ("ASU") No. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (Subtopic 205-40)*, management must evaluate whether there are conditions or events, when considered in the aggregate, that raise substantial doubt about the Company’s ability to continue as a going concern within one year after the date that the financial statements are issued. This evaluation initially does not take into consideration the potential mitigating effect of management’s plans that have not been fully implemented as of the date the financial statements are issued. When substantial doubt exists under this methodology, management evaluates whether the mitigating effect of its plans sufficiently alleviates substantial doubt about the company’s ability to continue as a going concern. The mitigating effect of management’s plans, however, is only considered if both (1) it is probable that the plans will be effectively implemented within one year after the date that the financial statements are issued, and (2) it is probable that the plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the entity’s ability to continue as a going concern within one year after the

date that the financial statements are issued. Generally, to be considered probable of being effectively implemented, the plans must have been approved before the date that the financial statements are issued.

The Company's financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities in the ordinary course of business. Through March 31, 2019, the Company has funded its operations with net proceeds of $89.9 million from its IPO, as well as an aggregate of $161.1 million of net proceeds from sales of the Company's preferred stock and convertible debt. Since inception, the Company has incurred recurring losses and negative cash flows from operations in each period and on an aggregate basis. As of March 31, 2019 and December 31, 2018, the Company had an accumulated deficit of $194.8 million and $173.8 million, respectively. The Company expects its operating losses and negative operating cash flows to continue into the foreseeable future as it continues to develop, manufacture and commercialize its products.

The Company expects that, based on its current operating plan, its cash, cash equivalents and marketable securities will be sufficient to fund its operating expenses and capital expenditure requirements for at least twelve months from the issuance date of this Quarterly Report on Form 10-Q. The future viability of the Company beyond that point is dependent on its ability to raise additional capital to finance its operations. Although the Company has been successful in raising capital in the past, there is no assurance that it will be successful in obtaining such additional financing on terms acceptable to the Company, if at all.

The Company expects that it will continue to incur significant expenses in connection with its ongoing business activities. As a result, the Company will need substantial additional funding to support its continuing operations and pursue its growth strategy. Until such time as the Company can generate significant revenue from product sales, if ever, it expects to finance its operations through the sale of equity, debt financings or other capital sources, including collaborations with other companies or other strategic transactions. The Company may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If the Company is unable to obtain funding, the Company could be forced to delay, reduce or eliminate some or all of its research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect its business prospects, or the Company may be unable to continue operations.

2. Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

The accompanying condensed consolidated financial statements and the related disclosures are unaudited and have been prepared in conformity with the accounting principles generally accepted in the United States of America ("GAAP") and include the accounts of Neon Therapeutics, Inc. and its wholly owned subsidiary, Neon Securities Corporation. All intercompany transactions and balances have been eliminated. The Company consolidates entities in which it has a controlling financial interest.

Additionally, certain information and footnote disclosures normally included in the Company's annual financial statements have been condensed or omitted. Accordingly, these interim condensed consolidated financial statements should be read in conjunction with the consolidated financial statements as of and for the year ended December 31, 2018, and notes thereto, which are contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2018 filed with the Securities and Exchange Commission (the "SEC") on March 11, 2019 (the "Annual Report on Form 10-K").

The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements and, in the opinion of management, reflect all normal recurring adjustments considered necessary for a fair presentation of the Company's financial position as of March 31, 2019, and the results of its operations for the three months ended March 31, 2019 and 2018, and its cash flows for the three months ended March 31, 2019 and 2018. The results of operations for the three months ended March 31, 2019 are not necessarily indicative of the results that may be expected for the full year or any other subsequent interim period.

Summary of Significant Accounting Policies

The significant accounting policies and estimates used in the preparation of the condensed consolidated financial statements are described in the Company's audited financial statements as of and for the year ended December 31, 2018, and the notes thereto, which are included in the Company's Annual Report on Form 10-K. There have been no material changes in the Company's significant accounting policies during the three months ended March 31, 2019, except as discussed below with respect to the adoption of ASU No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02"), as amended.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting periods. Significant estimates of accounting reflected in these condensed consolidated financial statements include, but are not limited to, estimates related to accrued expenses, the

valuation of common stock prior to the completion of the Company's IPO, stock-based compensation, the present value of lease liabilities and the corresponding right-of-use assets and income taxes. The Company bases its estimates on historical experience and other market specific or other relevant assumptions it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates, as there are changes in circumstances, facts and experience. Actual results could differ from those estimates or assumptions.

Recently Adopted Accounting Pronouncements

ASU No. 2016-02, Leases

In February 2016, the FASB issued ASU 2016-02, which requires lessees to recognize most leases on their balance sheet as a right-of-use asset and a lease liability, as well as provide disclosures with respect to certain qualitative and quantitative information related to a company's leasing arrangements. Leases are classified as either operating or finance based on criteria similar to existing lease accounting, with the classification affecting the pattern and classification of expense recognition in the statement of operations. The FASB subsequently issued ASU No. 2018-11, *Leases (Topic 842): Targeted Improvements*, which includes certain amendments to ASU 2016-02 intended to provide relief in implementing the new standard. Among these amendments is the option to not restate comparative periods presented in the financial statements. The Company adopted these amendments with ASU 2016-02 (collectively, the "New Leasing Standards") effective January 1, 2019.

The Company adopted the New Leasing Standards as of the effective date of January 1, 2019, with no restatement of prior periods or cumulative adjustment to retained earnings. Comparative periods in the Company's financial statements will be presented in accordance with the existing guidance under Accounting Standards Codification ("ASC") Topic 840, *Leases*. Upon adoption, the Company took advantage of the transition package of practical expedients permitted within ASU 2016-02, which allowed the Company not to reassess previous accounting conclusions around whether arrangements are, or contain, leases, as well as to carry forward both the historical classification of leases and the treatment of initial direct costs for existing leases. In addition, the Company also has made an accounting policy election to exclude leases with an initial term of twelve months or less from its balance sheet.

Under the New Leasing Standards, the Company determines whether an arrangement is or contains a lease at the inception of the contract based on the unique facts and circumstances around identified assets, if present, and control over those identified assets. Operating lease assets and liabilities are recognized at the commencement date of the lease based upon the present value of lease payments over the lease term. When determining the lease term, the Company includes options to extend or terminate the lease when it is reasonably certain that it will exercise that option. The Company uses the implicit rate when readily determinable and uses its estimated incremental borrowing rate when the implicit rate is not readily determinable based upon the information available at the commencement date in determining the present value of the lease payments. The incremental borrowing rate is determined using a secured borrowing rate for the same currency and term as the associated lease.

Adoption of the New Leasing Standards resulted in the recognition of operating lease right-of-use assets and operating lease liabilities of approximately $8.7 million and $8.9 million, respectively, as of January 1, 2019. As of March 31, 2019, the Company did not have any finance leases. The adoption of the New Leasing Standards did not materially impact the Company's condensed consolidated statement of operations.

ASU No. 2018-07, Improvements to Nonemployee Share-Based Payment Accounting

In June 2018, the FASB issued ASU No. 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* (“ASU 2018-07”). The standard expands the scope of ASC 718 to include all share-based payment arrangements related to the acquisition of goods and services from both nonemployees and employees. Under the amended guidance, equity-classified share-based payment awards issued to nonemployees will be measured at grant date fair value. Upon transition, the entity is required to remeasure these nonemployee awards at fair value as of the adoption date.

The Company adopted this standard as of the effective date of January 1, 2019. Prior to the adoption of ASU 2018-07, for share-based awards granted to nonemployees, compensation expense was recognized over the period during which services were rendered by such nonemployees until completed. At the end of each financial reporting period prior to completion of the service, the fair value of these awards was remeasured using the then-current fair value of the Company's common shares and updated assumption inputs in the Black-Scholes option-pricing model, as applicable. After the adoption of ASU 2018-07, equity-classified share-based payment awards issued to nonemployees are measured at grant date fair value similarly to those of employees and are no longer revalued as the equity instruments vest. The new standard allows entities to use the expected term to measure nonemployee options or elect to use the contractual term as the expected term, on an award-by-award basis. The adoption of the standard did not have a material impact on the Company's condensed consolidated financial statements.

Recently Issued Accounting Pronouncements

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement* ("ASU 2018-13"), which modifies the disclosure requirements on fair value measurements. ASU 2018-13 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted. The Company does not anticipate a material impact to the condensed consolidated financial statements as a result of the adoption of this standard.

In August 2018, the FASB issued ASU No. 2018-15, *Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract* ("ASU 2018-15"), which clarifies the accounting for implementation costs in cloud computing arrangements. ASU 2018-15 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of this amendment will have on its condensed consolidated financial statements.

3. Fair Value Measurement

The following tables present information about the Company's assets that are measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values (in thousands):

		Fair Value Measurements at March 31, 2019 Using:		
	Total	Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	$ 49,323	$ 49,323	$ —	$ —
Marketable securities:				
Corporate debt securities	32,000	—	32,000	—
	$ 81,323	$ 49,323	$ 32,000	$ —

		Fair Value Measurements at December 31, 2018 Using:		
	Total	Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	$ 53,188	$ 53,188	$ —	$ —
Marketable securities:				
Corporate debt securities	46,122	—	46,122	—
Commercial paper	4,489	—	4,489	—
	$ 103,799	$ 53,188	$ 50,611	$ —

There were no changes in valuation techniques or transfers between the fair value measurement levels during the three months ended March 31, 2019 or 2018. There were no liabilities measured at fair value on a recurring basis as of March 31, 2019 or December 31, 2018.

4. Marketable Securities

Marketable securities consisted of the following at March 31, 2019 and December 31, 2018 (in thousands):

	March 31, 2019			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Short-term investments:				
Corporate debt securities	$ 32,008	$ 1	$ (9)	$ 32,000
	$ 32,008	$ 1	$ (9)	$ 32,000

	December 31, 2018			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Short-term investments:				
Corporate debt securities	$ 46,197	$ —	$ (75)	$ 46,122
Commercial paper	4,489	—	—	4,489
	$ 50,686	$ —	$ (75)	$ 50,611

The contractual maturities of all securities held at March 31, 2019 are one year or less. As of March 31, 2019 and December 31, 2018, the aggregate fair value of securities that were in an unrealized loss position for less than twelve months was $22.7 million and $46.1 million, respectively. The Company does not intend to sell the investments, and it is not more likely than not that the Company will be required to sell the investments, before recovery of their amortized cost bases. As a result, the Company determined that it did not hold any securities with any other-than-temporary impairment as of March 31, 2019.

There were no sales of available-for-sale securities during the three months ended March 31, 2019 or 2018. Net unrealized holding gains or losses for the period that have been included in accumulated other comprehensive loss were not material to the Company's condensed consolidated results of operations.

5. Property and Equipment, Net

Property and equipment, net consisted of the following (in thousands):

	March 31, 2019	December 31, 2018
Software	$ 1,181	$ 1,180
Laboratory equipment	8,918	8,230
Computer equipment	102	102
Furniture and fixtures	371	371
Leasehold improvements	673	592
Assets under construction	439	511
	11,684	10,986
Less: Accumulated depreciation and amortization	(3,196)	(2,781)
	$ 8,488	$ 8,205

Depreciation and amortization expense for the three months ended March 31, 2019 and 2018 was $0.4 million and $0.3 million, respectively.

6. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	March 31, 2019	December 31, 2018
Accrued compensation costs	$ 1,814	$ 3,364
Accrued professional services	727	1,262
Accrued external research and manufacturing costs	2,963	3,001
Accrued additions of property and equipment	70	243
Other accrued expenses	663	552
	$ 6,237	$ 8,422

7. Leases

On January 21, 2016, the Company entered into an operating lease agreement for office and laboratory space at its current headquarters in Cambridge, Massachusetts. The lease commenced on September 28, 2016 and expires on September 27, 2024. The Company has the right to extend the lease for one additional five-year period at a market rental rate as determined by the

landlord and agreed to by the Company. Per the terms of the lease agreement, the Company does not have any residual value guarantees. In connection with the lease agreement, the Company issued a letter of credit to the landlord for $0.5 million. The Company secured the letter of credit for the full amount of the letter with cash on deposit, which is reported as restricted cash, and which is classified within other long-term assets.

The Company identified and assessed the following significant assumptions in recognizing the right-of-use asset and corresponding liability related to the lease:

- *Expected lease term* - The expected lease term includes the contractual lease period. The lease agreement contains a renewal option, which was not included in the calculation of the right-of-use asset and lease liabilities as the renewal is not reasonably certain.

- *Incremental borrowing rate*- As the Company's lease does not provide a readily determinable implicit rate, nor is it available from the lessor, the Company estimated the incremental borrowing rate based on information available at the commencement date in determining the present value of lease payments. The Company used the incremental borrowing rate on January 1, 2019 for operating leases that commenced prior to that date.

The Company recognized the right-of-use asset and corresponding lease liability on January 1, 2019 by calculating the present value of lease payments, discounted at 10%, the Company's estimated incremental borrowing rate, over the 5.7 years expected remaining lease term. Amortization of the operating lease right-of-use asset for the lease was $0.3 million for the three months ended March 31, 2019 and was included in operating expenses. The variable lease expense, which includes common area maintenance, utility charges and management fees was $0.2 million for the three months ended March 31, 2019. As of March 31, 2019 the remaining lease term was 5.40 years.

The Company also, from time to time, enters into short-term operating lease arrangements for certain laboratory and office equipment. Leases with a term of twelve months or less are not recorded on the balance sheet and the Company recognizes lease expense for these leases on a straight-line basis over the lease term. For lease agreements entered into or reassessed after the adoption of ASU 2016-02, the Company has elected to combine lease and non-lease components for all classes of underlying assets.

The components of lease expense and related cash flows were as follows (in thousands):

	Three Months Ended March 31, 2019
Lease cost	
Operating lease cost	$ 502
Variable lease cost	243
Short-term lease cost	108
Total lease cost	$ 853
Cash paid for amounts included in the measurement of lease liabilities	$ 469

Future lease payments for the Company's operating leases as of March 31, 2019 were as follows (in thousands):

Year Ending December 31,	
2019 (remaining nine months)	$ 1,422
2020	1,948
2021	2,006
2022	2,066
2023	2,128
Thereafter	1,632
Total future minimum lease payments	$ 11,202
Less: interest	(2,604)
Present value of operating lease liabilities	$ 8,598

Under the prior lease guidance, future minimum lease payments for the Company's operating leases as of December 31, 2018 were as follows (in thousands):

Year Ending December 31		
2019	$	1,891
2020		1,948
2021		2,006
2022		2,066
2023		2,129
Thereafter		1,632
Total future minimum lease payments	$	11,672

8. Commitments and Contingencies

Significant Agreements

Manufacturing Agreement

In December 2015, the Company entered into a manufacturing agreement (the "Manufacturing Agreement") with an independent third party (the "vendor") whereby the vendor performs manufacturing, analytical testing and quality assurance services related to the manufacture of drug product for use in the Company's preclinical and clinical activities. The Manufacturing Agreement included the development and establishment of a manufacturing suite (a "Cell") at the vendor's facility that would be used in the manufacturing process to fill orders of peptides ordered by the Company. All amounts incurred under the Manufacturing Agreement and subsequent amendments are recognized as research and development expense as incurred.

In October 2016, the Company and the vendor amended the Manufacturing Agreement (hereinafter the "2016 Manufacturing Agreement") to modify the payment due for the establishment of a second Cell and amend the fixed pricing for drug product produced by the vendor. The 2016 Manufacturing Agreement had a three-year term and was able to be terminated by the Company for convenience with six-months' notice.

In July 2017, the Company and the vendor further amended the 2016 Manufacturing Agreement (hereinafter the "2017 Manufacturing Agreement"). Under the 2017 Manufacturing Agreement, the Company will reimburse the vendor for specified manufacturing costs incurred in the manufacture of the peptides, plus a fixed profit margin. The 2017 Manufacturing Agreement has a five-year term and can be terminated by the Company for convenience with three-months' notice.

Other Agreements

License Agreement with the Broad Institute, Inc.

On November 13, 2015, the Company entered into a license agreement with the Broad Institute, Inc. (the "Broad"), a related party (see Note 12) and, in January and November 2018, the Company entered into amendments to the license agreement (as amended to date, the “Broad Agreement”). Under the Broad Agreement, the Company has been granted an exclusive worldwide license to certain intellectual property rights owned or controlled by the Broad, Dana-Farber Cancer Institute (the "DFCI") and The General Hospital Corporation d/b/a Massachusetts General Hospital ("MGH") to develop and commercialize any diagnostic, prognostic, preventative or therapeutic product for humans, including any neoantigen vaccine product. In particular, the Company has been granted both exclusive and non-exclusive licenses to a patent portfolio comprised of twelve patent families, including certain granted patents and pending patent applications in the United States and foreign jurisdictions.

Pursuant to the terms of the Broad Agreement, the Company has also been granted (i) a non-exclusive license under each institution's respective interest in certain of its patent rights to exploit the licensed products in the field in the territory during the term of the license and (ii) a non-exclusive license under each institution's licensed know-how, to exploit any diagnostic, prognostic, preventative or therapeutic product in the field in the territory during the term of the license. The Company is also entitled to sub-license the rights granted to it under the Broad Agreement. In connection with the Broad Agreement, the Company has also entered into a non-exclusive software license with the Broad under which it licenses certain object and source codes for several software programs. These licenses and rights are subject to certain limitations and retained rights, including field restrictions.

As consideration for the license, the Company paid the Broad a non-refundable license fee of $0.1 million. As additional consideration for the license, the Company must pay the Broad immaterial annual license maintenance fees. Additionally, the Company granted 60,000 shares of restricted common stock to each of the Broad, DFCI and MGH, which were determined to

have an aggregate fair value of $0.2 million, and reimbursed the Broad $0.6 million for a portion of its past patent expenses related to the in-licensed patent rights. In June 2018, to align with institutional policies in place between the Broad, DFCI and MGH, DFCI and MGH transferred certain of the shares of restricted common stock that they had previously received to the Broad. Under the Broad Agreement, the Company agreed to reimburse the Broad for future patent expenses related to the patents covered by the license agreement. The Company could be obligated to make up to $12.6 million of developmental milestone payments to the Broad if certain development milestones are achieved over the term of the license agreement. Additionally, under the terms of the license agreement, the Company could be obligated to make up to an aggregate of $97.5 million of payments upon the achievement of specified sales milestones and to pay tiered royalties of low to mid single-digit percentages on net sales of products licensed under the agreement. The Company is required to pay the Broad a low double-digit percentage of any consideration received by the Company from a sublicensee in consideration for a sublicense. No developmental or commercial milestones have been achieved to date. The Company has the right to terminate the agreement for any reason, with or without cause.

