# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**WASHINGTON, DC 20549**

# FORM 10-Q

**(Mark One)**

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

**For the quarterly period ended September 30, 2018**

**OR**

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

**For the transition period from _____ to _____**

**Commission File Number: 001-38672**

# ARVINAS, INC.
**(Exact Name of Registrant as Specified in its Charter)**

| **Delaware** | **47-2566120** |
|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(I.R.S. Employer Identification No.)** |
| **5 Science Park<br>395 Winchester Ave.<br>New Haven, Connecticut** | |
| **(Address of principal executive offices)** | **06511<br>(Zip Code)** |

**Registrant's telephone number, including area code: (203) 535-1456**

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 | ☒ | Small reporting company | ☒ |
| | | Emerging growth Company | ☒ |

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

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

As of November 01, 2018, the registrant had 32,350,972 shares of common stock, $0.001 par value per share, outstanding.

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## PART I—FINANCIAL INFORMATION

**Item 1. Financial Statements.**

### ARVINAS, INC. (SUCCESSOR TO ARVINAS HOLDING COMPANY, LLC) AND SUBSIDIARIES

### Condensed Consolidated Balance Sheets (unaudited)

| | September 30, 2018 | December 31, 2017 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 6,191,004 | $ 30,912,391 |
| Marketable securities | 83,602,865 | 8,258,982 |
| Account receivable | — | 25,000,000 |
| Other receivable | 2,178,878 | 1,040,452 |
| Prepaid expenses and other current assets | 3,545,309 | 316,903 |
| Total current assets | 95,518,056 | 65,528,728 |
| Property, equipment and leasehold improvements, net | 3,347,242 | 1,298,881 |
| Other assets | 20,760 | 20,760 |
| Total assets | $ 98,886,058 | $ 66,848,369 |
| **Liabilities and stockholders'/members' equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,300,760 | $ 596,527 |
| Accrued expenses | 4,851,146 | 3,545,936 |
| Deferred revenue | 13,501,056 | 13,553,136 |
| Current portion of long-term debt | 194,669 | 159,265 |
| Total current liabilities | 19,847,631 | 17,854,864 |
| Deferred revenue | 40,713,950 | 48,545,625 |
| Long term debt, net of current portion | 2,000,000 | 151,122 |
| Preferred unit warrant liability | — | 50,888 |
| Total liabilities | 62,561,581 | 66,602,499 |
| **Commitments and Contingencies** | | |
| Series A redeemable convertible preferred units, no par value, at redemption value, 22,463,665 units issued and outstanding at December 31, 2017 | — | 19,768,025 |
| Series B redeemable convertible preferred units, no par value, at redemption value, 24,977,489 units issued and outstanding at December 31, 2017 | — | 41,712,407 |
| Series A redeemable convertible preferred stock, $0.001 par value, at redemption value, 22,573,781 shares issued and outstanding at September 30, 2018 | 111,132,408 | — |
| Series B redeemable convertible preferred stock, $0.001 par value, at redemption value, 24,977,489 shares issued and outstanding at September 30, 2018 | 122,965,984 | — |
| Series C redeemable convertible preferred stock, $0.001 par value, at redemption value, 16,467,066 shares issued and outstanding at September 30, 2018 | 81,068,464 | — |
| Stockholders'/Members' equity: | | |
| Common units, no par value, 1,897,544 units issued and outstanding | — | 6,167 |
| Incentive units, no par value, 3,066,734 units issued as of December 31, 2017 | — | 1,186,419 |
| Common stock, $0.001 par value; 3,683,639 shares issued and outstanding as of September 30, 2018 | 3,684 | — |
| Accumulated deficit | (286,176,753) | (62,417,397) |
| Additional paid-in capital | 7,377,913 | — |
| Accumulated other comprehensive loss | (47,223) | (9,751) |
| Total members'/stockholders' equity | (278,842,379) | (61,234,562) |
| Total liabilities and members'/stockholders' equity | $ 98,886,058 | $ 66,848,369 |

*See accompanying notes*

**ARVINAS, INC. (SUCCESSOR TO ARVINAS HOLDING COMPANY, LLC) AND SUBSIDIARIES**

**Condensed Consolidated Statements of Operations and Comprehensive Loss (unaudited)**

| *Consolidated Statements of Operations* | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| Revenue | $ 3,375,264 | $ 1,668,861 | $ 10,883,755 | $ 5,006,583 |
| Operating expenses: | | | | |
| Research and development | 13,149,879 | 7,222,897 | 30,631,531 | 22,102,713 |
| General and administrative | 4,284,231 | 857,310 | 7,110,723 | 2,357,119 |
| Total operating expenses | 17,434,110 | 8,080,207 | 37,742,254 | 24,459,832 |
| Loss from operations | (14,058,846) | (6,411,346) | (26,858,499) | (19,453,249) |
| Other income (expenses) | | | | |
| Other income, net | 160,100 | 607 | 418,494 | 1,030 |
| Change in fair value of preferred unit warrant | — | 1,546 | (193,779) | 4,338 |
| Interest income | 523,338 | 24,140 | 1,273,988 | 165,606 |
| Interest expense | (12,264) | (12,219) | (32,804) | (38,905) |
| Total other income | 671,174 | 14,074 | 1,465,899 | 132,069 |
| Loss before income taxes | (13,387,672) | (6,397,272) | (25,392,600) | (19,321,180) |
| Benefit from income taxes | — | — | — | — |
| Net loss | (13,387,672) | (6,397,272) | (25,392,600) | (19,321,180) |
| Change in fair value of redeemable convertible preferred stock/units | (112,050,609) | — | (198,366,756) | — |
| Net loss attributable to common shares/units | $(125,438,281) | $ (6,397,272) | $(223,759,356) | $ (19,321,180) |
| Net loss per common share/unit, basic and diluted | $ (62.38) | $ (3.37) | $ (115.62) | $ (10.18) |
| Weighted average common shares/units outstanding, basic and diluted | 2,010,807 | 1,897,544 | 1,935,299 | 1,897,544 |

| *Consolidated Statements of Comprehensive Loss* | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| Net loss | $ (13,387,672) | $ (6,397,272) | $ (25,392,600) | $ (19,321,180) |
| Other comprehensive loss: | | | | |
| Unrealized gain (loss) on available-for-sale securities | 49,391 | 9,339 | (37,472) | 18,043 |
| Comprehensive loss | $ (13,338,281) | $ (6,387,933) | $ (25,430,072) | $ (19,303,137) |

*See accompanying notes*

## ARVINAS, INC. (SUCCESSOR TO ARVINAS HOLDING COMPANY, LLC) AND SUBSIDIARIES

### Condensed Consolidated Statements of Redeemable Convertible Preferred Units/Shares and Changes in Members'/Stockholders' Equity (unaudited)

| | Series A Redeemable Convertible Preferred | | Series B Redeemable Convertible Preferred | | Series C Redeemable Convertible Preferred | | Series A, B and C Convertible Preferred | |
|---|---|---|---|---|---|---|---|---|
| | Units | Amount | Units | Amount | Units | Amount | Shares | Amount |
| Balance at December 31, 2016 | 22,463,665 | $ 15,300,002 | 24,977,489 | $ 41,609,999 | — | $ — | — | $ — |
| Incentive unit-based compensation | — | — | — | — | — | — | — | — |
| Net loss | — | — | — | — | — | — | — | — |
| Unrealized gain on available-for-sale securities | — | — | — | — | — | — | — | — |
| Balance at September 30, 2017 | 22,463,665 | $ 15,300,002 | 24,977,489 | $ 41,609,999 | — | $ — | — | $ — |
| Balance at December 31, 2017 | 22,463,665 | $ 19,768,025 | 24,977,489 | $ 41,712,407 | — | $ — | — | $ — |
| Incentive unit-based compensation | — | — | — | — | — | — | — | — |
| Exercise of Series A redeemable convertible preferred warrant | 110,116 | 319,667 | — | — | — | — | — | — |
| Issuance of Series C redeemable convertible preferred units | — | — | — | — | 16,467,066 | 55,000,001 | — | — |
| Change in redemption value of redeemable convertible preferred units | — | 91,044,716 | — | 81,253,577 | — | 26,068,463 | — | — |
| Net loss | — | — | — | — | — | — | — | — |
| Conversion of redeemable convertible preferred units to redeemable convertible preferred shares | (22,573,781) | (111,132,408) | (24,977,489) | (122,965,984) | (16,467,066) | (81,068,464) | 64,018,336 | 315,166,856 |
| Conversion of common and incentive units to common and restricted stock | — | — | — | — | — | — | — | — |
| Unrealized loss on available-for-sale securities | — | — | — | — | — | — | — | — |
| Balance at September 30, 2018 | — | $ — | — | $ — | — | $ — | 64,018,336 | $ 315,166,856 |

| | Common | | Common | | Incentive | | Accumulated Deficit | Additional Paid-in Capital | Accumulated Other Comprehensive Loss | Total Members' /Stockholders' Equity |
|---|---|---|---|---|---|---|---|---|---|---|
| | Units | Amount | Shares | Amount | Units | Amount | | | | |
| Balance at December 31, 2016 | 1,897,544 | $ 6,167 | — | $ — | 9,966,886 | $ 941,371 | $ (33,797,760) | $ — | $ (28,679) | $ (32,878,901) |
| Incentive unit-based compensation | — | — | — | — | 232,329 | 162,901 | — | — | — | 162,901 |
| Net loss | — | — | — | — | — | — | (19,321,180) | — | — | (19,321,180) |
| Unrealized gain on available-for-sale securities | — | — | — | — | — | — | — | — | 18,043 | 18,043 |
| Balance at September 30, 2017 | 1,897,544 | $ 6,167 | — | $ — | 10,199,215 | $ 1,104,272 | $ (53,118,940) | $ — | $ (10,636) | $ (52,019,137) |
| Balance at December 31, 2017 | 1,897,544 | $ 6,167 | — | $ — | 11,927,381 | $ 1,186,419 | $ (62,417,397) | $ — | $ (9,751) | $ (61,234,562) |
| Incentive unit/share-based compensation | — | — | — | — | 5,424,605 | 6,189,011 | — | — | — | 6,189,011 |
| Exercise of Series A redeemable convertible preferred warrant | — | — | — | — | — | — | — | — | — | — |
| Issuance of Series C redeemable convertible preferred units | — | — | — | — | — | — | — | — | — | — |
| Change in redemption value of redeemable convertible preferred units | — | — | — | — | — | — | (198,366,756) | — | — | (198,366,756) |
| Net loss | — | — | — | — | — | — | (25,392,600) | — | — | (25,392,600) |
| Conversion of redeemable convertible preferred units to redeemable convertible preferred shares | — | — | — | — | — | — | — | | — | — |
| Conversion of common and incentive units to common and restricted stock | (1,897,544) | (6,167) | 3,683,639 | 3,684 | (17,351,986) | (7,375,430) | — | 7,377,913 | — | — |
| Unrealized loss on available-for-sale securities | — | — | — | — | — | — | — | — | (37,472) | (37,472) |
| Balance at September 30, 2018 | — | $ — | 3,683,639 | $ 3,684 | — | $ — | $ (286,176,753) | $ 7,377,913 | $ (47,223) | $ (278,842,379) |

