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

# FORM 10-Q

**(Mark One)**

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

**For the quarterly period ended March 31, 2018**

**OR**

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

**Commission File Number: 001-38345**

# ARMO BIOSCIENCES, INC.
**(Exact name of Registrant as specified in its charter)**

| **Delaware** | **27-3454138** |
|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(I.R.S. Employer Identification No.)** |
| **575 Chesapeake Drive Redwood City, CA 94063** | **94063** |
| **(Address of principal executive offices)** | **(Zip Code)** |

**Registrant's telephone number, including area code: 650-779-5075**

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

| | | | |
|---|---|---|---|
| Large accelerated filer | ☐ | Accelerated filer | ☐ |
| Non-accelerated filer | ☒ (Do not check if a smaller reporting company) | Smaller reporting company | ☐ |
| Emerging growth company | ☒ | | |

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

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

As of May 10, 2018, the Registrant had 30,405,109 shares of common stock outstanding.

**ARMO BIOSCIENCES, INC.**
**FORM 10-Q FOR THE QUARTER ENDED MARCH 31, 2018**
**INDEX**

## NOTE ABOUT FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements. All statements other than statements of historical facts contained in this report, *including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans, intentions, designs, expectations and objectives could be forward-looking statements.*. The words "believe," "may," "will," "estimate," "continue," "anticipate," "design," "intend," "expect," "could," "plan," "potential," "predict," "seek," "should," "would" or the negative version of these words and similar expressions are intended to identify forward-looking statements. We have based these forward-looking statements on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, strategy, short- and long-term business operations and objectives, and financial needs. The forward-looking statements are contained principally in "Management's Discussion and Analysis of Financial Condition and Result of Operations" and "Risk Factors."

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Quarterly Report on Form 10-Q may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, except as required by law, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Quarterly Report on Form 10-Q to conform these statements to actual results or to changes in our expectations.

## PART I—FINANCIAL INFORMATION

**Item 1. Financial Statements.**

**ARMO BIOSCIENCES, INC.**

**Condensed Balance Sheets**

**(Unaudited)**

(In thousands, except share and per share data)

| | MARCH 31, 2018 | DECEMBER 31, 2017 (Note 1) |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 165,313 | $ 49,475 |
| Prepaid expenses and other current assets | 3,872 | 2,574 |
| Restricted cash | 50 | 50 |
| Receivable from lessor for tenant improvements | 2,700 | — |
| Total current assets | 171,935 | 52,099 |
| Property and equipment, net | 327 | 250 |
| Other long-term assets | 2,808 | 3,843 |
| Total assets | $ 175,070 | $ 56,192 |
| **Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)** | | |
| Current liabilities: | | |
| Accounts payable | $ 6,605 | $ 5,764 |
| Accrued liabilities | 8,741 | 5,714 |
| Deferred rent | 525 | 136 |
| Other current liabilities | 23 | 32 |
| Total current liabilities | 15,894 | 11,646 |
| Lease incentive obligation | 2,314 | — |
| Commitments and contingencies (Note 6) | | |
| Redeemable convertible preferred stock, $0.0001 par value | | |
| Shares authorized: 95,180,211 at December 31, 2017 | | |
| Shares issued and outstanding: none at March 31, 2018; 20,211,087 at December 31, 2017 | — | 177,077 |
| Stockholders' equity (deficit): | | |
| Preferred stock, $0.0001 par value | | |
| Shares authorized: 10,000,000 at March 31, 2018 | | |
| Shares issued and outstanding: none at March 31, 2018 and December 31, 2017 | — | — |
| Common stock, $0.0001 par value | | |
| Shares authorized: 200,000,000 at March 31, 2018 and 118,000,000 at December 31, 2017 | | |
| Shares issued and outstanding: 30,405,109 at March 31, 2018 and 1,535,199 at December 31, 2017 | 3 | 1 |
| Additional paid-in capital | 313,935 | 2,822 |
| Accumulated deficit | (157,076) | (135,354) |
| Total stockholders' equity (deficit) | 156,862 | (132,531) |
| Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit) | $ 175,070 | $ 56,192 |

See accompanying notes to condensed financial statements.

**ARMO BIOSCIENCES, INC.**

**Condensed Statements of Operations and Comprehensive Loss**

**(Unaudited)**

(In thousands, except share and per share data)

| | Three Months Ended March 31, | |
|---|---|---|
| | 2018 | 2017 |
| Operating expenses: | | |
| Research and development | $ 19,037 | $ 7,727 |
| General and administrative | 3,078 | 1,687 |
| Total operating expenses | 22,115 | 9,414 |
| Loss from operations | (22,115) | (9,414) |
| Interest income | 393 | 18 |
| Net loss and comprehensive loss | $ (21,722) | $ (9,396) |
| Net loss per share, basic and diluted | $ (0.97) | $ (6.42) |
| Weighted average number of shares used in basic and diluted net loss per share | 22,369,774 | 1,462,565 |

See accompanying notes to condensed financial statements.

**ARMO BIOSCIENCES, INC.**

**Condensed Statements of Cash Flows**

**(Unaudited)**
(In thousands)

| | Three Months Ended March 31, 2018 | 2017 |
|---|---|---|
| **Operating activities** | | |
| Net loss | $ (21,722) | $ (9,396) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 52 | 52 |
| Stock-based compensation expense | 894 | 187 |
| Loss on disposal of property and equipment | 8 | — |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other current assets | (3,998) | (30) |
| Other long-term assets | (2,706) | (1,002) |
| Accounts payable | 821 | (3,291) |
| Accrued liabilities | 5,413 | 2,519 |
| Deferred rent | 389 | 60 |
| Lease incentive obligation | 2,314 | — |
| Net cash used in operating activities | (18,535) | (10,901) |
| **Investing activities** | | |
| Purchase of property and equipment | (137) | — |
| Net cash used in investing activities | (137) | — |
| **Financing activities** | | |
| Proceeds from issuance of common stock, net of issuance costs | 136,896 | — |
| Payment of initial public offering costs | (2,386) | — |
| Repurchase of common stock | — | (6) |
| Net cash provided by (used in) financing activities | 134,510 | (6) |
| Net increase (decrease) in cash, cash equivalents and restricted cash | 115,838 | (10,907) |
| Cash, cash equivalents and restricted cash at beginning of period | 49,525 | 26,787 |
| Cash, cash equivalents and restricted cash at end of period | $ 165,363 | $ 15,880 |
| **Supplemental disclosures for non-cash investing and financing activities** | | |
| Vesting of restricted stock | $ 9 | $ 17 |
| Deferred offering costs included in accounts payable and accrued expenses | $ 20 | $ 965 |
| Conversion of redeemable convertible preferred stock to common stock | $ 177,077 | $ — |

See accompanying notes to condensed financial statements.

**ARMO BIOSCIENCES, INC.**

**Notes to Condensed Financial Statements (Unaudited)**

## 1. Organization

***Description of the business***

ARMO BioSciences, Inc., (ARMO or the Company), is a late-stage immuno-oncology company that is developing a pipeline of novel, proprietary products that activate the immune system of cancer patients to recognize and eradicate tumors. The Company was incorporated on June 23, 2010 in Delaware under the name Targenics, Inc., and later merged with Ante BioSciences, Inc. on December 11, 2012, subsequently changing its name to ARMO BioSciences, Inc. on December 20, 2012.

On January 25, 2018, the Company completed its initial public offering (IPO) and issued 8,658,823 shares of its common stock for net proceeds of approximately $133 million. Upon the closing of the IPO, all shares of preferred stock then outstanding were automatically converted into 20,211,087 shares of common stock.

The Company is located in Redwood City, California.

***Recent Developments***

On May 9, 2018, Eli Lilly and Company, an Indiana corporation ("Parent"), Bluegill Acquisition Corporation, a Delaware corporation ("Merger Sub") and a wholly owned subsidiary of Parent, and the Company entered into an Agreement and Plan of Merger (the "Merger Agreement"). The Merger Agreement provides that, subject to the terms of the Merger Agreement, Merger Sub will commence a cash tender offer to purchase all of the outstanding shares of the Company common stock, par value $0.0001 per share, at a price of $50.00 per share, net to the seller in cash, without interest, and subject to withholding taxes. For additional information regarding the Merger Agreement, please refer to Note 9—Subsequent Events.

***Liquidity***

Since inception, the Company has incurred recurring net operating losses. As of March 31, 2018 and December 31, 2017, the Company had an accumulated deficit of $157.1 million and $135.4 million, respectively, and expects to incur losses for the foreseeable future. To date, the Company has financed its operations primarily through sales of its common stock in conjunction with the Company's initial public offering ("IPO") in January 2018 and sales of its convertible preferred securities prior to its IPO.

As of March 31, 2018 and December 31, 2017, the Company had cash and cash equivalents of $165.3 million and $49.5 million, respectively. Management believes that the Company's current cash and investments, including the net proceeds of approximately $133 million from the closing of its IPO in January 2018, as described above, will provide sufficient funds to enable the Company to meet its obligations through at least May 2019, i.e. a period of at least twelve months from the date the financial statements are issued. However, if the anticipated operating results are not achieved in future periods, the Company's planned expenditures may need to be reduced in order to extend the time period over which the then-available resources would be able to fund the Company's operations. The cost and timing of developing the Company's products are highly uncertain and are subject to substantial risks and many changes. As such, the Company may alter its expenditures as a result of contingencies such as the failure of one of these product candidates in clinical development, the acceleration of one or more of our product candidates in clinical development, the identification of a more promising product candidate in its research efforts or unexpected operating costs and expenditures. The Company will need to raise additional funds in the future. There can be no assurance, however, that such efforts will be successful or that, in the event they are successful, the terms and conditions of such financing will be favorable to the Company.

***Basis of presentation***

The accompanying unaudited condensed financial statements include the amounts of the Company and have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information and in accordance with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, pursuant to these rules and regulations, they do not include all of the information and footnotes required by GAAP for complete financial statements. The unaudited interim financial statements have been prepared on the same basis as the annual financial statements. In the opinion of management, the accompanying unaudited condensed financial statements reflect all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair presentation.

The December 31, 2017 condensed balance sheet data was derived from audited financial statements but does not include all disclosures required by U.S. GAAP. The condensed results of operations for the three months ended March 31, 2018 are not necessarily indicative of the results to be expected for the full year or for any other future year or interim period. The accompanying condensed financial statements should be read in conjunction with the audited financial statements and notes thereto for the preceding fiscal year contained in the Company's Annual Report on Form 10-K filed on March 30, 2018 with the United States Securities and Exchange Commission (SEC).

***Reverse stock split***

In January 2018, the Company's board of directors and its stockholders approved an amendment to the Company's amended and restated certificate of incorporation to effect a reverse split of shares of the Company's common stock and preferred stock on a 1-for-4.7093 basis (the Reverse Stock Split). The par value and the authorized shares of the common and convertible preferred stock were not adjusted as a result of the Reverse Stock Split. All issued and outstanding preferred and common stock, stock options and related per share amounts have been retroactively adjusted to reflect this Reverse Stock Split for all periods presented. The Reverse Stock Split was effected on January 12, 2018.

**2. Summary of significant accounting policies**

***Use of estimates***

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that impact the amounts reported in the financial statements and accompanying notes. Management bases its estimates on historical experience and market specific or other relevant assumptions that it believes are reasonable under the circumstances. On an ongoing basis, management evaluates its estimates, including those related to accruals for research and development costs, fair value of equity instruments and accounting for stock-based compensation. Actual results could materially differ from those estimates or assumptions.

***Cash equivalents***

The Company considers all liquid marketable securities with remaining maturities of three months or less at the date of purchase to be cash equivalents. Cash equivalents consist of money market accounts and are recorded at fair value.

***Restricted cash***

Restricted cash consists of funds held as collateral for corporate credit cards and is classified as a current asset at March 31, 2018 and December 31, 2017.

***Concentration of credit risk***

Financial instruments that potentially subject the Company to a concentration of credit risk consist primarily of cash and cash equivalents. The Company invests its excess cash in money market funds. Bank deposits are held by a single financial institution with a strong credit rating and these deposits may at times be in excess of insured limits. The Company is exposed to credit risk in the event of a default by the financial institution holding its cash and cash equivalents to the extent recorded on the balance sheet. The Company's investment policy limits investments to certain types of money market instruments including direct obligations issued by the U.S. government, interest-bearing certificates of deposit and prime commercial paper.

***Deferred offering costs***

Deferred offering costs, consisting of legal, accounting, filing and other fees related to the IPO were capitalized during our IPO process. During the three months ended March 31, 2018, $3.7 million in deferred offering costs were reclassified to additional paid in capital upon the effectiveness of the IPO. As of December 31, 2017, $2.4 million of deferred offering costs were capitalized and included in other long-term assets on the balance sheet.

***Stock-based compensation***

The Company measures its stock-based awards made to employees based on the estimated fair values of the awards as of the grant dates using the Black-Scholes option-pricing model. Stock-based compensation expense is recognized over the requisite service period using the straight-line method. As permitted by ASU 2016-09, the Company has elected to account for forfeitures of stock-based awards as those forfeitures occur.

***Net loss per share***

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding during the period. Since the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share as the inclusion of all potential dilutive common shares would have been anti-dilutive. Potentially dilutive common shares include redeemable convertible preferred stock and option shares to purchase commone stock. Shares of common stock subject to repurchase are excluded from the calculation of weighted-average shares as the vesting of such shares is contingent upon continued services being rendered by such holders.

***Adopted Accounting Pronouncements***

In January 2016, the FASB issued ASU No. 2016-01, *Financial Instruments Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*. This guidance makes amendments to the classification and measurement of financial instruments and revises the accounting related to: (1) the classification and measurement of investments in equity securities; and (2) the presentation of certain fair value changes for financial liabilities measured at fair value. In addition, the update also amends certain disclosure requirements associated with the fair value of financial instruments. The Company adopted this standard on January 1, 2018. The adoption of ASU No. 2016-01 did not have a significant impact on the Company's financial statements and related disclosures.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230: Classification of Certain Cash Receipts and Cash Payments*. This guidance addresses specific cash flow issues with the objective of reducing the diversity in practice for the treatment of these issues. The areas identified include: debt prepayment or debt extinguishment costs; settlement of zero-coupon debt instruments; contingent consideration payments made after a business combination; proceeds from the settlement of insurance claims; proceeds from the settlement of corporate-owned life insurance policies; distributions received from equity method investees; beneficial interests in securitization transactions; and application of the predominance principle with respect to separately identifiable cash flows. The Company adopted this standard on January 1, 2018. The adoption of ASU No. 2016-15 did not have a significant impact on the Company's financial statements and related disclosures.