License Agreement with the Dana-Farber Cancer Institute

On August 5, 2016, the Company entered into a license agreement with the DFCI to grant the Company an exclusive, royalty-free license to provide certain licensed know-how. The know-how in this agreement has particular utility in connection with the development of the licensed products referred to in the Broad Agreement. The agreement also grants a non-exclusive, royalty free right to certain clinical data being generated by the DFCI. In consideration for the licenses, the Company granted 120,000 shares of common stock to each of the Broad and the DFCI. The shares issued to the Broad were unrestricted and fully vested. The 120,000 shares issued to the DFCI contained a contingent repurchase option whereby, if the DFCI failed to achieve three specific milestones, the Company could repurchase the shares (one-third for each milestone) at the original purchase price, which is at zero cost. The Company has accounted for these awards consistent with equity awards with performance-based vesting conditions and, upon it being probable that the Company would not repurchase the award associated with a milestone, the expense associated with the equity grant would be recognized. During the three months ended March 31, 2018, the repurchase option associated with one-third of the shares expired due to the achievement of the specified criteria and the Company recognized $0.4 million of incremental stock-based compensation expense, which was reflected within research and development expenses in the accompanying condensed consolidated financial statements. Through March 31, 2019, the repurchase option on 80,000 of these shares has expired. The Company has the right to terminate the license agreement with the DFCI for any reason, with or without cause.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters arising out of the relationship between the parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and certain executive officers and other employees that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors, officers or employees. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of these indemnification obligations. The Company does not believe that the outcome of any existing claims under indemnification arrangements will have a material effect on its financial position, results of operations or cash flows, and it had not accrued any liabilities related to its obligations under these agreements in its condensed consolidated financial statements as of March 31, 2019 or December 31, 2018.

Legal Proceedings

The Company is not currently party to any material legal proceedings. At each reporting date, the Company evaluates whether or not 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 as incurred the costs related to its legal proceedings.

9. Preferred Stock and Common Stock

Preferred Stock

The Company's amended and restated certificate of incorporation authorizes the Company to issue up to 10,000,000 shares of undesignated preferred stock, $0.001 par value per share, none of which was issued or outstanding as of March 31, 2019 or December 31 2018.

Upon completion of the Company’s IPO on June 29, 2018, all shares of the Company's previously issued Redeemable Convertible Preferred Stock converted into an aggregate of 18,644,462 shares of common stock. As of March 31, 2019 and December 31, 2018, there were no shares of Redeemable Convertible Preferred Stock issued or outstanding.

Common Stock

As of March 31, 2019 and December 31, 2018, the Company's certificate of incorporation, as amended and restated, authorized the Company to issue 150,000,000 shares of common stock with a par value of $0.001 per share.

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, as may be declared by the Company's board of directors, if any. No dividends have been declared or paid during the three months ended March 31, 2019 or 2018.

As of March 31, 2019 and December 31, 2018 the Company has reserved for future issuance the following number of shares of common stock:

	March 31, 2019	December 31, 2018
Shares reserved for exercise of outstanding stock options	3,564,631	2,548,073
Shares reserved for vesting of restricted stock units	484,339	—
Shares reserved for future issuance under the 2018 Stock Option and Grant Plan	375,231	760,628
Shares reserved for future issuance under the 2018 Employee Stock Purchase Plan	553,142	270,000
	4,977,343	3,578,701

10. Stock-Based Compensation

2015 Stock Option and Grant Plan

The Company's 2015 Stock Option and Grant Plan, as amended (the "2015 Plan"), provided for the Company to grant incentive or nonqualified stock options, restricted stock awards, unrestricted stock awards or restricted stock units to employees, directors and consultants of the Company. As of June 26, 2018, the effective date of the 2018 Stock Option and Incentive Plan, and as of March 31, 2019 and December 31, 2018, no shares remained available for future issuance under the 2015 Plan.

2018 Stock Option and Incentive Plan

On June 13, 2018, the Company's stockholders approved the 2018 Stock Option and Incentive Plan (the "2018 Plan"), which became effective on June 26, 2018. The 2018 Plan provides for the grant of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock units, restricted stock awards, unrestricted stock awards and dividend equivalent rights to the Company's officers, employees, directors and other key persons (including consultants). The number of shares initially reserved for issuance under the 2018 Plan was 1,215,000 shares, which was cumulatively increased on January 1, 2019 and which will be cumulatively increased each January 1 thereafter by 4% of the number of shares of the Company's common stock outstanding on the immediately preceding December 31 or such lesser number of shares determined by the Company's compensation committee. Effective January 1, 2019, 1,132,570 additional shares were automatically added to the shares authorized for issuance under the 2018 Plan and these shares were subsequently registered on a Registration Statement on Form S-8.

As of the effective date of the 2018 Plan, the Company will not grant any further awards under the 2015 Plan. However, the shares of common stock underlying any awards that are forfeited, canceled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by the Company prior to vesting, satisfied without the issuance of stock, expire or are otherwise terminated (other than by exercise) under the 2018 Plan and the 2015 Plan will be added back to the shares of common stock available for issuance under the 2018 Plan.

The terms of stock options and restricted stock awards, including vesting requirements, are determined by the board of directors or its delegates, subject to the provisions of the 2018 Plan.

As of March 31, 2019, there were 375,231 shares available for future issuance under the 2018 Plan.

2018 Employee Stock Purchase Plan

On June 13, 2018, the Company's stockholders approved the 2018 Employee Stock Purchase Plan (the "ESPP"), which became effective on June 26, 2018. A total of 270,000 shares of common stock were reserved for issuance under the ESPP. In addition, the number of shares of common stock that may be issued under the ESPP will automatically increase on January 1, 2019, and each January 1 thereafter through January 1, 2028, by the lesser of (i) 405,000 shares of common stock, (ii) 1% of the number of shares of the Company's common stock outstanding on the immediately preceding December 31 or (iii) such lesser number of shares determined by the administrator of the Company's ESPP. Effective January 1, 2019, 283,142 additional shares were automatically added to the shares authorized for issuance under the ESPP and these shares were subsequently registered on a Registration Statement on Form S-8. No offering periods under the 2018 ESPP had been initiated as of March 31, 2019.

Stock Options

The following table summarizes changes in stock option activity during the three months ended March 31, 2019:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Contractual Term	Aggregate Intrinsic Value
			(in years)	(in thousands)
Outstanding as of December 31, 2018	2,548,073	$ 7.11	8.68	$ 1,965
Granted	1,033,628	6.16		
Exercised	(17,070)	2.65		
Forfeited	—	—		
Outstanding as of March 31, 2019	3,564,631	$ 6.85	8.88	$ 3,753
Options vested or expected to vest as of March 31, 2019	3,564,631	$ 6.85	8.88	$ 3,753
Options exercisable as of March 31, 2019	856,784	$ 5.27	8.11	$ 1,806

The weighted average grant-date fair value per share of stock options granted during the three months ended March 31, 2019 and 2018 was $4.82 per share and $8.25 per share, respectively.

The aggregate intrinsic value of stock options exercised during the three months ended March 31, 2019 was $0.1 million. There were no options exercised during the three months ended March 31, 2018.

Stock Option Valuation

The assumptions that the Company used to determine the fair value of the stock options granted to employees and directors were as follows, presented on a weighted average basis:

	Three Months Ended March 31,	
	2019	2018
Expected volatility	96.65%	102.42%
Risk-free interest rate	2.45%	2.55%
Expected dividend yield	—%	—%
Expected life (in years)	6.06	6.07

There were no stock option awards granted to nonemployees during the three months ended March 31, 2019 or 2018.

Restricted Stock Units

During the three months ended March 31, 2019, under the 2018 Plan, the Company granted restricted stock units ("RSUs"), as part of the Company's equity compensation program it provides to its employees. Pursuant to the terms of the applicable award agreements, each RSU represents the right to receive one share of the Company's common stock and the RSUs generally vest in equal annual installments over three years, provided the employee remains continuously employed with the Company through the vesting period. Upon vesting, shares of the Company's common stock are delivered to the employee, subject to the payment of applicable withholding taxes. The fair value of RSUs is based on the market value of the Company's common stock on the date of grant. Compensation expense is recognized over the applicable service period.

The following table summarizes RSU activity for the three months ended March 31, 2019:

	Number of Shares	Weighted Average Grant-Date Fair Value per Share
Unvested as of December 31, 2018	—	$ —
Granted	484,339	$ 6.25
Vested	—	$ —
Cancelled	—	$ —
Unvested as of March 31, 2019	484,339	$ 6.25

Restricted Stock Awards

Restricted stock awards originally issued under the terms of the 2015 Plan allow the Company, at its discretion, to repurchase unvested shares at the initial purchase price if the employee or nonemployee terminates his or her service relationship with the Company.

No restricted stock awards were issued during the three months ended March 31, 2019 or 2018.

The following table summarizes the Company's restricted common stock activity under the 2015 Plan since December 31, 2018:

	Number of Shares	Weighted Average Grant-Date Fair Value per Share
Unvested restricted common stock as of December 31, 2018	383,964	$ 1.97
Vested	(74,660)	$ 1.78
Unvested restricted common stock as of March 31, 2019	309,304	$ 2.02

The aggregate fair value of restricted common stock awards that vested during the three months ended March 31, 2019 and 2018, based upon the fair values of the stock underlying the restricted stock awards on the applicable vesting dates, was $0.4 million and $0.8 million, respectively.

Founder and Collaborator Awards

From May 2015 through July 2016, the Company issued 1,510,000 shares of restricted common stock outside of the 2015 Plan to nonemployee founders and collaborators. The shares were issued under the terms of the respective restricted common stock agreements and unvested shares are subject to repurchase by the Company upon the holder's termination of their relationship with the Company. The unvested shares of restricted common stock are subject to the Company's right to repurchase at the original purchase price per share. The Company did not issue any shares of restricted common stock during the three months ended March 31, 2019 and 2018.

Of the total shares of restricted common stock awarded to founders and collaborators, 300,000 shares vested immediately upon grant; 910,000 shares vest quarterly over a four-year period based on each grantee's continued service relationship with the Company in varying advisory capacities; and 180,000 shares vest upon the achievement of specified performance milestones. Additionally, 120,000 shares were issued as fully vested awards, but are subject to a repurchase option that expires upon the achievement of specified milestones. Through March 31, 2019, the repurchase option on 80,000 of these shares has expired.

Of these awards, the underlying restricted common stock agreement for 180,000 shares of restricted common stock provided for a put option whereby the recipient was able to sell its vested shares back to the Company at a price per share equal to the fair value of the Company's common stock upon both (i) the termination of the consulting agreement between the recipient and the Company for any reason and (ii) the determination by the recipient's employer that the ownership of the restricted common stock was in violation of the employer's conflict of interest policy. Prior to the closing of the Company's IPO, these awards were classified in the consolidated balance sheet as contingently redeemable common stock and were presented outside of permanent equity. As of December 31, 2017, $0.4 million was recorded in temporary equity related to these awards. Upon the closing of the Company's IPO, this put option expired and the amount recorded in temporary equity was recorded to additional paid in capital.

A summary of the changes in the Company's unvested restricted common stock awards granted to founders and collaborators since December 31, 2018 is as follows:

	Number of Shares	Weighted Average Grant-Date Fair Value per Share
Unvested restricted common stock as of December 31, 2018	350,625	$ 1.29
Vested	(56,875)	$ 1.29
Unvested restricted common stock as of March 31, 2019	293,750	$ 1.29

The aggregate fair value of restricted common stock awards issued outside of the 2015 Plan that vested during the three months ended March 31, 2019 and 2018, based upon the fair values of the stock underlying the restricted stock awards on the applicable vesting dates, was $0.3 million and $0.6 million, respectively.

Stock-Based Compensation Expense

The Company recorded stock-based compensation expense related to all stock-based awards in the following expense categories of its condensed consolidated statements of operations and comprehensive loss (in thousands):

	Three Months Ended March 31,	
	2019	2018
Research and development expenses	$ 820	$ 1,229
General and administrative expenses	909	421
	$ 1,729	$ 1,650

During the three months ended March 31, 2018, the Company recognized stock-based compensation expense of $0.4 million for awards with performance-based vesting conditions related to the expiration of an additional repurchase option on a portion of the unvested restricted common shares issued to DFCI (see Note 8).

As of March 31, 2019, the Company had an aggregate of $14.3 million of unrecognized stock-based compensation expense related to unvested stock option awards, excluding awards with performance-based vesting conditions, which is expected to be recognized over a weighted-average period of approximately 2.88 years. As of March 31, 2019, the Company also had an aggregate of $1.0 million of unrecognized stock-based compensation expense related to unvested restricted common stock awards, excluding awards with performance-based vesting conditions, which is expected to be recognized over a weighted-average period of approximately 0.88 years. Additionally as of March 31, 2019, the Company had an aggregate of $3.0 million of unrecognized stock-based compensation expense related to unvested RSUs, which is expected to be recognized over a weighted-average period of approximately 2.95 years.

11. Net Loss per Share

The Company excluded 603,054 shares of restricted common stock for the three months ended March 31, 2019 and 1,146,813 shares of restricted common stock for the three months ended March 31, 2018 from the calculation of basic net loss per share because these shares had not vested.

The Company's potential dilutive securities, which include stock options, unvested restricted common stock and redeemable convertible preferred stock, have been excluded from the computation of diluted net loss per share attributable to common stockholders whenever the effect of including them would be to reduce the net loss per share. In periods where there is a net loss, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The following potential shares of common stock, presented based on amounts outstanding at each period end, were excluded from the calculation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	Three Months Ended March 31,	
	2019	2018
Series A preferred stock (as converted to common stock)	—	11,099,994
Series B preferred stock (as converted to common stock)	—	7,544,468
Outstanding stock options	3,564,631	2,179,316
Unvested restricted stock units	484,339	—
Unvested restricted common stock	603,054	1,146,813
	4,652,024	21,970,591

12. Related Parties

A member of the Company's board of directors is a founding director and the current president of the Broad. In November 2015, the Company entered into the Broad Agreement with the Broad (see Note 8) and, as consideration, the Company granted 60,000 shares of restricted common stock to the Broad, which were determined to have a fair value of $0.1 million. Additionally, the Company must pay the Broad immaterial annual license maintenance fees. At the time the Company entered into the Broad Agreement, the Company reimbursed the Broad $0.6 million for a portion of past patent expenses and, under the terms of the license agreement, the Company is required to reimburse Broad for future patent expenses related to patents covered by the license agreement. The Company could be obligated to make up to $12.6 million of developmental milestone payments to the Broad if

certain development milestones are achieved over the term of the license agreement. Additionally, under the terms of the license agreement, the Company could be obligated to make up to an aggregate of $97.5 million of payments upon the achievement of specified sales milestones and to pay tiered royalties of low to mid single-digit percentages on net sales of products licensed under the agreement. The Company is required to pay the Broad a low double-digit percentage of any consideration received by the Company from a sublicensee in consideration for a sublicense. No developmental or commercial milestones have been achieved to date.

In August 2016, the Company entered into a license agreement with the DFCI in connection with the development of licensed products referred to in the 2015 Broad Agreement. As consideration, the Company granted 120,000 shares of restricted common stock to the Broad, which were determined to have a fair value of $0.2 million. In June 2018, to align with institutional policies in place between the Broad, the DFCI and MGH, the DFCI and MGH transferred certain of the shares of restricted common stock that they had previously received to the Broad. The Company recorded expenses related to payments to the Broad of $0.5 million and $0.2 million during the three months ended March 31, 2019 and 2018, respectively. At March 31, 2019 and December 31, 2018, the Company had $2.0 million and $2.0 million in accounts payable and accrued expenses due to the Broad, respectively.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operation

Overview

We are a clinical-stage immuno-oncology company and a leader in the field of neoantigen-targeted therapies, dedicated to transforming the treatment of cancer by directing the immune system towards neoantigens. Genetic mutations, which are a hallmark of cancer, can result in specific immune targets called neoantigens. The presence of neoantigens in cancer cells and their absence in normal cells makes them compelling, untapped targets for cancer therapy. By directing the immune system towards these targets, we believe our neoantigen-targeted therapies will offer a new level of patient and tumor specificity in the field of cancer immunotherapy that will drive a strong risk-benefit profile to dramatically improve patient outcomes.

We are leveraging our neoantigen platform and over a decade of insights from our founders to develop neoantigen-targeted therapies that use two distinct approaches, NEON / ONE and NEON / SELECT. These approaches focus on targeting a prioritized set of what we believe are the most therapeutically-relevant neoantigens. In NEON / ONE, these neoantigens are specific to each individual. In NEON / SELECT, these neoantigens are shared across subsets of patients or tumor types. We are applying these two approaches to develop neoantigen-targeted product candidates using multiple treatment modalities.

NEO-PV-01, our most advanced product candidate, is a personal neoantigen vaccine that is custom-designed and manufactured based on the unique mutational fingerprint of each individual patient. The neoantigen-targeted peptides in NEO-PV-01 are intended to generate an immune response that trains each patient's immune system to target his or her individual tumor's particular neoantigens and kill the cancer cells. NEO-PV-01 is currently being evaluated in multiple Phase 1b clinical trials.

NEO-PTC-01, our personal neoantigen T cell therapy, consists of multiple T cell populations, targeting what we predict to be the most therapeutically-relevant neoantigens from each patient's tumor. NEO-PTC-01 is currently in preclinical development, and we expect to file a clinical trial application, or CTA, in Europe in the second half of 2019 to evaluate NEO-PTC-01 in solid tumors in patients who are refractory to checkpoint inhibitors.

NEON / SELECT is our precision medicine approach to neoantigen-targeted therapies. Our first product candidate using this approach, NEO-SV-01, is a neoantigen vaccine for the treatment of a genetically defined subset of hormone-receptor-positive breast cancer, for which we expect to file an Investigational New Drug Application, or IND, in the second quarter of 2019.

To date, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, acquiring and discovering product candidates, securing related intellectual property rights and conducting research and development activities related to our product candidates.

On June 29, 2018, we completed our initial public offering, or IPO, in which we issued and sold 6,250,000 shares of our common stock at a public offering price of $16.00 per share in exchange for net proceeds of $89.9 million after deducting underwriting discounts, commissions and other offering costs. Upon the completion of the IPO, all shares of redeemable convertible preferred stock then outstanding converted into an aggregate of 18,644,462 shares of common stock.

From inception through March 31, 2019, we have funded our operations primarily through an aggregate of $89.9 million of net proceeds from our IPO, as well as an aggregate of $161.1 million of net proceeds from sales of our preferred stock and convertible debt. To date, we have not generated any revenue from product sales and do not expect to do so for several years, if at all. Due to our significant research and development expenditures, we have generated substantial operating losses in each period since inception, including net losses of $21.0 million and $16.5 million in the three months ended March 31, 2019 and 2018, respectively. As of March 31, 2019, we had an accumulated deficit of $194.8 million. We expect to incur substantial additional losses in the foreseeable future as we expand our research and development activities.