*See accompanying notes*

**ARVINAS, INC. (SUCCESSOR TO ARVINAS HOLDING COMPANY, LLC) AND SUBSIDIARIES**

**Condensed Consolidated Statements of Cash Flows (unaudited)**

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2018 | 2017 |
| **Cash flows from operating activities:** | | |
| Net loss | $ (25,392,600) | $ (19,321,180) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Amortization of debt discount | 13,473 | 13,473 |
| Change in fair value of preferred unit warrant liability | 193,779 | (4,338) |
| Depreciation and amortization | 483,052 | 246,367 |
| Net accretion of bond discounts/premiums | 213,190 | 312,561 |
| Non-cash compensation | 6,189,011 | 162,901 |
| Changes in operating assets and liabilities: | | |
| Account receivable | 25,000,000 | — |
| Other receivable | (1,138,426) | 887,835 |
| Prepaid expenses and other current assets | (2,565,154) | 22,940 |
| Accounts payable | 704,233 | (648,028) |
| Accrued expenses | 319,657 | 289,802 |
| Deferred revenue | (7,883,755) | (5,006,582) |
| Net cash used in operating activities | (3,863,540) | (23,044,249) |
| **Cash flows from investing activities:** | | |
| Purchase of marketable securities | (114,393,545) | — |
| Maturities of marketable securities | 38,799,000 | 12,033,000 |
| Sales of marketable securities | — | 9,077,435 |
| Purchase of property, equipment and leasehold improvements | (2,209,112) | (577,859) |
| Net cash provided by (used in) investing activities | (77,803,657) | 20,532,576 |
| **Cash flows from financing activities:** | | |
| Repayments of long term debt | (129,191) | (119,885) |
| Proceeds from long term debt | 2,000,000 | — |
| Proceeds from sale of redeemable convertible preferred units | 55,000,001 | — |
| Proceeds from exercise of redeemable convertible preferred warrant | 75,000 | — |
| Net cash provided by (used in) financing activities | 56,945,810 | (119,885) |
| Net decrease in cash and cash equivalents | (24,721,387) | (2,631,558) |
| Cash and cash equivalents, beginning of the period | 30,912,391 | 5,088,548 |
| Cash and cash equivalents, end of the period | $ 6,191,004 | $ 2,456,990 |
| **Supplemental disclosure of cash flow information:** | | |
| Purchases of property, equipment and leasehold improvements unpaid at period end | $ 322,301 | $ - |
| Deferred offering costs included in accrued expenses | $ 663,252 | $ - |
| Cash paid for interest | $ 19,331 | $ 25,433 |
| Change in redemption value of preferred units | $ (198,366,756) | $ - |

*See accompanying notes*

**Notes to Condensed Consolidated Financial Statements (unaudited)**

***1. Nature of Business***

Arvinas, Inc. (Arvinas) has five wholly owned subsidiaries, Arvinas Operations, Inc., Arvinas Androgen Receptor, Inc., Arvinas Estrogen Receptor, Inc., Arvinas BRD4, Inc. and Arvinas Winchester, Inc. (collectively, the Company). The Company is a biopharmaceutical company dedicated to improving the lives of patients suffering from debilitating and life-threatening diseases throughout the discovery, development and commercialization of therapies to degrade disease-causing proteins. The Company expects to incur additional operating losses and negative operating cash flows for the foreseeable future.

On October 1, 2018, the Company completed an initial public offering (IPO) in which the Company issued and sold 7,500,000 shares of common stock at a public offering price of $16.00 per share. In October 2018, the underwriters of the IPO exercised in part their option to purchase 200,482 additional shares of the Company's common stock at an offering price of $16.00 per share. The Company's aggregate gross proceeds from the sale of shares in the IPO, including the option, was $123.2 million before fees and expenses of $12.0 million, of which $2.8 million were recorded within Other current assets as of September 30, 2018.

The Company's Board of Managers approved a one-for-3.25 reverse stock split of its issued and outstanding shares of common units and a proportional adjustment to the existing conversion ratios for the Company's Series A, Series B, and Series C preferred units effective as of September 14, 2018. Accordingly, all share/unit and per share/unit amounts for all periods presented in the accompanying financial statements and notes thereto have been retroactively adjusted, where applicable, to reflect this reverse unit split and adjustment of the preferred unit conversion ratios. Immediately prior to the effectiveness of the registration statement on September 26, 2018, the Company converted from a Delaware limited liability company to a Delaware corporation. Pursuant to the plan of conversion, each outstanding Series A, Series B, and Series C preferred units converted into an equal number of shares of Series A, Series B, and Series C preferred stock, each outstanding common unit converted into a share of common stock and each outstanding incentive unit converted into a number of shares of common stock and restricted stock based on a conversion price determined by the board of directors. The Company issued 1,786,095 shares of common stock and 1,268,923 shares of restricted stock.

On October 1, 2018, all of the outstanding shares of convertible preferred stock automatically converted into 19,697,928 shares of common stock at the applicable conversion ratio then in effect. Subsequent to the closing of the IPO, there were no shares of preferred stock outstanding. The financial statements as of September 30, 2018, including share and per share amounts, do not give effect to the IPO, as it closed on October 1, 2018.

***2. Summary of Significant Accounting Policies***

***Unaudited Interim Financial Statements***

The accompanying condensed consolidated financial statements are unaudited and have been prepared by the Company in accordance with accounting principles generally accepted in the United States (U.S. GAAP) and pursuant to the rules and regulations of the Securities and Exchange Commission. The year-end condensed consolidated balance sheet data was derived from the Company's audited financial statements but does not include all disclosures required by U.S. GAAP. These condensed consolidated financial statements should be read in conjunction with the Company's audited financial statements for the year ended December 31, 2017 included in the Company's final prospectus for its IPO, filed pursuant to Rule 424(b) under the Securities Exchange Act of 1933, as amended, with the Securities Exchange Commission on September 27, 2018 (the Prospectus). The condensed consolidated financial statements, in the opinion of management, reflect all normal and recurring adjustments necessary for a fair statement of the Company's financial position and results of operations.

***Recently Issued Accounting Pronouncements***

In February 2016, the FASB issued ASU No. 2016-02, *Leases*. ASU 2016-02 requires lessees to present right-of-use assets and lease liabilities on the balance sheet for all leases with terms longer than 12 months. The guidance is to be applied using a modified retrospective approach at the beginning of the earliest comparative period in the financial statements and is effective for years beginning after December 15, 2018. Early adoption is permitted. The Company is still in the process of determining the effect that the adoption of ASU 2016-02 will have on the accompanying consolidated financial statements.

During the nine months ended September 30, 2018, there were no changes to the Company's significant accounting policies as described in Note 2 to the financial statements included in the Company's consolidated financial statements as of December 31, 2017 and 2016 and for the years then ended included in the Prospectus.

***3. Research Collaboration and License Agreements***

In December 2017, the Company entered into a Research Collaboration and License Agreement with Pfizer, Inc. (the Pfizer Agreement) Under the terms of the Pfizer Agreement, the Company received an upfront non-refundable payment and certain additional payments totaling $28.0 million in the nine months ended September 30, 2018 in exchange for use of the Company's technology license and to fund Pfizer-related research as defined within the agreement. These payments are being recognized as revenue over the total estimated period of performance. The Company is also eligible to receive up to an additional $37.5 million in non-refundable option payments if Pfizer exercises its options for all targets under the agreement. The Company is also entitled to receive up to $225 million in development milestone payments and up to $550 million in sales-based milestone payments for all designated targets under the Pfizer Agreement, as well as tiered royalties based on sales.

In September 2015, the Company entered into an Option and License Agreement with Genentech, Inc. and F. Hoffman-La Roche Ltd. (the Genentech Agreement). During 2015, the Company received an upfront non-refundable payment of $11.0 million in exchange for use of the Company's technology license and to fund Genentech-related research as defined within the Genentech agreement. In November 2017, the Company entered into an Amended and Restated Option, License, and Collaboration Agreement with Genentech, Inc. and F. Hoffman-La Roche Ltd. (the Genentech Modification), amending the Genentech Agreement. Under the Genentech Modification, the Company received additional upfront non-refundable payments of $34.5 million to fund Genentech-related research and Genentech has the right to designate up to ten targets. The Company is eligible to receive up to $27.5 million in additional expansion target payments if Genentech exercises its options on all remaining targets. Upfront non-refundable payments are recognized as revenue over the total estimated period of performance. The Company is eligible to receive up to $44.0 million per target in development milestone payments, $52.5 million in regulatory milestone payments and $60.0 million in commercial milestones based on sales thresholds as well as tiered royalties based on sales.

In April 2015, the Company entered into a Research Collaboration and License Agreement with Merck Sharp & Dohme Corp. (the Merck Agreement). During 2015, the Company received an upfront non-refundable payment of $7 million, which is being recognized as revenue over the total estimated period of performance, in exchange for use of the Company's technology license. The Merck Agreement also provided for research program funding to support Merck-related research. The Merck Agreement expired in April 2018.

Information about contract liabilities is as follows:

| | September 30, 2018 | December 31, 2017 |
|---|---|---|
| Contract liabilities | $ 54,215,006 | $ 62,098,761 |
| Revenues recognized in the period from: | | |
| Amounts included in deferred revenue in previous periods | $ 10,354,342 | $ 6,600,000 |

Changes in deferred revenue from December 31, 2017 to September 30, 2018 were due to billings of $3.0 million under the Pfizer Agreement and $10.9 million of revenue recognized on the research collaboration and license agreements.

The aggregate amount of the transaction price allocated to performance obligations that are unsatisfied as of September 30, 2018 was $54.2 million, which is expected to be recognized as revenue in years ending:

| | December 31 |
|---|---|
| Remainder of 2018 | $ 3.4 |
| 2019 | 13.5 |
| 2020 | 13.5 |
| 2021 | 13.5 |
| 2022 | 8.6 |
| 2023 | 1.7 |
| | $ 54.2 |

***4. Fair Value Measurements***

ASC Topic 820, *Fair Value Measurements and Disclosures*, requires disclosure of the fair value of financial instruments held by the Company. ASC 825, *Financial Instruments*, defines fair value and establishes a three-level valuation hierarchy for disclosures of fair value measurement that enhances disclosure requirements for fair value measures. The Company's principal financial instruments are comprised of cash, marketable securities, accounts receivable, accounts payable, accrued liabilities and long-term debt. The carrying value of all financial instruments approximates fair value. The three levels of valuation hierarchy are defined as follows:

Level 1—Inputs are based upon observable or quoted prices for identical instruments traded in active markets.

Level 2—Inputs are based upon quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, and model-based valuation techniques for which all significant assumptions are observable in the market or can be corroborated by observable market data for substantially the full term of the assets or liabilities. The Company's Level 2 investments consist primarily of corporate notes and bonds and U.S. government and agency securities.

Level 3—Inputs are generally unobservable and typically reflect management's estimates of assumptions that market participants would use in pricing the asset or liability. The fair values are therefore determined using model-based techniques that include option pricing models, discounted cash flow models, and similar techniques.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as considers counterparty credit risk in its assessment of fair value.

The Company's marketable securities consist of corporate bonds and a government bond which are adjusted to fair value each balance sheet date, based on quoted prices, which are considered Level 2 inputs. The fair value of the preferred unit warrant liability is measured on a recurring basis and is considered a Level 3 instrument in the fair value hierarchy. See Note 7 for the valuation method used and significant assumptions used in the valuation.