In November 2016, the FASB issued ASU No. 2016-18, *Restricted Cash, Statement of Cash Flows (Topic 230)*. ASU 2016-18 requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The Company adopted this standard in its first quarter ended March 31, 2018. The Company has revised the presentation of restricted cash in its Statements of Cash Flows. Cash, cash equivalents and restricted cash as reported on the Statements of Cash Flows is composed of the individual lines on the Balance sheets labeled as cash and cash equivalents and restricted cash.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation—Stock Compensation (Topic 718), Scope of Modification Accounting*. This pronouncement provides guidance about which changes to the terms or conditions of a share-based payment award may require an entity to apply modification accounting under Topic 718. This guidance is effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period, with early adoption permitted. The Company adopted this standard on January 1, 2018. The adoption of ASU No. 2017-09 did not have a significant impact on the Company's financial statements and related disclosures.

***Recent accounting pronouncements***

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*, which requires an entity that is a lessee to recognize the assets and liabilities arising from most leases on the balance sheet. This guidance also requires disclosures about the amount, timing, and uncertainty of cash flows arising from leases. This guidance is effective for annual reporting periods beginning after December 15, 2018, and interim periods within those annual periods, using a modified retrospective approach, and early adoption is permitted. The Company plans to adopt this standard on January 1, 2019 and is currently evaluating the effect that this guidance will have on its financial statements and related disclosures.

In March 2018, the FASB issued ASU No. 2018-05, *Income Taxes (topic 740):* Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118 (SEC Update). This standard adds various SEC paragraphs pursuant to the issuance of SEC Staff Accounting Bulletin No. 118, which clarifies the SEC Staff's views on income tax accounting implications of the Tax Cuts and Jobs Act. It requires reporting of provisional amounts for specific income tax effects of the Act for which the accounting under ASC Topic 740 will be incomplete, but a reasonable estimate can be determined. Provision amounts for income tax effects of the Act for which a reasonable estimate cannot be determined, ASC Topic 740 should be applied based on provisions of the tax laws that were in effect immediately prior to the Act being enacted. Provisional amounts for income tax effects for which a reasonable estimate cannot be determined would be reported in the first reporting period in which a reasonable estimate can be determined. In accordance with this standard and SAB 118, the Company reported provisional amounts for income tax effects from the Act as of December 31, 2017 and amounts will be finalized before December 22, 2018.

The Company has reviewed other recent accounting pronouncements and concluded they are either not applicable to the business, or no material effect is expected on the financial statements as a result of future adoption.

**3. Fair value measurements**

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The Company primarily applies the market approach for recurring fair value measurements.

The Company measures certain financial assets and liabilities at fair value on a recurring basis based on the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants. The carrying amount of the Company's cash equivalents, prepaid expenses, accounts payable and accrued liabilities approximate fair value due to their short maturities. The fair value of these financial assets was determined based on a hierarchy of three levels of inputs, of which the first two are considered observable and the last unobservable, as follows:

Level 1—Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date.

Level 2—Inputs (other than quoted market prices included in Level 1) that are either directly or indirectly observable, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the instrument's anticipated life.

Level 3—Unobservable inputs that are supported by little or no market activity and reflect management's best estimate of what market participants would use in pricing the asset or liability at the measurement date.

Consideration is given to the risk inherent in the valuation technique and the risk inherent in the inputs to the model.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability. The Company did not have any non-financial assets or liabilities that were measured or disclosed at fair value on a recurring basis at March 31, 2018 or December 31, 2017.

Financial assets subject to fair value measurements on a recurring basis and the level of inputs used in such measurements are as follows (in thousands):

| | March 31, 2018 | | | |
|---|---|---|---|---|
| | LEVEL 1 | LEVEL 2 | LEVEL 3 | TOTAL |
| **Assets** | | | | |
| Cash equivalents—money market funds | $165,313 | $ — | $ — | $165,313 |

| | December 31, 2017 | | | |
|---|---|---|---|---|
| | LEVEL 1 | LEVEL 2 | LEVEL 3 | TOTAL |
| **Assets** | | | | |
| Cash equivalents—money market funds | $ 49,475 | $ — | $ — | $ 49,475 |

The Company classifies money market funds as Level 1. The Company has no Level 2 or Level 3 assets or liabilities as of March 31, 2018 or December 31, 2017. There were no transfers between Level 1 and Level 2 during the periods.

There were no unrealized or realized gains or losses during the quarter ended March 31, 2018 and 2017.

The Company did not have any financial liabilities subject to fair value measurements on a recurring basis at March 31, 2018 and December 31, 2017.

**4. Property and equipment, net**

The following table is a summary of property and equipment, net (in thousands):

| | MARCH 31, 2018 | DECEMBER 31, 2017 |
|---|---|---|
| Computer equipment | $ 24 | $ 24 |
| Software | 30 | 30 |
| Lab equipment | 964 | 969 |
| Furniture and fixtures | 26 | 10 |
| Leasehold improvements | 56 | 56 |
| | 1,100 | 1,089 |
| Less: Accumulated depreciation and amortization | (773) | (839) |
| Property and equipment, net | $ 327 | $ 250 |

Depreciation and amortization expense was $52,000 and $52,000 for the three months ended March 31, 2018 and 2017, respectively.

**5. Accrued liabilities**

Accrued liabilities consist of the following (in thousands):

| | MARCH 31, 2018 | DECEMBER 31, 2017 |
|---|---|---|
| Accrued payroll and related expenses | $ 728 | $ 208 |
| Accrued research and clinical trial expenses | 7,714 | 4,443 |
| Other accrued liabilities | 299 | 1,063 |
| | $ 8,741 | $ 5,714 |

**6. Commitments and contingencies**

***Facility lease***

The Company leases its laboratory and office facilities in Redwood City, California under a noncancelable operating lease agreement. The original lease agreement, entered into in February 2013, was scheduled to terminate in May 2017. In October 2016, the Company amended the lease agreement to provide an extension to the original lease term. Under this amendment, the lease terminates in May 2022. The monthly rental payment increased as a result of the amendment, with such increases effective beginning in May 2017.

The Company executed a lease and gained access to 25,956 square feet of additional office space in Redwood City, California under a noncancelable operating lease agreement with a 7-year term that began in March 2018. The lease agreement is an operating lease with an aggregate base rent commitment over the course of the 7-year term of approximately $10.1 million before including operating expenses such as utilities, building maintenance, and insurance. The Company has no obligation to pay rent during the first two months of the lease. The cost of construction of the tenant improvements will be paid by the lessor up to a maximum amount of $3.2 million. The Company expects the cost of the tenant improvements to be $2.7 million, based on current plans for the improvements and has recorded a receivable from the lessor for that amount on the balance sheet.

Rent expense is recognized on a straight-line basis over the non-cancelable term of the operating leases. The Company records the difference between cash rent payments and the recognition of rent expense as a deferred rent liability on the balance sheets.

The lease incentive obligation will be amortized on a straight-line basis as a reduction of rent expense.

The Company's current future minimum lease payments under all operating leases, are as follows (in thousands):

| | |
|---|---|
| Last Nine Months of 2018 | $ 836 |
| 2019 | 1,885 |
| 2020 | 1,949 |
| 2021 | 2,014 |
| 2022 | 1,685 |
| Thereafter | 3,960 |
| | $12,329 |

Rent expense for the quarters ended March 31, 2018 and 2017 was $131,000 and $132,000, respectively.

***Contractual payments***

On March 31, 2018, the Company executed an agreement with a contract manufacturing organization (CMO) for process development and manufacturing services for the Company's lead product, AM0010. Under the terms of that agreement, the Company is required to make an initial non-refundable payment of $4.0 million to the CMO for committed future development and manufacturing services. The Company received the related invoice from the CMO in April 2018, and the payment was made at that time.

***Contingencies***

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of business activities. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. The Company is not subject to any current pending legal matters or claims that would have a material adverse effect on its financial position, results of operations or cash flows.

**7. Stock-Based Awards**

**2018 Equity Incentive Plan**

In January 2018, the Company adopted the 2018 Equity Incentive Plan (the 2018 Plan), which became effective upon the closing of the Company's IPO. The 2018 Plan replaced the 2012 Stock Plan (the 2012 Plan) and provides for the granting of stock-based awards to employees, directors, and consultants under similar terms, conditions and provisions as the 2012 Plan. The 2018 Plan had 3,175,864 shares of common stock available for future issuance at the time of its inception. Shares available for issuance under the 2012 Plan did not transfer to the 2018 Plan upon adoption of the new plan. The 2018 Plan provides for automatic annual increases in shares available for grant, beginning on January 1, 2019 through January 1, 2028 by a number equal to the lesser of 1,905,518 shares, or 4% of the shares of common stock outstanding on the last business day of the prior fiscal year, or a number of shares determined by the Board of Directors.

The following table sets forth the summary of activity under the 2012 Plan and the 2018 Stock Plan (in thousands, except share and per share amounts):

| | | OUTSTANDING OPTIONS | | | |
|---|---|---|---|---|---|
| | SHARES AVAILABLE FOR GRANT | SHARES | WEIGHTED-AVERAGE EXERCISE PRICE | WEIGHTED-AVERAGE REMAINING CONTRACTUAL LIFE (IN YEARS) | AGGREGATE INTRINSIC VALUE |
| **Balance at December 31, 2017** | 1,042,744 | 2,269,610 | $ 4.79 | 8.58 | $ 11,030 |
| Retirement of shares available for grant under the 2012 Plan | (1,042,744) | — | | | |
| Increase in shares reserved for issuance under the 2018 Plan | 3,175,864 | — | | | |
| Options granted | (301,190) | 301,190 | 39.16 | | |
| **Balance at March 31, 2018** | 2,874,674 | 2,570,800 | $ 8.82 | 8.68 | $ 74,681 |
| Vested at March 31, 2018 | | 783,940 | $ 2.75 | 7.28 | $ 27,178 |
| Exercisable at March 31, 2018 | | 2,272,609 | $ 4.84 | 8.51 | $ 74,031 |

During the quarter ended March 31, 2018, the Company granted 301,190 stock options to purchase shares of common stock with a weighted-average grant date fair value of $30.78 per share and a weighted-average exercise price of $39.16 per share. The grant date fair value of those awards was $9.3 million.

**2018 Employee Stock Purchase Plan**

In January 2018, the Company adopted the 2018 Employee Stock Purchase Plan (ESPP) and reserved a total of 317,586 shares of common stock for issuance under the ESPP. The ESPP provides for automatic annual increases in shares available for grant, beginning on January 1, 2019 through January 1, 2038 by a number equal to the lesser of 476,380 shares, or 1% of the shares of common stock outstanding on the last business day of the prior fiscal year, or a number of shares determined by the Board of Directors. Eligible employees may purchase common stock at 85% of the lesser of the fair market value of common stock on the offering date or the purchase date with a six-month look-back feature. The initial offering period of 24 months began on January 25, 2018, the effective date of the IPO and will end on February 15, 2020, and consists of four consecutive purchase periods, beginning on January 25, 2018, August 16, 2018, February 16, 2019 and August 16, 2019 and ending on August 15, 2018, February 15, 2019, August 15, 2019 and February 15, 2020.

***Stock-Based Compensation Expense***

Total stock-based compensation expense was recorded as follows (in thousands):

| | THREE MONTHS ENDED MARCH 31, | |
|---|---|---|
| | 2018 | 2017 |
| Research and development | $ 409 | $ 84 |
| General and administrative | 485 | 103 |
| Total | $ 894 | $ 187 |

There were no capitalized stock-based compensation costs or recognized stock-based compensation tax benefits during the quarters ended March 31, 2018 and 2017. As of March 31, 2018, there was total unrecognized compensation expense of $17.8 million, to be recognized over a period of approximately 3.3 years.

**8. Net loss per share**

The following weighted-average outstanding shares of potentially dilutive securities were excluded from the computation of diluted net loss per share for the periods presented, because including them would have been anti-dilutive:

| | As of March 31, | |
|---|---|---|
| | 2018 | 2017 |
| Convertible redeemable preferred stock, as converted to common stock | — | 14,733,837 |
| Option shares to purchase common stock | 2,570,800 | 1,277,006 |
| Common stock subject to repurchase and unvested restricted shares issued under the 2012 Plan | 14,053 | 70,983 |
| Total | 2,584,853 | 16,081,826 |

**9. Subsequent events**

On May 9, 2018, Eli Lilly and Company, an Indiana corporation ("Parent"), Bluegill Acquisition Corporation, a Delaware corporation ("Merger Sub") and a wholly owned subsidiary of Parent and the Company entered into an Agreement and Plan of Merger (the "Merger Agreement"). The Merger Agreement provides that, subject to the terms of the Merger Agreement, Merger Sub will commence a cash tender offer (the "Offer") to purchase all of the outstanding shares of the Company common stock, par value $0.0001 per share, at a price of $50.00 per share, net to the seller in cash, without interest, and subject to withholding taxes.

Consummation of the Offer is subject to various conditions set forth in the Merger Agreement, including, but not limited to (i) at least a majority of shares of the Company common stock then outstanding being tendered into the Offer, (ii) the receipt of certain antitrust approvals, waivers and consents, and (iii) the other conditions set forth in Exhibit A to the Merger Agreement.

The Offer will expire at one minute after 11:59 p.m., New York City time, on the date that is 20 business days (calculated in accordance with the rules of the Securities Exchange Act of 1934, as amended) following the commencement date of the Offer unless extended in accordance with the terms of the Offer and the Merger Agreement and the applicable rules and regulations of the United States Securities and Exchange Commission (the "SEC").

Following consummation of the Offer, Merger Sub will merge with and into the Company with the Company surviving as a wholly owned subsidiary of Parent (the "Merger"). In the Merger, each outstanding Share that is not tendered and accepted pursuant to the Offer (other than the Shares held in the treasury of the Company, Shares held by Parent or Merger Sub, and Shares as to which appraisal rights have been perfected in accordance with applicable law) will be cancelled and converted into the right to receive the Offer Price, on the terms and conditions set forth in the Merger Agreement.