We anticipate that our expenses will increase significantly in connection with our ongoing activities, as we:

- advance NEO-PV-01 into later-stage clinical development;
- advance our development programs into and through preclinical and clinical development;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- hire additional clinical, quality assurance and scientific personnel;
- expand our operational, financial and management systems and increase personnel, including personnel 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 sales, marketing, medical affairs and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly with third parties; and

- acquire or in-license other product candidates and technologies.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources, including collaborations with other companies or other strategic transactions. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions.

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

As of March 31, 2019, we had cash, cash equivalents and marketable securities of $81.3 million. We believe that, based on our current operating plan, our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements for at least twelve months from the issuance date of this Quarterly Report on Form 10-Q. We have based this estimate on assumptions that may prove to be wrong and we could exhaust our available capital resources sooner than we expect. See "—Liquidity and Capital Resources."

Components of Results of Operations

Revenue

We have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products for several years, if at all. If our development efforts for our current or future product candidates are successful and result in marketing approval or collaboration or license agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from collaboration or license agreements that we may enter into with third parties.

Operating Expenses

Research and Development Expenses

Research and development expenses represent costs incurred by us for the discovery, development and manufacture of our product candidates and include:

- expenses incurred under agreements with third parties, including contract research organizations, contract manufacturing organizations and suppliers;
- license fees to acquire and maintain in-process technology and data;
- costs associated with the development of our Real-time Epitope Computation for ONcology, or RECON, bioinformatics engine;
- personnel-related costs, including salaries, benefits and non-cash stock-based compensation expense, for personnel engaged in research and development functions;
- costs of outside consultants, including their fees, related travel expenses and stock-based compensation expense;
- the costs of laboratory supplies and acquiring, developing and manufacturing preclinical study and clinical trial materials;
- costs related to compliance with regulatory requirements; and
- facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and general support services.

We expense research and development costs as incurred. We recognize costs for certain development activities, such as clinical trials and manufacturing costs, based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment or other information provided to us by our vendors. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our financial statements as prepaid or accrued external research and development expenses. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. These amounts are recognized as an expense as the goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered or the services rendered.

We use our employee and infrastructure resources across our multiple research and development programs directed toward developing our NEON / ONE and NEON / SELECT approaches, as well as identifying and developing product candidates. We track outsourced development and manufacturing costs, including external clinical and regulatory costs, by development product candidates, but we do not allocate costs such as personnel costs or other internal costs to specific development of product candidates. These external and unallocated research and development expenses are summarized in the table below:

	Three Months Ended March 31,	
	2019	2018
	(in thousands)	
NEO-PV-01	$ 4,095	$ 5,357
NEO-PTC-01	1,588	602
Other early-stage development expenses	2,715	563
Unallocated expenses	7,774	6,636
Total research and development expenses	$ 16,172	$ 13,158

At this time, we cannot reasonably estimate or know the nature, timing, and estimated costs of the efforts that will be necessary to complete the development of our product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from sales of our products, if approved. This is due to the numerous risks and uncertainties associated with developing our product candidates, including the uncertainty related to:

- the addition and retention of key research and development personnel;
- successful enrollment in and completion of our current clinical trials for NEO-PV-01, as well as the cost of future clinical trials for NEO-PV-01, NEO-PTC-01 and NEO-SV-01;
- costs associated with the preclinical development and clinical trials for our early discovery product candidates;
- maintaining agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if our product candidates are approved;
- receipt of marketing approvals from applicable regulatory authorities;
- commercializing products, if and when approved, whether alone or in collaboration with others;
- the terms and timing of any collaboration, license or other arrangement, including the terms and timing of any milestone payments thereunder;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our products if and when approved; and
- continued acceptable safety profiles of our products following approval.

A change in the outcome of any of these variables with respect to the development of any of our product candidates would significantly change the costs, timing and viability associated with the development of that product candidate.

Research and development activities account for a significant portion of our operating expenses. We expect our research and development expenses to increase over the next several years as we continue to implement our business strategy, which includes advancing clinical development of NEO-PV-01 and progressing NEO-PTC-01 and NEO-SV-01 into clinical development, expanding our research and development efforts, seeking regulatory approvals for any product candidates that successfully complete clinical trials, accessing and developing additional product candidates and hiring additional personnel to support our research and development efforts. In addition, product candidates in later stages of clinical development generally incur higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. As a result, we expect our research and development expenses to increase as our product candidates advance into later stages of clinical development.

General and Administrative Expenses

General and administrative expenses consist of personnel-related costs, including salaries, benefits and non-cash stock-based compensation expense, for our personnel in executive, legal, finance and accounting, human resources, business operations and other administrative functions, legal fees related to patent, intellectual property and corporate matters, fees paid for accounting, regulatory and tax services, insurance costs, consulting fees and facility-related costs not otherwise included in research and development expenses.

We anticipate that our general and administrative expenses will increase in the future to support our continued research and development activities and the increased costs of operating as a public company, including costs of accounting, audit, legal,

regulatory and tax-related services associated with maintaining compliance with exchange listing and Securities and Exchange Commission, or SEC, requirements, additional insurance costs, investor and public relations costs and other administration and professional services.

Other Income, Net

Other income, net consists primarily of interest income related to our investments in cash equivalents and marketable securities.

Results of Operations

Comparison of the Three Months Ended March 31, 2019 and 2018

The following table summarizes our results of operations for the three months ended March 31, 2019 and 2018, along with the changes in those items in dollars:

	Three Months Ended March 31,		
	2019	2018	Change
	(in thousands)		
Operating expenses:			
Research and development	$ 16,172	$ 13,158	$ 3,014
General and administrative	5,408	3,599	1,809
Total operating expenses	21,580	16,757	4,823
Loss from operations	(21,580)	(16,757)	(4,823)
Other income (expense), net	556	237	319
Net loss	$ (21,024)	$ (16,520)	$ (4,504)

Research and Development

Research and development expenses increased by $3.0 million from $13.2 million for the three months ended March 31, 2018 to $16.2 million for the three months ended March 31, 2019. The increase in research and development expenses was primarily attributable to the following:

- $1.2 million of increased external manufacturing costs to support NEO-PV-01, NEO-PTC-01 and NEO-SV-01;
- $0.7 million of increased external research and development costs to support our ongoing NEO-PV-01 clinical trials, as well as costs related to the preparation for additional planned clinical trials;
- $0.7 million for increased personnel-related costs due to increased headcount; and
- $0.4 million for increased external costs related to advancing our preclinical development candidates.

General and Administrative

General and administrative expenses increased by $1.8 million from $3.6 million for the three months ended March 31, 2018 to $5.4 million for the three months ended March 31, 2019. The increase in general and administrative expenses was primarily attributable to the following:

- $0.8 million for increased personnel-related costs, including $0.5 million of increased non-cash stock-based compensation expense primarily due to increased general and administrative headcount to support the growth of our organization;
- $0.6 million for increased expenses associated with obtaining and maintaining intellectual property protection;
- $0.4 million of increased other general and administrative costs primarily due to the increased costs of being a public company, as well as additional professional fees, insurance and tax related expenditures.

Other Income (Expense), Net

Other income increased from $0.2 million for the three months ended March 31, 2018 to $0.6 million for the three months ended March 31, 2019 due primarily to increased interest and investment income on our cash, cash equivalents and marketable securities as a result of the investment of the net proceeds received from our IPO.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have incurred significant losses in each period and on an aggregate basis. We have not yet commercialized any of our product candidates, which are in various phases of preclinical and clinical development, and we do not expect to generate revenue from sales of any products for several years, if at all. We have funded our operations through March 31, 2019 with aggregate net proceeds of $89.9 million from our IPO, as well as an aggregate of $161.1 million of net proceeds from sales of our preferred stock and convertible debt. As of March 31, 2019, we had cash, cash equivalents and marketable securities of $81.3 million.

Historical Cash Flows

The following table provides information regarding our cash flows for each of the periods presented (in thousands):

	Three Months Ended March 31,	
	2019	2018
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (21,155)	$ (14,929)
Investing activities	17,674	2,202
Financing activities	45	(1,091)
Net decrease in cash, cash equivalents and restricted cash	$ (3,436)	$ (13,818)

Cash Used in Operating Activities

The cash used in operating activities resulted primarily from our net losses adjusted for non-cash charges and changes in components of working capital, which are primarily the result of increased expenses and timing of vendor payments.

During the three months ended March 31, 2019, operating activities used $21.2 million of cash, primarily resulting from our net loss of $21.0 million and net cash used by changes in our operating assets and liabilities of $2.5 million, partially offset by net non-cash charges of $2.4 million. Net cash used by changes in our operating assets and liabilities for the three months ended March 31, 2019 consisted primarily of a $2.0 million decrease in accrued expenses and other liabilities, a $0.3 million decrease in operating lease liabilities and a $0.2 million increase in prepaid expenses and other current assets.

During the three months ended March 31, 2018, operating activities used $14.9 million of cash, primarily resulting from our net loss of $16.5 million and net cash used by changes in our operating assets and liabilities of $0.6 million, partially offset by net non-cash charges of $2.2 million. Net cash used by changes in our operating assets and liabilities for the three months ended March 31, 2018 consisted primarily of a $0.5 million decrease in accrued expenses and other liabilities.

Cash Provided by Investing Activities

During the three months ended March 31, 2019, net cash provided by investing activities was $17.7 million, consisting of proceeds from the sales and maturities of marketable securities of $18.7 million, partially offset by purchases of property and equipment of $1.0 million.

During the three months ended March 31, 2018, net cash provided by investing activities was $2.2 million, consisting of proceeds from the sales and maturities of marketable securities of $15.7 million, partially offset by purchases of marketable securities of $12.0 million and purchases of property and equipment of $1.5 million.

Cash Provided by (Used in) Financing Activities

During the three months ended March 31, 2019, net cash provided by financing activities was $0.1 million, consisting entirely of proceeds from the exercise of stock options.

During the three months ended March 31, 2018, net cash used in financing activities was $1.1 million, consisting entirely of payments of initial public offering costs.

Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing research and development activities, particularly as we advance the preclinical activities and clinical trials of our product candidates. As a result, we expect to incur substantial operating losses and negative operating cash flows for the foreseeable future.

Based on our current operating plan, we expect that our existing cash, cash equivalents and marketable securities, will enable us to fund our operating expenses and capital expenditure requirements for at least twelve months from the issuance date of this Quarterly Report on Form 10-Q. However, we have based this estimate on assumptions that may prove to be wrong and we could exhaust our capital resources sooner than we expect.

Because of the numerous risks and uncertainties associated with the development of our product candidates or programs and because the extent to which we may enter into collaborations with third parties for development of our product candidates is unknown, we may incorrectly estimate the timing and amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidates. Our funding requirements and timing and amount of our operating expenditures will depend largely on:

- the initiation, progress, scope, timing, costs and results of preclinical or nonclinical testing and studies and clinical trials for our product candidates;
- the clinical development plans we establish for these product candidates;
- the number and characteristics of product candidates that we develop or may in-license;
- the terms of any collaboration agreements we may choose to execute;
- the outcome, timing and cost of meeting regulatory requirements established by the U.S. Food and Drug Administration, or the FDA, the European Medicines Agency, or the EMA, and other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending intellectual property disputes, including any patent infringement actions that may be brought by third parties in the future against us or our product candidates;
- the effect of competing technological and market developments;
- the cost and timing of formulation development and manufacturing, including the completion of commercial-scale outsourced manufacturing activities; and
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own.

A change in the outcome of any of these or other variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, our operating plans may change in the future and we may need additional funds to meet operational needs and capital requirements associated with these changed operating plans.

In addition to the variables described above, if and when any of our product candidates successfully complete development, we will incur substantial additional costs associated with regulatory filings, marketing approval, post-marketing requirements, maintaining our intellectual property rights and regulatory protection, in addition to other commercial costs. We cannot reasonably estimate these costs at this time.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity or debt financings and collaboration arrangements. We currently have no credit facility or committed sources of capital. To the extent that we raise additional capital through the future sale of equity or debt, the ownership interests of our stockholders will be diluted and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders. If we raise additional funds through the issuance of debt securities, these securities could contain covenants that would restrict our operations. We may require additional capital beyond our currently anticipated amounts and additional capital may not be available on reasonable terms, or at all. If we raise additional funds through collaboration arrangements or other strategic transactions in the future, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate development or future commercialization efforts.

Off-Balance Sheet Arrangements

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

Contractual Obligations and Commitments

During the three months ended March 31, 2019, there have been no material changes from the contractual obligations and commitments previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2018, which was filed with the SEC on March 11, 2019.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of these condensed consolidated 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 condensed consolidated financial statements, as well as the reported expenses incurred during the reporting periods. 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. Actual results may differ from these estimates under different assumptions or conditions.

Effective January 1, 2019, we adopted Accounting Standards Update, or ASU, No. 2016-02, *Leases (Topic 842),* or ASU 2016-02, with no restatement of prior periods or cumulative adjustment to retained earnings. Comparative periods in the Company's financial statements will be presented in accordance with the existing guidance under Accounting Standards Codification Topic 840, or ASC 840. Adoption of the new standard resulted in the recognition of operating lease right-of-use assets and operating lease liabilities of approximately $8.7 million and $8.9 million, respectively, as of January 1, 2019. The adoption of the new standard did not materially impact the Company's condensed consolidated statement of operations. See Note 2 and Note 7 to our condensed consolidated financial statements included within Part I, Item 1 of this Quarterly Report on Form 10-Q for further information on the application of ASU 2016-02.

During the three months ended March 31, 2019, there were no other material changes to our critical accounting policies as reported in our Annual Report on Form 10-K for the year ended December 31, 2018, which was filed with the SEC on March 11, 2019.

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

As of March 31, 2019, we had cash, cash equivalents and marketable securities of $81.3 million. This amount was comprised of cash and cash equivalents of $49.3 million and short-term marketable securities of $32.0 million. Our cash and cash equivalents consist primarily of money market funds that are invested in U.S. government-backed securities. Our short-term marketable securities consist of corporate debt securities with an original maturity greater than ninety days and less than one year from the balance sheet date. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term nature of our cash equivalents and marketable securities, a sudden change in interest rates would not be expected to have material effect on our business, financial condition or results of operations. Because of the short-term nature of the investments in our portfolio, an immediate change by 100 basis points in market interest rates would not have a material impact on the fair market value of our investment portfolio or on our financial position or results of operations.

We are not currently exposed to significant market risk related to changes in foreign currency exchange rates. However, we have contracted with and may continue to contract with vendors that are located in Europe. We may be subject to fluctuations in foreign currency rates in connection with certain of these agreements. Transactions denominated in currencies other than the United States dollar are recorded based on exchange rates at the time such transactions arise. While we have not engaged in the hedging of our foreign currency transactions to date, we are evaluating the costs and benefits of initiating such a program and may in the future hedge selected significant transactions denominated in currencies other than the U.S. dollar as we expand our international operation and our risk grows.

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the three months ended March 31, 2019.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

The Company has established disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e)) designed to ensure that information required to be disclosed in the reports that the Company files or submits under the Securities Exchange Act of 1934, as amended, or Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and is accumulated and communicated to management, including the principal executive officer (our Chief Executive Officer) and principal financial and accounting officer (our Chief Financial Officer), to allow timely decisions regarding required disclosure.

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)) as of March 31, 2019. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our 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 March 31, 2019, our Principal Executive Officer and Principal Financial and Accounting 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 15(d)-15(f) under the Exchange Act) that occurred during the period covered by this Quarterly Report on Form 10-Q 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 be involved in lawsuits, claims, investigations and proceedings, consisting of intellectual property, commercial, employment and other matters which arise in the ordinary course of business. While the outcome of any such proceedings cannot be predicted with certainty, as of March 31, 2019, we were not party to any legal proceedings that we would expect to have a material adverse impact on our financial position, results of operations or cash flow.

Item 1A. Risk Factors

In evaluating the Company and our business, careful consideration should be given to the following risk factors, in addition to the other information set forth in this Quarterly Report on Form 10-Q and in other documents that we file with the SEC. Investing in our common stock involves a high degree of risk. If any of the following risks and uncertainties actually occurs, our business, prospects, financial condition and results of operations could be materially and adversely affected. The risks described below are not intended to be exhaustive and are not the only risks facing the Company. New risk factors can emerge from time to time, and it is not possible to predict the impact that any factor or combination of factors may have on our business, prospects, financial condition and results of operations.

Risks Related to Our Business, Technology and Industry

We have incurred net losses in every year since our inception and anticipate that we will continue to incur net losses in the future.

We are a clinical-stage biopharmaceutical company with a limited operating history. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception in October 2013. For the year ended December 31, 2018 and the three months ended March 31, 2019, we reported net losses of $76.9 million and $21.0 million, respectively. As of March 31, 2019, we had an accumulated deficit of $194.8 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates. We anticipate that our expenses will increase substantially if, and as, we:

- advance NEO-PV-01 into later-stage clinical development;
- advance our development programs into and through preclinical and clinical development;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- hire additional clinical, quality assurance and scientific personnel;
- expand our operational, financial and management systems and increase personnel, including personnel 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 sales, marketing, medical affairs and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly with third parties; and
- acquire or in-license other product candidates and technologies.

To become and remain profitable, we 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 for which we may obtain marketing approval 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 also could cause you to lose all or part of your investment.

Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. We may encounter unforeseen

expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We will require additional capital to fund our operations and, if we fail to obtain necessary financing, we will not be able to complete the development and commercialization of our product candidates.

Our operations have consumed substantial amounts of cash since our inception. We expect to continue to spend substantial amounts to conduct further research and development and preclinical or nonclinical testing and studies and clinical trials of our current and future programs, to seek regulatory approvals for our product candidates and to launch and commercialize any products for which we receive regulatory approval, including potentially building our own commercial organization. As of March 31, 2019, we had approximately $81.3 million in cash, cash equivalents and marketable securities. Based on our current operating plan, we believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements for at least twelve months from the issuance date of this Quarterly Report on Form 10-Q. However, our future capital requirements and the period for which our existing resources will support our operations may vary significantly from what we expect. We will in any event require additional capital in order to complete clinical development of any of our current programs. Our monthly spending levels will vary based on new and ongoing development and corporate activities. Because the length of time and activities associated with development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and commercialization activities. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of preclinical or nonclinical testing and studies and clinical trials for our product candidates;
- the clinical development plans we establish for these product candidates;
- the number and characteristics of product candidates that we develop or may in-license;
- the terms of any collaboration agreements we may choose to execute;
- the outcome, timing and cost of meeting regulatory requirements established by the U.S. Food and Drug Administration, or FDA, the European Medicines Agency, or EMA, and other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending intellectual property disputes, including any patent infringement actions that may be brought by third parties in the future against us or our product candidates;
- the effect of competing technological and market developments;
- the cost and timing of formulation development and manufacturing, including the completion of commercial-scale outsourced manufacturing activities; and
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own.