The following is a summary of the Company's available-for-sale securities as of September 30, 2018 and December 31, 2017.

***September 30, 2018***

| Description | Effective Maturity | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
|---|---|---|---|---|---|
| Corporate bonds | 2018-2019 | $82,650,526 | — | (46,931) | $82,603,595 |
| Government securities | 2018 | 999,562 | | (292) | 999,270 |
| | | $83,650,088 | — | (47,223) | $83,602,865 |

***December 31, 2017***

| Description | Effective Maturity | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
|---|---|---|---|---|---|
| Corporate bonds | 2018 | $ 8,268,732 | — | $ (9,751) | $ 8,258,982 |

The following tables summarize the fair values and levels within the fair value hierarchy in which the fair value measurements fall for assets and liabilities measured on a recurring basis as of:

***September 30, 2018***

| Description | Level 1 | Level 2 | Level 3 | Total |
|---|---|---|---|---|
| Assets: | | | | |
| Corporate bonds | $ — | $ 82,603,595 | $ — | $ 82,603,595 |
| Government securities | $ — | $ 999,270 | $ — | $ 999,270 |

***December 31, 2017***

| Description | Level 1 | Level 2 | Level 3 | Total |
|---|---|---|---|---|
| Assets: | | | | |
| Corporate bonds | $ — | $ 8,258,982 | $ — | $ 8,258,982 |
| Liabilities: | | | | |
| Preferred unit warrant liability | $ — | $ — | $ 50,888 | $ 50,888 |

The following table presents the changes in Level 3 instruments measured on a recurring basis for the nine months ended September 30, 2018 and 2017:

| | Preferred Unit Warrant Liability | |
|---|---|---|
| | September 30, 2018 | September 30, 2017 |
| Balance at beginning of period | $ 50,888 | $ 56,759 |
| Change in fair value | 193,779 | (4,338) |
| Exercise of warrant | (244,667) | — |
| Balance at end of period | $ — | $ 52,421 |

Fluctuation in the fair value of the Company's Series A redeemable convertible preferred units is the primary driver for the change in the fair value of the Preferred Unit Warrant liability. As the fair value of the Series A redeemable convertible preferred units increase, the value to the holder of the instrument generally increases. Additionally, unit price volatility is one of the significant unobservable inputs used in the fair value measurement of the Company's Preferred Unit Warrant liability. Decreases in expected volatility would generally result in a lower fair value measurement.

***5. Property, Equipment and Leasehold Improvements***

Property, equipment and leasehold improvements consist of the following at:

| | September 30, 2018 | December 31, 2017 |
|---|---|---|
| Laboratory equipment | $ 3,579,854 | $ 1,952,685 |
| Office equipment | 547,328 | 305,522 |
| Leasehold improvements | 730,643 | 72,294 |
| | 4,857,825 | 2,330,501 |
| Less: accumulated depreciation | (1,510,583) | (1,031,620) |
| Property, equipment and leasehold improvements, net | $ 3,347,242 | $ 1,298,881 |

Depreciation expense totaled $191,547 and $92,147 for the three months ended September 30, 2018 and 2017, respectively, and $483,052 and $246,367 for the nine months ended September 30, 2018 and 2017, respectively.

***6. Accrued Expenses***

Accrued expenses consisted of the following at:

| | September 30, 2018 | December 31, 2017 |
|---|---|---|
| Employee expenses | $ 1,784,061 | $ 1,047,022 |
| Research and development expenses | 1,912,377 | 1,982,525 |
| Professional fees and other | 1,154,708 | 516,389 |
| | $ 4,851,146 | $ 3,545,936 |

***7. Long-Term Debt***

In August 2013, Arvinas, Inc. entered into a Loan Agreement and a Stock Subscription Warrant, with Connecticut Innovations, Inc. (CII). Under the Loan Agreement, the Company can draw up to $750,000 for the purpose of purchasing laboratory equipment, information technology equipment and leasehold improvements. Leasehold improvements are limited to $100,000. Interest on the loan is compounded on a monthly basis at a rate of 7.50% per annum and is required to be paid on a monthly basis beginning on the date of the first draw of funds for 10 months, then with principal payments beginning on June 1, 2015 and payable monthly until the maturity date of July 31, 2019. The Company has the ability to prepay the amount due at any time prior to the maturity date without premium or penalty. The loan is secured by substantially all of the Company's assets. As of September 30, 2018, and December 31, 2017, the amount outstanding under the Loan Agreement was $214,309 and $343,500, respectively.

In connection with the issuance of the loan, and as additional consideration, Arvinas, Inc. granted CII a warrant to purchase 110,116 shares of Arvinas, Inc. Series A Preferred Stock at a purchase price of $0.6811 per share, with a term of 7 years from the date of issuance (CII Series A Preferred Stock Warrant). Effective January 1, 2015, the CII Series A

Preferred Stock Warrant was exchanged for a warrant to purchase 110,116 units of the Company's Series A redeemable convertible preferred units (CII Series A Preferred Unit Warrant). In July 2018, CII exercised the CII Series A Preferred Unit Warrant. The fair value of the CII Series A Preferred Unit Warrant of $61,796 was determined using the Black-Scholes option pricing model and was recorded as a debt discount and is being amortized as non-cash interest expense over the term of the loan. At September 30, 2018 and Dec ember 31, 2017, the total unamortized debt discount on the loan totaled $10,299 and $19,569, respectively. Interest expense recorded related to the amortization of the debt discount in each of the nine months ended September 30, 2018 and 2017 was $9,269. The Company evaluated the CII Series A Preferred Unit Warrant issued under authoritative guidance and determined that the CII Series A Preferred Unit Warrant does not meet the conditions to be classified as equity and has classified the CII Series A Preferred Unit Warrant as a liability at fair value on the accompanying condensed consolidated balance sheets.

The fair value of the CII Series A Preferred Unit Warrant was determined using the Black-Scholes option pricing model with the following assumptions:

| | December 31, 2017 |
|---|---|
| Expected volatility | 100% |
| Expected term (years) | 2.67 |
| Risk free interest rate | 1.91% |
| Expected dividend yield | 0% |
| Fair value of underlying Series A redeemable convertible preferred units | $ 0.98 |

In January 2014, Arvinas, Inc. entered into an Assistance Agreement with the State of Connecticut (2014 Assistance Agreement). Under the terms of the 2014 Assistance Agreement, the Company could borrow from the State of Connecticut in three separate tranches if it meets minimum financing criteria and creates a minimum number of full time jobs in the State of Connecticut. Each of the three tranches were forgivable if the Company maintained a minimum number of full time jobs in the State of Connecticut for a minimum period at the minimum annual salary as defined in the 2014 Assistance Agreement. The 2014 Assistance Agreement requires that the Company be located in the State of Connecticut through January 2024 with a default penalty of repayment of the full original funding amount of $2.5 million plus liquidated damages of 7.5%. Each of the three tranches was forgiven and, in the period forgiven, the amount forgiven was recorded as a component of other income, as it is reasonably assured that the Company will comply with the location requirement.

In June 2018, Arvinas, Inc. entered into an Assistance Agreement with the State of Connecticut (2018 Assistance Agreement) to provide funding for the expansion and renovation of laboratory and office space (Project). Under the terms of the 2018 Assistance Agreement, the Company could borrow from the State of Connecticut a maximum of $2.0 million, provided that the funding does not exceed more than 50% of the total Project costs. In September 2018, the Company borrowed $2.0 million under the 2018 Assistance Agreement, bearing interest at 3.25% per annum and interest payments will be required for the first 60 months from the funding date. Thereafter, the loan begins to fully amortize through month 120, maturing in June 2028. According to the terms of the 2018 Assistance Agreement, up to $1.0 million of the funding can be forgiven if the Company meets certain employment conditions, as defined in the agreement. The Company may also be required to prepay a portion of the loan if the employment conditions are not met. The 2018 Assistance Agreement requires that the Company be located in the State of Connecticut through June 2028 with a default penalty of repayment of the full original funding amount of $2.0 million plus liquidated damages of 7.5% of the total amount of funding received.

Anticipated future minimum payments on long-term debt, excluding the discount on debt of $10,299, for the years ending December 31 are:

| | |
|---|---|
| 2018 | $ 29,706 |
| 2019 | 184,603 |
| Beyond 5 years | 2,000,000 |
| Total | $ 2,214,309 |

During the three months ended September 30, 2018 and 2017, interest expense was $12,264 and $12,219, respectively. During the nine months ended September 30, 2018 and 2017, interest expense was $32,804 and $38,905, respectively.

***8. Incentive Equity Plans***

In the Fourth Amendment to the Company's Incentive Share Plan (the Incentive Plan) adopted in March 2018, the Company was authorized to issue up to an aggregate of 6,199,477 incentive units pursuant to the Incentive Plan. Generally, incentive units were granted at no less than fair value as determined by the board of managers and had vesting periods ranging from one to four years. The Incentive Plan was terminated in September 2018. In September 2018, the Company's board of directors adopted and the Company's stockholders approved the 2018 Stock Incentive Plan (the 2018 Plan), which became effective upon the effectiveness of the registration statement on Form S-1 for the Company's IPO. The number of common shares initially available for issuance under the 2018 Plan is the sum of (1) 4,067,007 shares of common stock; plus (2) the number of shares of common stock (up to 1,277,181) issued in respect of incentive units granted under the Incentive Plan that are subject to vesting immediately prior to the effectiveness of the registration statement that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by the Company at their original issuance price pursuant to a contractual repurchase right; plus (3) an annual increase on the first day of each fiscal year beginning with the fiscal year ending December 31, 2019 and continuing to, and including, the fiscal year ending December 31, 2028, equal to the lowest of 4,989,593 shares of the Company's common stock, 4% of the number of shares of the Company's common stock outstanding on the first day of the fiscal year and an amount determined by the Company's board of directors.

During the nine months ended September 30, 2018, the Company granted 1,715,368 incentive units to employees and directors under the Incentive Plan. The weighted average fair value of incentive units granted to employees in the nine months ended September 30, 2018 was $4.54 per unit. In September 2018, each outstanding incentive unit was converted into a number of shares of common stock based upon the IPO price. Certain of the shares of common stock issued in respect of incentive units continue to be subject to vesting in accordance with the vesting schedule that was applicable to such incentive units, The Company granted 1,257,826 restricted shares to employees and directors as part of the conversion. The Company also granted 1,744,650 stock options to purchase shares of common stock to employees and directors who were holders of incentive units at the time of the incentive unit conversion and 186,150 in new employee grants. The weighted average fair value of stock options granted to employees and directors in the nine months ended September 30, 2018 was $9.87 per share.

During the nine months ended September 30, 2018, the Company recognized compensation expense of $5,195,802 relating to the issuance of employee and director incentive units, and at September 30, 2018, there was approximately $18,900,000 of compensation expense that is expected to be amortized over a weighted average period of approximately three years.

In September 2018, in connection with the conversion of the incentive units, the Company granted 11,097 restricted shares of common stock and 251,010 stock options to purchase shares of common stock to consultants. During the nine months ended September 30, 2018, the Company recognized compensation expense of $993,209 relating to consultant incentive grants and, at September 30, 2018, there was $2,260,078 of compensation expense remaining to be amortized over a weighted average period of approximately two years.