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

*The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our condensed financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q. As discussed in the section titled "Note About Forward-Looking Statements," the following discussion and analysis contains forward-looking statements that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to these differences include, but are not limited to, those identified below, those discussed in "Note About Forward-Looking Statements" and those discussed in the section titled "Risk Factors" under Part II, Item 1A in this Quarterly Report on Form 10-Q.*

**Overview**

We are a late-stage immuno-oncology company that is developing a pipeline of novel, proprietary product candidates that activate the immune system of cancer patients to recognize and eradicate tumors. Our vision is to improve and prolong the lives of cancer patients by advancing and expanding the field of immuno-oncology through novel combinations and treatment sequences of our pipeline products with standard of care chemotherapies and checkpoint inhibitors or with other emerging immunotherapies that elicit complementary and synergistic treatment effects. To achieve this vision, we have assembled a seasoned and talented group of industry veterans, scientists, clinicians, key opinion leaders and investors.

Our lead product candidate, AM0010 (pegilodecakin), stimulates the survival, expansion and tumor killing (cytotoxic) capacity of a particular white blood cell of the immune system, called the CD8+ T cell through the up-regulation of gamma interferon and expression of the major histocompatibility (MHC) complex, which facilitates antigen presentation on tumor cells. We have focused on CD8+ T cells because these cells have been shown to recognize and kill cancer cells. An abundance of longer-surviving tumor-infiltrating CD8+ T cells improves the prognosis and lengthens the survival of cancer patients. AM0010 also reduces tumor promoting inflammation, shifting the immune environment away from regulation, which favors the neoplasia, towards activation, which leads to tumor cell death by T effector cells. These anti-inflammatory properties may also provide a protective effect against the autoimmunity and inflammation-based adverse events seen frequently with commonly used immune-based treatments and chemotherapies, thereby reducing the morbidity associated with these complications.

AM0010 was advanced into late-stage clinical development as an immuno-oncology drug based on the results of our Phase 1/1b clinical trial in over 350 cancer patients across more than 14 different types of cancer and many treatment settings. AM0010 was well-tolerated in patients as a single agent and in combination with chemotherapeutic drugs or immune checkpoint inhibitors, nivolumab and pembrolizumab. In this ongoing Phase 1/1b clinical trial, we have observed objective tumor responses, including partial and complete responses. We have also seen improvements, compared to results published by Garon et al., Pembrolizumab for the Treatment of Non-Small Cell Lung Cancer, The New England Journal of Medicine (2015) (the Garon Article) and other studies published in medical literature, in objective tumor response rates and overall survival in patients treated with AM0010 in combination with chemotherapeutic drugs or immune checkpoint inhibitors, nivolumab and pembrolizumab, which bind to a protein called PD-1. Based on the results from this Phase 1/1b clinical trial, the initial focus of our late-stage AM0010 development program is pancreatic ductal adenocarcinoma (PDAC), non-small cell lung cancer (NSCLC) and renal cell carcinoma (RCC).

In January 2018, we closed on our initial public offering of our common stock on the NASDAQ Global Select Market, in which we issued 7,529,412 shares of our common stock at a price of $17 per share. Shortly following the close of the offering, the underwriters exercised their option to purchase an additional 1,129,411 shares at the IPO price. In aggregate, we received approximately $133 million in proceeds, which amount is net of $10.3 million in underwriters' discount and estimated offering costs of $3.7 million.

We have financed our operations primarily through net proceeds from our initial public offering of $133 million that closed in January 2018 and the sale of $177.1 million of redeemable convertible preferred stock in prior periods. We have devoted substantially all of our resources to identifying and developing product candidates, in particular AM0010, including conducting preclinical studies and clinical trials and providing general and administrative support for these operations. We rely, and expect to continue to rely, on third parties to conduct some or all aspects of our clinical trials, research and preclinical testing and all of our product manufacturing. As of March 31, 2018, we had cash and cash equivalents of $165.3 million.

We have never generated revenue and have incurred significant net losses since inception. We do not expect to receive any revenue from any product candidates that we develop unless and until we obtain regulatory approval and commercialize our product candidates or enter into collaborative arrangements with third parties. Our net losses were $21.7 million and $9.4 million for the three-months ended March 31, 2018 and 2017, respectively. As of March 31, 2018, we had an accumulated deficit of $157.1 million. We

will continue to require additional capital to continue our research and development, manufacturing and commercialization activities. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our product development efforts.

On May 9, 2018, Eli Lilly and Company, an Indiana corporation ("Parent"), Bluegill Acquisition Corporation, a Delaware corporation ("Merger Sub") and a wholly owned subsidiary of Parent and the Company entered into an Agreement and Plan of Merger (the "Merger Agreement"). The Merger Agreement provides that, subject to the terms of the Merger Agreement, Merger Sub will commence a cash tender offer (the "Offer") to purchase all of the outstanding shares of the Company common stock, par value $0.0001 per share, at a price of $50.00 per share, net to the seller in cash, without interest, and subject to withholding taxes.

Consummation of the Offer is subject to various conditions set forth in the Merger Agreement, including, but not limited to (i) at least a majority of shares of the Company common stock then outstanding being tendered into the Offer, (ii) the receipt of certain antitrust approvals, waivers and consents, and (iii) the other conditions set forth in Exhibit A to the Merger Agreement. The Offer will expire at one minute after 11:59 p.m., New York City time, on the date that is 20 business days (calculated in accordance with the rules of the Securities Exchange Act of 1934, as amended) following the commencement date of the Offer unless extended in accordance with the terms of the Offer and the Merger Agreement and the applicable rules and regulations of the United States Securities and Exchange Commission.

Following consummation of the Offer, Merger Sub will merge with and into the Company with the Company surviving as a wholly owned subsidiary of Parent (the "Merger"). In the Merger, each outstanding Share that is not tendered and accepted pursuant to the Offer (other than the Shares held in the treasury of the Company, Shares held by Parent or Merger Sub, and Shares as to which appraisal rights have been perfected in accordance with applicable law) will be cancelled and converted into the right to receive the Offer Price, on the terms and conditions set forth in the Merger Agreement.

There can be no assurance that the Offer will commence or be completed, nor any assurance the Merger will be completed.

**Financial Operations Overview**

***Revenue***

To date, we have not generated any revenue.

***Operating expenses***

The largest component of our total operating expenses has historically been our investment in research and development activities, including the clinical development of our product candidates. We expect to incur significant operating expenses and increasing operating losses for the foreseeable future as we:

- invest significantly to further develop, and seek regulatory and marketing approval for, our product candidates;
- further expand indications for our existing product candidates and our pipeline of potential product candidates;
- further develop our manufacturing capabilities to support clinical development and ultimately commercialization of our product candidates
- hire additional clinical, scientific, commercial, management and administrative personnel;
- establish any sales, marketing and distribution infrastructure to commercialize any drugs for which we may obtain marketing approval;
- maintain, expand and protect our intellectual property portfolio;
- acquire or in-license other assets and technologies; and
- procure additional operational, financial and management information systems and implement processes to support our ongoing development efforts, any commercialization efforts and operating as a public company.

***Research and development expenses***

Research and development (R&D) expenses represent costs incurred for the discovery and development of our product candidates. To date, substantially all of our costs have been associated with the development of our lead product candidate, AM0010, and the vast majority of these costs are related to external R&D expenses. We recognize as expense all R&D costs as they are incurred. Our external R&D expenses consist primarily of:

- expenses incurred under agreements with contract research organizations (CROs) investigative clinical trial sites and other vendors involved in conducting our clinical trials;
- expenses incurred with contract manufacturing organizations (CMOs) for manufacturing process development, scale up and both drug substance and drug product manufacturing for our product candidates
- expenses incurred with third party vendors for performing preclinical testing on our behalf; and
- consultant fees and certain laboratory supply costs related to the execution of preclinical studies and clinical trials.

Internal costs are associated with activities performed by our R&D organization and often benefit multiple programs. These costs are not separately allocated to specific product candidates. Unallocated, internal R&D costs consist primarily of:

- personnel costs, which include salaries, bonuses, benefits and stock-based compensation expense;
- facilities and other expenses, which include costs associated with rent, maintenance and related facilities costs as well as the depreciation and amortization expense associated with property and equipment; and
- certain laboratory supplies and non-capitalized equipment used for internal R&D activities.

Although the rate at which we incur R&D expenses may vary from period to period, we expect our R&D expenses generally to increase substantially for the foreseeable future as we continue to invest in R&D activities.

Product candidates in later stages of clinical trials typically have higher development costs than those in earlier stages of development primarily due to the increased size and duration of such trials and increased requirements for drug supply. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain. As a result, we are unable to determine the duration and completion costs of many of our R&D projects or when, and to what extent, we will generate revenue from the commercialization and sale of any of our product candidates. In addition, we may enter into collaboration arrangements for any of our product candidates, which could affect our development plans or capital requirements.

***General and administrative expenses***

General and administrative expenses consist primarily of personnel costs, facilities costs, including rent and maintenance of facilities, depreciation and amortization expense related to property and equipment, expenses for outside professional services, including legal, human resources, information technology, tax, audit and accounting services, and other consulting expenses. Personnel costs consist of salaries, bonuses, benefits and stock-based compensation expense. We expect our general and administrative expenses to increase for the foreseeable future due to anticipated increases in headcount to advance our product candidates and as a result of preparing to become, and operating as, a public company, including expenses related to compliance with the rules and regulations of the Securities and Exchange Commission, additional insurance expenses, investor relations activities and other administrative and professional services.

***Interest income***

Interest income consists primarily of interest earned on our investments.

**Critical Accounting Policies and Estimates**

There have been no significant changes during the three months ended March 31, 2018 to our critical accounting policies and significant judgments and estimates as disclosed in our management's discussion and analysis of financial condition and results of operations included in our Annual Report on Form 10-K for the year ended December 31, 2017.

**Results of Operations**

***Comparison of the quarters ended March 31, 2018 and 2017***

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

| | Three Months Ended March 31, | | Dollar Change | % Change |
|---|---|---|---|---|
| | 2018 | 2017 | | |
| Operating expenses: | | | | |
| Research and development | $ 19,037 | $ 7,727 | $ 11,310 | 146.4% |
| General and administrative | 3,078 | 1,687 | 1,391 | 82.5% |
| Total operating expenses | 22,115 | 9,414 | 12,701 | 134.9% |
| Loss from operations | (22,115) | (9,414) | (12,701) | 134.9% |
| Interest income | 393 | 18 | 375 | 2083.3% |
| Net loss and comprehensive loss | $(21,722) | $(9,396) | $(12,326) | 131.2% |

***Research and development***

R&D expenses increased by $11.3 million, or 146.4%, for the quarter ended March 31, 2018 as compared to the quarter ended March 31, 2017. The increase was primarily due to a $3.8 million increase in spending for the manufacture of the AM0010 product, a $2.2 million increase related to our ongoing Phase 3 randomized pivotal clinical trial (SEQUOIA) with AM0010, a $2.0 million increase related to our newly launched Phase 2b clinical trial (CYPRESS) with AM0010, an additional $1.9 million for initial research into our AM00001 product candidate and $1.3 million of expenses driven by an increase in the number of personnel, an increase in the number of site visits and an increase in consulting costs related to the manufacture of our AM0010 product. For the quarter ended March 31, 2018 and 2017, substantially all of our R&D expense related to the development of the AM0010 (76% and 82% in each quarter, respectively).

***General and administrative***

General and administrative expense for the quarter ended March 31, 2018 increased by $1.4 million, or 82.5%, from the quarter ended March 31, 2017. This increase was primarily due to the following increases: $0.4 million for general and patent related legal expenses and other professional services; $0.7 million for compensation related expenses including stock based compensation; $0.2 million in insurance costs; and $0.1 million in facility travel costs.

***Interest income***

Interest income for the quarter ended March 31, 2018 increased by $0.4 million from the quarter ended March 31, 2017. The increase was due to higher average cash and cash equivalent balances, as well as higher average interest rates in 2018.

**Liquidity and Capital Resources**

***Sources of liquidity***

As of March 31, 2018, we had $165.3 million in cash and cash equivalents, an accumulated deficit of $157.1 million and working capital of $153.7 million. In January 2018, we closed on our initial public of our common stock on the NASDAQ Global Select Market, in which we received approximately $133 million in proceeds, which amount is net of $10.3 million in underwriters' discount and offering costs of $3.7 million. We expect to continue to incur substantial costs in order to conduct research and development activities necessary to develop and commercialize our product candidates. Additional capital will be needed to undertake these activities and commercialization efforts, and, therefore, we intend to raise such capital through the issuance of additional equity, borrowings, and potentially strategic alliances with other companies. However, if such financing is not available at adequate levels or on acceptable terms, we could be required to significantly reduce operating expenses and delay, reduce the scope of or eliminate some of the development programs or commercialization efforts, out-license intellectual property rights to our product candidates and sell unsecured assets, or a combination of the above, any of which may have a material adverse effect on the our business, results of operations, financial condition and/or out ability to fund our scheduled obligations on a timely basis or at all. Our ability to continue as a going concern is dependent upon our ability to successfully accomplish these plans and secure sources of financing and ultimately attain profitable operations.

***Funding requirements***

Our primary use of cash is to fund operating expenses, which consist of research and development expenditures as well as general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay or prepay these expenses.

To the extent that 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 valuable rights to our product candidates, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we 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.

Our ability to continue as a going concern is dependent upon our ability to successfully accomplish these plans and secure sources of financing and ultimately achieve profitable operations. As of the date of this Quarterly Report on Form 10-Q, with the proceeds from our initial public offering, we believe that we have sufficient capital to fund our operating and capital requirements for the next 12 months.

Please see the section entitled "Risk Factors" for additional risks associated with our substantial capital requirements and the challenges we may face in raising capital.