We do not have any committed external source of funds or other support for our development efforts and we cannot be certain that additional funding will be available on acceptable terms, or at all. Until we can generate sufficient product or 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, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. If we raise additional funds 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. If we raise additional capital through marketing 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, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. We also could be required to seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or relinquish our rights to product candidates or technologies that we otherwise would seek to develop or commercialize ourselves. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our products or product candidates or one or more of our other research and development initiatives. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

In the past, our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements and it is possible that their report on our financial statements may include it such an explanation again in the future.

We believe we have sufficient capital to fund our operations for at least twelve months from the issuance date of this Quarterly Report on Form 10-Q. Going forward, if we are unable to obtain sufficient funding to support our operations, we could be forced to delay, reduce or eliminate all of our research and development programs, product portfolio expansion or commercialization efforts, and our financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern. In the future, reports from our independent registered public accounting firm may also contain statements expressing substantial doubt about our ability to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms or at all.

Our most advanced product candidates are uniquely manufactured for each patient and we may encounter difficulties in production, particularly with respect to scaling our manufacturing capabilities. If we or any of our third-party manufacturers with whom we contract encounter these types of difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

The manufacturing process used to produce our product candidates is complex and novel and has not been validated for clinical or commercial production. For example, for NEO-PV-01, we custom design and manufacture up to 20 individually selected peptides with a proprietary formulation to construct a unique vaccine for each patient. Similarly, for NEO-PTC-01, we will harvest T cells from a patient and activate and expand these T cells *ex vivo* and ultimately infuse the T cells back into the patient's body. As a result of these complexities, the cost to manufacture our product candidates is generally higher than traditional small molecule chemical compounds and the manufacturing process is less reliable and is more difficult to reproduce.

Our manufacturing process will be susceptible to product loss or failure due to logistical issues associated with the collection of a patient's tumor and blood or other samples, shipping that material to analytical laboratories, and shipping the final product back to the location using cold chain distribution where it will be administered to the patient, manufacturing issues associated with the differences in patient starting materials, interruptions in the manufacturing process, contamination, equipment or reagent failure, improper installation or operation of equipment, vendor or operator error, inconsistency in cell growth, and variability in product characteristics. Even minor deviations from normal manufacturing processes could result in reduced production yields, lot failures, product defects, product delays, product recalls, product liability claims and other supply disruptions. If for any reason we lose a patient's starting material or one of our custom manufactured products at any point in the process, the manufacturing process for that patient will need to be restarted and the resulting delay may adversely affect that patient's outcome. If microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, the manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could result in our inability to produce or ship product. Because our product candidates are manufactured for each particular patient, we will be required to maintain a chain of identity with respect to materials as they move from the patient to the manufacturing facility, through the manufacturing process and back to the patient. Maintaining this type of chain of identity is difficult and complex and the failure to do so could result in adverse patient outcomes, loss of product, or regulatory action, including withdrawal of any approved products from the market. Further, as product candidates are developed through preclinical to later-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered in an effort to optimize processes and results. If we make these types of changes, we may not achieve our intended objectives and any of these changes could cause our product candidates to perform differently than we expect, potentially affecting the results of clinical trials.

Although we continue to optimize our manufacturing process, doing so is a difficult and uncertain task and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including, among others, cost overruns, potential problems with process scale-out, process reproducibility, stability issues, lot consistency and timely availability of reagents or raw materials. If we are unable to adequately validate or scale-up the manufacturing process with our current manufacturer, we will need to transfer to another manufacturer and complete the manufacturing validation process, which can be a lengthy process. We ultimately may not be successful in transferring our production system or the manufacturer on whom we rely may not have the necessary capabilities to complete the implementation and development process. If we are able to adequately validate and scale-up the manufacturing process for our product candidates with a contract manufacturer, we will still need to negotiate an agreement for commercial supply with that contract manufacturer and it is not certain we will be able to come to agreement on terms acceptable to us. As a result, we may ultimately be unable to reduce the cost of goods for our product candidates to levels that will allow for an attractive return on investment if and when those product candidates are approved and commercialized.

The manufacturing process for any products that we may develop is subject to the FDA and foreign regulatory authority

approval processes and we will need to contract with manufacturers who we believe can meet applicable FDA and foreign regulatory authority requirements on an ongoing basis. If we or our contract manufacturing organizations, or CMOs, are unable to reliably produce products to specifications acceptable to the FDA or other regulatory authorities, we may not obtain or maintain the approvals we need to commercialize our products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our CMOs will be able to manufacture the approved product to specifications and under required good manufacturing practices acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates, impair commercialization efforts, increase our cost of goods and have an adverse effect on our business, financial condition, results of operations and growth prospects.

Our future success depends on our ability to manufacture our products on a timely basis with acceptable manufacturing costs, while at the same time maintaining good quality control and complying with applicable regulatory requirements and an inability to do so could have a material adverse effect on our business, financial condition, prospects and results of operations. In addition, we could incur higher manufacturing costs if manufacturing processes or standards change and we could need to replace, modify, design or build and install equipment, all of which would require additional capital expenditures. Specifically, because our product candidates may have a higher cost of goods than conventional therapies and may require long-term follow up evaluations, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater.

We expect to evaluate the use of one or more CMOs, as well as the possibility of establishing our own capabilities and infrastructure, including a manufacturing facility. If we choose to build our own manufacturing facility, we will need significant funding and will need to select an adequate location. We expect that development of our own manufacturing facility would provide us with enhanced control of material supply for both clinical trials and the commercial market, enable the more rapid implementation of process changes, and allow for better long-term margins. However, we have no experience in developing a manufacturing facility and may never be successful in developing our own manufacturing facility or capability. If we determine to establish our own manufacturing capabilities and infrastructure, we will also need to hire additional personnel to manage our operations and facilities and develop the necessary infrastructure to continue the research and development, and eventual commercialization, if approved, of our product candidates. If we fail to select the correct location, complete the construction in an efficient manner, recruit the required personnel and generally manage our growth effectively, the development and production of our product candidates could be curtailed or delayed. We may establish multiple manufacturing facilities as we expand our commercial footprint to multiple geographies, which may lead to regulatory delays or could prove costly. Even if we are successful, our manufacturing capabilities could be affected by cost-overruns, unexpected delays, equipment failures, labor shortages, natural disasters, power failures and numerous other factors that could prevent us from realizing the intended benefits of our manufacturing strategy and have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the FDA, the EMA and other foreign regulatory authorities may require us to submit samples of any lot of any approved product, together with the protocols showing the results of applicable tests at any time. Under some circumstances, the FDA, the EMA or other foreign regulatory authorities may require that we not distribute a lot until the relevant agency authorizes its release. Slight deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. Lot failures or product recalls could cause us to delay product launches or clinical trials, which could be costly to us and otherwise harm our business, financial condition, results of operations and prospects. Problems in our manufacturing process could restrict our ability to meet market demand for our products.

We also may encounter problems hiring and retaining the experienced scientific, quality control and manufacturing personnel needed to operate our manufacturing processes, which could result in delays in production or difficulties in maintaining compliance with applicable regulatory requirements.

Any problems in our manufacturing process or facilities could make us a less attractive collaborator for potential partners, including larger pharmaceutical companies and academic research institutions, which could limit our access to additional attractive development programs.

Our business is highly dependent on the success of our lead product candidate, NEO-PV-01, as well as NEO-PTC-01, NEO-SV-01 and our other preclinical programs. All of our product candidates will require significant additional nonclinical and clinical development before we can seek regulatory approval for and launch a product commercially.

Our business and future success depends on our ability to obtain regulatory approval of and then successfully launch and commercialize our lead product candidate, NEO-PV-01, as well as NEO-PTC-01, NEO-SV-01 and our other preclinical programs. NEO-PV-01 is currently being investigated in three Phase 1b clinical trials, and we plan to initiate one additional exploratory clinical trial evaluating NEO-PV-01. In addition, we are currently conducting additional research and development to optimize the manufacturing process for NEO-PTC-01 and NEO-SV-01 and to determine the other indications that we will be targeting with

our NEON / SELECT approach. In particular, given that NEO-PV-01 is our first clinical program, we may be exposed to additional risks related to trial execution, difficulties with patient enrollment, trial design and establishing trial protocols. Meanwhile, NEO-PTC-01 involves the activation and expansion of neoantigen-specific T cells *ex vivo*, an approach that may be less effective than anticipated. Finally, the success of our NEON / SELECT program (including NEO-SV-01) depends on our ability to validate high priority shared neoantigen targets and to develop neoantigen-targeted therapies for these shared targets that are therapeutically-relevant across subsets of patients or tumor types. We may, however, be unable to achieve either or both of these goals.

All of our product candidates will require additional clinical and nonclinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity, and significant marketing efforts before we can generate any revenue from product sales. In addition, because NEO-PV-01 is our most advanced product candidate, if NEO-PV-01 encounters safety or efficacy problems, developmental delays or regulatory issues or other problems, our development plans and business would be significantly harmed.

The successful development of biopharmaceuticals, such as neoantigen-targeted therapies, is highly uncertain.

Successful development of biopharmaceuticals, such as neoantigen-targeted therapies, is highly uncertain and is dependent on numerous factors, many of which are beyond our control. Neoantigen-targeted therapies that appear promising in the early phases of development may fail to reach the market for several reasons including:

- nonclinical or preclinical testing or study results may show the neoantigen-targeted therapies to be less effective than desired or to have harmful or problematic side effects;
- clinical trial results may show the neoantigen-targeted therapies to be less effective than expected (e.g., a clinical trial could fail to meet its primary endpoint(s)) or could have unacceptable side effects or toxicities;
- we may fail to receive the necessary regulatory approvals or experience a delay in receiving those approvals, including delays that may be caused by slow enrollment in clinical trials, patients dropping out of trials, the required length of time to achieve trial endpoints, additional time requirements for data analysis or biologics license application, or BLA, preparation, discussions with the FDA, an FDA request for additional nonclinical or clinical data, or unexpected safety or manufacturing issues;
- manufacturing costs, turnaround time, formulation issues, pricing or reimbursement issues, or other factors that make the neoantigen-targeted therapy uneconomical; and
- the proprietary rights of others and their competing products and technologies that may prevent the neoantigen-targeted therapy from being commercialized.

The length of time necessary to complete clinical trials and to submit an application for marketing approval for a final decision by a regulatory authority may vary significantly from one therapy to the next and may be difficult to predict.

Even if we are successful in getting market approval for our product candidates, commercial success of any approved products will also depend in large part on the availability of coverage and adequate reimbursement from third-party payors, including government payors such as the Medicare and Medicaid programs and managed care organizations, which may be affected by existing and future healthcare reform measures designed to reduce the cost of healthcare. In order to qualify for reimbursement, third-party payors could require us to conduct additional studies, including post-marketing studies related to the cost effectiveness of a product, which could be costly and divert our resources. If government and other healthcare payors were not to provide adequate coverage and reimbursement levels for any of our products once approved, market acceptance and commercial success would be reduced.

In addition, if any of our products is approved for marketing, we will be subject to significant regulatory obligations regarding the submission of safety and other post-marketing information and reports and registration, and will need to continue to comply (or ensure that our third-party providers comply) with current good manufacturing practices, or cGMPs, and good clinical practices, or GCPs, for any clinical trials that we conduct post-approval. In addition, there is always the risk that we or a regulatory authority might identify previously unknown problems with a product post-approval, such as adverse events of unanticipated severity or frequency. Compliance with these requirements is costly and any failure to comply or other issues with our product candidates post-approval could have a material adverse effect on our business, financial condition, prospects and results of operations.

Clinical development is a lengthy and expensive process with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of any product candidates.

To obtain the requisite regulatory approvals to commercialize any product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our products are safe, pure and potent or effective in humans. Clinical testing is expensive and can take many years to complete and the outcome of any clinical trial is inherently uncertain. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful and a clinical trial can fail at any

stage of testing. The outcome of nonclinical studies and early clinical trials may not be predictive of the success of later clinical trials and interim results of a clinical trial do not necessarily predict final results. For example, our ongoing Phase 1b clinical trials of NEO-PV-01 are open-label, but we expect later-stage clinical trials of NEO-PV-01 will require placebo comparison or comparison with an active comparator. Differences in trial design between early stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. Moreover, nonclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that have believed their product candidates performed satisfactorily in nonclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

Successful completion of clinical trials is a prerequisite to submitting a BLA to the FDA, a Marketing Authorization Application, or MAA, to the EMA, and similar marketing applications to comparable foreign regulatory authorities for each product candidate and, consequently, the ultimate approval and commercial marketing of any product candidates. We do not know whether any of our clinical trials will begin or be completed on schedule, if at all.

We may experience delays in completing our preclinical or nonclinical testing and studies and initiating or completing clinical trials. We also may experience numerous unforeseen events or circumstances during, or as a result of, any future clinical trials that we may conduct that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- regulators or institutional review boards, or IRBs, or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- 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 candidates may fail to show safety, purity or potency, or 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 development programs;
- the number of patients required for clinical trials of any product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipated or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipated;
- our CROs and other third-party contractors involved in our clinical trials may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or they 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;
- the cost of preclinical or nonclinical testing and studies and clinical trials of any product candidates may be greater than we anticipate;
- the potential insufficiency or inadequacy of the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates;
- our ability to manufacture and supply product to patients consistent with clinical trial protocols;
- our product candidates may have undesirable side effects or other unexpected characteristics, 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 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 could also encounter delays if a clinical trial is suspended or terminated by us, the IRBs of the institutions in which such trials are being conducted, or the FDA or other regulatory authorities, or if a clinical trial is recommended for suspension or termination by the relevant Data Safety Monitoring Board, or DSMB. A suspension or termination may be imposed 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 that results in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product or treatment, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Many of the factors that could 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. 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.

Our product development costs will increase if we experience delays in conducting clinical testing or receiving marketing approvals. We do not know whether any of our preclinical or nonclinical testing and studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical or nonclinical testing and studies or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business, financial condition, prospects and results of operations. Any delays in our nonclinical or future clinical development programs may harm our business, financial condition, prospects and results of operations significantly.

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, which would have an adverse effect on our business.

With the exception of NEO-PV-01, all of our other product candidates are still in the preclinical discovery stage and their risk of failure is high. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our planned Investigational New Drug applications, or INDs, in the United States, or similar applications in other jurisdictions. We cannot be certain of the timely completion or outcomes of our preclinical testing and studies and cannot predict if the FDA or other regulatory authorities will accept our proposed clinical programs or if the outcomes of our preclinical testing and studies will ultimately support the further development of our programs. 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.

Our planned clinical trials or those of our future collaborators may reveal significant adverse events not seen in our preclinical or nonclinical studies and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates.

Before obtaining regulatory approvals for the commercial sale of any products, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our product candidates are both safe and effective for use in each target indication. Clinical testing is expensive and can take many years to complete and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. In addition, initial success in clinical trials may not be indicative of results obtained when those trials are completed. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through nonclinical studies and initial clinical trials. Companies in the biopharmaceutical industry have suffered significant setbacks in later-stage clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved as products and 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.

We intend to develop NEO-PV-01, and may develop future product candidates, in combination with one or more cancer therapies. This combination may have additional side effects that were not present in initial clinical trials of our product candidates with other cancer therapies. The uncertainty resulting from the use of our product candidates in combination with other cancer therapies may make it difficult to accurately predict side effects in future clinical trials.

If significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to our clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of one or more product candidates altogether. We, the FDA or other applicable regulatory authorities, or an IRB, may suspend clinical trials of a product candidate at any time for various reasons, including a belief that trial subjects are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects presented do not preclude the drug from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of the approved product due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition, prospects and results of operations.

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

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. The enrollment of patients depends on many factors, including:

- the patient eligibility and exclusion criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- the ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

In addition, our clinical trials will compete with other clinical trials for product candidates that are similar therapeutic areas as our product candidates, which may reduce the number and types of patients available to us. In addition, 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 those sites. Moreover, because our product candidates 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 and bone marrow transplantation, rather than enroll patients in a clinical trial. This may be particularly true for patients with late-stage disease who may perceive that our approach is not effective for patients with that disease profile.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our planned clinical trials. These delays could also prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

We expect to develop NEO-PV-01 and, potentially future product candidates, in combination with other therapies, and safety or supply issues with combination use products may delay or prevent development and approval of our product candidates.

We intend to develop NEO-PV-01, and likely other product candidates, in combination with one or more approved or unapproved cancer therapies.

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 risks that the FDA or similar regulatory authorities outside of the United States could revoke approval of the therapy used in combination with our product or that safety, efficacy, manufacturing or supply issues could arise with any of those existing therapies. If the therapies we use in combination with our product candidates are replaced as the standard of care for the indications we choose for any of our product candidates, the FDA or similar regulatory authorities outside of the United States may require us to conduct additional clinical trials. The occurrence of any of these risks could result in our own products, if approved, being removed from the market or being less successful commercially.

We also plan to evaluate NEO-PV-01 or any other future product candidates in combination with one or more cancer therapies that have not yet been approved for marketing by the FDA or similar regulatory authorities outside of the United States. We will not be able to market and sell NEO-PV-01 or any product candidate we develop in combination with an unapproved cancer therapy if that unapproved cancer therapy does not ultimately obtain marketing approval. In addition, unapproved cancer therapies face the same risks described with respect to our product candidates currently in development and clinical trials, including the potential for serious adverse effects, delay in their clinical trials and lack of FDA approval.

If the FDA or similar regulatory authorities outside of the United States do not approve these other drugs or revoke their approval of, or if safety, efficacy, manufacturing, or supply issues arise with, the drugs we choose to evaluate in combination with NEO-PV-01 or any product candidate we develop, we may be unable to obtain approval of or market NEO-PV-01 or any product candidate we develop.

Neoantigen-targeted therapies are a novel approach and negative perception of the efficacy or safety of any of our product candidates could adversely affect our ability to conduct our business or obtain regulatory approvals for our product candidates.

Neoantigen-targeted therapies remain novel and unproven technologies, with no neoantigen-targeted therapy approved to date in the U.S. or EU. Neoantigen vaccines, neoantigen T cell therapies or any other modality that we seek to use may not gain the acceptance of the public or the medical community. For example, earlier cancer vaccines attempted to direct the immune system against a class of molecules found predominantly, but not exclusively, at the tumor site. Since the targets of these cancer vaccines were are also found on normal cells, they were regarded as 'self', which caused the immune system to prohibit destruction of the cancerous cells. As a result, these cancer vaccines did not generate potent immune responses. Our neoantigen vaccines may be perceived to face the same challenges as the earlier cancer vaccines, which could limit our ability to enroll patients in our clinical trials or if approved, negatively impact our vaccines' market acceptance. Further, with respect to our NEO-PTC-01 program, the use of T cells as a potential cancer treatment is a recent scientific development and may not become broadly accepted by

physicians, patients, hospitals, cancer treatment centers and others in the medical community.