The fair value of the incentive common units granted during the nine months ended September 30, 2018 and 2017 was determined using the Black-Scholes option pricing model with the following assumptions:

| | September 30, 2018 | September 30, 2017 |
|---|---|---|
| Expected volatility | 66-71% | 75-78% |
| Expected term (years) | 5.6-6.1 | 1.5-6.1 |
| Risk free interest rate | 2.5-2.9% | 1.1-2.1% |
| Expected dividend yield | 0% | 0% |
| Fair value of underlying common units | $1.08-8.48 | $ 0.72 |

The fair value of the underlying common units indicated above was utilized as the exercise price within the Black-Scholes option pricing model.

The fair value of the stock options granted during the nine months ended September 30, 2018 was determined using the Black-Scholes option pricing model with the following assumptions:

| | September 30, 2018 |
|---|---|
| Expected volatility | 68% |
| Expected term (years) | 5.0-10.0 |
| Risk free interest rate | 2.9-3.0% |
| Expected dividend yield | 0% |
| Exercise price | $ 16.00 |

The following table provides a summary of the incentive unit activity under the Incentive Plan in the nine months ended September 30, 2018. These amounts include incentive units granted to employees, directors and consultants.

| | Units | Weighted Average Fair Value |
|---|---|---|
| Outstanding at December 31, 2017 | 3,669,963 | $ 0.45 |
| Granted | 1,715,368 | $ 4.54 |
| Forfeited | (34,982) | $ 4.85 |
| Cancelled | (5,350,349) | $ 1.86 |
| Outstanding at September 30, 2018 | — | $ — |

The following table provides a summary of the restricted stock grant activity under the Incentive Plan in the nine months ended September 30, 2018. These amounts include restricted stock granted to employees, directors and consultants.

| | Shares | Weighted Average Grant Date Fair Value Per Share |
|---|---|---|
| Unvested restricted stock at December 31, 2017 | — | $ — |
| Granted | 1,268,923 | $ 16.00 |
| Unvested restricted stock at September 30, 2018 | 1,268,923 | $ 16.00 |

The following table provides a summary of the stock option activity under the 2018 Plan in the nine months ended September 30, 2018. These amounts include stock options granted to employees, directors and consultants.

| | Options | Weighted Average Fair Value |
|---|---|---|
| Outstanding at December 31, 2017 | — | $ — |
| Granted | 2,181,810 | $ 10.13 |
| Outstanding at September 30, 2018 | 2,181,810 | $ 10.13 |
| Exercisable at September 30, 2018 | 357,658 | $ 9.62 |

The 1,995,660 stock options to purchase shares of common stock to employees, directors, and consultants granted at the time of the incentive unit conversion have the same vesting terms as the profit units that were outstanding in September 2018 before the profit interests were converted into common stock. At the time of issuance of the stock options, 357,658 stock options to purchase shares of common stock became immediately vested, resulting in stock compensation expense of $3,627,507.

At September 30, 2018, there were 1,134,055 restricted shares under the Incentive Plan and 1,949,915 stock options under the 2018 Plan that vested and are expected to vest.

***9. Income Taxes***

The Company's effective tax rate was 0.0% for the nine months ended September 30, 2018 and 2017. The primary reconciling items between the federal statutory rate of 21.0% and 34.0% for the nine months ended September 30, 2018 and 2017, respectively, and the Company's overall effective tax rate of 0.0% was the effect of the valuation allowance recorded against the full amount of its net deferred tax assets.

Valuation allowance is established when it is more likely than not that some portion or all of a deferred tax asset will not be realized. The realization of deferred tax assets depends on the generation of future taxable income during the period in which related temporary differences become deductible.

The Company is subject to tax in the U.S. Federal jurisdiction and the states of Connecticut and Massachusetts. The Company pays franchise tax in the states mentioned above due to its loss position. As a result, there is no state income tax provision recorded for the nine months ended September 30, 2018 and 2017.

***10. Net Loss Per Common Share/Unit***

Basic and diluted loss per common share/unit were calculated as follows:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| Net loss | $ (13,387,672) | $ (6,397,272) | $ (25,392,600) | $ (19,321,180) |
| Change in redemption value of preferred shares/units | (112,050,609) | — | (198,366,756) | — |
| Net loss attributable to common shares/units—basic and diluted | $ (125,438,281) | $ (6,397,272) | $ (223,759,356) | $ (19,321,180) |
| Weighted average number of common shares/units outstanding, basic and diluted | 2,010,807 | 1,897,544 | 1,935,299 | 1,897,544 |
| Net loss per common stock/unit | $ (62.38) | $ (3.37) | $ (115.62) | $ (10.18) |

The Company's potential dilutive securities have been excluded from the computation of diluted net loss per common share/unit as the effect would be to reduce the net loss per common share/unit. The incentive units that convert into restricted shares have been excluded from basic loss per share given that the incentive units had no obligation to share in losses and have been excluded from dilutive loss per share due to anti-dilutive effect. The following common share/unit equivalents have been excluded from the calculations of diluted loss per common share/unit because their inclusion would have been antidilutive for the periods ended September 30:

| | 2018 | 2017 |
|---|---|---|
| Redeemable convertible preferred stock/units | 19,664,047 | 14,597,268 |
| Incentive units | — | 3,789,455 |
| Restricted stock | 1,268,923 | — |
| Stock options | 2,181,810 | — |
| Preferred unit warrant | — | 33,881 |
| | 23,114,780 | 18,420,604 |

***11. Related Parties***

Dr. Craig Crews, founder of the Company and the Chief Scientific Advisor to the Company, is a common unit holder in the Company and has a consulting agreement with the Company. The Company entered into an amendment to the amended and restated consulting agreement with Professor Crews, which became effective upon the closing of the IPO and continues in effect for three years. Pursuant to the amendment, Professor Crews will be paid $20,833 per month for his services. During nine months ended September 30, 2018 and 2017, the Company paid Professor Crews $113,611 and $112,500, respectively, related to his consulting agreement. In connection with the conversion of incentive units, the Company also granted Professor Crews 235,150 stock options to purchase common stock at an exercise price of $16.00 per share, vesting over three years.

During the nine months ended September 30, 2018 and 2017, the Company also paid Yale University, a commo n unit holder in the Company, $107,289 and $102,063, respectively, for reimbursable patent costs. In July 2016, the Company entered into a Corporate Sponsored Research Agreement (SRA) with Yale University, under the direction of Professor Crews, which was amended in April 2018. The SRA requires quarterly payments of $101,161 through April 2018, in exchange for performing the research on the agreed upon program and related research reports. The amended SRA extended the agreement until April 2021 and amended the scope of work. The amended SRA requires quarterly payments of $250,000 through the end of the agreement. The total payments made under the SRA for the nine months ended September 30, 2018 and 2017 were $601,161 and $303,482, respectively.

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

*You should read the following discussion and analysis of financial condition and operating results together with our consolidated financial statements and the related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our final prospectus for our initial public offering filed pursuant to Rule 424(b) under the Securities Act of 1933, as amended, with the Securities and Exchange Commission on September 27, 2018, or Prospectus. This discussion contains forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth in the section titled "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q, our actual results may differ materially from those anticipated in or implied by these forward-looking statements. For convenience of presentation some of the numbers have been rounded in the text below.*

**Overview**

We are a biopharmaceutical company dedicated to improving the lives of patients suffering from debilitating and life-threatening diseases through the discovery, development and commercialization of therapies to degrade disease-causing proteins. We use our proprietary technology platform to engineer proteolysis targeting chimeras, or PROTACs, that are designed to harness the body's own natural protein disposal system to selectively and efficiently degrade and remove disease-causing proteins. We believe that our targeted protein degradation approach is a new therapeutic modality that may provide distinct advantages over existing modalities, including traditional small molecule therapies and gene-based medicines. Our small molecule PROTAC technology has the potential to address a broad range of intracellular disease targets, including those representing the up to 80% of proteins that cannot be addressed by existing small molecule therapies, commonly referred to as undruggable targets. We are using our PROTAC platform to build an extensive pipeline of protein degradation product candidates to target diseases in a wide range of organ systems and tissues. We are preparing to advance our lead product candidates, ARV-110 and ARV-471, into Phase 1 clinical trials. We expect to initiate a Phase 1 clinical trial for ARV-110 in men with metastatic castration-resistant prostate cancer, or mCRPC, in the first quarter of 2019 and a Phase 1 clinical trial for ARV-471 in women with metastatic ER positive / HER2 negative breast cancer, or ER+ breast cancer, in mid-2019.

We are developing ARV-110, a PROTAC targeting the androgen receptor protein, or AR, for the treatment of men with mCRPC. We expect to submit an investigational new drug application, or IND, to the U.S. Food and Drug Administration, or FDA, for ARV-110 in the fourth quarter of 2018, initiate a Phase 1 trial in the first quarter of 2019 and receive preliminary clinical data in the second half of 2019. We are developing ARV-471, a PROTAC targeting the estrogen receptor protein, or ER, for the treatment of women with metastatic ER+ breast cancer. We expect to submit an IND to the FDA for ARV-471 in the first half of 2019, initiate a Phase 1 trial in mid-2019 and receive preliminary clinical data in 2020.

We commenced operations in 2013, and our operations to date have been limited to organizing and staffing our company, business planning, raising capital, conducting discovery and research activities, filing patent applications, identifying potential product candidates, undertaking preclinical studies and establishing arrangements with third parties for the manufacture of initial quantities of our product candidates. To date, we have not generated any revenue from product sales and have financed our operations primarily through sales of our equity interests, proceeds from our collaborations, grant funding and debt financing. Through September 30, 2018, we raised approximately $111.9 million in gross proceeds from the sale of series A, series B and series C convertible preferred units, and had received an aggregate of $88.9 million in payments from collaboration partners, grant funding and loans from the State of Connecticut.

In October 2018, we completed an initial public offering, or IPO, in which we issued and sold an aggregate of 7,700,482 shares of our common stock, including 200,482 additional shares of common stock at a subsequent closing upon the exercise in part by the underwriters of their option to purchase additional shares , at a public offering price of $16.00 per share, for aggregate gross proceeds of $123.2 million before fees and expenses.

We are a development stage company and our lead product candidates and our research initiatives are at a preclinical stage of development. Our ability to generate revenue from product sales sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates. Since inception, we have incurred significant operating losses. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. Our net loss was $25.4 million for the nine months ended September 30, 2018, $24.0 million for the year ended December 31, 2017 and $14.4 million for the year ended December 31, 2016. As of September 30, 2018, we had an accumulated deficit of $286.2 million.

Our total operating expenses were $37.7 million for the nine months ended September 30, 2018, $32.3 million for the year ended December 31, 2017 and $23.1 million for the year ended December 31, 2016. We anticipate that our

expenses will increase substantially due to costs associated with our preclinical activities for our lead product candidates and the advance ment of these candidates into Phase 1 clinical trials in the United States, which we expect to initiate in the first quarter of 2019 for ARV-110 and in mid-2019 for ARV-471, development activities associated with our other product candidates, research activities in oncology, neurological and other disease areas to expand our pipeline, hiring additional personnel in research, clinical trials, quality and other functional areas, increased expenses incurred with contract manufacturing organizations, or CMOs, to supply us with product for our preclinical and clinical studies, as well as other associated costs including the management of our intellectual property portfolio. We expect to incur additional costs associated with operating as a public company.