***Off-balance sheet arrangements***

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

***Cash flows***

The following table summarizes our cash flows for each of the periods indicated (in thousands):

| | Three Months Ended March 31, | |
|---|---|---|
| | **2018** | **2017** |
| Cash used in operating activities | $ (18,535) | $(10,901) |
| Cash used in investing activities | (137) | — |
| Cash provided by (used in) financing activities | 134,510 | (6) |
| Net increase/(decrease) in cash, cash equivalents and restricted cash | $115,838 | $(10,907) |

***Cash used in operating activities***

Net cash used in operating activities was $18.5 million and $10.9 million for the quarters ended March 31, 2018 and 2017, respectively. After reflecting a net loss of $21.7 million and $9.4 million, respectively, in each quarter, the net cash used is partially offset by net changes in operating assets and liabilities of $2.2 million and $1.7 million. Finally, non-cash charges of $1.0 million and $0.2 million, respectively for each quarter, primarily for stock-based compensation expense and depreciation and amortization, further reduced the net cash used in operating activities.

***Cash used in investing activities***

Net cash used in investing activities was $0.1 million for the quarter ended March 31, 2018 and resulted from the purchase of property and equipment.

***Cash provided by financing activities***

Net cash provided by financing activities was $135 million for the quarter ended March 31, 2018 from the receipt of net proceeds from our initial public offering. Net cash used in financing activities was $6,000 for the quarter ended March 31, 2017 from the repurchase of common stock.

**Contractual Obligations and Commitments**

In March 2018, we executed a lease for 25,956 square feet of additional office space in Redwood City, California under a noncancelable operating lease agreement with a 7-year term that began in March 2018. The lease agreement is an operating lease with an aggregate base rent commitment over the course of the 7-year term of approximately $10.1 million before factoring in operating expenses such as utilities, building maintenance, and insurance. We have no obligation to pay rent during the first two months of the lease. The cost of construction of the tenant improvements will be paid by the lessor up to a maximum amount of $3.2 million. The Company expects the cost of the tenant improvements to be $2.7 million, based on current plans for the improvements.

In addition, we enter into contracts in the normal course of business with CROs for preclinical studies and clinical trials and CMOs for the manufacture of clinical trial materials. These agreements provide for termination at the request of either party with less than one year notice and are, therefore, cancelable contracts and not reflected in the table above. As of March 31, 2018, we had commitments of $5.0 million with CMOs, $8.5 million with CROs and an aggregate of $1.8 million with other clinical sites, all related to our AM0010 program as well as $1.1 million with our anti-PD-1 checkpoint inhibitor program.

In addition, we remain obligated to pay up to an aggregate of $10.0 million in at-risk milestone payments upon the occurrence of certain events pursuant to the Merck Agreement.

Other than the items mentioned above, there have been no material changes to our contractual obligations since the date of our Annual Report on Form 10-K.

***Adopted Accounting Pronouncements***

In January 2016, the FASB issued ASU No. 2016-01, *Financial Instruments Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*. This guidance makes amendments to the classification and measurement of financial instruments and revises the accounting related to: (1) the classification and measurement of investments in equity securities; and (2) the presentation of certain fair value changes for financial liabilities measured at fair value. In addition, the update also amends certain disclosure requirements associated with the fair value of financial instruments. We adopted this standard on January 1, 2018. The adoption of ASU No. 2016-01 did not have a significant impact on our financial statements and related disclosures.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230: Classification of Certain Cash Receipts and Cash Payments*. This guidance addresses specific cash flow issues with the objective of reducing the diversity in practice for the treatment of these issues. The areas identified include: debt prepayment or debt extinguishment costs; settlement of zero-coupon debt instruments; contingent consideration payments made after a business combination; proceeds from the settlement of insurance claims; proceeds from the settlement of corporate-owned life insurance policies; distributions received from equity method investees; beneficial interests in securitization transactions; and application of the predominance principle with respect to separately identifiable cash flows. We adopted this standard on January 1, 2018. The adoption of ASU No. 2016-15 did not have a significant impact on our financial statements and related disclosures.

In November 2016, the FASB issued ASU No. 2016-18, *Restricted Cash, Statement of Cash Flows (Topic 230)*. ASU 2016-18 requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. We adopted this standard in our first quarter ended March 31, 2018. We have revised the presentation of restricted cash in our Statements of Cash Flows. Cash, cash equivalents and restricted cash as reported on the Statements of Cash Flows is composed of the individual lines on the Balance Sheets labeled as cash and cash equivalents and restricted cash.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation—Stock Compensation (Topic 718), Scope of Modification Accounting*. This pronouncement provides guidance about which changes to the terms or conditions of a share-based payment award may require an entity to apply modification accounting under Topic 718. This guidance is effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period, with early adoption permitted. We adopted this standard on January 1, 2018. The adoption of ASU No. 2017-09 did not have a significant impact on our financial statements and related disclosures. The cost of construction of the tenant improvements will be paid by the lessor up to a maximum amount of $3.2 million. The Company expects the cost of the tenant improvements to be $2.7 million, based on current plans for the improvements.

***Recent Accounting Pronouncements***

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*, which requires an entity that is a lessee to recognize the assets and liabilities arising from most leases on the balance sheet. This guidance also requires disclosures about the amount, timing, and uncertainty of cash flows arising from leases. This guidance is effective for annual reporting periods beginning after December 15, 2018, and interim periods within those annual periods, using a modified retrospective approach, and early adoption is permitted. We plan to adopt this standard on January 1, 2019 and are currently evaluating the effect that this guidance will have on our financial statements and related disclosures.

In March 2018, the FASB issued ASU No. 2018-05, Income Taxes (topic 740): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118 (SEC Update). This standard adds various SEC paragraphs pursuant to the issuance of SEC Staff Accounting Bulletin No. 118, which clarifies the SEC Staff's views on income tax accounting implications of the Tax Cuts and Jobs Act. It requires reporting of provisional amounts for specific income tax effects of the Act for which the accounting under ASC Topic 740 will be incomplete, but a reasonable estimate can be determined. Provision amounts for income tax effects of the Act for which a reasonable estimate cannot be determined should be applied based on provisions of the tax laws that were in effect immediately prior to the Act being enacted. Provisional amounts for income tax effects for which a reasonable estimate cannot be determined would be reported in the first reporting period in which a reasonable estimate can be determined. The Company reported provisional amounts for which it can reasonably estimate in the three months ended March 31, 2018.

We have reviewed other recent accounting pronouncements and concluded they are either not applicable to the business, or no material effect is expected on the financial statements as a result of future adoption.

**Off-Balance Sheet Arrangements**

We have not entered into any off-balance sheet arrangements and do not have any holdings in variable interest entities.

**JOBS Act Accounting Election**

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act 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. We also rely on other exemptions provided by the JOBS Act, including without limitation, providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act. We will remain an emerging growth company until the earlier of (1) December 31, 2023, (2) the last day of the fiscal year (a) in which we have total annual gross revenue of at least $1.07 billion, or (b) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of the prior June 30th, and (3) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

***Foreign Currency Exchange Risk***

Our results of operations and cash flows are subject to fluctuations due to changes in foreign currency exchange rates, particularly changes in the Euro, British Pound Sterling and Swedish Krona. Due to the relative size of our international operations to date, our foreign currency exposure has been fairly limited and thus we have not instituted a hedging program. We expect our international operations to continue to grow in the future and we are continually monitoring the foreign currency exposure to determine when we should begin a hedging program. The substantial majority of our agreements have been and we expect will continue to be denominated in U.S. dollars.

***Interest Rate Sensitivity***

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. As of March 31, 2018, we had cash and cash equivalents of $165.3 million, which consisted primarily of bank deposits and money market funds. Such interest-earning instruments carry a degree of interest rate risk. We have not been exposed nor do we anticipate being exposed to material risks due to changes in interest rates.

**Item 4. Controls and Procedures.**

***Evaluation of Disclosure Controls and Procedures***

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")), as of March 31, 2018, the end of the period covered by this Quarterly Report on Form 10-Q. Based upon such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of such date.

***Changes in Internal Control Over Financial Reporting***

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the 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.

***Inherent Limitations on Effectiveness of Controls***

Our management, including our principal executive officer and principal financial officer, do not expect that our disclosure controls or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

## PART II—OTHER INFORMATION

**Item 1. Legal Proceedings.**

We are not currently a party to any material litigation or other material legal proceedings.

**Item 1A. Risk Factors.**

*A description of the risks and uncertainties associated with our business is set forth below. You should carefully consider the risks described below, as well as the other information in this Quarterly Report on Form 10-Q, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," particularly before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could materially and adversely affect our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.*

**Risks Related to Our Business**

***We are a late-stage immuno-oncology company with a limited operating history. We have incurred significant losses since inception and we expect to incur losses for the foreseeable future and may never achieve or maintain profitability.***

We are a late-stage immuno-oncology company with a limited operating history. 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. Our net loss was $21.7 million and $9.4 million for the quarters ended March 31, 2018 and 2017, respectively. As of

March 31, 2018, we had an accumulated deficit of $157.1 million. We expect that it will be several years, if ever, before we have a product candidate ready for commercialization. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The size of our future net losses may fluctuate significantly from quarter to quarter and will depend, in part, on the rate at which we incur expenses and our ability to generate revenue. We anticipate that our expenses will increase substantially if and as we:

- continue to advance our research and clinical and preclinical development of our product candidates;
- initiate clinical trials for our product candidates;
- seek to identify additional product candidates;
- seek marketing approvals for our product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any medicines for which we may obtain marketing approval;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, quality control and scientific personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development; and
- acquire or in-license other product candidates and technologies.

To become and remain profitable, we must develop and eventually commercialize a product with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our product candidates, obtaining marketing approval for these product candidates, manufacturing, marketing and selling those product candidates for which we may obtain marketing approval and satisfying any post-marketing requirements. We may never succeed in these activities and, even if we succeed in commercializing one or more of our product candidates, we may never generate revenues that are 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 and we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

***We need to obtain substantial additional funding to complete the development and any commercialization of our product candidates, if approved. If we are unable to raise this necessary capital when needed, we would be forced to delay, reduce or eliminate our product development programs, commercialization efforts or other operations.***

Since our inception, we have used substantial amounts of cash to fund our operations and expect our expenses to increase substantially in the foreseeable future. Developing our product candidates and conducting clinical trials for the treatment of cancer and any other indications which we may pursue in the future will require substantial amounts of capital. We will also require a significant additional amount of capital to commercialize any approved products. Accordingly, we expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, initiate clinical trials of, and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

Based on current business plans and assuming no financing, we believe that our existing cash and cash equivalents will be sufficient to fund our cash requirements through at least the next twelve months. We have based this estimate on assumptions that may prove to be incorrect or require adjustment as a result of business decisions, and we could utilize our available capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the scope, rate of progress, results and costs of drug discovery, preclinical development, laboratory testing and clinical trials for our product candidates;
- the scope and costs of manufacturing development and commercial manufacturing activities;

- the cost associated with commercializing our product candidates, if they receive regulatory approval;
- the cost and timing of developing our ability to establish sales and marketing capabilities, if any;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- our ability to attract, hire and retain qualified personnel;
- the costs associated with being a public company; and
- the extent to which we acquire or in-license other product candidates and technologies.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

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

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

***We are heavily dependent on the success of our lead product candidate, AM0010, since all of our other product candidates are still in the preclinical development stage and will require significant clinical trials. If we are unable to successfully complete clinical development, obtain regulatory approval for, or commercialize AM0010, or experience delays in doing so, our business will be materially harmed.***

To date, we have invested a substantial majority of our efforts and financial resources for the preclinical and clinical development of AM0010. Our future success is dependent on our ability to successfully develop, obtain regulatory approval for, and commercialize AM0010. Before we can generate any revenue from sales of AM0010, we will be required to conduct additional clinical development, seek and obtain regulatory approval, secure adequate manufacturing supply to support commercial sales and build a commercial organization. Further, the commercial success of AM0010 will also depend on patent protection, acceptance of AM0010 by patients, the medical community and third-party payors, its ability to compete with other therapies, secure adequate healthcare coverage and reimbursement, and maintenance of an acceptable safety profile following approval, among other factors. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize AM0010, which would materially harm our business.

AM0010 is currently our only product candidate to have advanced into clinical trials. All of our other programs are in a pre-clinical or research and development stage, and we cannot be certain any of these product candidates will be eligible for the filing of an IND application or for clinical evaluation. We cannot be certain that AM0010 will be successful in our clinical trials or receive regulatory approval. If we do not receive regulatory approval for, or otherwise fail to successfully commercialize, AM0010, we may need to

spend significant additional time and resources to identify other product candidates, advance them through preclinical and clinical development and apply for regulatory approvals, which would adversely affect our business, prospects, financial condition and results of operations. In addition, because AM0010 is our most advanced product candidate, and because our other product candidates may be used in combination with AM0010, if our clinical trials or any future clinical trials of AM0010 which we may conduct encounter safety or efficacy problems, developmental delays or regulatory issues or other problems, our development plans and business would be significantly harmed.

***Our preclinical studies and clinical trials of our product candidates may not be successful. If we are unable to commercialize our product candidates, if approved, or if we experience significant delays in doing so, our business will be materially harmed.***

Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates, if approved. Even if we successfully develop and commercialize AM0010, we may not be successful in developing and commercializing our other product candidates, and our commercial opportunities may be limited. The success of our product candidates will depend on many factors, including the following:

- successful enrollment in, and completion of, clinical trials;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and non-patent exclusivity for our product candidates;
- launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- acceptance of our product candidates, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- a continued acceptable safety profile of the medicines following approval; and
- enforcing and defending intellectual property rights and claims.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business.

***We are developing our lead product candidate, AM0010, to be used in combination with standard of care cancer therapies, which exposes us to several risks beyond our control.***

We are developing our lead product candidate, AM0010, to be used in combination with standard of care cancer therapies. This exposes us to supply risk to the extent there is not an adequate supply of the standard of care therapies that AM0010 is designed or, if approved, approved to be used in combination with, as well as pricing risk if the standard of care therapies is expensive and the addition of AM0010 would be too costly. In addition, if the standard of care were to evolve or change, the clinical utility of our lead product candidate, AM0010, could be diminished or eliminated. We may experience these risks with respect to our other product candidates. If any of these were to occur, our business could be materially harmed.