Our success will depend upon physicians who specialize in the treatment of diseases targeted by our product candidates prescribing treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments with which they are more familiar and for which greater clinical data may be available. Adverse events in clinical trials of our product candidates or in clinical trials of others developing similar products and the resulting publicity, as well as any other adverse events in the field of neoantigen-targeted therapies cancer vaccines, or T cell therapies, could result in a decrease in demand for any product that we may develop. In addition, responses by the U.S., state or foreign governments to negative public perception may result in new legislation or regulations that could limit our ability to develop or commercialize any product candidates, obtain or maintain regulatory approval or otherwise achieve profitability. More restrictive statutory regimes, government regulations or negative public opinion would have an adverse effect on our business, financial condition, prospects and results of operations and may delay or impair the development and commercialization of our product candidates or demand for any products we may develop.

NEO-PV-01 includes a development-stage vaccine adjuvant, poly-ICLC. It is difficult for us to predict how our use of poly-ICLC will be viewed by the FDA or other regulatory agencies as we attempt to demonstrate the safety of NEO-PV-01.

We use an adjuvant, poly-ICLC, with our NEO-PV-01 vaccine product candidate, which makes it difficult to predict how the FDA and applicable other regulatory agencies will evaluate the safety of NEO-PV-01. Adjuvants are compounds that are added to vaccines to enhance the activation of and improve the immune response and efficacy of vaccines. Any vaccine, because of the presence of an adjuvant, may have side effects that may pose too great a safety risk to warrant approval of the vaccine. Development-stage vaccine adjuvants, such as poly-ICLC, may pose an increased safety risk to patients. Poly-ICLC has been used as an adjuvant in other investigational vaccine trials but has never been approved by the FDA for commercial use. The existence of additional trials using this adjuvant may provide support for approval of our product candidates, however, negative safety or efficacy results from other trials using poly-ICLC could similarly jeopardize the continued development of our product candidates that use poly-ICLC as an adjuvant.

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 research and development activities involve the use of biological and hazardous materials and 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, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, as well as environmental damage that could result in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these types of materials generally comply with the standards prescribed by applicable laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these types of materials. In the event of any contamination or injury, we may be held liable for any resulting damages in an amount that could potentially exceed our resources, and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of changes to applicable laws and regulations and cannot be certain of our future compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

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 or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological waste or hazardous waste insurance coverage or workers compensation or property and casualty and general liability insurance policies that include coverage for damages and fines arising from biological or hazardous waste exposure or contamination.

We may incur substantial liabilities and may be required to limit commercialization of our product candidates if we face product liability lawsuits.

We face an inherent risk of product liability as a result of testing our product candidates in clinical trials and will face an even greater risk if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical trials, manufacturing, marketing or sale. We could face product liability claims that may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. In addition, we could face claims asserted under state consumer

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

- our inability to bring a product candidate to the market or commercialize any product candidate;
- decreased demand for our products;
- injury to our reputation;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the withdrawal of IRB approval for the conduct of clinical trials using our product candidates; and
- a decline in our share price.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with collaborators. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, that indemnification may not be available or adequate should any claim arise. Although we currently carry $10.0 million in clinical trial insurance, that amount of insurance coverage may not be adequate and, in the future, we may be unable to maintain this insurance coverage or we may not be able to obtain additional or replacement insurance at a reasonable cost, if at all. Our insurance policies also have various exclusions and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay those amounts.

The market opportunities for our product candidates may be limited or small.

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

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

The biopharmaceutical industry is characterized by intense competition and rapid innovation. Our competitors may be able to develop other compounds or drugs that are able to achieve similar or better results. Our potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations and well-established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel therapeutics or to in-license novel therapeutics that could make the product candidates that we develop obsolete. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further due to advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than our product candidates, or they may develop proprietary

technologies or secure patent protection that we may need for the development of our technologies and products. We believe the key competitive factors that will affect the development and commercial success of our product candidates are efficacy, safety, tolerability, reliability, convenience of use, price and reimbursement.

We anticipate competing with the largest pharmaceutical companies in the world, many of which are all currently conducting research in neoantigen based therapies and all of which have greater financial and human resources than we currently have. In addition to these fully-integrated biopharmaceutical companies, we will also face competition from other immunotherapy-focused oncology companies. Further, we directly compete with a number of neoantigen therapeutics-focused companies, some of whom are developing vaccines, while others are developing T cell therapies and/or T cell receptor-based therapies. These competitors include Aduro Biotech, Inc., Achilles Therapeutics Limited, Adaptimmune Therapeutics plc, Adicet Bio, Inc., Advaxis, Inc., Agenus Inc., AgenTus Therapeutics, Inc., BioNTech AG, bluebird bio, Inc., Celgene Corporation, Genocea Biosciences, Inc., Gilead Sciences, Inc., Gritstone Oncology, Inc., Immatics Biotechnologies GmbH, IMV Inc., Iovance Biotherapeutics, Inc., ISA Pharmaceuticals, B.V., Lion TCR Pte. Ltd., Medigene AG, Moderna, Inc., Nouscom AG, PACT Pharma, Inc., Regeneron Pharmaceuticals, Inc., Vaccibody AS, Zelluna Immunotherapy AS and ZIOPHARM Oncology, Inc.

Even if we obtain regulatory approval of our product candidates, the availability and price of our competitors' products could limit the demand and the price we are able to charge for our product candidates. We may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances.

We rely on our RECON bioinformatics engine to identify neoantigen targets. Our competitive position could be materially harmed if our competitors develop a platform similar to RECON and develop rival product candidates.

We rely on unpatented know-how, inventions and other proprietary information to strengthen our competitive position. We consider know-how to be our primary intellectual property with respect to our RECON (Real-time Epitope Computation for Oncology) bioinformatics engine. The algorithms comprising RECON require accurate input data to enable the algorithms to detect patterns. Our clinical trials allow us to collect clinical data together with myriad samples of blood and tumor tissue, which we use as a feedback loop to make improvements to RECON. However, know-how can be difficult to protect. In particular, we anticipate that, with respect to this platform, this know-how may over time be disseminated within the industry through independent development, the publication of journal articles describing the method and the movement of skilled personnel.

We cannot rule out that our competitors may have or obtain the knowledge necessary to analyze and characterize similar data to our known data for the purpose of identifying and developing products that could compete with NEO-PV-01, NEO-PTC-01, NEO-SV-01 or any of our future product candidates. Our competitors may also have significantly greater financial, product development, technical and human resources and access to other human tumors than we do. Further, our competitors may have significantly greater experience in using translational science methods to identify and develop product candidates.

We may not be able to prohibit our competitors from using technology or methods that are the same as or similar to RECON to develop their own product candidates. If our competitors develop bioinformatics and engage in the computation and analysis of complex algorithms to identify neoantigen targets and develop associated therapies, our ability to develop and market a promising product or product candidate may diminish substantially, which could have a material adverse effect on our business, financial condition, prospects and results of operations.

Continuous and up-to-date clinical data is a key feature of RECON. We cannot guarantee that we will be permitted by regulatory authorities, or have the resources to obtain, continuous clinical data that would be input into RECON. For example, regulatory authorities may require that we refrain from inputting any additional data into RECON after we commence a pivotal clinical trial. If we are prevented or impeded from adding additional clinical data into RECON, we will not be able to advance RECON and its utility may be diminished. In addition, we cannot guarantee that any changes or additions we make to RECON will ultimately result in improved therapeutic outcomes for any product candidates that are generated as a result of RECON. As a result, our ability to develop product candidates through the use of RECON that provide therapeutic benefit may be significantly impacted, which could have a material adverse effect on our business, financial condition, prospects and results of operations.

Even if a product candidate we develop 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 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, other cancer treatments like chemotherapy and radiation therapy are well established in the medical community and doctors may continue to rely on these therapies. If the 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 any product candidate, if approved for commercial sale, will depend on a number of factors, including:

- efficacy and potential advantages compared to alternative treatments;
- price competitiveness;
- 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 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;
- adoption of a companion diagnostic and/or complementary diagnostic; and
- the prevalence and severity of any side effects.

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

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of technology research, product development and manufacturing, regulatory affairs and, if any product candidates are submitted for or receive marketing approval, sales, marketing and distribution. 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 our product candidates, 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 commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth and our management may also 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, contractors and consultants to provide certain services, including substantially all aspects of regulatory approval, clinical management and manufacturing. There can be no assurance that the services of independent organizations, advisors, contractors and consultants will continue to be available to us on a timely basis when needed or that we will be able to 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 independent organizations, advisors, contractors or consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing independent organizations, advisors, contractors or consultants or find other competent resources on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and expanding the roster of independent organizations, advisors and consultants on whom we rely on an outsourced basis, we may not be able successfully to implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

If we lose key management personnel, or if we fail to recruit additional highly skilled personnel, our ability to identify and develop new or next generation product candidates will be impaired, could result in loss of markets or market share and could make us less competitive.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel, including Hugh O'Dowd, our Chief Executive Officer, Yasir B. Al-Wakeel, our Chief Financial Officer, Richard Gaynor, our President of Research & Development, and Robert Ang, our Chief Business Officer. The loss of the services of any of our executive officers, other key employees and other scientific and medical advisors and our inability to find suitable replacements could result in delays in product development and harm our business.

We conduct our operations at our facility in Cambridge, Massachusetts. This region is home to many other biopharmaceutical companies and many academic and research institutions and competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided restricted stock, restricted stock units and stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with certain of our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain "key man" insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers, as well as junior, mid-level and senior scientific and medical personnel.

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

Our operations, and those of our CROs, CMOs and other independent organizations, advisors, contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce and process our product candidates on a patient-by-patient basis. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of the suppliers of these materials are affected by a man-made or natural disaster or other business interruption.

Our internal computer systems, or those used by our CROs or other independent organizations, advisors, contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our CROs and other independent organizations, advisors, contractors and consultants are vulnerable to damage from computer viruses and unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Because information systems, networks and other technologies are critical to many of our operating activities, shutdowns or service disruptions at our company or vendors that provide information systems, networks or other services to us pose increasing risks. Disruptions of this nature may be caused by events such as computer hacking, phishing attacks, ransomware, dissemination of computer viruses, worms and other destructive or disruptive software, denial of service attacks and other malicious activity, as well as power outages, natural disasters (including extreme weather), terrorist attacks or other similar events. While we have not experienced any material system failure or security breach to date, if an event of that nature were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Additionally, a security breach related to RECON's proprietary combination of algorithms could adversely affect our ability to apply RECON to predict therapeutically-relevant neoantigens or result in our competitors having access to these algorithms, which could adversely affect our competitive position. Likewise, we currently, and may in the future continue to, rely on third parties for the manufacture of our product candidates and to conduct clinical trials and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our internal computer systems or those used by our CROs or other independent organizations, advisors, contractors or consultants, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, suffer reputational harm and experience delays in the further development and commercialization of our product candidates.

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

We are exposed to the risk of fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with the laws enforced by the FDA and other similar foreign regulatory bodies, provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the United States and similar foreign laws, or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under these laws will increase significantly and our costs associated with compliance with these laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs.

Our relationships with healthcare providers and physicians and third-party payors will 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 and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Arrangements with third-party payors and customers can expose pharmaceutical manufactures to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, or the FCA, which may constrain the business or financial arrangements and relationships through which companies sell, market and distribute pharmaceutical products. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. The applicable federal, state and foreign healthcare laws and regulations laws 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 a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity can be found guilty of violating this statute without actual knowledge of the statute or specific intent to violate it. 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. The 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. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;
- federal civil and criminal false claims laws and civil monetary penalty laws, including the FCA, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by Medicare, Medicaid, or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose, among other things, requirements on certain covered healthcare providers, health plans and healthcare clearinghouses, as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization. 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 the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- the federal Physician Payment Sunshine Act, created under the Patient Protection and Affordable Care Act, and its implementing regulations, which require manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors)

and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and may be broader in scope than their U.S. federal equivalents; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

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 business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business.

The failure to comply with any of these laws or regulatory requirements subjects entities to possible legal or regulatory action. Depending on the circumstances, our failure to meet applicable regulatory requirements can result in 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. Any action for violation of these laws, even if successfully defended, could cause a pharmaceutical manufacturer to incur significant legal expenses and divert management's attention from the operation of the business. Prohibitions, restrictions on sales or withdrawal of future marketed products could materially affect a pharmaceutical manufacturer's business in an adverse way.

We have adopted a code of business conduct and ethics, a copy of which is available on the Investors section of our website. However, even after adopting and implementing appropriate corporate policies, it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with applicable laws or regulations. Our efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any actions of this nature are instituted against us and if we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, any of which could adversely affect our ability to operate our business, financial condition, prospects and results of operations. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

We may not be successful in our efforts to identify additional product candidates. Due to our limited resources and access to capital, we must prioritize development of certain product candidates; these decisions may prove to be wrong and may adversely affect our business.

Although we intend to explore therapeutic opportunities beyond those that we are currently developing, we may fail to identify viable new product candidates for clinical development for a number of reasons, which could result in harm to our business.

Research programs to pursue the development of our existing and planned product candidates for additional indications and to identify new product candidates and disease targets require substantial technical, financial and human resources, whether or

not they are ultimately successful. Our research programs may initially show promise in identifying potential indications and/or product candidates, yet fail to yield results for clinical development for a number of reasons, including:

- the research method used may not be successful in identifying potential indications and/or product candidates;
- potential product candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective therapies; or
- it may take greater human and financial resources than we will possess to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, thereby limiting our ability to develop, diversify and expand our product portfolio.

Because we have limited financial and human resources, we intend to initially focus on research programs and product candidates for a limited set of indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities.

Accordingly, there can be no assurance that we will ever be able to identify additional therapeutic opportunities for our product candidates or develop suitable potential product candidates through internal research programs, which could materially adversely affect our business, financial condition, prospects and results of operations. We may focus our efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful.

Our business could be materially and adversely affected by a variety of risks associated with marketing our product candidates internationally.

We plan to seek regulatory approval of our product candidates outside of the United States and, accordingly, if we obtain necessary approvals, we expect that we will be subject to additional risks related to operating in foreign countries, including:

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- import and export regulations;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practices Act, or FCPA, or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations.

We currently have no marketing and sales organization and have no organizational experience marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to generate product revenue.

We currently have no sales, marketing or distribution capabilities and have no organizational experience marketing products. In the future, we intend to develop an in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

In addition to establishing internal sales, marketing and distribution capabilities, we may pursue collaborative arrangements regarding the sales and marketing of our products. However, there can be no assurance that we will be able to establish or maintain these types of collaborative arrangements, or if we are able to do so, that our partners will have effective sales forces. Any revenue

we receive from collaboration partners will depend upon the efforts of these third parties, which may not be successful. We may have little or no control over the marketing and sales efforts that these third parties undertake and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

There can be no assurance that we will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any, assuming they receive regulatory approval, in the United States or overseas.

Comprehensive tax reform legislation could adversely affect our business and financial condition.

In December 2017, the U.S. government enacted comprehensive tax legislation, referred to as the Tax Reform Act, that includes significant changes to the taxation of business entities. These changes include, among others, a permanent reduction to the corporate income tax rate, limiting interest deductions, limiting the deduction for net operating losses to 80% of annual taxable income and eliminating net operating loss carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2017 (though any such tax losses may be carried forward indefinitely), allowing for the expensing of capital expenditures, putting into effect the migration from a "worldwide" system of taxation to a territorial system, and modifying or repealing many business deductions and credits (including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as "orphan drugs"). The overall impact of this tax reform is uncertain, and it is possible that our business, financial condition prospects and results of operations could be adversely affected by the limitations imposed on certain tax deductions and credits. We continue to examine the impact this tax reform legislation may have on our business. We urge our stockholders to consult with their legal and tax advisors with respect to applicable tax laws, including this legislation, and the potential tax consequences of investing in our common stock.

Our ability to use net operating losses and research and development credits to offset future taxable income may be subject to certain limitations.

As of December 31, 2018, we had federal net operating loss carryforwards of $117.1 million of which $79.1 million will begin to expire in 2034 and $38.0 million which can be carried forward indefinitely. We also had state net operating loss carryforwards of $118.7 million, which begin to expire in 2034. As of December 31, 2018, we also had federal and state research and development tax credit carryforwards of $5.2 million and $1.5 million, respectively, which begin to expire in 2034 and 2029, respectively. These net operating loss and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. In addition, in general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change net operating losses or tax credits, or NOLs or credits, to offset future taxable income or taxes. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders or groups of stockholders who owns at least 5% of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a specified testing period. Our existing NOLs or credits may be subject to limitations arising from previous ownership changes, and if we are deemed to have undergone an ownership change in connection with or after our initial public offering, our ability to utilize NOLs or credits could be further limited by Sections 382 and 383 of the Code. In addition, future changes in our stock ownership, many of which are outside of our control, could result in an ownership change under Sections 382 and 383 of the Code. Our NOLs or credits may also be impaired under state law. Accordingly, we may not be able to utilize a material portion of our NOLs or credits. Furthermore, our ability to utilize our NOLs or credits is conditioned upon our attaining profitability and generating U.S. federal and state taxable income. As described above under "Risk Factors-Risks Related to Our Business, Technology and Industry," we have incurred significant net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future. Therefore, we do not know whether or when we will generate the U.S. federal or state taxable income necessary to utilize our NOL or credit carryforwards. Under the Tax Reform Act, NOLs generated after December 31, 2017 will not be subject to expiration. The Tax Reform Act also reduced the corporate income tax rate to 21%, from a prior rate of 35%. This may cause a reduction in the potential economic benefit of our NOLs and other available deferred tax assets.

Risks Related to Government Regulation

The regulatory approval process for our product candidates in the United States, European Union and other jurisdictions is currently uncertain and will be lengthy, time-consuming and inherently unpredictable and we may experience significant delays in the clinical development and regulatory approval, if any, of our product candidates.

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of drug products, including biologics, are subject to extensive regulation by the FDA in the United States and regulatory authorities in states and other countries. We are not permitted to market any biological product in the United States until we receive a biologics license from the FDA. We have not previously submitted a BLA to the FDA, or similar marketing application to comparable foreign authorities. A BLA must include extensive nonclinical and clinical data and supporting information to establish that the product

candidate is safe, pure and potent for each desired indication. The BLA must also include significant information regarding the chemistry, manufacturing and controls for the product, and the manufacturing facilities must complete a successful pre-license inspection. We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. For example, the NEON / ONE product candidate that we design and manufacture is molecularly different for each patient and the FDA has not approved any personal neoantigen therapies to date. Similarly, we use data from our clinical trials to continuously improve the algorithms composing our RECON bioinformatics engine. The FDA or other regulatory authorities may require that we refrain from inputting any additional data into our RECON bioinformatics engine before we commence any pivotal clinical trials of our product candidates. As a result, our ability to develop product candidates and obtain regulatory approval may be significantly impacted.

The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support approval. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain approval of any product candidates that we develop based on the completed clinical trials.