We do not expect to generate revenue from sales of any product for many years, if ever. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research or product development programs or any future commercialization efforts, or to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us.

## Financial Operations Overview

### *Revenue*

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products in the foreseeable future. Our revenues to date have been generated through research collaboration and license agreements. Revenue is recognized ratably over our expected performance period under each agreement. We expect that our revenue for the next several years will be derived primarily from our current collaboration agreements and any additional collaborations that we may enter into in the future. To date, we have not received any royalties under any of the collaboration agreements.

#### *Genentech License Agreement*

In September 2015, we entered into an Option and License Agreement with Genentech, Inc. and F. Hoffmann-La Roche Ltd, collectively referred to as Genentech, focused on PROTAC discovery and research for target proteins, or Targets, based on our proprietary technology, other than excluded Targets as described below. This collaboration was expanded in November 2017 through an Amended and restated Option, License and Collaboration Agreement, which we refer to as the Restated Genentech Agreement.

Under the Restated Genentech Agreement, Genentech has the right to designate up to ten targets for further discovery and research utilizing our PROTAC platform technology. We are eligible to receive up to $27.5 million in additional expansion target payments if Genentech exercises its options for all remaining targets. Genentech may designate as a Target any protein to which a PROTAC, by design, binds to achieve its mechanism of action, subject to certain exclusions. Genentech also has the right to remove a Target from the collaboration and substitute a different Target that is not an Excluded Target.

At the time we entered into the original agreement with Genentech we received an upfront payment of $11.0 million, and at the time we entered into the Restated Genentech Agreement, we also received an additional $34.5 million in upfront payments and expansion target payments for the three expansion Targets currently included in the collaboration through September 30, 2018. We are also eligible to receive payments aggregating up to $44.0 million per target upon the achievement of specified development milestones; payments aggregating up to $52.5 million per target (assuming approval of two indications) subject to the achievement of specified regulatory milestones; and payments aggregating up to $60.0 million per PROTAC directed against the applicable target, subject to the achievement of specified sales milestones. These milestone payments are subject to reduction if we do not have a valid patent claim covering the licensed PROTAC at the time the milestone is achieved. We are also eligible to receive, on net sales of licensed PROTACs, mid-single digit royalties, which may be subject to reductions.

#### *Pfizer License Agreement*

In December 2017, we entered into a Research Collaboration and License Agreement with Pfizer, Inc., or Pfizer, setting forth our collaboration to identify or optimize PROTACs that mediate for degradation of target proteins, or Targets, using our proprietary platform technology that are identified in the agreement or subsequently selected by Pfizer, subject to certain exclusions. We refer to this agreement as the Pfizer Collaboration Agreement.

Under the Pfizer Collaboration Agreement, Pfizer has designated a number of initial Targets. For each identified Target, we and Pfizer will conduct a separate research program pursuant to a research plan. Pfizer may make substitutions for any of the initial Target candidates, subject to the stage of research for such Target.

In the nine months ended September 30, 2018, we received an aggregate of $28.0 million in upfront payments and certain additional payments under the terms of the Pfizer Collaboration Agreement. We are also entitled to receive further potential option and development and sales-based milestone payments aggregating up to an additional $802.0 million, subject to the achievement of specified development and sales-based milestones for all designated targets. In addition, we are eligible to receive, on net sales of PROTAC-related products, mid- to high-single digit tiered royalties, which may be subject to reductions.

***Prior License Agreement***

In April 2015, we entered into a collaboration agreement with Merck Sharp & Dohme Corp. We received an upfront non-refundable payment of $7.0 million, which was recognized as revenue over the total estimated period of performance. The agreement expired in April 2018.

***Operating Expenses***

Our operating expenses since inception have consisted solely of research and development costs and general and administrative costs.

***Research and Development Expenses***

Research and development expenses consist primarily of costs incurred for our research activities, including our discovery efforts, and the development of our product candidates, and include:

- salaries, benefits and other related costs, including stock-based compensation expense, for personnel engaged in research and development functions;
- expenses incurred under agreements with third parties, including contract research organizations and other third parties that conduct research and preclinical activities on our behalf as well as third parties that manufacture our product candidates for use in our preclinical and potential future clinical trials;
- costs of outside consultants, including their fees, stock-based compensation and related travel expenses;
- the costs of laboratory supplies and acquiring, developing preclinical studies and clinical trial materials;
- facility-related expenses, which include direct depreciation costs of equipment and allocated expenses for rent and maintenance of facilities and other operating costs; and
- third-party licensing fees.

We expense research and development costs as incurred.

We track outsourced development costs and certain personnel costs by product candidate. Other internal costs are not allocated.

The following table summarizes our external research and development expenses by product candidate or development program:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| **(in thousands)** | **2018** | **2017** | **2018** | **2017** |
| AR program development costs | $ 3,152 | $ 2,746 | $ 8,186 | $ 8,063 |
| ER program development costs | 965 | 2,043 | 3,280 | 5,498 |
| Other research and development costs | 9,033 | 2,434 | 19,166 | 8,542 |
| Total research and development costs | $ 13,150 | $ 7,223 | $ 30,632 | $ 22,103 |

Research and development activities are central to our business model. We expect that our research and development expenses will continue to increase substantially for the foreseeable future as we advance ARV-110 and

ARV-471 into clinical trials, including our Phase 1 clinical trials, and continue to discover and develop additional product candidates.

We cannot reasonably estimate or determine with certainty the duration and costs of future clinical trials of ARV-110 and ARV-471 or any other product candidate we may develop or if, when, or to what extent we will generate revenue from the commercialization and sale of any product candidate for which we obtain marketing approval. We may never succeed in obtaining marketing approval for any product candidate. The successful development and commercialization of our product candidates is highly uncertain. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- successful completion of preclinical studies;
- successful initiation of clinical trials;
- successful patient enrollment in and completion of clinical trials;
- receipt and related terms of marketing approvals from applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- making arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our product candidates;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- obtaining and maintaining third-party coverage and adequate reimbursement;
- maintaining a continued acceptable safety profile of the products following approval; and
- effectively competing with other therapies.

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

***General and Administrative Expenses***

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in our executive, finance, business development and administrative functions. General and administrative expenses also include legal fees relating to intellectual property and corporate matters; professional fees for accounting, auditing, tax and consulting services; insurance costs; travel expenses; and facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

We expect that our general and administrative expenses will increase in the future as we increase our personnel headcount to support increased research and development activities relating to our product candidates. We also expect to incur increased expenses associated with being a public company, including costs of accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with Nasdaq and SEC requirements; director and officer insurance costs; and investor and public relations costs.

***Interest Income (Expense)***

Interest income consists of interest income earned on our cash, cash equivalents and short-term investments. Our interest income had decreased due to lower investment balances as we proceeded through 2017. Interest income has increased in 2018 as we invest our excess cash from the proceeds of the series C financing and the payments received under the collaboration agreements. Interest expense consists of interest paid or accrued on our outstanding debt. Interest expense was approximately $39,000 for the nine months ended September 30, 2017 and $33,000 for the nine

months ended September 30, 2018 . Interest expense will increase in the remainder of 2018 and beyond as we drew down $2.0 million under our loan agreement with the State of Connecticut in the September 2018.

***Income Taxes***

Since our inception in 2013, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in any year or for our federal earned research and development tax credits, due to our uncertainty of realizing a benefit from those items. As of December 31, 2017, we had federal net operating loss carryforwards of $53.1 million, which begin to expire in 2033. As of December 31, 2017 and 2016, we also had federal and state research and development tax credit carryforwards of $2.5 million and $1.2 million, respectively, which begin to expire in 2033 and 2028, respectively.

As of September 30, 2018, Arvinas, Inc. had five wholly owned subsidiaries organized as C-corporations: Arvinas, Operations, Inc., Arvinas Androgen Receptor, Inc., Arvinas Estrogen Receptor, Inc., Arvinas BRD4, Inc. and Arvinas Winchester, Inc. These subsidiaries are separate filers for federal tax purposes. Net operating loss carryforwards are generated from the C-corporation subsidiaries' filings. We have provided a valuation allowance against the full amount of the deferred tax assets since, in the opinion of management, based upon our earnings history, it is more likely than not that the benefits will not be realized.

In December 2017, the United States enacted the Tax Cuts and Jobs Act, or TCJA. The TCJA significantly changes U.S. corporate income tax laws by, among other provisions, reducing the maximum U.S. corporate income tax rate from 35% to 21% starting in 2018. During the year ended December 31, 2017, we reduced our deferred income tax asset by approximately $7.2 million as a result of the re-measurement of deferred tax assets and liabilities to the new lower statutory rate of 21%. The rate change did not result in an income tax expense as the change was offset by the change in the valuation allowance.

## Critical Accounting Policies and Use of Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, costs and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

For a discussion of our significant accounting policies and recent accounting pronouncements, see Note 2 to our consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q and Note 2 to the financial statements included in our consolidated financial statements as of December 31, 2017 and 2016 and for the years then ended included in the Prospectus.

## Results of Operations

***Comparison of Three Months Ended September 30, 2018 and 2017***

***Revenues***

Revenues for the three months ended September 30, 2018 were $3.4 million, compared with $1.7 million for the three months ended September 30, 2017. The increase of $1.7 million was due to an increase in license and rights to technology and research and development activities related to the Pfizer Collaboration Agreement that was initiated in January 2018 and the Restated Genentech Agreement that was initiated in November 2017.

***Research and Development Expenses***

Research and development expenses for the three months ended September 30, 2018 were $13.1 million, compared with $7.2 million for the three months ended September 30, 2017. The increase of $5.9 million was primarily due to an increase in equity compensation expense of $2.4 million, direct research expenses of $0.4 million related to our

AR program and $4.1 million related to our platform and exploratory targets spending , partially offset by a $ 1.1 million decrease related to our ER program. The increase in platform and exploratory targets was primarily related to costs associated with the development programs with our collaboration partners and our continued investment in our exploratory programs.

***General and Administrative Expenses***

General and administrative expenses were $4.3 million for the three months ended September 30, 2018, compared with $0.9 million for the three months ended September 30, 2017. The increase of $3.4 million was primarily due to an increase of $2.9 million related to employee expenses, including equity compensation expense of $2.5 million, and $0.3 million related to patent and corporate legal fees and other professional fees.

***Other Income (Expenses)***

Other income (expenses) was $0.7 million for the three months ended September 30, 2018, compared with $0.1 million for the three months ended September 30, 2017. The increase of $0.6 million was primarily due to an increase in interest income of $0.5 million. The increase in interest income was the result of our higher average cash, cash equivalent and short-term investment balances for the three months ended September 30, 2018 compared to the three months ended September 30, 2017.

***Comparison of Nine Months Ended September 30, 2018 and 2017***

***Revenues***

Revenues for the nine months ended September 30, 2018 were $10.9 million, compared with $5.0 million for the nine months ended September 30, 2017. The increase of $5.9 million was due to an increase in licensing revenue and rights to technology and research and development activities related to the Pfizer Collaboration Agreement that was initiated in January 2018 and the Restated Genentech Agreement that was initiated in November 2017.