***We cannot predict if we will receive regulatory approval to commercialize our product candidates.***

We currently have no products approved for sale or marketing in any country and may never be able to obtain regulatory approval for any of our product candidates. As a result, we are not currently permitted to market any of our product candidates in the United States or in any other country until we obtain regulatory approval from the FDA or regulatory authorities outside the United States. Our product candidates are in early stages of development, only one of our product candidates has been tested on humans and we have not submitted an application, or received marketing approval, for any of our product candidates. We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA. All of our product candidates will require extensive preclinical testing and clinical trials. We cannot predict with any certainty if or when we might submit a BLA for regulatory approval for any of our product candidates or whether any such BLA will be accepted for review by FDA, or whether any BLA will be approved upon review.

***The development and commercialization of our lead product candidate, AM0010, is dependent on intellectual property we license from Merck. If we breach our agreement with Merck or the agreement is terminated, we could lose license rights that are important to our business.***

Pursuant to our license agreement with Merck, we acquired exclusive rights to patents, patent applications and know-how owned or controlled by Merck relating to PEGylated human IL-10 for all therapeutic purposes in humans.

Our lead product candidate, AM0010, is a long acting form of IL-10 that we have developed. Our existing license agreement with Merck imposes various development, regulatory, commercial diligence, financial and other obligations. If we fail to comply with our obligations under the agreement with Merck, or otherwise materially breach the agreement with Merck, and fail to remedy such failure or cure such breach within 90 days, Merck will have the right to terminate the agreement. If the Merck Agreement is terminated by Merck for our uncured material breach, we would lose our license and all rights to the product candidate would revert to Merck, including a fully paid-up, worldwide, exclusive license to our patents and know-how to develop, manufacture and exploit AM0010 and an assignment of all regulatory filings and approvals for AM0010 to Merck. The loss of the license from Merck would prevent us from developing and commercializing AM0010 and could subject us to claims of breach of contract and patent infringement by Merck if any continued research, development, manufacture or commercialization of AM0010 is covered by the affected patents. Accordingly, the loss of our license with Merck would materially harm our business.

***If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA or similar regulatory authorities outside the United States or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.***

Before obtaining regulatory approval for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and the outcome is uncertain. Despite promising preclinical and early clinical trial data, any product candidate can unexpectedly fail at any stage of preclinical or clinical development. The historical failure rate for product candidates is high. The outcome of preclinical 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. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our proposed indications. Success in preclinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and preclinical studies. In particular, while we have conducted certain preclinical studies of our product candidates, only AM0010 has been evaluated in clinical trials and we do not know whether our other product candidates will perform in clinical trials as they have performed in preclinical studies using animal models. For example, in clinical trials, it is possible that our product candidates may cause unacceptable levels of toxicity or other adverse side effects resulting in the FDA or comparable foreign regulatory authorities ordering us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. In addition, if our clinical results are not successful, we may terminate the clinical trials for a product candidate and abandon any further research or studies of the product candidate. Any delay in, or termination of, our clinical trials will delay and possibly preclude the filing of any BLAs with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues.

***Our clinical trials of our product candidates may fail to adequately demonstrate safety and efficacy to the satisfaction of regulatory authorities or otherwise fail to produce positive results, and we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.***

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and the outcome is inherently uncertain. A failure of one or more clinical trials can occur at any time during the clinical trial process. The outcome of preclinical testing 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. There is a high failure rate for drugs proceeding through clinical trials, and product candidates in later stages of clinical trials may fail to show the required safety and efficacy despite having progressed through preclinical studies and initial clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier clinical trials, and we cannot be certain that we will not face similar setbacks. Even if our clinical trials are completed, the results may not be sufficient to support obtaining regulatory approval for our product candidates.

Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate; enrollment in these clinical trials may be slower than we anticipate; or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; and
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate the trials.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements; or
- have the medicine removed from the market after obtaining marketing approval.

Product development costs will also increase if we experience delays in testing or marketing approvals. We do not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates, could allow our competitors to bring products to market before we do, and could impair our ability to successfully commercialize our product candidates, if approved, any of which may harm our business and results of operations.

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

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial therapies or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable medicines. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

***If we 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. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to study sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- our 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 in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site. 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 rather than enroll patients in any future clinical trial.

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

***The design or our execution of clinical trials may not support regulatory approval.***

The design or execution of a clinical trial can determine whether its results will support regulatory approval and flaws in the design or execution of a clinical trial may not become apparent until the clinical trial is well advanced. In some instances, there can be significant variability in safety or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates.

Further, the FDA and comparable foreign regulatory authorities have substantial discretion in the approval process an in determining when or whether regulatory approval will be obtained for any of our product candidates. Our product candidates may not be approved even if they achieve their primary endpoints in future Phase 3 clinical trials or registration trials. The FDA or other non-U.S. regulatory authorities may disagree with our trial design and our interpretation of data from preclinical studies and clinical trials. In

addition, any of these regulatory authorities may change requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a pivotal Phase 3 clinical trial that has the potential to result in FDA or another agencies' approval. In addition, any of these regulatory authorities may also approve a product candidate for fewer or more limited indications than we request or may grant approval contingent on the performance of costly post-marketing clinical trials. The FDA or other non-U.S. regulatory authorities may not approve the labeling claims that we believe would be necessary or desirable for the successful commercialization of our product candidates, if approved.

***We may not be successful in our efforts to identify or discover additional product candidates in the future.***

A significant portion of the research that we are conducting involves new compounds and drug discovery methods, including our proprietary technology. The drug discovery that we are conducting using our proprietary technology may not be successful in identifying compounds that are useful in treating cancer. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying appropriate biomarkers or potential product candidates; or
- potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be medicines that will receive marketing approval and achieve market acceptance.

Research programs to identify new product candidates require substantial technical, financial and human resources. If we are unable to identify suitable compounds for preclinical and clinical development, we will not be able to obtain product revenues in future periods, which likely would result in significant harm to our financial position and adversely impact our stock price.

***Even if any of our product candidates receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, hospitals, cancer treatment centers, healthcare payors and others in the medical community necessary for commercial success.***

If any of our product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. For example, current cancer treatments like chemotherapy and radiation therapy are well established in the medical community, and doctors may continue to rely on these treatments. Our product candidates are novel, proprietary medicines that activate a cancer patient's own immune system to recognize and eradicate tumors. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- efficacy and potential advantages compared to alternative treatments;
- the ability to offer our medicines for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- sufficient third-party coverage or reimbursement; and
- the prevalence and severity of any side effects.

***If any of our product candidates are approved for marketing and commercialization and we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market our product candidates, we will be unable to successfully commercialize our product candidates if and when they are approved.***

We have no sales, marketing or distribution capabilities or experience. To achieve commercial success for any approved product for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization, which would be expensive and time consuming, or outsource these functions to other third parties. In the future, we may choose to build a focused sales and marketing infrastructure to sell, or participate in sales activities with our collaborators for, some of our product candidates if and when they are approved.

There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our medicines on our own include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future medicines;
- the lack of complementary medicines to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues or the profitability of these product revenues to us are likely to be lower than if we were to market and sell any medicines that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are favorable to us. In entering into third-party marketing or distribution arrangements, any revenue we receive will depend upon the efforts of the third parties and we cannot assure you that such third parties will establish adequate sales and distribution capabilities or devote the necessary resources and attention to sell and market our medicines effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

***We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.***

The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical, specialty pharmaceutical and biotechnology companies among others. We compete in the segments of the pharmaceutical, biotechnology and other related markets that develop immunotherapies for the treatment of cancer. There are other companies working to develop immunotherapies for the treatment of cancer, including divisions of large pharmaceutical and biotechnology companies of various sizes. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

We are developing our initial product candidates for the treatment of cancer. There are a variety of available drug therapies marketed for cancer. For example, Bristol-Myers Squibb, Merck and Roche have recently received approval for immune checkpoint inhibitors for non-small cell lung cancer. Bristol-Myers Squibb has also received approval for an immune checkpoint inhibitor for renal cell carcinoma. Several checkpoint inhibitors are also under investigation in pancreatic cancer. In many cases, these drugs are administered in combination to enhance efficacy, and cancer drugs are frequently prescribed off-label by healthcare professionals. Some of the currently approved drug therapies are branded and subject to patent protection, and others are available on a generic basis. Many of these approved drugs are well established therapies and are widely accepted by physicians, patients and third-party payors. Insurers and other third-party payors may also encourage the use of generic products. We expect that if our product candidates are approved, they will be priced at a significant premium over competitive generic products. This may make it difficult for us to achieve our business strategy of using our product candidates in combination with existing therapies or replacing existing therapies with our product candidates.

There are also a number of product candidates in preclinical development by third parties to treat cancer. Our competitors may develop products that are more effective, safer, more convenient or less costly than any that we are developing or that would render

our product candidates obsolete or non-competitive. Our competitors may also obtain marketing approval from the FDA or other regulatory authorities for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical studies, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

***Our product candidates, for which we intend to seek approval, may face competition sooner than anticipated.***

Our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of biosimilar products. Biosimilar products are expected to become available over the coming years. Even if our product candidates achieve marketing approval, they may be priced at a significant premium over competitive biosimilar products, if any have been approved by then. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the ACA) created a new regulatory scheme authorizing the FDA to approve biosimilars. Under the ACA, a manufacturer may submit an application for licensure of a biologic product that is "biosimilar to" or "interchangeable with" a previously approved biological product or "reference product." Under this new statutory scheme, an application for a biosimilar product may not be submitted to the FDA until four years following approval of the reference product. The FDA may not approve a biosimilar product until 12 years from the date on which the reference product was approved. Even if a product is considered to be a reference product eligible for exclusivity, another company could market a competing version of that product if the FDA approves a full Biologics License Application (BLA) for such product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. Furthermore, recent legislation has proposed that the 12-year exclusivity period for each a reference product may be reduced to seven years.

***We may not be able to maintain orphan drug marketing exclusivity for AM0010 in the United States or the European Union, and orphan drug marketing exclusivity may not be available for any of our other product candidates.***

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biologic intended to treat a rare disease or condition (with a population of less than 200,000), which is defined as one occurring in a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug or biologic will be recovered from sales in the United States. In the European Union, following the opinion of the EMA's Committee for Orphan Medicinal Products, the European Commission grants orphan drug designation to a product if (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five in 10,000 persons in the European Union when the application is made, or (b) the product, without the incentives derived from orphan medicinal product status, would not generate sufficient return in the European Union to justify investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the European Union, or if such a method exists, the product will be of significant benefit to those affected by the condition.

Generally, if a drug with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the FDA or the European Commission and the competent authorities in the EU Member States from approving another marketing application for the same drug (or similar medicinal product in the EU) for that time period, except in limited circumstances. The applicable period is seven years in the United States and 10 years in the EU. The EU exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

We have been granted orphan drug designation for AM0010 in the United States and the European Union for the treatment of pancreatic cancer. Although we may apply for orphan drug designation for other product candidates we may develop in both the United States and European Union, applicable regulatory authorities may not grant us this designation. In addition, even if such status

is obtained for any other product candidate that we may develop, that exclusivity may not effectively protect the candidate from competition because other drugs, such as those with different active ingredients or molecular structures, can be approved for the same condition. Furthermore, even after an orphan drug is approved, the FDA can subsequently approve another drug for the same condition if the FDA concludes that the later drug is clinically superior, in that it is shown to be safer, more effective or makes a major contribution to patient care. In the European Union, a marketing authorization may be granted to a similar product during the 10-year period of market exclusivity for the same therapeutic indication at any time if:

- The second applicant can establish in its application that its product, although similar to the orphan medicinal product already authorized, is safer, more effective or otherwise clinically superior;
- The holder of the marketing authorization for the original orphan medicinal product consents to a second orphan medicinal product application; or
- The holder of the marketing authorization for the original orphan medicinal product cannot supply enough orphan medicinal product.

Any inability to secure orphan drug designation or to maintain the exclusivity benefits of this designation could have an adverse impact on our ability to develop and commercialize our product candidates, depending on the extent to which we would be protected by other patents and regulatory exclusivities, and may adversely affect our business, prospects, financial condition and results of operations.

***A Fast Track product designation or other designation to facilitate product candidate development may not lead to faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval.***

We have received a Fast Track product designation for AM0010 in combination with FOLFOX as a second-line therapy in patients with pancreatic cancer and we may seek Fast Track designation for other of our current or future product candidates. Receipt of a designation to facilitate product candidate development is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for a designation, the FDA may disagree. In any event, the receipt of such a designation for a product candidate may not result in a faster development process, review, or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate marketing approval by the FDA. In addition, the FDA may later decide that the products no longer meet the designation conditions.

***Even if we are able to commercialize any product candidates, such products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which would harm our business.***

The regulations that govern marketing approvals, pricing and reimbursement for new medicines vary widely from country to country. In the United States, enacted legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a medicine before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a medicine in a particular country, but then be subject to price regulations that delay our commercial launch of the medicine, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the medicine in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

Our ability to commercialize any medicines successfully also will depend in part on the extent to which reimbursement for these medicines and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any medicine that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining reimbursement for newly approved medicines, and coverage may be more limited than the purposes for which the medicine is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for reimbursement does not imply that any medicine will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new medicines, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the medicine and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost medicines and may be incorporated into existing payments for other services. Net prices for medicines may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of medicines from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved medicines that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize medicines and our overall financial condition.

In addition, in order to be eligible to have its products paid for with federal funds under the Medicaid and Medicare programs and purchased by certain federal agencies and grantees, a manufacturer also must participate in the Department of Veterans Affairs Federal Supply Schedule, or FSS, pricing program, established by Section 603 of the Veterans Health Care Act of 1992. Under this program, the manufacturer is obligated to make its "covered drugs" (biologics or innovator drugs) available for procurement on an FSS contract and charge a price to four federal agencies, Department of Veterans Affairs, Department of Defense, Public Health Service, and Coast Guard, that is no higher than the statutory federal ceiling price. Failure to timely submit the pricing required under the VA FSS program or submission of false information under the program could result in civil monetary penalties. In addition, if we determine that the price points submitted to the VA under this program were incorrect, we have an obligation to restate the pricing and we are liable for any overpayments the government made as a result of our incorrect prices. Pursuant to regulations issued by the DoD TRICARE Management Activity, now the Defense Health Agency, to implement Section 703 of the National Defense Authorization Act for Fiscal Year 2008, each of our covered drugs will be subject to quarterly rebates for prescriptions dispensed to TRICARE beneficiaries by TRICARE network retail pharmacies. The formula for determining the rebate is based on the price points that are required to be calculated by us under the Veterans Health Care Act. The requirements under the FSS and DoD TRICARE programs could reduce the revenue we may generate from any products that are commercialized in the future and could adversely affect our business and operating results.