Moreover, while we are not aware of any specific genetic or biomarker diagnostic tests for which regulatory approval would be necessary in order to advance any of our product candidates to clinical trials or potential commercialization, in the future, regulatory agencies may require the development and approval of these types of tests. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and we may never obtain regulatory approval for our product candidates.

In addition, clinical trials can be delayed or terminated for a variety of reasons, including delays or failures related to:

- obtaining regulatory authorization to begin a trial, if applicable;
- the availability of financial resources to begin and complete the planned trials;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval at each clinical trial site by an independent IRB or ethics committee;
- recruiting suitable patients to participate in a trial in a timely manner;
- having patients complete a trial or return for post-treatment follow-up;
- deviations from trial protocols by clinical trial sites, noncompliance with GCP requirements or clinical trial sites dropping out of a trial;
- addressing any patient safety concerns that arise during the course of a trial;
- addressing any conflicts with new or existing laws or regulations;
- adding new clinical trial sites; or
- manufacturing qualified materials under cGMP regulations for use in clinical trials.

Patient enrollment is a significant factor in the timing of commencement and completion of trials and can be affected by many factors. A clinical trial may be suspended or terminated by us, the IRBs for the institutions in which such trials are being conducted, or the FDA or other regulatory authorities, or a clinical trial may be recommended for suspension or termination by the applicable DSMB, 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. If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing any clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue.

The FDA may disagree with our regulatory plan and we may fail to obtain regulatory approval of our product candidates.

The general approach for FDA approval of a new biologic or drug is to provide dispositive data from two well-controlled, Phase 3 clinical trials of the relevant biologic or drug in the relevant patient population. Phase 3 clinical trials typically involve hundreds of patients, have significant costs and take years to complete. We believe that we may be able to utilize an accelerated approval approach for our product candidates given the limited alternatives for cancer treatments, but the FDA may not agree with our plans.

In addition, our clinical trials results may also not support approval of our product candidates. Our 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 our product candidates are safe and effective for any of their proposed indications;
- 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 our product candidates' clinical and other benefits outweigh their safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from nonclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may be deemed by the FDA or comparable foreign regulatory authorities to be insufficient to support the submission of a BLA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve or find deficiencies with the manufacturing processes and controls or facilities of third-party manufacturers with which we contract for clinical and commercial supplies or any facilities that we may own in the future; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner that could render our clinical data insufficient for approval.

We may rely on third parties to conduct investigator-sponsored clinical trials of NEO-PV-01, NEO-PTC-01 and our other product candidates. Any failure by a third party to meet its obligations with respect to the clinical development of our product candidates may delay or impair our ability to obtain regulatory approval for NEO-PV-01, NEO-PTC-01, NEO-SV-01 and our other product candidates.

We may rely on academic and private, non-academic institutions to conduct and sponsor clinical trials relating to NEO-PV-01, NEO-PTC-01, NEO-SV-01 and our other product candidates. We will not control the design or conduct of the investigator-sponsored trials. It is possible that the FDA or non-U.S. regulatory authorities will not view these investigator-sponsored trials as providing adequate support for future clinical trials, whether controlled by us or third parties, for any one or more reasons, including due to elements of the design or execution of the trials, safety concerns or safety concerns or other trial results.

Our arrangements with academic and private, non-academic institutions will likely provide us certain information rights with respect to the investigator-sponsored trials, including access to and the ability to use and reference the data resulting from the investigator-sponsored trials, including for our own regulatory filings. However, we would not have control over the timing and reporting of the data from investigator-sponsored trials, nor would we own the data from the investigator-sponsored trials. If we are unable to confirm or replicate the results from investigator-sponsored trials or if those trials produce negative results, we would likely be further delayed or prevented from advancing further clinical development of our product candidates. Further, if investigators or institutions breach their obligations with respect to the clinical development of our product candidates, or if the data they generate prove to be inadequate compared to the first-hand knowledge we might have gained had their trials instead been sponsored and conducted by us, then our ability to design and conduct any future clinical trials ourselves may be adversely affected.

Additionally, the FDA or non-U.S. regulatory authorities may disagree with the sufficiency of our right of reference to the preclinical, manufacturing or clinical data generated by these investigator-sponsored trials, or our interpretation of preclinical, manufacturing or clinical data from these investigator-sponsored trials. If so, the FDA or other non-U.S. regulatory authorities may require us to obtain and submit additional preclinical, manufacturing, or clinical data before we may initiate our planned trials and/or may not accept such additional data as adequate to initiate our planned trials.

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

Obtaining and maintaining regulatory approval of a product candidate in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval for that product candidate in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory 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 nonclinical studies or clinical trials as 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 regulatory 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 our product candidates in those jurisdictions. Obtaining foreign regulatory 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 and/or 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.

Even if we receive regulatory approval of any product candidates or therapies, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

If any of our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. In addition, we will be subject to continued compliance with cGMP and GCP requirements for any clinical trials that we conduct post-approval.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA, and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP, and in certain cases, current Good Tissue Practices, or cGTP, regulations. As a result, we and our contract manufacturers, including our outsourced peptide manufacturer and vaccine adjuvant supplier, will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any BLA, other marketing application, and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require that we implement a risk evaluation and mitigation strategy, or REMS, program as a condition of approval of our product candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, we will have to comply with requirements including submissions of safety and other post-marketing information and reports and establishment registration.

The FDA may seek consent decrees or withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning or untitled letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses and a company that is found to have improperly promoted off-label uses may be subject to significant liability. The policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. 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.

Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, if approved, which could make it difficult for us to sell any product candidates or therapies profitably.

The success of our product candidates, if approved, depends on the availability of adequate coverage and reimbursement from third-party payors. In addition, because our product candidates represent new approaches to the treatment of cancer, we cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our product candidates or assure that coverage and reimbursement will be available for any product that we may develop.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors are critical to new product acceptance.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products, with no assurance that the payor would agree to provide coverage and adequate reimbursement. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of product candidates. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates. Because our product candidates may have a higher cost of goods than conventional therapies and may require long-term follow up evaluations, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater. There is significant uncertainty related to insurance coverage and reimbursement of newly approved products. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

Payment methodologies may be subject to changes in healthcare legislation, regulatory initiatives and judicial challenges. For example, in order for a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. For the 2018 and 2019 fiscal years, CMS altered the reimbursement formula from Average Sale Price, or ASP, plus 6% to ASP minus 22.5% on specified covered outpatient drugs, or SCODs, but did so without issuing a formal notice of proposed rulemaking. On December 27, 2018, the District Court for the District of Columbia invalidated that formula change, ruling the change was not an "adjustment" that was within the Secretary's discretion to make, but was instead a fundamental change in the reimbursement calculation, and that such a dramatic change was beyond the scope of the Secretary's authority. The court has not determined whether reimbursement rates should be retroactively returned to the ASP plus 6% rate and the difference in such reimbursement made to the covered facilities or if some other remedy is more appropriate. It is unclear how the invalidation of the formula could affect pharmaceutical manufacturers and hospitals who prescribe their products now and in the future. Additional state and federal healthcare reform measures are expected to 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 certain pharmaceutical products or additional pricing pressures and therefore may affect our business, financial condition, prospects and results of operations.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause public and private payor 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. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship

between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, Congress and the current administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs, and the current administration recently released a "Blueprint," or plan, to reduce the cost of drugs. The current administrations' Blueprint contains certain measures that the U.S. Department of Health and Human Services is already working to implement. For example, on November 30, 2018, CMS announced a proposed rule that would amend the Medicare Advantage and Medicare Part D prescription drug benefit regulations to reduce out of pocket costs for plan enrollees and allow Medicare plans to negotiate lower rates for certain drugs. Among other things, the proposed rule changes would allow Medicare Advantage plans to use pre authorization, or PA, and step therapy, or ST, for six protected classes of drugs, with certain exceptions; permit plans to implement PA and ST in Medicare Part B drugs; and changes the definition of "negotiated prices" while adding a definition of "price concession" in the regulations. It is unclear whether these proposed changes we be accepted, and if so, what effect such changes will have on our business.

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, cost containment initiatives and additional legislative changes.

Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any changes of this nature were to be imposed on us, they could adversely affect the operation of our business.

In the United States, there have been, and continue to be, a number of legislative initiatives to contain healthcare costs. For example, in March 2010, Congress passed the Patient Protection and Affordable Care Act, or the ACA, 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 method 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 manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

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 the Trump administration to repeal or replace certain aspects of the ACA. While Congress has not passed repeal legislation, the Tax Reform 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." As a result of the individual mandate repeal, subsequent litigation challenged the validity of the ACA. On December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseverable feature of the ACA, and therefore because the mandate was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the ACA are invalid as well. The Trump administration and CMS have both stated that the ruling will have no immediate effect and, on December 30, 2018, the same judge issued an order staying the judgment pending appeal. It is unclear how this decision and any subsequent appeals and other efforts to repeal and replace the ACA will impact the ACA and our business.

Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the ACA, effective January 1, 2019, to increase from 50% to 70% the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." It is possible that Congress may consider other legislation to repeal or replace certain elements of the ACA. In addition, since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Further, the Trump administration has concluded that cost-sharing reduction, or CSR, payments to insurance companies required under the ACA have not received necessary appropriations from Congress and announced that it will discontinue these payments immediately until those appropriations are made. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under

the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but the request for a restraining order was denied by a federal judge in California on October 25, 2017. Furthermore, on June 14, 2018, the U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12 billion in ACA risk corridor payments to third-party payors who argued were owed to them. The effects of this gap in reimbursement on third-party payors, the viability of the ACA marketplace, providers, and the potential effect on our business, are not yet known.

Additionally, CMS has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. On November 30, 2018, CMS announced a proposed rule that would amend the Medicare Advantage and Medicare Part D prescription drug benefit regulations to reduce out of pocket costs for plan enrollees and allow Medicare plans to negotiate lower rates for certain drugs. Among other things, the proposed rule changes would allow Medicare Advantage plans to use PA and ST for six protected classes of drugs, with certain exceptions; permit plans to implement PA and ST in Medicare Part B drugs; and proposed to change the definition of "negotiated prices" while adding a definition of "price concession" in the regulations.

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, including 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, including the BBA, will remain in effect through 2027, unless additional congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers. In addition, on May 30, 2018, 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 I 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 drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act, but the manufacturer must develop an internal policy and respond to patient requests according to that policy.

These laws, and state and federal healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding and/or otherwise affect the prices we may obtain for any product candidates for which we may obtain regulatory approval or the frequency with which any such approved product candidate is prescribed or used. Litigation and legislative efforts to change or repeal the ACA are likely to continue, with unpredictable and uncertain results.

European Union drug marketing and reimbursement regulations may materially affect our ability to market and receive coverage for our products in the European member states.

We intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval for our product candidates in one or more foreign jurisdictions, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the European Union, or the EU, the pricing of biologics is subject to governmental control and other market regulations that could put pressure on the pricing and usage of our product candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidates and may be affected by existing and future healthcare reform measures.

Much like the Anti-Kickback Statute prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the European Union. The provision of benefits or advantages to physicians is governed by the national anti-bribery laws of European Union Member States, such as the U.K. Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain European Union member states must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual European Union member states. These requirements are provided in the national laws, industry codes or professional codes of conduct that are applicable in the European Union member states. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

In addition, in most foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed.

The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. In some countries, we may be required to conduct a clinical study or other studies that compare the cost-effectiveness of any of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and, generally, prices tend to be significantly lower in the European Union. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales by us or our strategic partners and the potential profitability of any of our product candidates in those countries would be negatively affected.

European data collection is governed by restrictive regulations governing the use, processing and cross-border transfer of personal information.

The collection and use of personal health data in the European Union is governed by the provisions of the General Data Protection Regulation (EU) 2016/679, or GDPR. This directive imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, notification of data processing obligations to the competent national data protection authorities and the security and confidentiality of the personal data, and substantial fines for breaches of the data protection rules. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the United States. Failure to comply with the requirements of the GDPR and the related national data protection laws of the European Union Member States may result in fines and other administrative penalties. Since we anticipate beginning our NEO-PTC-01 program in the Netherlands, our operations in the EU may be subject to the GDPR. The GDPR regulations may impose additional responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with these and/or new data protection rules. We may be required to obtain additional consent to process and transfer data outside the EU, which may affect our ability to enroll enough patients in our trials. These regulations may be onerous and adversely affect our business, financial condition, prospects and results of operations.

The exit of the United Kingdom from the European Union may materially affect the regulatory regime that governs our handling of EU personal data and expose us to legal and business risks under European data privacy and protection law.

The anticipated exit of the United Kingdom, or the UK, from the European Union, or the EU, on March 29, 2019, which is often referred to as Brexit, could add legal risk, uncertainty, complexity and cost to our handling of EU personal information and our privacy and data security compliance programs. It is possible that, over time, the UK Data Protection Act could become less aligned with the GDPR, which could require us to implement different compliance measures for the UK and the European Union and result in potentially enhanced compliance obligations for EU personal data. This risk would apply more immediately in the event of a “no-deal” Brexit (including no transition period).

In the event of a no-deal Brexit, it is highly unlikely that the European Commission, or the EC, would grant an adequacy finding to the UK (which is a finding that the UK's privacy legal framework provides an adequate level of privacy protection to EU individuals). Absent an adequacy finding, transfers of personal data from the EU to the UK would be illegal without adequate safeguards provided for under EC-approved mechanisms, such as current standard contractual clauses or, if approved in the future, an EU-UK privacy shield similar to the current framework in place between the EU and the United States. The extensive authority of UK intelligence and law enforcement agencies, including to conduct surveillance on personal data flows, could reduce the likelihood that the EC would give the UK an adequacy finding and reduce the likelihood that the EC would approve an EU-UK privacy shield. Accordingly, we would be exposed to legal risk for any of our EU-UK personal data transfers, including those that involve sensitive data such as patient and genetic data. Given the uncertainties surrounding the UK’s departure from the EU, it is difficult to precisely identify or quantify the risks described above.

Additional laws and regulations governing international operations.

If we expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The FCPA prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all

transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, we will need to dedicate additional resources to complying with these laws, and these laws may preclude us from developing, manufacturing or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The U.S. Securities and Exchange Commission, or SEC, also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

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 the 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 the 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. 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, including when and if we conduct clinical trials outside the United States. 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.

Risks Related to Our Intellectual Property

Our success depends in part on our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology and we may not be able to ensure their protection.

Our commercial success will depend in large part on obtaining and maintaining patent, trademark and trade secret protection of our proprietary technologies and product candidates, which include NEO-PV-01, NEO-PTC-01, NEO-SV-01, as well as other product candidates that may be developed through our NEON / ONE and NEON / SELECT programs, their respective components, formulations, combination therapies, methods used to manufacture them and methods of treatment, as well as successfully defending these patents against third-party challenges. Our ability to stop unauthorized third parties from making, using, selling, offering to sell or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. If we are unable to secure and maintain patent protection for any product or technology we develop or if the scope of the patent protection secured is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours and our ability to commercialize any product candidates we may develop may be adversely affected.

The patenting process is expensive and time-consuming and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, we may not pursue or obtain patent protection in all relevant markets. 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. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and are reliant on our licensors or licensees. Our pending and future patent applications may not result in issued patents that protect our technology or products, in whole or in part. In addition, our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from using our technology or from developing competing products and technologies.

We depend on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which would harm our business.

We are dependent on patents, know-how and proprietary technology, both our own and those licensed from others. As a result, any termination of these licenses could result in the loss of significant rights and could harm our ability to commercialize our product candidates.

Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including:

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

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which are described below. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

If we fail to comply with our obligations under our patent licenses with third parties, we could lose license rights that are important to our business.

We are a party to license agreements with the Dana-Farber Cancer Institute, Inc., the Eli and Edythe L. Broad Institute of MIT and Harvard, and others, pursuant to which we in-license key patent and patent applications for our product candidates. These existing licenses impose various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, our licensors may have the right to terminate the license, in which event we would not be able to develop or market the products covered by the intellectual property licensed under these agreements.

We have limited control over the maintenance and prosecution of these in-licensed patents and patent applications and may have limited control over other intellectual property that may be in-licensed. For example, we cannot be certain that the maintenance and prosecution activities by these licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We also have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights or defend certain of the intellectual property that is licensed to us. It is possible that the licensors' infringement proceedings or defense activities may be less vigorous than had we conducted them ourselves.

Our proprietary position depends upon patents that are manufacturing, formulation or method-of-use patents, which may not prevent a competitor or other third party from using the same product candidate for another use.

Composition-of-matter patents on the active pharmaceutical ingredient, or API, in prescription drug products are generally considered to be the strongest form of intellectual property protection for drug products because those types of patents provide protection without regard to any particular method of use or manufacture or formulation of the API used. We do not currently have any claims in our owned or in-licensed issued U.S. patents that cover the composition-of-matter of NEO-PV-01, NEO-PTC-01, NEO-SV-01 or our other product candidates. We are pursuing claims in our pending owned or in-licensed patent applications that cover the composition-of-matter of NEO-PV-01, NEO-PTC-01, NEO-SV-01 or our other product candidates. We cannot be certain that claims in any future patents issuing from our pending owned or in-licensed patent applications or our future owned or in-licensed patent applications will cover the composition-of-matter of our current or future product candidates. In addition, there are likely to be additional challenges in obtaining composition-of-matter patents for NEO-PV-01 and, potentially, other product candidates developed in our NEON / ONE program in the future, given the highly bespoke nature of our personalized therapies.

Method-of-use patents protect the use of a product for the specified method and formulation patents cover formulations of the API. These types of patents do not prevent a competitor or other third party from developing or marketing an identical product for an indication that is outside the scope of the patented method or from developing a different formulation that is outside the scope of the patented formulation. Moreover, with respect to method-of-use patents, even if competitors or other third parties do not actively promote their product for our targeted indications or uses for which we may obtain patents, physicians may recommend

that patients use these products off-label, or patients may do so themselves. Although off-label use may infringe or contribute to the infringement of method-of-use patents, the practice is common and this type of infringement is difficult to prevent or prosecute. In addition, there are numerous publications and other prior art that may be relevant to our owned and in-licensed formulation and method-of-use patents and may be used to challenge the validity of these owned or in-licensed patents in litigation or other intellectual property-related proceedings. If these types of challenges are successful, our owned and in-licensed patents may be narrowed or found to be invalid and we may lose valuable intellectual property rights. Any of the foregoing could have a material adverse effect on our business, financial conditions, prospects and results of operations.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates or uses thereof in the United States or in foreign countries. Even if patents do successfully issue, third parties may challenge their validity, enforceability or scope, which may result in those patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the breadth or strength of protection provided by the patent applications we hold with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. Since patent applications in the United States and other countries are confidential for a period of time after filing, at any moment in time, we cannot be certain that we were in the past or will be in the future the first to file any patent application related to our product candidates. Furthermore, for our United States patent applications in which all claims are entitled to a priority date before March 16, 2013, a third party can invoke, or the United States patent office, or USPTO, can institute an interference proceeding to determine who was the first to invent any of the subject matter covered by the patent claims included in our applications.