***Research and Development Expenses***

Research and development expenses for the nine months ended September 30, 2018 were $30.6 million, compared with $22.1 million for the nine months ended September 30, 2017. The increase of $8.5 million was related to an increase in our platform and exploratory costs of $7.5 million and equity compensation expense of $3.1 million, partially offset by a decrease of $2.1 million in our AR and ER programs. Direct research expenses related to our AR program increased by $0.1 million between these periods while our ER program expenses decreased by $2.2 million as the programs moved from lead optimization to IND-enabling activities. The increase in platform and exploratory targets was primarily related to costs associated with the development programs with our collaboration partners and our continued investment in our exploratory programs, including increases in personnel costs, outside laboratory costs, and general research and development overhead costs.

***General and Administrative Expenses***

General and administrative expenses were $7.1 million for the nine months ended September 30, 2018, compared with $2.4 million for the nine months ended September 30, 2017. The increase of $4.7 million was primarily due to an increase of $3.7 million related to employee expenses, including equity compensation expense of $2.9 million, and an increase of $0.8 million in patent and corporate legal fees and other professional fees.

***Other Income (Expenses)***

Other income (expenses) was $1.5 million for the nine months ended September 30, 2018, compared with $0.1 million for the nine months ended September 30, 2017. Other income (expense) is comprised primarily of interest income, interest expense, changes in the fair value of a preferred unit warrant, and refundable state research and development credits. Interest income was $1.3 million for the nine months ended September 30, 2018, compared with $0.2 million for the nine months ended September 30, 2017. The increase in interest income was the result of higher average cash, cash equivalent and short-term investment balances in the nine months ended September 30, 2018 compared with the nine months ended September 30, 2017.

## Liquidity and Capital Resources

### *Sources of Liquidity*

We do not currently have any approved products and have never generated any revenue from product sales. To date, we have financed our operations primarily through the sale of equity interests and through payments from collaboration partners, grant funding and loans from the State of Connecticut. Through September 30, 2018, we raised approximately $111.9 million in gross proceeds from the sale of series A, series B and series C convertible preferred units, and had received an aggregate of $88.9 million in payments from collaboration partners, grant funding and loans from the State of Connecticut. In October 2018, we completed our IPO in which we issued and sold an aggregate of 7,700,482 shares of common stock, including 200,482 additional shares of common stock at a subsequent closing upon the exercise in part by the underwriters of their option to purchase additional shares at a public offering price of $16.00 per share, for aggregate gross proceeds of $123.2 million before fees and expenses.

#### *Cash Flows*

Our cash, cash equivalents and marketable securities totaled $89.8 million as of September 30, 2018, $39.2 million as of December 31, 2017 and $35.6 million as of December 31, 2016. We had outstanding loan balances of $2.2 million as of September 30, 2018, $0.3 million as of December 31, 2017 and $0.5 million as of December 31, 2016.

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

| | Nine Months Ended September 30, | |
|---|---|---|
| **(in thousands)** | **2018** | **2017** |
| Net cash used in operating activities | $ (3,554) | $ (23,044) |
| Net cash provided by (used in) investing activities | (78,126) | 20,532 |
| Net cash provided by (used in) financing activities | 56,959 | (120) |
| Decrease in cash and cash equivalents | $ (24,721) | $ (2,632) |

#### *Operating Activities*

Net cash used in operating activities for the nine months ended September 30, 2018 was $3.6 million, primarily due to our net loss of $25.4 million, a reduction in deferred revenue of $7.9 million, and an increase in other current assets of $4.4 million, partially offset by the receipt of a $25.0 million up-front payment received from a collaboration partner and previously recorded as an account receivable, an increase in accounts payable and accrued expenses of $2.0 million and non-cash charges of $7.1 million. The reduction in deferred revenue is primarily due to $10.9 million of revenue recognized, partially offset by $3.0 million in target payments received from a collaboration partner. The increase in other current assets is primarily due to incurring costs in preparation of the IPO.

Net cash used in operating activities for the nine months ended September 30, 2017 was $23.0 million, attributable to our net loss of $19.3 million and a decrease in deferred revenue of $5.0 million for revenue recognized during the period, partially offset by non-cash charges of $0.7 million and other changes in operating assets and liabilities of $0.6 million.

#### *Investing Activities*

Net cash used in investing activities for the nine months ended September 30, 2018 was $78.1 million, attributable to the net investment of excess cash of $75.6 million and the purchases of property and equipment of $2.5 million.

Net cash provided by investing activities for the nine months ended September 30, 2017 was $20.5 million, attributable to the maturity and sale of marketable securities of $21.1 million, partially offset by the purchase of property and equipment of $0.6 million.

#### *Financing Activities*

Net cash provided by financing activities for the nine months ended September 30, 2018 was $56.9 million, attributable to the net proceeds of $55.0 million from the sale of series C preferred units, loan proceeds of $2.0 million, partially offset by payments on our long-term debt of $0.1 million.

Net cash used in financing activities for the nine months ended September 30, 2017 was $0.1 million for payments on our long-term debt.

***Funding Requirements***

Since our inception, we have incurred significant operating losses. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future as we advance the preclinical and clinical development of our product candidates. We expect to incur additional costs associated with operating as a public company.

Specifically, we anticipate that our expenses will increase substantially if and as we:

- initiate a planned Phase 1 clinical trial of our product candidate, ARV-110, in men with mCRPC;
- initiate a planned Phase 1 clinical trial of our product candidate, ARV-471, in women with metastatic ER+ breast cancer;
- apply our PROTAC platform to advance additional product candidates into preclinical and clinical development;
- expand the capabilities of our PROTAC platform;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- ultimately establish a sales, marketing and distribution infrastructure and scale up external manufacturing capabilities to commercialize any products for which we may obtain marketing approval;
- expand, maintain and protect our intellectual property portfolio;
- hire additional clinical, regulatory and scientific personnel; and
- add operational, financial and management information systems and personnel to support our research, product development and future commercialization efforts and support our operations as a public company.

We believe that our cash, cash equivalents and marketable securities as of September 30, 2018, together with the net proceeds from our IPO, will enable us to fund our operating expenses and capital expenditure requirements for at least the next 24 months. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. This estimate also assumes that we do not obtain any additional funding through collaborations or other strategic alliances, including under the license and option agreements that we entered into with Pfizer and Genentech. Our future capital requirements will depend on many factors, including:

- the progress, costs and results of our planned Phase 1 clinical trials for ARV-110 and ARV-471 and any future clinical development of ARV-110 and ARV-471;
- the scope, progress, costs and results of preclinical and clinical development for our other product candidates and development programs;
- the number and development requirements of other product candidates that we pursue, including our neurodegenerative research programs;
- the success of our collaborations with Pfizer and Genentech;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims; and
- our ability to establish collaboration arrangements with other biotechnology or pharmaceutical companies on favorable terms, if at all, for the development or commercialization of our product candidates.

As a result of these anticipated expenditures, we will need to obtain substantial additional financing in connection with our continuing operations. Until such time, if ever, as we can generate substantial revenue from product sales, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. Although we may receive potential future payments under

our collaborations with Pfizer and Genentech, we do not currently have any committed external source of funds. Adequat e additional funds may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we may be required to delay, limit, reduce or terminate our research, product development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

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 and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us.

**Contractual Obligations**

The following is a summary of our significant contractual obligations as of September 30, 2018:

| | | Payments Due by Period | | | |
|---|---|---|---|---|---|
| **Contractual Obligation (in thousands)** | **Total** | **Less Than 1 Year** | **More Than 1 Year and Less Than 3** | **More Than 3 years and Less Than 5** | **More Than 5 years** |
| Operating lease obligation(1) | $ 3,040 | $ 684 | $ 1,459 | $ 897 | $ — |
| Minimum license obligations(2) | $ 375 | $ 75 | $ 150 | $ 150 | $ — |
| Sponsored research agreements(3) | $ 3,128 | $ 1,618 | $ 1,510 | $ — | $ — |
| Long-term debt(4) | $ 2,214 | $ 214 | $ — | $ — | $ 2,000 |

(1) Represents future minimum lease payments under our operating leases and equipment for office and lab space in New Haven, Connecticut that expire in February 2022 and December 2022.
(2) Represents minimum annual license fee under our license agreement with Yale University. The license agreement requires annual payments of $75,000 until the first sale to a third party of any licensed product, as defined in the agreement. Management cannot estimate if or when there may be a sale of a licensed product. These amounts do not include any potential contingent payments upon the achievement by us of specified clinical, regulatory and commercial events, as applicable, or patent prosecution or royalty payments we may be required to make. We have excluded these potential payments in the contractual obligations table because the timing and likelihood of these contingent payments are not currently known and would be difficult to predict or estimate. See “Business—Licenses and Strategic Collaborations” for additional information about the license agreement, including with respect to potential payments thereunder.
(3) Represents payments due under research agreements based on expected completion date of research activities.
(4) See Note 7 to the condensed consolidated financial statements as of September 30, 2018 and December 31, 2017 and for the periods ended September 30, 2018 and 2017 appearing in this Form 10-Q.

In August 2013, we entered into a Loan Agreement, or Loan, with Connecticut Innovations, Inc., or CII, the strategic venture capital arm and a component unit of the State of Connecticut. Under the Loan, we borrowed $750,000 for the purchase of laboratory equipment, information technology equipment and leasehold improvements. Interest on the Loan is compounded on a monthly basis at a rate of 7.50% per annum. The Loan provided for monthly, interest-only payments for ten months. Beginning on June 1, 2015 we were required to make monthly principal and interest payments through July 31, 2019. We can prepay the amount due at any time without premium or penalty. The Loan is secured by substantially all of our assets. The amount outstanding under the Loan was $0.2 million as of September 30, 2018 and $0.3 million as of December 31, 2017. In connection with the issuance of the Loan, we granted CII a warrant to purchase 33,881 of our series A preferred units at a purchase price of $0.6811 per unit, with a seven-year term from the date of issuance. The warrant was exercised in July 2018.

In January 2014, we entered into an Assistance Agreement with the State of Connecticut, or the 2014 Assistance Agreement. Under the terms of the 2014 Assistance Agreement, we borrowed $2.5 million. Borrowings under the 2014 Assistance Agreement were forgivable if we maintained a minimum number of full time jobs in the State of Connecticut for a minimum period at a minimum annual salary. As of September 30, 2018, the full principal amount under the 2014 Assistance Agreement has been forgiven. While borrowings under the 2014 Assistance Agreement have been forgiven, we remain subject to an ongoing covenant to be located in the State of Connecticut through January 2024. Upon violation of this covenant we would be required to repay the full original funding amount of $2.5 million plus liquidated damages of 7.50%.

In June 2018, we entered into an additional Assistance Agreement with the State of Connecticut, or the 2018 Assistance Agreement, to provide funding for the expansion and renovation of laboratory and office space. Under the terms of the 2018 Assistance Agreement, we borrowed from the State of Connecticut the maximum amount of $2.0 million

in September 2018. The funding cannot exceed more than 50% of the total costs of the expansion and renovation. Borrowin gs under the 2018 Assistance Agreement bear an interest rate of 3.25% per annum and interest payments are required for the first 60 months from the funding date. Interest expense related to the Assistance Agreement is expected to be $65,000 annually for th e first five years. Thereafter, the loan begins to fully amortize through month 120, maturing in June 2028. Up to $1.0 million of the funding can be forgiven if we meet certain employment conditions. We may be required to prepay a portion of the loan if the employment conditions are not met. The 2018 Assistance Agreement requires that we be located in the State of Connecticut through June 2028 with a default penalty of repayment of the full original funding amount of $2.0 million plus liquidated damages of 7.5% of the total amount of funding received.