***If the market opportunities for any product that we or our strategic partners develop are smaller than we believe they are, our revenue may be adversely affected and our business may suffer.***

We are focused on the development of treatments for cancer. Our projections of addressable patient populations that have the potential to benefit from treatment with our product candidates are based on estimates. If any of the foregoing estimates are inaccurate, the market opportunities for any of our product candidates could be significantly diminished and have an adverse material impact on our business.

***Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any medicines that we may develop.***

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any medicines that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or medicines caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or medicines that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize any medicines that we may develop.

Although we maintain product liability insurance coverage, it may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage as we advance our clinical trials and if we successfully commercialize any medicine. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

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

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

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

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.

***Changes in healthcare law and implementing regulations, as well as changes in healthcare policy, may impact our business in ways that we cannot currently predict, and may have a material adverse effect on our business and results of operations.***

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of drug candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any drug candidates for which we obtain marketing approval. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

In March 2010, the ACA was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things: (i) introduced a new average manufacturer price definition for drugs that are inhaled, infused, instilled, implanted or injected and not generally dispensed through retail community pharmacies; (ii) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and expanded rebate liability from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well; (iii) established an annual fee that pharmaceutical manufacturers of branded prescription drugs must pay to the federal government; (iv) expanded the list of covered entities eligible to participate in the 340B drug pricing program by adding new entities to the program; and (v) established 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 implemented, and there have been legal and political challenges to certain aspects of the ACA. Since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA. Moreover, the Tax Cuts and Jobs Act of 2017 was enacted on December 22, 2017, and 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". Congress may consider other legislation to repeal or replace additional elements of the ACA. We continue to evaluate the effect that the ACA, the repeal of the individual mandate, and any additional possible repeal and replacement efforts may have on our business but expect that the ACA, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of our existing products that we successfully commercialize or to successfully commercialize our product

candidates, if approved. In addition to the ACA, there will continue to be proposals by legislators at both the federal and state levels, regulators and third party payors to keep healthcare costs down while expanding individual healthcare benefits.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year pursuant to the Budget Control Act of 2011 and subsequent laws, which began in 2013 and will remain in effect through 2025 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Additional changes that may affect our business include the expansion of new programs such as Medicare payment for performance initiatives for physicians under the Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, which will first affect physician payment in 2019. At this time, it is unclear how the introduction of the Medicare quality payment program will impact overall physician reimbursement. Also, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and federal and state bills, including some that have been enacted into law, designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products.

We expect that these and other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs, once regulatory approval is obtained.

***We will be subject to federal, state and foreign healthcare and abuse laws and false claims laws, as well as information privacy and security laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.***

If we obtain FDA, European Commission or other comparable foreign regulatory authorities' approval for any of our product candidates and begin commercializing those products in the United States or outside the United States, our operations will be subject to various federal, state and foreign fraud and abuse laws and regulations, including, without limitation, the federal Anti-Kickback Statute, the federal civil False Claims Act, and the Physician Payments Sunshine Act. In addition, we may be subject to privacy and data security laws and regulation by United States federal and state governments and by foreign data protection laws in jurisdictions in which we conduct our business.

These laws and regulations may impact, among other things, our arrangements with third-party payors, healthcare professionals who participate in our clinical research programs, healthcare professionals and others who purchase, recommend, prescribe or arrange for the purchase or order of our approved products, and our proposed sales, marketing, distribution and education programs. The U.S. federal and state laws and regulations that may affect our ability to operate include, without limitation, the following:

- the federal Anti-Kickback Statute, which prohibits persons from, among other things, knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or arrangement for recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. The term "remuneration" has been broadly interpreted to include anything of value. The government can establish a violation of the Anti-Kickback Statute without proving that a person or entity had actual knowledge of the statute of specific intent to violate it;
- the federal civil False Claims Act, which imposes significant penalties and can be enforced by private citizens through civil qui tam actions, prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment of federal funds, and knowingly making or causing to be made a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. 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 federal False Claims Act. Criminal prosecution is also possible for making or presenting a false, fictitious or fraudulent claim to the federal government;

- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which, among other things, imposes criminal and civil liability for executing or attempting to execute a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering

  up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which impose obligations upon entities subject to the law, such as health plans, healthcare clearinghouses and healthcare providers and their respective business associates, including mandatory contractual terms with respect to safeguarding the privacy, security and transmission of individually identifiable health information and notification obligations in the event of a breach of the privacy or security of individually identifiable health information;

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

- the federal transparency requirements under the Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies reimbursed under Medicare, Medicaid, or CHIP to report to the U.S. Department of Health and Human Services information related to payments and other transfers of value provided to physicians and teaching hospitals and ownership and investment interests held by physicians and physician family members;

- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, that impose similar restrictions and may apply to items or services reimbursed by any non-governmental third-party payors, including private insurers; and

- state and foreign laws that require pharmaceutical companies to implement compliance programs, comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or to track and report gifts, compensation and other remuneration provided to physicians and other health care providers. Some of these states also prohibit certain marketing-related activities, including the provision of gifts, meals, or other items to certain health care providers, and restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs. In addition, there are other federal, state and foreign laws that govern the privacy and security of health information or personally identifiable information in certain circumstances, including state health information privacy and data breach notification laws which govern the collection, use, disclosure, and protection of health-related and other personal information, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus requiring additional compliance efforts.

Once we have an approved and marketed product in the United States, we will be required to spend substantial time and money to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations. Even then, governmental authorities may conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. Healthcare reform legislation has strengthened these federal and state healthcare laws. Violations of these laws can subject us to criminal, civil and administrative sanctions including imprisonment, monetary penalties, damages, fines, disgorgement, and exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, reputation harm, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and we may be required to curtail or restructure our operations. Moreover, we expect that there will continue to be federal and state laws and regulations, proposed and implemented, that could impact our future operations and business. The extent to which future legislation or regulations, if any, relating to healthcare fraud and abuse laws or enforcement, may be enacted or what effect such legislation or regulation would have on our business remains uncertain.

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 generally prohibited in the European Union.

The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of European Union Member States, such as the UK Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain EU 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 EU Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, civil penalties, fines or imprisonment.

***Failure to comply with data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business.***

We and our partners may be subject to federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the FTC Act), that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA, as amended by HITECH. Depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

International data protection laws, including the European Union Directive 95/46/EC (the EU Data Protection Directive) and member state implementing legislation, may also apply to health-related and other personal information obtained outside of the United States The EU Data Protection Directive and the national implementing legislation of the individual European Union Member States impose strict obligations on the ability to process health-related and other personal information of EU data subjects, including in relation to collection, analysis and transfer. These include 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. The EU Data Protection Directive prohibits the transfer of personal data to countries outside of the European Economic Area, or EEA, such as the United States, which are not considered by the European Commission to provide an adequate level of data protection. Switzerland has adopted similar restrictions.

Although there are legal mechanisms to allow for the transfer of personal data from the EEA and Switzerland to the United States, uncertainty about compliance with EU data protection laws remains and data protection authorities from the different EU Member States may interpret the EU Data Protection Directive and national laws differently, and guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal data in the EU.

In December 2015, a proposal for an EU General Data Protection Regulation, intended to replace the current EU Data Protection Directive, was agreed between the European Parliament, the Council of the European Union and the European Commission. The EU General Data Protection Regulation, which was officially adopted in April 2016 and will be applicable in May 2018, will introduce new data protection requirements in the EU, as well as substantial fines for breaches of the data protection rules. The EU General Data Protection Regulation will increase our responsibility and liability in relation to personal data that we process, and we may be required to put in place additional mechanisms to ensure compliance with the new EU data protection rules.

Failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, patients about whom we or our partners obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

***Our future success depends on our ability to retain key employees, consultants and advisors and to attract, retain and motivate qualified personnel.***

We are highly dependent on the management, research and development, clinical, financial and business development expertise of our executive officers, as well as the other members of our scientific and clinical teams. Although we have employment offer letters with each of our executive officers, each of them may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or employees.

Recruiting and retaining qualified scientific and clinical personnel and, if we are successful in obtaining marketing approval for AM0010 or other product candidates, sales and marketing personnel, is critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval for and commercialize our product candidates. Competition to hire qualified personnel in our industry is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. Furthermore, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited, and our business, prospects, financial condition and results of operations may be adversely affected.

***We expect to expand our product development capabilities and implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.***

As our development progresses, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of research, drug development, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations, which may adversely affect our business, prospects, financial condition or results of operations.

***Our anticipated international operations may expose us to business, regulatory, political, operational, financial, pricing and reimbursement risks associated with doing business outside of the United States.***

Our business strategy incorporates potential international expansion as we seek to obtain regulatory approval for, and commercialize, AM0010 in patient populations outside the United States. If AM0010 is approved, we may hire sales representatives and conduct physician and patient association outreach activities outside of the United States. Doing business internationally involves a number of risks, including but not limited to:

- multiple, conflicting, and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements, and other governmental approvals, permits, and licenses;
- failure by us to obtain and maintain regulatory approvals for the use of our products in various countries;
- rejection or qualification of foreign clinical trial data by the competent authorities of other countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism, and political unrest, outbreak of disease, boycotts, curtailment of trade, and other business restrictions;

- certain expenses including, among others, expenses for travel, translation and insurance; and
- regulatory and compliance risks that relate to anti-corruption compliance and record-keeping that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its accounting provisions or its anti-bribery provisions or provisions of anti-corruption or anti-bribery laws in other countries.

For example, in June 2016, the United Kingdom held a referendum and voted in favor of leaving the European Union. This has created political and economic uncertainty, particularly in the United Kingdom and the European Union, and could cause disruptions to, and create uncertainty surrounding, our business in the United Kingdom and European Union, and could have a material impact on the regulatory regime applicable to our operations in the United Kingdom.

Any of these factors could significantly harm our future international expansion and operations and, consequently, our results of operations.

***Even if we obtain FDA approval of any of our product candidates, we may never obtain approval or commercialize such products outside of the United States, which would limit our ability to realize their full market potential.***

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our target market will be reduced and our ability to realize the full market potential of our products will be harmed.

***Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.***

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, such as the recent global financial crisis, could result in a variety of risks to our business, including reduced ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

***Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.***

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards, or NOLs, and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. As a result, if we earn net taxable income, our ability to use our pre-change NOLs to offset such taxable income may be subject to limitations. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes, which could adversely affect our future cash flows.

***U.S. federal income tax reform could adversely affect us.***

On December 22, 2017, President Trump signed into law the "Tax Cuts and Jobs Act" (TCJA) that significantly reforms the Internal Revenue Code of 1986, as amended. The TCJA, among other things, includes changes to U.S. federal tax rates, imposes significant additional limitations on the deductibility of interest, allows for the expensing of capital expenditures, and puts into effect the migration from a "worldwide" system of taxation to a territorial system. We do not expect tax reform to have a material impact to our projection of minimal cash taxes or to our net operating losses. Our net deferred tax assets and liabilities will be revalued at the newly enacted U.S. corporate rate, and the impact will be recognized in our tax expense in the year of enactment. We continue to examine the impact this tax reform legislation may have on our business. The impact of this tax reform on holders of our common stock is uncertain and could be adverse. This Quarterly Report on Form 10-Q does not discuss any such tax legislation or the manner in which it might affect our stockholders or prospective stockholders. We urge our stockholders and prospective stockholders to consult with their legal and tax advisors with respect to such legislation and the potential tax consequences of investing in our common stock.

***We or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.***

Earthquakes or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

***Our internal information technology systems, or those of our third-party CROs or other contractors or consultants, may fail or suffer security breaches, loss or leakage of data, and other disruptions, which could result in a material disruption of our product candidates' development programs, compromise sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business***.

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit confidential information (including but not limited to intellectual property, proprietary business information and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have outsourced elements of our operations to third parties, and as a result we manage a number of third party contractors who have access to our confidential information.

Despite the implementation of security measures, given their size and complexity and the large amounts of confidential information that they maintain, our internal information technology systems and those of our third-party CROs and other contractors and consultants are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners, and/or other third parties, or from cyber-attacks by malicious third parties (including the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), which may compromise our system infrastructure or lead to data leakage.

While we have not experienced any such system failure, accident or security breach to date, there can be no assurances that our data protection efforts and our investment in information technology will prevent significant breakdowns, data leakages, breaches in our systems or other cyber incidents that could have a material adverse effect upon the reputation, business, operations or financial condition of the company. For example, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs and the further development of our product candidates could be delayed. In addition, the loss of clinical trial data for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Furthermore, significant disruptions of our internal information technology systems or security breaches could adversely affect our business and/or result in the loss, misappropriation, and/or unauthorized access, use, or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information, and personal information), which could result in financial, legal, business, and reputational harm to us. For example, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our

patients or employees, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

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

Among other matters, 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. Trade Laws also restrict the export or transfer of certain controlled equipment, materials, software and technology as well as transactions with certain restricted parties or sanctioned countries. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other adverse consequences. In particular, 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. We expect to rely on third parties for research, preclinical studies, and clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. Such interactions would inherently increase the risk of violating applicable Trade Laws. 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 Dependence on Third Parties**

***We rely on third parties to conduct our clinical trials and some aspects of our research and preclinical studies, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research or testing.***

We rely on third parties, such as contract research organizations, clinical data management organizations, medical institutions and clinical investigators, to conduct our clinical trials. We currently rely and expect to continue to rely on third parties to conduct some aspects of our research and preclinical studies. Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it would delay our product development activities.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as Good Clinical Practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our medicines.

We also rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our medicines, producing additional losses and depriving us of potential product revenue.

***We contract with third parties for the manufacture of our product candidates for preclinical studies, clinical trials and for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or medicines or that such supply will not be available to us at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.***

We do not have any manufacturing facilities. We currently rely, and expect to continue to rely, on third-party manufacturers for the manufacture of our product candidates for preclinical and clinical testing and for commercial supply of any of these product candidates for which we or our collaborators obtain marketing approval. We do not have a long term supply agreement with our third-party manufacturer, and we purchase our required drug supply on a purchase order basis.