We cannot be certain that we are the first to invent the inventions covered by pending patent applications and, if we are not, we may be subject to priority disputes. We may be required to disclaim part or all of the term of certain patents or all of the term of certain patent applications. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. No assurance can be given that, if challenged, our patents would be declared by a court to be valid or enforceable or that even if found valid and enforceable, a competitor's technology or product would be found by a court to infringe our patents. We may analyze patents or patent applications of our competitors that we believe are relevant to our activities and consider that we are free to operate in relation to our product candidates, but our competitors may achieve issued claims, including in patents we consider to be unrelated, that block our efforts or potentially result in our product candidates or our activities infringing those issued claims. The possibility also exists that others will develop products that have the same effect as our products on an independent basis that do not infringe our patents or other intellectual property rights or will design around the claims of patents that we have had issued that cover our products.

Past or future patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. In March 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, the United States moved from a "first to invent" to a "first-to-file" patent system. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. The America Invents Act includes a number of other significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted, redefine prior art and establish a new post-grant review system. The effects of these changes are currently unclear as the USPTO continues to promulgate new regulations and procedures in connection with the America Invents Act and many of the substantive changes to patent law, including the "first-to-file" provisions, only became effective in March 2013. In addition, the courts have yet to address many of these provisions and the applicability of the act and new regulations on the specific patents discussed in this filing have not been determined and would need to be reviewed. However, 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, prospects and results of operations.

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

- others may be able to make or use compounds or cells that are similar to the biological compositions of our product candidates but that are not covered by the claims of our patents;
- the active biological ingredients in our current product candidates will eventually become commercially available in biosimilar drug products and no patent protection may be available with regard to formulation or method of use;
- we or our licensors, as the case may be, may fail to meet our obligations to the U.S. government regarding any in-licensed

patents and patent applications funded by U.S. government grants, leading to the loss of patent rights;

- we or our licensors, as the case may be, might not have been the first to file patent applications for certain inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that our pending patent applications will not result in issued patents;
- it is possible that there are prior public disclosures that could invalidate our or our licensors' patents, as the case may be, or parts of our or their patents;
- it is possible that others may circumvent our owned or in-licensed patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours;
- the laws of foreign countries may not protect our or our licensors', as the case may be, proprietary rights to the same extent as the laws of the United States;
- the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not cover our product candidates;
- our owned or in-licensed issued patents may not provide us with any competitive advantages, may be narrowed in scope, or be held invalid or unenforceable as a result of legal challenges by third parties;
- the inventors of our owned or in-licensed patents or patent applications may become involved with competitors, develop products or processes that design around our patents or become hostile to us or the patents or patent applications on which they are named as inventors;
- it is possible that our owned or in-licensed patents or patent applications omit individual(s) that should be listed as inventor(s) or include individual(s) that should not be listed as inventor(s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable;
- we have engaged in scientific collaborations in the past and will continue to do so in the future and our collaborators may develop adjacent or competing products that are outside the scope of our patents;
- we may not develop additional proprietary technologies for which we can obtain patent protection;
- it is possible that product candidates or diagnostic tests we develop may be covered by third parties' patents or other exclusive rights; or
- the patents of others may have an adverse effect on our business.

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

In addition to patent protection, we rely heavily upon know-how and trade secret protection, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants and third-parties, to protect our confidential and proprietary information, especially where we do not believe patent protection is appropriate or obtainable. For example, significant elements of our NEON / ONE and NEON / SELECT approaches, including aspects of sample preparations, methods of manufacturing, cell culturing conditions and computational-biological algorithms, including RECON's algorithms, and related processes and software, are based on unpatented trade secrets and know-how that are not publicly disclosed.

It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party's relationship with us is to be kept confidential and not disclosed to third parties, except in certain specified circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual and that are related to our current or planned business or research and development or made during normal working hours on our premises or using our equipment or proprietary information are our exclusive property. We have also adopted policies and conduct training that provides guidance on our expectations and our advice for best practices in protecting our trade secrets.

In addition to contractual measures, we try to protect the confidential nature of our proprietary information through other appropriate precautions, such as physical and technological security measures. These measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor and any recourse we might take against this type of misconduct may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that could prevent us from receiving legal recourse. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any of that information was independently

developed by a competitor, our competitive position could be harmed.

In addition, courts outside the United States are sometimes less willing to protect trade secrets. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. Even if we are successful, these types of lawsuits may consume our time and other resources. Although we take steps to protect our proprietary information and trade secrets, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. As a result, we may not be able to meaningfully protect our trade secrets.

Third-party claims of intellectual property infringement may prevent or delay our product discovery and development efforts.

Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation, *inter partes* review, post grant review, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates and/or proprietary technologies infringe their intellectual property rights. Numerous U.S. and foreign issued patents and pending patent applications that are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

If a third party claims that we infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims that, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;
- substantial damages for infringement, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages plus the patent owner's attorneys' fees;
- a court prohibiting us from developing, manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third party licenses its product rights to us, which it is not required to do;
- if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts and/or grant cross-licenses to intellectual property rights for our products; and
- the requirement that we redesign our product candidates or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, financial condition, prospects and results of operations.

Third parties may assert that we are employing their proprietary technology without authorization. Generally, conducting clinical trials and other development activities in the United States is not considered an act of infringement. If and when NEO-PV-01, NEO-PTC-01, NEO-SV-01 or another of our neoantigen-targeting therapy product candidates is approved by the FDA, a third party who believes that our technology infringes its patent may then be able to seek to enforce its patent by filing a patent infringement lawsuit against us. We are aware of U.S. Patent No. 10,055,540 entitled "Neoantigen Identification, Manufacture, and Use." If a claim is subsequently asserted that NEO-PV-01, NEO-PTC-01, NEO-SV-01 or another of our neoantigen-targeting therapy product candidates or RECON infringes this patent, we believe that we have reasonable defenses, such as noninfringement or invalidity. There can be no assurance that these defenses will succeed. We also have patent rights in this technology space. Further, while we do not believe that any claims of other outstanding patents that could otherwise materially adversely affect commercialization of our neoantigen therapies product candidates, if approved, are valid and enforceable, we may be incorrect in this belief or we may not be able to prove that position in a litigation. In this regard, patents issued in the United States by law enjoy a presumption of validity that can be rebutted only with evidence that is "clear and convincing," a heightened standard of proof.

There may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications

can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents.

If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, constructs or molecules used in or formed during the manufacturing process or any final product itself, the holders of those patents may be able to block our ability to commercialize our product candidate unless we obtained a license under the applicable patents or until those patents were to expire or are finally determined to be invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of that patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until the applicable patent expires or is finally determined to be invalid or unenforceable. In either case, a license may not be available on commercially reasonable terms, or at all, particularly if the applicable patent is owned or controlled by one of our primary competitors. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could significantly harm our business. Even if we obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee time and resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any license of this nature would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates and we may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could significantly harm our business.

Our use of open source software could impose limitations on our ability to commercialize our products.

Our use of open source software could impose limitations on our ability to commercialize our products. Our products utilize open source software that contain modules licensed for use from third-party authors under open source licenses. In particular, some of the software that powers RECON may be provided under license arrangements that allow use of the software for research or other non-commercial purposes. As a result, in the future, as we seek to use RECON in connection with commercially available products, we may be required to license that software under different license terms, which may not be possible on commercially reasonable terms, if at all. If we are unable to license software components on terms that permit its use for commercial purposes, we may be required to replace those software components, which could result in delays, additional cost and/ or additional regulatory approvals.

Use and distribution of open source software may entail greater risks than use of third-party commercial software as open source licensors generally do not provide warranties or other contractual protections regarding infringement claims or the quality of the software code. Some open source licenses contain requirements that we make available source code for modifications or derivative works we create based upon the type of open source software we use. If we combine our proprietary software with open source software in a certain manner, we could, under certain of the open source licenses, be required to release the source code of our proprietary software to the public. This could allow our competitors to create similar products with lower development effort and time, and ultimately could result in a loss of product sales for us. Although we monitor our use of open source software, the terms of many open source licenses have not been interpreted by U.S. courts, and there is a risk that those licenses could be construed in a manner that could impose unanticipated conditions or restrictions on our ability to commercialize our products. In that case we could be required to seek licenses from third parties in order to continue offering our products, to re-engineer our products or to discontinue the sale of our products in the event re-engineering cannot be accomplished on a timely basis, any of which could materially and adversely affect our business, financial condition, prospects and results of operations.

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at universities or other biopharmaceutical or pharmaceutical companies, including our competitors or potential competitors. Although we there are no currently pending misappropriation or improper disclosure claims and although we try to ensure that

our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. We may then have to pursue litigation to defend against these claims. If we fail in defending any claims of this nature, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against these types of claims, 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, that perception could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct this type of litigation or proceedings. Some of our competitors may be able to sustain the costs of this type of litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of intellectual property litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace.

We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in-licenses.

Presently, we have intellectual property rights through licenses from third parties to develop NEO-PV-01, NEO-PTC-01, NEO-SV-01 and certain other product candidates and we may file additional patent applications of our own in the future that may be directed to these or other product candidates. Because our programs may involve additional product candidates that may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights.

Our product candidates may also require specific formulations to work effectively and efficiently and these rights may be held by others. We may develop products containing our compounds and pre-existing pharmaceutical compounds. We may be required by the FDA or comparable foreign regulatory authorities to provide a companion diagnostic test or tests with our product candidates, which test or tests may be covered by intellectual property rights held by others. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary or important to our business operations. In addition, we may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. Were that to happen, we may need to cease use of the compositions or methods covered by those third-party intellectual property rights and seek to develop alternative approaches that do not infringe on those intellectual property rights, which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, which means that our competitors may also receive access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

Additionally, we sometimes collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of whether we hold that type of option, we may be unable to negotiate a license from the institution within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain our existing intellectual property rights, we may have to abandon development of a program our business financial condition, prospects and results of operations could suffer.

The licensing and acquisition of third-party intellectual property rights is a competitive area and companies, that may be more established or have greater resources than we do may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete these types of negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to develop or market.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable or may refuse to stop the other party from using

the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these types of claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

We may choose to challenge the patentability of claims in a third party's U.S. patent by requesting that the USPTO review the patent claims in an *ex-parte* re-examination, *inter partes* review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third party's patent in patent opposition proceedings in the European Patent Office, or EPO, or another foreign patent office. The costs of these opposition proceedings could be substantial, and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office then we may be exposed to litigation by a third party alleging that the patent may be infringed by our product candidates or proprietary technologies.

In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications are typically not published in the United States until 18 months after their respective filing dates. Further, publications in the scientific literature often lag behind actual discoveries. Consequently, we cannot be certain that others have not filed patent applications for technology covered by our owned and in-licensed issued patents or our pending applications, or that we or, if applicable, a licensor were the first to invent the technology. It is possible that our competitors may have filed, and may in the future file, patent applications covering our products or technology similar to ours and that those patent applications may have priority over our owned and in-licensed patent applications or patents, which could require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to those owned by or in-licensed to us, we or, in the case of in-licensed technology, the licensor may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. If we or one of our licensors is a party to an interference proceeding involving a U.S. patent application on inventions owned by or in-licensed to us, we may incur substantial costs, divert management's time and expend other resources, even if we are successful.

Interference proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome in an interference proceeding could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, or at all. Litigation or interference proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, that perception could have a substantial adverse effect on the price of our common stock.

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

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies also require compliance with a number of procedural, documentary, fee payment and other provisions during the patent application process and following the issuance of a patent. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction.

Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. Were a noncompliance event to occur, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court, the USPTO or in foreign jurisdictions.

If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are

commonplace and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. These types of mechanisms include re-examination, post grant review and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). These types of proceedings could result in revocation or amendment to our patents such that they no longer cover our product candidates. The outcome for any particular patent following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, or if we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of the patent protection on our product candidates. A loss of patent protection for our product candidates could have a material adverse impact on our ability to commercialize or license our technology and product candidates and, as a result, on our business, financial condition, prospects and results of operations. Recently, one of our in-licensed European patents related to our NEO-PV-01 and NEO-PTC-01 product candidates was involved in a European opposition proceeding at the EPO involving several opponents. Following an oral hearing, the EPO decided to revoke this in-licensed patent, which is one asset within our broader intellectual property portfolio that relates to our personal neoantigen product candidates. We and our licensors have filed an appeal of this decision and, over what we believe will be a multi-year period while the appeal is pending at the EPO, the claims in the originally granted patent remain effective and enforceable. If we are unsuccessful in this appeal, we will be unable to assert this patent against our competitors marketing products in relevant European countries that would have been deemed to be infringing.

Likewise, our in-licensed patents directed to our proprietary technologies and our product candidates are expected to expire in 2031, without taking into account any possible patent term adjustments or extensions. Our earliest in-licensed patents may expire before, or soon after, our first product achieves marketing approval in the United States or foreign jurisdictions. Upon the expiration of our current patents, we may lose the right to exclude others from practicing these inventions. The expiration of these patents could also have a similar material adverse effect on our business, financial condition, prospects and results of operations. We own or in-license pending patent applications directed to proprietary technologies or our product candidates that, if issued as patents, are expected to expire from 2031 through 2038, without taking into account any possible patent term adjustments or extensions. However, we cannot be assured that the USPTO or relevant foreign patent offices will grant any of these patent applications.

Changes in patent law in the United States and in non-U.S. jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity and is therefore costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, in the case, *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.,* the U.S. Supreme Court held that certain claims to DNA molecules are not patentable. While we do not believe that any of our owned or in-licensed patents will be found invalid based on this decision, we cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents. Any similar any adverse changes in the patent laws of other jurisdictions could also have a material adverse effect on our business, financial condition, prospects and results of operations.

We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world.

We have limited intellectual property rights outside the United States. Filing, prosecuting and defending 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 can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we 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 where enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products against third parties in violation of our proprietary rights generally. The initiation of proceedings by third parties to challenge the scope or validity of our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. 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 develop or license.

We may incur substantial costs as a result of litigation or other proceedings relating to patents and we may be unable to protect our rights to our products and technology.

If we or our licensors choose to go to court to stop a third party from using the inventions claimed in our owned or in-licensed patents, that third party may ask the court to rule that our patents are invalid and/or should not be enforced against that third party. These types of lawsuits are expensive and would consume time and other resources even if we or our licensors, as the case may be, were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that our patents are not valid and that we or our licensors, as the case may be, do not have the right to stop others from using the inventions in question.

There is also the risk that, even if the validity of our patents is upheld, the court will refuse to stop the third party on the ground that the third party's activities do not infringe our owned or in-licensed patents. In addition, the U.S. Supreme Court has recently changed some legal principles that affect patent applications, granted patents and assessment of the eligibility or validity of these patents. As a consequence, issued patents may be found to contain invalid claims according to the newly revised eligibility and validity standards. Some of our owned or in-licensed patents may be subject to challenge and subsequent invalidation or significant narrowing of claim scope in proceedings before the USPTO or during litigation under the revised criteria, which could also make it more difficult to obtain patents.

We or our licensors, as the case may be, may not be able to detect infringement against our owned or in-licensed patents, which may be especially difficult for manufacturing processes or formulation patents. Even if we or our licensors detect infringement by a third party of our owned or in-licensed patents, we or our licensors, as the case may be, may choose not to pursue litigation against or settlement with the third party. If we, or our licensors later sue such third party for patent infringement, the third party may have certain legal defenses available to it that otherwise would not be available but for the delay between when the infringement was first detected and when the suit was brought. These legal defenses may make it impossible for us or our licensors to enforce our owned or in-licensed patents, as the case may be, against that third party.

If another party questions the patentability of any of our claims in our owned or in-licensed U.S. patents, the third party can request that the USPTO review the patent claims such as in an *inter partes* review, *ex parte* re-examination or post-grant review proceedings. These proceedings are expensive and may result in a loss of scope of some claims or a loss of the entire patent. In addition to potential USPTO review proceedings, we are currently, and may in the future become, party, to patent opposition proceedings at the EPO or similar proceedings in other foreign patent offices where either our owned or in-licensed foreign patents are challenged. Recently, one of our in-licensed European patents related to our NEO-PV-01 and NEO-PTC-01 product candidates was involved in a European opposition proceeding at the EPO involving several opponents. Following an oral hearing, the EPO decided to revoke this in-licensed patent, which is one asset within our broader intellectual property portfolio that relates to the our personal neoantigen product candidates. We and our licensors have filed an appeal of this decision and, over what we believe will be multi-year period while an appeal is pending at the EPO, the claims in the originally granted patent remain effective and enforceable. If we are unsuccessful in this appeal, we will be unable to assert this patent against our competitors marketing products in relevant European countries that would have been deemed to be infringing.

In the future, we may be involved in similar proceedings challenging the patent rights of others, and the outcome of that type of proceeding is highly uncertain. An adverse determination in any proceeding of that nature could reduce the scope of or invalidate our patent rights, allow third parties to commercialize our technology or products and compete directly with us without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. The costs of these opposition or similar proceedings could be substantial and may result in a loss of scope of some claims or a loss of the entire patent. An unfavorable result at the USPTO, EPO or other patent office may result in the loss of our right to exclude others from practicing one or more of our inventions in the relevant country or jurisdiction, which could have a material adverse effect on our business.

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

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

If we do not obtain patent term extension and data exclusivity for any product candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984 Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent per product may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. However, even if we were to seek a patent term extension, it may not be granted because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, the failure to apply within applicable deadlines, the failure to apply prior to expiration of relevant patents or the failure otherwise to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded under an extension request could be less than we request. If we are unable to obtain patent term extension or if the term of any requested extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, prospects and results of operations could be materially harmed.

Risks Related to Our Reliance on Third Parties

We will rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize any potential product candidates.

We presently and, in the future, will depend upon third parties, including independent investigators, to conduct our clinical trials under agreements with universities, medical institutions, CROs, strategic partners and others. As a result, we have to negotiate budgets and contracts with CROs and trial sites, which may result in delays to our development timelines and increased costs.

We presently do, and in the future will continue to, rely heavily on third parties over the course of our clinical trials, and, as a result, will have limited control over the clinical investigators and limited visibility into their day-to-day activities, including with respect to their compliance with the approved clinical protocol. Nevertheless, our reliance on third parties does not relieve us of our regulatory responsibilities and we will be responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards. We and these third parties are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to suspend or terminate these trials or perform additional nonclinical studies or clinical trials before approving our marketing applications. We cannot be certain that, upon inspection, regulatory authorities will determine that any of our clinical trials comply with the applicable GCP requirements. In addition, our clinical trials must be conducted with biologic products produced under cGMP requirements and may require a large number of patients.