Pursuant to our license agreement with Yale, we are required to pay Yale, subject to the achievement of specified development and regulatory milestones, payments aggregating up to approximately $3.0 million for the first licensed product and up to approximately $1.5 million for the second licensed product. We are not required to make any milestone payments for any licensed products beyond the first two. While the agreement remains in effect, we are required to pay Yale low-single digit royalties on aggregate worldwide net sales of certain licensed products, which may be subject to reductions.

**Off-Balance Sheet Arrangements**

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

**Emerging Growth Company Status**

As an “emerging growth company,” the Jumpstart Our Business Startups Act of 2012 allows us to delay adoption of new or revised accounting standards applicable to public companies until such standards are made applicable to private companies. However, we have irrevocably elected not to avail ourselves of this extended transition period for complying with new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

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

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. Our interest-earning assets consist of cash, cash equivalents, and marketable securities. Interest income earned on these assets was $1.3 million and $166,000 for the nine months ended September 30, 2018 and 2017, respectively. Our interest income is sensitive to changes in the general level of interest rates, primarily U.S. interest rates. At September 30, 2018, our cash equivalents consisted of bank deposits and money market funds, and our marketable securities included interest-earning securities. Such interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations in interest income have not been significant for us. Our outstanding debt was $2,214,000 and $343,500 as of September 30, 2018 and December 31, 2017, respectively, and carries a fixed interest rate of 3.25% per annum on the $2.0 million of debt and 7.50% per annum on the $214,000 of debt.

**Item 4. Controls and Procedures.**

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

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2018. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the “Exchange Act”), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2018, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

## PART II—OTHER INFORMATION

### Item 1. Legal Proceedings.

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

### Item 1A. Risk Factors.

*Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below together with all of the other information contained in this Quarterly Report on Form 10-Q, including our consolidated financial statements and the related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our consolidated financial statements and related notes in our final prospectus for our initial public offering filed pursuant to Rule 424(b) under the Securities Act of 1933, as amended, with the Securities and Exchange Commission on September 27, 2018, or the Prospectus. If any of the following risks actually occur, our business, prospects, operating results and financial condition could suffer materially. In such event, the trading price of our common stock could decline and you might lose all or part of your investment.*

#### Risks Related to Our Financial Position and Need For Additional Capital

***We have incurred significant losses since our inception. We expect to incur losses over at least the next several years and may never achieve or maintain profitability.***

Our net loss was $25.4 million for the nine months ended September 30, 2018, $24.0 million for the year ended December 31, 2017 and $14.4 million for the year ended December 31, 2016. As of September 30, 2018, we had an accumulated deficit of $286.2 million. To date, we have not generated any revenue from product sales and have financed our operations primarily through sales of our equity interests, proceeds from our collaborations, grant funding and debt financing. We are still in the early stages of development of our product candidates and expect to initiate our first clinical trial in the first quarter of 2019. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We anticipate that our expenses will increase substantially if and as we:

- initiate a planned Phase 1 clinical trial of our product candidate, ARV-110, in men with metastatic castration-resistant prostate cancer, or mCRPC;
- initiate a planned Phase 1 clinical trial of our product candidate, ARV-471, in women with metastatic ER positive / HER2 negative breast cancer, or ER+ breast cancer;
- apply our PROTAC platform to advance additional product candidates into preclinical and clinical development;
- expand the capabilities of our PROTAC platform;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- ultimately establish a sales, marketing and distribution infrastructure and scale up external manufacturing capabilities to commercialize any products for which we may obtain marketing approval;
- expand, maintain and protect our intellectual property portfolio;
- hire additional clinical, regulatory and scientific personnel; and
- add operational, financial and management information systems and personnel to support our research, product development and future commercialization efforts and support our operations as a public company.

Our expenses could increase beyond our expectations if we are required by the U.S. Food and Drug Administration, or FDA, the European Medicines Agency, or EMA, or other regulatory authorities to perform trials in addition to those that we currently expect, or if there are any delays in establishing appropriate manufacturing arrangements for or in completing our clinical trials or the development of any of our product candidates.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses we will incur or when, if ever, we will be able to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

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

We are currently only in the preclinical testing stages for our most advanced research programs. We have not initiated clinical development of any product candidate and expect that it will be many years, if ever, before we have a product candidate ready for commercialization. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability. To become and remain profitable, we must succeed in developing, obtaining marketing approval for and commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, discovering additional product candidates, establishing arrangements with third parties for the manufacture of clinical supplies of our product candidates, obtaining marketing approval for our product candidates and manufacturing, marketing and selling any products for which we may obtain marketing approval.

If one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Even if we are able to generate revenues from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations.

***We will need substantial additional funding. If we are unable to raise capital when needed, we may be required to delay, limit, reduce or terminate our research or product development programs or future commercialization efforts.***

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we prepare for and initiate our planned Phase 1 clinical trials of ARV-110 and ARV-471, advance our neurodegenerative programs and continue research and development and initiate additional clinical trials of and potentially seek marketing approval for our lead programs and our other 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 manufacturing, marketing, sales and distribution. 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 may be required to delay, limit, reduce or terminate our research, product development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We had cash, cash equivalents and marketable securities of approximately $89.8 million as of September 30, 2018 and $39.2 million as of December 31, 2017. We believe that our cash, cash equivalents and marketable securities as of September 30, 2018, together with the net proceeds from our initial public offering, will enable us to fund our operating expenses and capital expenditure requirements for at least the next 24 months. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. This estimate also assumes that we do not obtain any additional funding through collaborations or other strategic alliances, including under the license and option agreements that we entered into with Pfizer, Inc., or Pfizer, and Genentech, Inc. and F. Hoffman-La Roche Ltd, collectively referred to as Genentech. Our future capital requirements will depend on many factors, including:

- the progress, costs and results of our planned Phase 1 clinical trials for ARV-110 and ARV-471 and any future clinical development of ARV-110 and ARV-471;
- the scope, progress, costs and results of preclinical and clinical development for our other product candidates and development programs;
- the number and development requirements of other product candidates that we pursue, including our neurodegenerative research programs;
- the success of our collaborations with Pfizer and Genentech;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;

- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims; and
- our ability to establish collaboration arrangements with other biotechnology or pharmaceutical companies on favorable terms, if at all, for the development or commercialization of our product candidates.

Identifying potential product candidates and conducting preclinical testing 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 obtain substantial additional funds to achieve our business objectives. Adequate additional funds may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans.

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

Until such time, if ever, as we can generate substantial revenue from product sales, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. Although we may receive potential future payments under our collaborations with Pfizer and Genentech, we do not currently have any committed external source of funds. 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 and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends.

We have in the past entered into financing arrangements with the State of Connecticut and related entities. These include $4.5 million in partially forgivable loans from the State of Connecticut and a loan agreement with Connecticut Innovations, Incorporated, or CII, the strategic venture capital arm and a component unit of the State of Connecticut, in an aggregate principal amount of $750,000. We also granted CII a warrant to purchase 110,116 of our series A preferred units, which it exercised in July 2018. Covenants in these financing arrangements impose certain limitations and obligations on us, including restrictions on our ability to incur additional debt, to enter into certain business combinations, and from moving our principal offices out of Connecticut. If we were to move our principal offices out of Connecticut or certain employment conditions are not met, we would be obligated to repay the full amount of our previously forgiven loans to the State of Connecticut, currently $2.5 million, and prepay a portion of our unforgiven loans to the State of Connecticut, currently $2.0 million, plus liquidated damages of 7.50%. Additionally, CII would be entitled to obligate us to purchase all of our outstanding securities owned by CII for a specified guaranteed return pursuant to a put agreement with CII.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us.

***Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.***

We commenced operations in 2013, and our operations to date have been limited to organizing and staffing our company, business planning, raising capital, conducting discovery and research activities, filing patent applications, identifying potential product candidates, undertaking preclinical studies and establishing arrangements with third parties for the manufacture of initial quantities of our product candidates. All of our product candidates are still in preclinical development. We have not yet demonstrated our ability to successfully initiate or complete any clinical trials, obtain marketing approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with a research and

development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

***The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.***

On December 22, 2017, President Trump signed into law new legislation that significantly revises the Internal Revenue Code of 1986, as amended. The newly enacted federal income tax law contains, among other things, significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for net interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2017 (though any such net operating losses may be carried forward indefinitely), one-time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain how various states will respond to the newly enacted federal tax law. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge prospective investors in our common stock to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

***We might not be able to utilize a significant portion of our net operating loss carryforwards and research and development tax credit carryforwards.***

As of December 31, 2017, we had federal net operating loss carryforwards of $52.3 million, which will, if not used, expire at various dates through 2036, and federal research and development tax credit carryforward of $1.7 million, which will, if not used, expire at various dates through 2036. These net operating loss and tax credit carryforwards could expire unused and be unavailable to offset our future income tax liabilities. Under the newly enacted federal income tax law, federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. It is uncertain how various states will respond to the newly enacted federal tax law.

In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an “ownership change,” which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. We have not determined if we have experienced Section 382 ownership changes in the past and if a portion of our net operating loss and tax credit carryforwards are subject to an annual limitation under Section 382. In addition, we may experience ownership changes in the future as a result of subsequent changes in our stock ownership, some of which may be outside of our control. If we determine that an ownership change has occurred and our ability to use our historical net operating loss and tax credit carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

## Risks Related to the Discovery and Development of Our Product Candidates

***Our approach to the discovery and development of product candidates based on our PROTAC technology platform is unproven, which makes it difficult to predict the time, cost of development and likelihood of successfully developing any products.***

Our PROTAC technology platform is a relatively new technology. Our future success depends on the successful development of this novel therapeutic approach. No product candidates that use a chimeric small molecule approach to protein degradation, such as our PROTACs, have been tested in humans or approved in the United States or Europe, and the data underlying the feasibility of developing chimeric small molecule-based therapeutic products is both preliminary and limited. We have not yet succeeded and may not succeed in demonstrating the efficacy and safety of any of our product candidates in clinical trials or in obtaining marketing approval thereafter. We have not yet initiated a clinical trial of

any product candidate and we have not yet assessed safety of any product candidate in humans. As such, there may be adverse effects from treatment with any of our current or future product candidates that we cannot predict at this time.

As a result of these factors, it is more difficult for us to predict the time and cost of product candidate development, and we cannot predict whether the application of our PROTAC platform, or any similar or competitive protein degradation platforms, will result in the development, and marketing approval of any products. Any development problems we experience in the future related to our PROTAC platform or any of our research programs may cause significant delays or unanticipated costs or may prevent the development of a commercially viable product. Any of these factors may prevent us from completing our preclinical studies or any clinical trials that we may initiate or commercializing any product candidates we may develop on a timely or profitable basis, if at all.

***We are very early in our development efforts. All of our product candidates are still in preclinical development. If we are unable to commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.***

We are very early in our development efforts. All of our product candidates are still in preclinical development. Our ability to generate revenue from product sales, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of one or more of our product candidates. The success of our product candidates will depend on several factors, including the following:

- successful completion of preclinical studies;
- successful initiation of clinical trials;
- successful patient enrollment in and completion of clinical trials;
- receipt and related terms of marketing approvals from applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- making arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our product candidates;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- obtaining and maintaining third-party coverage and adequate reimbursement;
- maintaining a continued acceptable safety profile of the products following approval; and
- effectively competing with other therapies.