We may be unable to establish or maintain supply agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish these agreements, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us; and
- reliance on the third party for regulatory compliance, quality assurance, and safety and pharmacovigilance reporting.

Third-party manufacturers may not be able to comply with current good manufacturing practices, or cGMP, regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or medicines, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our medicines and harm our business and results of operations.

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

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply for bulk drug substances. If any one of our current contract manufacturer cannot perform as agreed, we may be required to replace that manufacturer. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement.

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

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

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

***We may form or seek strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.***

We may form or seek strategic alliances, create joint ventures or collaborations or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

**Risks Related to Our Intellectual Property**

***If we are unable to obtain and maintain patent or trade secret protection for our product candidates and preclinical programs, or if the scope of the patent protection obtained is not of sufficient scope, our competitors could develop and commercialize medicines and technology similar or identical to ours, and our ability to successfully commercialize our products may be adversely affected.***

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates and preclinical programs. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies that are important to our business. Our pending and future patent applications may not result in patents being issued which protect our product candidates and/or preclinical programs or which effectively prevent others from commercializing competitive technologies, products or product candidates.

Obtaining and enforcing patents is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications, or maintain, enforce and/or license patents that may issue based on our patent applications, at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development results before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation, resulting in court decisions, including Supreme Court decisions, that have increased uncertainties as to the ability to enforce patent rights in the future. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa.

Further, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates and preclinical programs, and as a result the impact of such third-party intellectual property rights upon the patentability of our own patents and patent applications, as well as the impact of such third-party intellectual property upon our freedom to operate, is highly uncertain. Patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

***We cannot ensure that patent rights relating to inventions described and claimed in our pending patent applications will issue or that patents based on our patent applications will not be challenged and rendered invalid and/or unenforceable.***

There are multiple pending U.S. and foreign patent applications in our portfolio. However, we cannot predict:

- if and when patents may issue based on our patent applications;
- the scope of protection of any patent issuing based on our patent applications;
- whether the claims of any patent issuing based on our patent applications will provide protection against competitors,
- whether or not third parties will find ways to invalidate or circumvent our patent rights;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications;
- whether we will need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose; and/or
- whether the patent applications that we own or in-license will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries.

We cannot be certain that the claims in our pending patent applications directed to our product candidates and/or technologies will be considered patentable by the United States Patent and Trademark Office (USPTO) or by patent offices in foreign countries. One aspect of the determination of patentability of our inventions depends on the scope and content of the "prior art", that information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of

a patent claim. Even if the patents do issue based on our patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents in our portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position 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. In the event of litigation or administrative proceedings, we cannot be certain that the claims in any of our issued patents will be considered valid by courts in the United States or foreign countries. Certain of our patent applications are directed to methods of use of our product candidates. Patents containing claims only to such methods of use do not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products "off-label." Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

Patent rights are of limited duration. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from biosimilar or generic products. A patent term extension based on regulatory delay may be available in the United States. However, only a single patent can be extended for each regulatory approval, and any patent can be extended only once, for a single product. Moreover, the scope of protection during the period of the patent term extension does not extend to the full scope of the claim, but instead only to the scope of the product as approved. Laws governing analogous patent term extensions in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family. Additionally, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing drugs similar or identical to ours.

Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that patent applications in our portfolio were the first filed patent applications related to our product candidates.

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative product candidates in a non-infringing manner. Furthermore, changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. Furthermore, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States.

The United States has recently enacted, and is currently continuing to implement, wide-ranging patent reform legislation. The United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Additionally, the Leahy-Smith Act, enacted on September 16, 2011 implemented wide-ranging modifications to the United States patent law, the judicial interpretations and implementations of which remain highly uncertain. 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 future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would diminish the value of our patents and patent applications or narrow the scope of our patent protection or weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We may be subject to a third party pre-issuance submission of prior art to the USPTO and/or patent offices abroad, or become involved in opposition, derivation, revocation, reexamination, post-grant review, ex partes review, inter partes review or interference proceedings challenging our owned or licensed patent rights, or the patent rights of others, in the US and/or abroad. An adverse determination in any such submission, proceeding or litigation 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 medicines without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. Generic drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' patents. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and medicines. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

***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. To file and prosecute patent applications and defend and/or enforce patents relating to our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States is less extensive than those in the United States. Moreover, the standards of patentability are not the same worldwide and thus a finding of patentability in one jurisdiction provides no assurance that a patent office in a different jurisdiction will find the same or even narrower claims are patentable. In addition, the laws of some foreign countries do not protect intellectual property to the same extent as federal and state laws in the United States. Moreover, our patent strategy relies upon claims to protect methods of treatment, including methods of treatment that involve a combination therapy. Many foreign jurisdictions do not consider such method of treatment claims to be patent eligible subject matter and/or will only consider as patent eligible claims drawn to "use of" a composition in treatment. The scope and enforceability of such "use" claims is largely untested, and thus as associated with a high level of uncertainty as to the relative commercial value of such claims in preventing our competitors from infringing our foreign patent rights.

Because patents are of national or regional effect, 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, and further, we may not be able to prevent third parties from exporting otherwise infringing products to territories where we have patents, but where enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Additionally, certain countries in Europe and developing countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. 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.

To date, we have not sought to enforce any issued patents in these foreign jurisdictions. However, many companies have encountered significant problems in protecting and defending intellectual property 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 biotechnology products and treatment methods, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in such countries in violation of our proprietary rights generally.

Proceedings to enforce and/or defend our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, put our patents at risk of being invalidated or interpreted narrowly, put our patent applications at risk of not issuing, and 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 not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in-licenses.***

Because our programs may include multiple product candidates, one or more of such product candidates may require the use of proprietary rights held by third parties. Consequently, the growth of our business will likely depend in part on our ability to acquire, in-license or use such proprietary rights. The licensing and acquisition of third-party intellectual property rights is a competitive area

and companies (some of which 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. Thus, there can be no assurance that we will be able to successfully complete negotiations and ultimately acquire the rights to the intellectual property that we may seek to acquire in the future. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license alternative technology. Alternatively, or in addition to obtaining an exclusive or non-exclusive license to one or more third party patents, we may choose to expend resources to initiate litigation or administrative proceedings to invalidate such patent(s) and/or render such patent(s) unenforceable. Such proceedings will require significant financial and personnel resources which may result in the delay in the development of our product candidates.

***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.***

The USPTO and foreign governmental patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process in order to maintain the pendency of a patent application or the enforceability of issued patents. Examples of 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. Additionally, even after issuance of a patent, periodic maintenance fees or annuities are required by the USPTO and foreign patent agencies at multiple times during the life of the patent to maintain the patent in force, and many foreign patent agencies require payment of annuities while a patent application is still pending. Failure to timely pay such maintenance fees or annuities can result the lapse or abandonment of patent rights. In many cases, the patent or patent application can be reinstated by the payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in irrevocable abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Certain of the foregoing requirements which can affect pendency or enforceability of patents and patent applications are outside of our direct control such as non-U.S. patents and patent applications owned by us for which we must rely on third parties to take the requisite actions or for those patents and patent applications licensed to us by another entity for which we do not control prosecution. The loss of rights associated with our failure to comply with these procedural requirements may enable our competitors to enter the market, which would have a material adverse effect on our business.

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

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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

Our commercial success depends upon our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights and intellectual property of third parties. The biotechnology and pharmaceutical industries are characterized by an extensive history of litigation regarding patents and other intellectual property rights. In addition to litigation in the US and abroad, there is common recourse to administrative proceedings to challenge patents, including interference, post-grant review, inter-parties review and reexamination proceedings before the USPTO, as well as oppositions and comparable proceedings in foreign jurisdictions.

A patent does not grant the right to practice the scope of the claims by the patentee, but merely grants the right to exclude others from practicing the claimed invention. Therefore, there is no assurance that we have the right to practice within the scope of the claims of our own existing patents or patents that may issue based on our applications. We have not analyzed all patents or patent applications

of our competitors of which we are aware to determine whether our current or planned development activities fall within the pending or issued claims of the patent applications or patents of our competitors. to assess whether we are free to operate. Even where we have analyzed, or in the future will analyze, patents or patent applications of our competitors and conclude that we the development and commercialization of our product candidates does not fall within the scope of the pending or issued claims of such patents or patent or patent applications, our competitors may achieve issued claims that a court may interprets so as to subject us to infringement liability. Any of these outcomes could impair our ability to commercialize our product candidates and/or prevent competition from third parties, which may have an adverse impact on our business.

There may be third-party patents, of which we are currently unaware or have not sufficiently analyzed with claims to materials, formulations, methods of manufacture or methods for treatment related to the manufacture, use or sale of our product candidates. Numerous U.S. and foreign issued patents and pending patent applications, which 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. Furthermore, because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents in one or more jurisdictions that our product candidates may be alleged to infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents.

While our product candidates are in preclinical studies and clinical trials, we believe that their use in these preclinical studies and clinical trials falls within the scope of the exemptions provided by 35 U.S.C. Section 271(e) in the United States, which exempts from patent infringement liability activities reasonably related to the development and submission of information to the FDA. If and when our products are approved by the FDA, the exemption under 35 USC 271(e) is no longer applicable and a third party may then seek to enforce its patents by filing a patent infringement lawsuit against us or our licensee(s). Consequently, the lack of currently pending or threatened patent litigation should not be construed as an indication that third parties view commercialization of our technology that is currently in clinical development as non-infringing of their patent rights.

We are testing our product candidates in combination with other product candidates or products that may be covered by patents held by other companies or institutions. Combinations currently under clinical evaluation may result in label claims requiring the use of compositions covered by patents owned by third parties. In the event that a labeling instruction is required in product packaging recommending that combination, we could be accused of, or held liable for, direct, contributory or induced infringement of the third-party patents covering the product candidate or product recommended for administration with our product candidates.

Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. Thus, we may in the future become party to, or threatened with, litigation or other adversarial proceedings initiated by third parties regarding intellectual property rights with respect to, for example, our product candidates, preclinical and/or clinical programs, product candidate formulations, product candidate manufacturing, constructs or molecules used in or formed during the manufacturing process, methods of use, including combination therapies, or patient selection methods or any final product or technology.

We cannot provide any assurances that our activities relating to current candidate products, or any future product candidates that we may develop, do not or will not infringe existing or future third-party patents. The result of such litigation and/or other adversarial proceedings is highly unpredictable and may result in the loss or significant diminution of the scope of our patent rights relating to our product candidates potentially enabling third parties to compete with our products. Additionally, our participation in these proceedings can be prolonged and very expensive requiring us to divert assets from our discovery and development efforts which may adversely affect our development timelines.

Intellectual property litigation, as well as defense of patent rights in any legal proceeding in the US or abroad, is extremely expensive. Defense of infringement claims, and defense against third party assertions attacking patent rights, regardless of merit, would involve substantial expense and would be a substantial diversion of employee resources from our business. 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.

We may also be required to indemnify parties with whom we have contractual relationships against such claims. As a result, we could be forced to stop or delay research, development, manufacturing and/or sales of the product candidate that is the subject of the suit.

As a result of patent infringement claims, or in order to avoid potential claims, we could be required to obtain, or choose to seek, a license from a third party in order to continue developing, manufacturing, and/or marketing our product candidates and technology, and would most likely be required to pay license fees or royalties or both, that could be significant. If third parties are successful against us in litigation, such could cause us to pay substantial monetary damages, including treble damages and attorneys' fees if we

are found to be willfully infringing a third party's patents. In addition to monetary damages, a third party asserting a claim of infringement against us may be able to obtain preliminary, temporary or permanent injunctive relief to block our ability to develop and/or commercialize the product candidate unless we obtained a license under the applicable patent(s), or until such patents expire or are held invalid or unenforceable. Consequently, in the event we were held to infringe a patent of third party, there is no assurance that a license would be available on commercially reasonable terms or at all. Even if we were to obtain a license, the license may require significant up-front payments as well as ongoing payments and royalties based on sales of our products which may materially affect our revenue. Moreover, the license obtained could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us. As a general rule, a patentee is not under any obligation to grant a license to its patent rights, whether or not the patentee is practicing the patented technology. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, we may be required redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. Therefore, in the event that our product candidate(s) are found to infringe patent rights of a third party our ability to commercialize our product candidates may be prevented, impaired or delayed, which could in turn significantly harm our business.

Ultimately, a finding of infringement, or even a threat of infringement suit, could prevent us from commercializing our product candidates, force us to redesign our product candidates to avoid infringement, or force us to cease some or much of our business operations, which could materially harm our business. Even if we are successful in defending against such claims, such litigation is expensive and time consuming and would divert management's attention from our core business. Any of these events could harm our business significantly. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar substantial negative impact on our business.

In addition to or alternative to infringement claims against us, third parties may initiate interference, derivation, reexamination, post-grant review, ex partes review, inter partes review proceedings in the USPTO requiring our participation to defend our rights. We may also become involved in opposition proceedings in the European Patent Office or other patent offices in foreign jurisdictions regarding our intellectual property. The results of such proceedings can result in revocation, either in whole or in part, of the claims of the patent or result in significant restrictive amendments to the claims of such patents such that the surviving amended claims no longer cover our product candidates. In either the US or abroad, even if we are successful in defending our patent rights, such proceedings are expensive and time consuming and would divert management's attention from our core business.

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

Competitors may infringe our patents or the patents of our licensors. Notably, our and our licensors' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover the technology. Patents are not self-effectuating and too counter infringement or unauthorized use, we may be required or choose to pursue litigation against one or more third parties. Whether initiated by a third party against us, or initiated by us against a third party, and even if resolved favorably to us, litigation or other legal proceedings relating to intellectual property may cause us to incur significant expenses, as well as distract our technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios.

In addition, defendants in such infringement suits could counterclaim that the patent we seek to enforce, and which may also cover our product candidate, 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. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, indefiniteness, written description, non-enablement, or obviousness-type double patenting.

With respect to validity of our patents, we cannot be certain that there is no prior art that was not of record in the prosecution of our patent applications that is material to the patentability of the claims or that prior art that was cited during prosecution will not be reconsidered. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Thus, in the course of such litigation a court may decide that one or more of our patents is not valid or is unenforceable. 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 claims, regardless of their merit, would involve substantial expense and would be a substantial diversion of employee resources from our business. The outcome following legal assertions of invalidity and unenforceability is unpredictable. If a party were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patents directed to our product candidates. Such a loss of patent rights could have a material adverse impact on our business.