Our failure or any failure by these third parties to comply with these applicable regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

The third parties who presently or may in the future conduct our clinical trials will not be our employees and, except for remedies that may be available to us under our agreements with those third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing nonclinical and clinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their

contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates in a timely manner or at all. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

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

We expect to rely on third parties to manufacture our clinical product supplies, and we intend to rely on third parties to produce and process our product candidates, if approved.

We do not currently own any facility that may be used as our clinical-scale manufacturing and processing facility and expect to rely on outside vendors to manufacture supplies and process our product candidates. We have not yet caused any product candidates to be manufactured or processed on a commercial scale and may not be able to do so for any of our product candidates. We will make changes as we work to optimize the manufacturing process. For example, we may switch or be required to switch from non-cGMP materials to commercial grade materials in order to get regulatory approval of our product candidates. We cannot be sure that even minor changes in the process will result in therapies that are safe and effective and approved for commercial sale.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA or other foreign regulatory agencies following inspections that will be conducted after we submit an application to the FDA or other foreign regulatory agencies. We do not directly control the manufacturing process of, and will be completely dependent on, our contract manufacturing partners for compliance with regulatory requirements, known as cGMP requirements, for the manufacture of our product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no direct control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it finds deficiencies with or withdraws any approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

Our existing and future collaborations will be important to our business. If we are unable to maintain any of these collaborations, or if these collaborations are not successful, our business could be adversely affected.

We have limited capabilities for product development and do not yet have any capability for sales, marketing or distribution. Accordingly, we have entered into collaborations with other companies to provide us with important technologies and funding for our programs and technology and we expect to receive additional technologies and funding under these and other collaborations in the future. Our existing therapeutic collaborations and any future collaborations we may enter into may pose a number of risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs or license arrangements based on clinical trial results, changes in the collaborators' strategic focus or available funding or external factors, such as a strategic transaction that may divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products and product candidates if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;

- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- collaborators may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;
- collaborators 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 our product or products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or terminations of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in a manner that may invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- if a collaborator of ours is involved in a business combination, the collaborator might deemphasize or terminate the development or commercialization of any product candidate we licensed to it; and
- collaborations may be terminated by the collaborator, and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

If our collaborations do not result in the successful discovery, development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of our technology and product candidates could be delayed and we may need additional resources to develop product candidates and our technology. All of the risks relating to product development, regulatory approval and commercialization described in this Quarterly Report on Form 10-Q also apply to the activities of our therapeutic collaborators.

Additionally, if one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators as the way we are perceived in the business and financial communities could be adversely affected.

For some of our programs, we may in the future determine to collaborate with pharmaceutical and biotechnology companies for development and potential commercialization of product candidates. Collaborations are complex and time-consuming to negotiate and document. 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 face significant competition in seeking appropriate collaborations. Our ability to reach a definitive agreement for a collaboration 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 proposed collaborator's evaluation of a number of factors. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay one or more of our other development programs, delay a product candidate's potential commercialization, reduce the scope of any sales or marketing 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 expertise and additional capital, which may not be available to us on acceptable terms, or at all. If we fail to enter into collaborations or do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates, bring them to market and generate revenue from sales of drugs or continue to develop our technology and our business may be materially and adversely affected.

We are dependent on single-source suppliers for some of the components and materials used in and the processes required to develop our product candidates.

We currently depend on single-source suppliers for some of the components and materials used in and processes required to develop our product candidates. We cannot ensure that these suppliers or service providers will remain in business, have sufficient capacity or supply to meet our needs or that they will not be purchased by one of our competitors or another company that is not interested in continuing to work with us. Our use of single-source suppliers of raw materials, components, key processes and finished goods exposes us to several risks, including disruptions in supply, price increases or late deliveries. For example, we obtain our vaccine adjuvant, poly-ICLC, which is administered simultaneously with NEO-PV-01, from a single-source supplier. Additionally, we rely on a single-source supplier to manufacture our peptides. There are, in general, relatively few alternative sources of supply for substitute components. Our current vendors may be unable or unwilling to meet our future demands for our

clinical trials or commercial sale. Establishing additional or replacement suppliers for these components, materials and processes could take a substantial amount of time and it may be difficult to establish replacement suppliers who meet regulatory requirements. Any disruption in supply from any single-source supplier or service provider could lead to supply delays or interruptions, which would damage our business, financial condition, prospects and results of operations.

If we were to have to switch to a replacement supplier, the manufacture and delivery of NEO-PV-01 or our other product candidates or components of our product candidates, such as vaccine adjuvants, could be interrupted for an extended period, which could adversely affect our business. We may not be able to quickly establish additional or replacement suppliers for the adjuvants, peptides or any of the components or processes used in our product candidates, if required. If we are able to find a replacement supplier, the replacement supplier would need to be qualified, which might require additional regulatory authority approval, which could result in further delay. For example, the FDA could require additional supplemental data and clinical trial data if we rely upon a new supplier for the adjuvants and peptides used in our product candidates. While we seek to maintain adequate inventory of the single source components and materials used in our products, any interruption or delay in the supply of components or materials or our inability to obtain components or materials from alternate sources at acceptable prices, or at all, in a timely manner, could impair our ability to meet the demand of our customers and cause them to cancel orders.

In addition, as part of the FDA's approval of our product candidates, we will also require FDA approval of the individual components of our process, which include the manufacturing processes and facilities of our single-source suppliers. Our current single-source suppliers have not undergone this process, nor have they had any components included in any product approved by the FDA.

Our reliance on these suppliers, service providers and manufacturers subjects us to a number of risks that could harm our reputation, business, financial condition, prospects and results of operations, including, among other things:

- delays to the development timelines for our product candidates;
- interruption of supply resulting from modifications to or discontinuation of a supplier's operations;
- delays in product shipments resulting from uncorrected defects, reliability issues or a supplier's variation in a component;
- a lack of long-term supply arrangements for key components with our suppliers;
- inability to obtain adequate supply in a timely manner or to obtain adequate supply on commercially reasonable terms;
- difficulty and cost associated with locating and qualifying alternative suppliers for our components in a timely manner;
- production delays related to the evaluation and testing of products from alternative suppliers and corresponding regulatory qualifications;
- delay in delivery due to our suppliers prioritizing other customer orders over ours;
- damage to our reputation caused by defective components produced by our suppliers;
- increased cost of our warranty program due to product repair or replacement based upon defects in components produced by our suppliers; and
- fluctuation in delivery by our suppliers due to changes in demand from us or their other customers.

If any of these risks materialize, our costs could significantly increase and our ability to meet demand for our products could be impacted.

Risks Related to Our Common Stock

We do not know whether there will be an active, liquid and orderly trading market for our common stock or what the market price of our common stock will be and, as a result, it may be difficult for you to sell your shares of our common stock.

We are a newly public company and there has historically been no public market for shares of our common stock. An active trading market for our shares may never develop or be sustained and, as a result, you may not be able to sell your shares quickly or at the market price if trading in shares of our common stock is not active. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration.

The price of our stock may be volatile and you could lose all or part of your investment.

The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this "Risk Factors" section, these factors may include:

- the commencement, enrollment or results of our ongoing clinical trials or any future clinical trials we may conduct 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 our regulatory filings, including without limitation the FDA's issuance of a "refusal to file" letter, a clinical hold 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;
- changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning our manufacturers;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- our inability to establish collaborations if and when needed;
- our failure to commercialize our product candidates;
- additions or departures of key scientific or management personnel;
- serious safety concerns related to the use of our product candidates;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- the size and growth of our initial cancer target markets;
- our ability to successfully treat additional types of cancers or cancers at different stages;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry or neoantigen-targeted therapies in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- adoption of new accounting standards;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including intellectual property or stockholder litigation;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the market for biopharmaceutical 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. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, financial condition, prospects and results of operations.

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.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Our executive officers and directors and Third Rock Ventures III, L.P., a venture capital fund affiliated with certain of our directors, beneficially held, as of March 31, 2019, in the aggregate, approximately 39% of our outstanding voting stock. Therefore, these stockholders and other principal stockholders will have the ability to influence us through their ownership positions. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction.

This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

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 Jumpstart Our Business Startups Act, or the JOBS Act, which was enacted in April 2012. 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 of 2002, as amended, or 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 could be an emerging growth company for up to five years following the year in which we complete our initial public offering, which occurred in June 2018, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering, (b) in which we have total annual gross revenue of at least $1.07 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1 billion in non-convertible debt 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 irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

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

We are considered a "smaller reporting company" under Rule 12b-2 of the Exchange Act. We are therefore entitled to rely on certain reduced disclosure requirements, such as an exemption from providing selected financial data and executive compensation information. These exemptions and reduced disclosures in our SEC filings due to our status as a smaller reporting company also mean our auditors are not required to review our internal control over financial reporting and may make it harder for investors to analyze our results of operations and financial prospects. 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 common stock prices may be more volatile. We will remain a smaller reporting company until our public float exceeds $250 million or our annual revenues exceed $100 million with a public float greater than $700 million.

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

As a public company, and particularly after we are no longer an "emerging growth company" under applicable SEC regulations, we incur significant legal, accounting and other expenses. We will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, which will require, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and the Nasdaq Global Select Market to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, Congress enacted the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period and up to five years from the pricing of their initial public offerings. We intend to take advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned. If that were to happen, we would incur additional and unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

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

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

If our pre-initial public offering stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lapsing of any applicable legal restrictions on resale, the trading price of our common stock could decline.

Shares held by directors, executive officers and other affiliates may be subject to certain limitations of Rule 144 under the Securities Act of 1933, as amended, or the Securities Act. In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our existing equity compensation plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, any lock-up agreements and Rule 144 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline. Additionally, the number of shares of our common stock reserved for issuance under our 2018 Stock Option and Incentive Plan automatically increases on each January 1 by 4% of the outstanding number of shares of our common stock on the immediately preceding December 31 or such lesser number of shares as determined by our compensation committee. Unless our compensation committee elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution.

The holders of 18,644,462 shares of our common stock as of March 31, 2019 are entitled to rights with respect to the registration of their shares under the Securities Act. 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 held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

We have broad discretion in the use of our existing cash, cash equivalents and marketable securities and may not use them effectively.

Our management has broad discretion in the application of our existing cash, cash equivalents and marketable securities and you will not have the opportunity as part of your investment decision to assess whether these proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of our existing cash, cash equivalents and marketable

securities, their ultimate use may vary substantially from their currently intended use. Our management might not apply our existing cash, cash equivalents and marketable securities in ways that ultimately increase the value of your investment. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest our cash in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders. If we do not invest our cash in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

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

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we may enter into license or collaboration agreements with other companies that include development funding and significant upfront and milestone payments and/or royalties, which may become an important source of our revenue. Accordingly, our revenue may depend on development funding and the achievement of development and clinical milestones under current and any potential future license and collaboration agreements and sales of our products, if approved. These upfront and milestone payments may vary significantly from period to period and any variance could cause a significant fluctuation in our operating results from one period to the next.

In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award as determined by our board of directors, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly.

Further, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and cost of, and level of investment in, research and development activities relating to our current and any future product candidates, which will change from time to time;
- our ability to enroll patients in clinical trials and the timing of enrollment;
- the cost of manufacturing our current and any future product candidates, which may vary depending on FDA guidelines and requirements, the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we will or may incur to acquire or develop additional product candidates and technologies;
- the timing and outcomes of clinical studies for NEO-PV-01, NEO-PTC-01, NEO-SV-01 and any other future product candidates or the timing and outcomes of clinical trials for competing product candidates;
- competition from existing and potential future products that compete with NEO-PV-01, NEO-PTC-01, NEO-SV-01 and any other future product candidates and changes in the competitive landscape of our industry, including consolidation among our competitors or partners;
- any delays in regulatory review or approval NEO-PV-01, NEO-PTC-01, NEO-SV-01 or any of our other future product candidates;
- the level of demand for NEO-PV-01, NEO-PTC-01, NEO-SV-01 and any of our other future product candidates, if approved, which may fluctuate significantly and be difficult to predict;
- the risk/benefit profile, cost and reimbursement policies with respect to our products candidates, if approved, and existing and potential future products that compete with NEO-PV-01, NEO-PTC-01, NEO-SV-01 and any of our other future product candidates;
- our ability to commercialize NEO-PV-01, NEO-PTC-01, NEO-SV-01 and any of our other product candidates, if approved, within and outside of the United States, either independently or working with third parties;
- our ability to adequately support our future growth;
- potential unforeseen business disruptions that increase our costs or expenses;
- future accounting pronouncements or changes in our accounting policies; and
- the changing and volatile global economic environment.

The cumulative effect of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market or if the forecasts we

provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. The price of our common stock could decline even when we have met any previously publicly stated revenue and/or earnings guidance we may provide.

Anti-takeover provisions under our organizational documents and Delaware law could delay or prevent a change of control, which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders may only be called only by the chairman of the board of directors, the chief executive officer or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds (2/3) of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds (2/3) of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval, which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

Our amended and restated bylaws designate specific courts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.

Pursuant to our amended and restated bylaws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of or based on a breach of a fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders; (3) any action asserting a claim against us or any of our current or former directors, officers, employees or stockholders arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws; or (4) any action asserting a claim governed by the internal affairs doctrine. Our amended and restated bylaws further provide that, unless the Company consents in writing to the selection of an alternative forum, the United States District Court for the District of Massachusetts is the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act (the "Federal Forum Provision"). In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our

common stock is deemed to have notice of and consented to the foregoing provisions. We have chosen the United States District Court for the District of Massachusetts as the exclusive forum for these causes of action because our principal executive offices are located in Cambridge, Massachusetts. We recognize that the forum selection clauses in our amended and restated bylaws may impose additional litigation costs on stockholders in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware or the Commonwealth of Massachusetts, as applicable. Additionally, the forum selection clauses in our amended and restated bylaws may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage the filing of lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert the provision is not enforceable. The Court of Chancery of the State of Delaware or the United States District Court for the District of Massachusetts, as applicable, 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 may be more or less favorable to us than our stockholders.

In *Sciabacucchi v. Salzberg*, C.A. No. 2017-0931-JTL (Del. Ch.), some companies that have adopted similar federal district court forum selection provisions were sued in the Court of Chancery of the State of Delaware by stockholders who assert that those federal district court forum selection provisions are not enforceable. On December 19, 2018, Court of Chancery issued a decision in *Sciabacucchi* declaring that provisions in certificates of incorporation of Delaware companies that purport to require claims under the Securities Act of 1933, as amended, or the Securities Act, be brought in federal court are ineffective and invalid under Delaware law. On January 17, 2019, the decision was appealed to the Delaware Supreme Court. While the Delaware Supreme Court recently dismissed the appeal on jurisdictional grounds, we expect that the appeal will be re-filed after the Court of Chancery issues a final judgment. Unless and until the Court of Chancery's decision in *Sciabacucchi* is reversed or otherwise abrogated, the Company does not intend to enforce its Federal Forum Provision designating the District of Massachusetts as the exclusive forum for Securities Act claims. In the event that the Delaware Supreme Court affirms the Court of Chancery's *Sciabacucchi* decision or otherwise makes a determination that provisions such as the Federal Forum Provision are invalid, the Company's Board of Directors intends to amend promptly the Company's bylaws to remove the Federal Forum Provision. Such amendment could cause the Company to incur additional costs, which could have an adverse effect on our business, financial condition or results of operations.

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

Recent Sales of Unregistered Equity Securities

Not applicable.

Use of Proceeds from Initial Public Offering of Common Stock

On June 29, 2018, we completed our initial public offering, or IPO, and sold 6,250,000 shares of our common stock, at a public offering price of $16.00 per share for an aggregate offering of $100.0 million. The offer and sale of the shares in the IPO were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-225330), which was filed on May 31, 2018, amended subsequently and declared effective on June 26, 2018. Morgan Stanley, BofA Merrill Lynch, and Mizuho Securities acted as joint book-running managers of the offering and as representatives of the underwriters. Oppenheimer & Co. acted as lead manager for the offering. The offering commenced on June 26, 2018 and did not terminate until the sale of all of the shares offered.

We received aggregate net proceeds from the IPO of $89.9 million, after deducting underwriting discounts, commissions and other offering expenses paid by us. No offering expenses 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.

As of March 31, 2019, we had used approximately $55.0 million of the net proceeds from the IPO, primarily to fund the ongoing clinical development of NEO-PV-01 and to advance our pre-clinical programs and research activities. We have invested the remaining net proceeds from the IPO in a variety of capital preservation investments, including money market funds, investment-grade corporate debt securities and U.S. Treasury obligations. There has been no material change in the planned use of proceeds from our IPO as described in the Company's prospectus filed under Rule 424(b)(4), which was filed with the SEC on June 28, 2018 (File No. 333-224330).

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

(a) Exhibits required by Item 601 of Regulation S-K.

Exhibit Number	Description
31.1*	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1 +	Certifications pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of The Sarbanes-Oxley Act of 2002, by Hugh O'Dowd, President and Chief Executive Officer of the Company and Yasir B. Al-Wakeel, Chief Financial Officer of the Company.
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Calculation Linkbase Document
101.LAB*	XBRL Taxonomy Label Linkbase Document
101.PRE*	XBRL Taxonomy Presentation Linkbase Document
101.DEF*	XBRL Taxonomy Definitions Linkbase Document

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* Filed herewith.

\+ The certifications furnished in Exhibit 32.1 hereto are deemed to be furnished with this Quarterly Report on Form 10-Q and will not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

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.

NEON THERAPEUTICS, INC.

Date: May 13, 2019

By: /s/ Hugh O'Dowd

Hugh O'Dowd

President, Chief Executive Officer (Principal Executive Officer)

Date: May 13, 2019

By: /s/ Yasir B. Al-Wakeel

Yasir B. Al-Wakeel, B.M.B.Ch.

Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO RULE 13a-14(a) / RULE 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Hugh O'Dowd, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended March 31, 2019 of Neon Therapeutics, Inc.;

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

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

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

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

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

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

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

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

Date: May 13, 2019

By: /s/ Hugh O'Dowd

Hugh O'Dowd

President, Chief Executive Officer (Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO RULE 13a-14(a) / RULE 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Yasir B. Al-Wakeel, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended March 31, 2019 of Neon Therapeutics, Inc.;

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

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

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

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

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

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

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

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

Date: May 13, 2019

By: /s/ Yasir B. Al-Wakeel

Yasir B. Al-Wakeel, B.M.B.Ch.

Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

CERTIFICATIONS OF CEO AND CFO 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 Neon Therapeutics, Inc. (the "Company") for the quarter ended March 31, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company 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:

(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.

Date: May 13, 2019

By: /s/ Hugh O'Dowd

Hugh O'Dowd

President, Chief Executive Officer (Principal Executive Officer)

Date: May 13, 2019

By: /s/ Yasir B. Al-Wakeel

Yasir B. Al-Wakeel, B.M.B.Ch.

Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)