In addition, in an infringement proceeding, a court may refuse to stop the other party from making, using and/or selling the technology at issue in the infringement suit on the grounds that the claims of the asserted patent(s) do not cover the third party's activities that are the basis of the lawsuit. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, because substantial discovery can be required in connection with intellectual property litigation, there is a risk that confidential information could be compromised by disclosure during this type of litigation. There could also 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, it could have a material adverse effect on the price of our common stock.

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

Additionally, under the Merck Agreement, we have the first right, but not the obligation, to bring a suit to enforce the patent rights covering the compound or its manufacture or use that we license from Merck and patent rights we jointly own with Merck, against any infringer of such rights. Pursuant to the terms of the Merck Agreement, Merck is required to reasonably cooperate, and to join any suit brought by us, if necessary. Should we choose to bring suit against any third party infringer, we will be responsible for all fees and expenses for such action, which, like other litigation and legal proceeding, may result in significant expenses to us. If Merck chooses to join the suit, they will bear one-half of the fees and expenses. We will need Merck's written consent in order to enter into any settlement, if such settlement would cause Merck to incur any financial liability or require Merck to admit liability, wrongdoing or fault. Such additional steps that require Merck's cooperation may increase the time and expenses associated with such proceedings. If, within a specified period of receiving notice of infringement, we fail to obtain a discontinuance of infringement of a licensed patent right or a jointly owned patent right, or if we fail to bring suit against any infringer, Merck will have the right to bring a suit to enforce such patent rights, and we will similarly be required to cooperate and, if necessary, join the suit. If we choose to join a suit brought by Merck, we will bear one-half of the fees and expenses. Merck will also need our written consent in order to enter into any settlement if such settlement would cause us to incur any financial liability or require us to admit liability, wrongdoing or fault. Litigation or other legal proceedings we, or Merck, may bring in connection with protecting such licensed patents or our jointly owned patents may cause us to incur significant expenses, beyond that which we may incur in connection with protecting our own patent rights, as we may face additional challenges in enforcing rights to patents that we do not directly own and may incur additional expenses in connection with working with Merck or joining Merck to a suit, if necessary. In the event we are unsuccessful in a suit to protect such licensed patent rights or jointly owned patent rights and Merck brings a suit to protect such rights, we will be required to cooperate but will not have control over the suit or proceeding and may face challenges in managing such process and protecting our best interests.

***We rely on trade secret and proprietary know how which can be difficult to trace and enforce, and if we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.***

In addition to seeking patents for some of our technology and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Elements of our candidate products, including processes for their preparation and manufacture, involve proprietary know-how, information, or technology that is not covered by patents, and thus for these aspects we consider trade secrets and know-how to be our primary intellectual property. Any disclosure to, either intentional or unintentional, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Trade secrets and know-how can be difficult to protect. In particular, we anticipate that with respect to this technology platform, these trade secrets and know-how will over time be disseminated within the industry through independent development, the publication of journal articles describing the methodology, and the movement of personnel skilled in the art from academic to industry scientific positions.

We rely on written agreements to protect proprietary know-how that may or may not be patentable. We require our employees to enter into written employment agreements containing provisions of confidentiality and obligations to assign to us any inventions generated in the course of their employment. We further seek to protect our trade secrets, proprietary know-how, and information in part, by entering into non-disclosure and confidentiality agreements with parties who are given access to them, such as our corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties. Typically, we enter into confidentiality and invention or patent assignment agreements with our consultants, contractors, and outside scientific collaborators. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be harmed.

Furthermore, we cannot ensure that competitors will not gain access to our trade secrets or independently develop substantially equivalent information and techniques. We cannot ensure that technology which we choose to protect as a trade secret may not be independently developed by third parties who may file for and potentially obtain patent rights covering such technology giving them the potential to assert any such patent rights against us. Additionally, the laws of some foreign countries do not provide protection for trade secrets or proprietary rights to the same extent or in the same manner as the laws of the United States potentially generating significant problems in protecting and defending our intellectual property both in the United States and abroad. We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

***We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.***

We have received confidential and proprietary information from third parties. In addition, we employ individuals who have been previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

***Patent terms may be inadequate to protect our competitive position on our product candidates and preclinical programs 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 and preclinical programs 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 such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

***If we do not obtain protection under the Hatch-Waxman Amendments and similar foreign legislation for extending the term of patents covering each of our product candidates, our business may be materially harmed.***

Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, 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 Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents, or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced, possibly materially. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

**Risks Related to the Ownership of Our Common Stock**

***Our stock price has been subject to fluctuations and will likely continue to be subject to fluctuations and decline, due to factors beyond our control and you may lose all or part of your investment.***

The market price of our common stock is subject to wide fluctuations in response to various factors, some of which are beyond our control. Since shares of our common stock were sold in our initial public offering in January 2018 at a price of $17.00 per share, the reported high and low sales prices of our common stock has ranged from $57.19 to $27.00 through March 15, 2018. The market price of our common stock may fluctuate significantly in response to numerous factors, many of which are beyond our control, including:

- overall performance of the equity markets;
- our operating performance and the performance of other similar companies;
- results of clinical trials of AM0010 and any other future product candidates or those of our competitors;
- changes in our projected operating results that we provide to the public, our failure to meet these projections or changes in recommendations by securities analysts that elect to follow our common stock;
- regulatory or legal developments in the United States and other countries;
- the level of expenses related to AM0010 and any other future product candidates or clinical development programs;
- announcements of acquisitions, strategic alliances or significant agreements by us or by our competitors;
- recruitment or departure of key personnel;
- the economy as a whole and market conditions in our industry;
- trading activity by a limited number of stockholders who together beneficially own a majority of our outstanding common stock;
- the expiration of market standoff or contractual lock-up agreements;
- the size of our market float.

In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many immuno-oncology companies. Stock prices of many immuno-oncology companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies. In the past, stockholders have filed securities class action litigation following periods of market volatility. If we were to become involved in securities litigation, it could subject us to substantial costs, divert resources and the attention of management from our business and adversely affect our business.

***Substantial amounts of our outstanding shares may be sold into the market when lock-up or market standoff periods end. If there are substantial sales of shares of our common stock, the price of our common stock could decline.***

The price of our common stock could decline if there are substantial sales of our common stock, particularly sales by our directors, executive officers and significant stockholders, or if there is a large number of shares of our common stock available for sale. After our initial public offering in January 2018, we had approximately 30,405,109 outstanding shares of common stock. A significant majority of our outstanding shares of common stock are currently restricted from resale as a result of market standoff and "lock-up" agreements. These shares will become available to be sold 181 days after the date of our initial public offering, which occurred in January 2018. Shares held by directors, executive officers and other affiliates will be subject to volume limitations under Rule 144 under the Securities Act of 1933, as amended (the Securities Act), and various vesting agreements.

The market price of the shares of our common stock could decline as a result of the sale of a substantial number of our shares of common stock in the public market or the perception in the market that the holders of a large number of shares intend to sell their shares.

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

- the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- our ability to successfully recruit patients for preclinical studies and clinical trials, and any delays caused by difficulties in such recruitment efforts;
- our ability to obtain regulatory approval for our product candidates, and the timing and scope of any such approvals we may receive;
- the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time;
- the cost of manufacturing our product candidates, which may vary depending on the quantity of production and the terms of our agreements with manufacturers;
- our ability to attract, hire and retain qualified personnel;
- expenditures that we will or may incur to develop additional product candidates;
- the level of demand for our product candidates should they receive approval, which may vary significantly;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future drugs that compete with our product candidates;
- the changing and volatile U.S., European and global economic environments; and
- future accounting pronouncements or changes in our accounting policies.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide.

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

We are an "emerging growth company" as defined in the JOBS Act, and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- not being required to hold a non-binding advisory vote on executive compensation or obtain stockholder approval of any golden parachute payments not previously approved.

We cannot predict if investors will find our common stock less attractive because we will 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. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. 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 means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

***If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could result in sanctions or other penalties that would harm our business.***

The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal controls over financial reporting. Commencing with our fiscal year ending December 31, 2020, we must perform system and process design evaluation and testing of the effectiveness of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. This will require that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. We have never been required to test our internal controls within a specified period and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner.

We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls over financial reporting, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities.

***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 few securities analysts commence coverage of us, or if industry analysts cease coverage of us, the trading price for our common stock would be negatively affected. If one or more of the analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research about our business, our common stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our common stock price and trading volume to decline.

***We do not intend to pay dividends for the foreseeable future.***

We have never declared nor paid cash dividends on our capital stock. We currently intend to retain any future earnings to finance the operation and expansion of our business, and we do not expect to declare or pay any dividends in the foreseeable future. Consequently, stockholders must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investment.

***The concentration of our stock ownership will likely limit your ability to influence corporate matters, including the ability to influence the outcome of director elections and other matters requiring stockholder approval.***

As of March 15, 2018, our executive officers, directors and the holders of more than 5% of our outstanding common stock, in the aggregate, beneficially owned approximately 58.1% of our common stock. As a result, these stockholders, acting together, will have significant influence over all matters that require approval by our stockholders, including the election of directors and approval of significant corporate transactions. Corporate actions might be taken even if other stockholders oppose them. This concentration of ownership might also have the effect of delaying or preventing a change of control of our company that other stockholders may view as beneficial.

***Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock.***

Our status as a Delaware corporation and the anti-takeover provisions of the Delaware General Corporation Law may discourage, delay or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change of control would be beneficial to our existing stockholders. In addition, our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that may make the acquisition of our company more difficult, including the following:

- a classified board of directors with three-year staggered terms, which could delay the ability of stockholders to change the membership of a majority of our board of directors;
- the ability of our board of directors to issue shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of our board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by a majority vote of our entire board of directors, the chairman of our board of directors or our chief executive officer, which could delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors;
- the requirement for the affirmative vote of holders of at least 66 2/3% of the voting power of all of the then-outstanding shares of the voting stock, voting together as a single class, to amend the provisions

  of our amended and restated certificate of incorporation or our amended and restated bylaws, which may inhibit the ability of an acquirer to effect such amendments to facilitate an unsolicited takeover attempt; and
- advance notice procedures with which stockholders must comply to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

In addition, as a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation Law. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a certain period of time. A Delaware corporation may opt out of this provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of this provision.

These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law 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 our then-current board of directors, including delay or impede a merger, tender offer or proxy contest involving our company. The existence of these provisions could negatively affect the price of our common stock and limit opportunities for you to realize value in a corporate transaction.

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

Our amended and restated certificate of incorporation will provide that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our certificate of incorporation or our bylaws or any action asserting a claim against us that is governed by the internal affairs doctrine. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees and may discourage these types of lawsuits. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

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

***Use of Proceeds***

On January 25, 2018, our Registration Statements on Form S-1 (File Nos. 333-222371 and 333-222704) were declared effective by the SEC for our initial public offering of common stock, pursuant to which we sold an aggregate of 8,658,823 shares of our common stock at an initial public offering price of $17.00 per share. There has been no material change in the planned use of proceeds from our initial public offering as described in our Prospectus.

**Item 3. Defaults Upon Senior Securities.**

None.

**Item 4. Mine Safety Disclosures.**

Not applicable.

**Item 5. Other Information.**

None.

**Item 6. Exhibits.**

We have filed the exhibits listed on the accompanying Exhibit Index, which is incorporated herein by reference.

**Exhibit Index**

| Exhibit Number | Exhibit Description |
|---|---|
| 31.1 | Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 31.2 | Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 32.1† | Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 32.2† | Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 101.INS | XBRL Instance Document. |
| 101.SCH | XBRL Taxonomy Extension Schema Document. |
| 101.CAL | XBRL Taxonomy Extension Calculation Linkbase Document. |
| 101.DEF | XBRL Taxonomy Extension Definition Linkbase Document. |
| 101.LAB | XBRL Taxonomy Extension Label Linkbase Document. |
| 101.PRE | XBRL Taxonomy Extension Presentation Linkbase Document. |

† The certifications attached as Exhibit 32.1 and 32.2 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Coupa Software Incorporated under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

**SIGNATURES**

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

ARMO BioSciences, Inc.

Date: May 15, 2018

By: **/s/ Peter Van Vlasselaer, Ph.D.**
**Peter Van Vlasselaer, Ph.D.**
**Chief Executive Officer and Director**
***(Principal Executive Officer)***

Date: May 15, 2018

By: **/s/ Herb Cross**
**Herb Cross**
**Chief Financial Officer**
***(Principal Financial Officer)***

**Exhibit 31.1**

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER**
**PURSUANT TO**
**SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Peter Van Vlasselaer, certify that:

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

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

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

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

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

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

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

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

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

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

Date: May 15, 2018

By: */s/ Peter Van Vlasselaer*
Name: Peter Van Vlasselaer, Ph.D.
Title: **Chief Executive Officer**
**(Principal Executive Officer)**

**Exhibit 31.2**

**CERTIFICATION OF PRINCIPAL FINANCIAL AND ACCOUNTING OFFICER**
**PURSUANT TO**
**SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Herb Cross, certify that:

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

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

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

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

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

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

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

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

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

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

Date: May 15, 2018

By: */s/ Herb Cross*
Name: **Herb Cross**
Title: **Chief Financial Officer (Principal Financial and Accounting Officer)**

**Exhibit 32.1**

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

I, Peter Van Vlasselaer, Chief Executive Officer of ARMO BioSciences, Inc. (the "Company"), certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The quarterly report on Form 10-Q for the Company for the quarter ended March 31, 2018 (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 15, 2018

By: */s/ Peter Van Vlasselaer*
Name: **Peter Van Vlasselaer, Ph.D.**
Title: **Chief Executive Officer**
**(Principal Executive Officer)**

**Exhibit 32.2**

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

I, Herb Cross, Chief Financial Officer of ARMO BioSciences, Inc. (the "Company"), certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The quarterly report on Form 10-Q for the Company for the quarter ended March 31, 2018 (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 15, 2018

By: */s/ Herb Cross*
Name: **Herb Cross**
Title: **Chief Financial Officer (Principal Financial and Accounting Officer)**