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.

***Drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.***

All of our product candidates are in preclinical development and their risk of failure is high. We are unable to predict when or if any of our product candidates will prove effective or safe in humans or will receive marketing approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our planned Investigational New Drug Applications, or INDs, in the United States or similar applications in other jurisdictions. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA or similar regulatory authorities outside the United States will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our programs.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to the outcome. A failure of one or more clinical trials can occur at any stage of testing. 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 experience 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 may 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 trials for various reasons, including noncompliance with regulatory requirements;
- 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;
- the cost of clinical trials of our product candidates may be greater than we anticipate; and
- 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.

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;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

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

Further, cancer therapies are sometimes characterized as first-line, second-line, or third-line, and the FDA often approves new therapies initially only for third-line use. When cancer is detected early enough, first-line therapy, usually hormone therapy, surgery, radiation therapy or a combination of these, is sometimes adequate to cure the cancer or prolong life without a cure. Second- and third-line therapies are administered to patients when prior therapy is not effective. Our planned clinical trials for ARV-110 and ARV-471 will be with patients who have received one or more prior treatments. Subsequently, for those products that prove to be sufficiently beneficial, if any, we would expect to seek approval potentially as a first-line therapy, but any product candidates we develop, even if approved, may not be approved for first-line therapy, and, prior to any such approvals, we may have to conduct additional clinical trials.

***If serious adverse events, undesirable side effects, or unexpected characteristics are identified during the development of any product candidates we may develop, we may need to abandon or limit our further clinical development of those product candidates.***

We have not evaluated any product candidates in human clinical trials. Moreover, we are not aware of any clinical trials involving chimeric small molecules, such as our PROTACs. It is impossible to predict when or if any product candidates we may develop will prove safe in humans. There can be no assurance that our PROTAC technology will not cause undesirable side effects.

A potential risk in any protein degradation product is that healthy proteins or proteins not targeted for degradation will be degraded or that the degradation of the targeted protein in itself could cause adverse events, undesirable side effects, or unexpected characteristics. It is possible that healthy proteins or proteins not targeted for degradation could be degraded using our PROTAC technology in any of our planned or future clinical studies. There is also the potential risk of delayed adverse events following treatment using our PROTAC technology.

If any product candidates we develop are associated with serious adverse events, or undesirable side effects, or have characteristics that are unexpected, we may need to abandon their development or limit development to certain uses or subpopulations in which the adverse events, undesirable side effects or other characteristics are less prevalent, less severe, or more acceptable from a risk-benefit perspective, any of which would have a material adverse effect on our business, financial condition, results of operations, and prospects. Many product candidates that initially showed promise in early-stage testing for treating cancer or other diseases have later been found to cause side effects that prevented further clinical development of the product candidates or limited their competitiveness in the market.

***The results of early-stage clinical trials and preclinical studies may not be predictive of future results. Initial success in clinical trials may not be indicative of results obtained when these trials are completed or in later stage trials.***

The results of preclinical studies may not be predictive of the results of clinical trials, and the results of any early-stage clinical trials we commence may not be predictive of the results of the later-stage clinical trials. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. In particular, the small number of patients in our planned early clinical trials may make the results of these trials less predictive of the outcome of later clinical trials. For example, even if successful, the results of the dose-escalation portion of our planned Phase 1 clinical trials of ARV-110 and ARV-471 may not be predictive of the results of further clinical trials of these product candidates or any of our other product candidates. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. Our current or future clinical trials may not ultimately be successful or support further clinical development of any of our product candidates. There is a high failure rate for product candidates proceeding through clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving encouraging results in earlier studies. Any such setbacks in our clinical development could materially harm our business and results of operations.

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

From time to time, we may publish interim top-line or preliminary data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our reputation and business prospects.

***If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary marketing approvals could be delayed or prevented.***

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside of the United States. In particular, we are preparing to advance ARV-110 into a Phase 1 clinical trial for

men with mCRPC and ARV-471 into a Phase 1 clinical trial for women with metastatic ER+ breast cancer. We cannot predict how difficult it will be to enroll patients for trials in these indications. Therefore, our ability to identify and enroll eligible patients for ARV-110 and ARV-471 clinical trials may be limited or may result in slower enrollment than we anticipate. In addition, some of our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. Patient enrollment is affected by other factors including:

- the severity of the disease under investigation;
- the eligibility criteria for the trial in question;
- the perceived risks and benefits of the product candidates under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the burden on patients due to inconvenient procedures;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

***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 products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential 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.

***We may develop ARV-471 in combination with other drugs. If the FDA or similar regulatory authorities outside of the United States do not approve these other drugs, revoke their approval of such drugs, or if safety, efficacy, manufacturing or supply issues arise with the drugs we choose to evaluate in combination with ARV-471, we may be unable to obtain approval of ARV-471 or market ARV-471.***

We intend to conduct a Phase 1b clinical trial with ARV-471 for the treatment of women with metastatic ER+ breast cancer for use in combination with a CDK 4/6 inhibitor, such as palbociclib, once a recommended dose is identified from the dose-escalation portion of the ARV-471 Phase 1 clinical trial. We did not develop or obtain marketing approval for, nor do we manufacture or sell, any of the currently approved drugs that we may study in combination with ARV-471. If the FDA or similar regulatory authorities outside of the United States revoke their approval of the drug or drugs in combination with which we determine to develop ARV-471, we will not be able to market ARV-471 in combination with such revoked drugs.

If safety or efficacy issues arise with any of these drugs, we could experience significant regulatory delays, and the FDA or similar regulatory authorities outside of the United States may require us to redesign or terminate the applicable clinical trials. If the drugs we use are replaced as the standard of care for the indications we choose for ARV-471, the FDA or similar regulatory authorities outside of the United States may require us to conduct additional clinical trials. In addition, if manufacturing or other issues result in a shortage of supply of the drugs with which we determine to combine with ARV-471, we may not be able to complete clinical development of ARV-471 on our current timeline or at all.

Even if ARV-471 were to receive marketing approval or be commercialized for use in combination with other existing drugs, we would continue to be subject to the risks that the FDA or similar regulatory authorities outside of the

United States could revoke approval of the drug used in combination with A RV-471 or that safety, efficacy, manufacturing or supply issues could arise with these existing drugs. Combination therapies are commonly used for the treatment of cancer, and we would be subject to similar risks if we develop any of our other product candidates for use in combination with other drugs or for indications other than cancer. This could result in our own products being removed from the market or being less successful commercially.

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

A key element of our strategy is to apply our PROTAC platform to address a broad array of targets and new therapeutic areas. The therapeutic discovery activities that we are conducting may not be successful in identifying product candidates that are useful in treating cancer or other diseases. 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:

- 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 drugs that will receive marketing approval or achieve market acceptance; or
- potential product candidates may not be effective in treating their targeted diseases.

Research programs to identify new product candidates require substantial technical, financial and human resources. We may choose to focus our efforts and resources on a potential product candidate that ultimately proves to be unsuccessful. If we are unable to identify suitable product candidates for preclinical and clinical development, we will not be able to obtain revenues from sale of products in future periods, which likely would result in significant harm to our financial position and adversely impact our stock price.

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

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face and will continue to face competition from third parties that use protein degradation, antibody therapy, inhibitory nucleic acid, gene editing or gene therapy development platforms and from companies focused on more traditional therapeutic modalities, such as small molecule inhibitors. The competition is likely to come from multiple sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, government agencies and public and private research institutions.

We are aware of several biotechnology companies focused on developing chimeric small molecules for protein degradation including C4 Therapeutics, Inc., Cullgen Inc. and Kymera Therapeutics, Inc., all of which are currently in preclinical development. Further, several large pharmaceutical companies have disclosed preclinical investments in this field, including Amgen Inc., AstraZeneca plc, GlaxoSmithKline plc, Genentech and Novartis International AG.

Many of our current or potential competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. 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 or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval 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. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products. There are generic products currently on the market for certain of the indications that we are pursuing, and additional products are expected to become available on a generic basis over the coming years. If our product candidates are approved, we expect that they will be priced at a significant premium over competitive generic products.

## Risks Related to Dependence on Third Parties

***We expect to depend on collaborations with third parties for the research, development, and commercialization of certain of the product candidates we may develop. If any such collaborations are not successful, we may not be able to capitalize on the market potential of those product candidates.***

We anticipate seeking third-party collaborators for the research, development, and commercialization of some of our PROTAC programs. For example, in September 2015 we entered into a collaboration with Genentech, which we amended and restated in November 2017, and in December 2017 we entered into a collaboration with Pfizer. Our likely collaborators for any other collaboration arrangements include large and mid-size pharmaceutical companies and biotechnology companies. Any such arrangements with third parties will likely limit our control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of any product candidates we may seek to develop with them. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We cannot predict the success of any collaboration that we enter into.

Collaborations involving our research programs or any product candidates we may develop, including our collaborations with Genentech and Pfizer, pose the following risks to us:

- Collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations. For example, our collaboration with Genentech is managed by a joint research committee and joint project team, which is composed of representatives from us and Genentech, with Genentech having final decision-making authority. Similarly, our collaboration with Pfizer is managed by a joint research committee composed of an equal number of representatives from us and Pfizer, with Pfizer having final decision-making authority.
- Collaborators may not pursue development and commercialization of any product candidates we may develop or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors such as an acquisition or business combination that diverts resources or creates competing priorities.
- Genentech and Pfizer have broad rights to select any target for protein degradation development, so long as not excluded by us under the terms of each collaboration and may select targets we are considering but have not taken sufficient action to exclude under the collaboration.
- Collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing.
- Collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours.
- Collaborators with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products.
- Collaborators may not properly obtain, maintain, enforce, or defend our intellectual property or proprietary rights or may use our proprietary information in such a way that could jeopardize or invalidate our proprietary information or expose us to potential litigation. For example, Pfizer and Genentech have the first right to enforce or defend certain intellectual property rights under the applicable collaboration arrangement with respect to particular licensed programs, and although we may have the right to assume the enforcement and defense of such intellectual property rights if the collaborator does not, our ability to do so may be compromised by their actions.
- Disputes may arise between the collaborators and us that result in the delay or termination of the research, development, or commercialization of our products or product candidates or that result in costly litigation or arbitration that diverts management attention and resources.
- We may lose certain valuable rights under circumstances identified in our collaborations, including if we undergo a change of control.
- Collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates. For example, each of Genentech and Pfizer can terminate its agreement with us in its entirety or with respect to a specific target for convenience upon

60 days' notice or in connection with a material breach of the agreement by us that remains uncur ed for a specified period of time. In 2015, we entered into a collaboration agreement with Merck Sharp & Dohme Corp., or Merck, that expired in April 2018 with Merck not electing to continue research in any targets.

- Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished, or terminated.

If our collaborations do not result in the successful development and commercialization of products, or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of product candidates could be delayed, and we may need additional resources to develop product candidates. In addition, if one of our collaborators terminates its agreement with us, we may find it more difficult to find a suitable replacement collaborator or attract new collaborators, and our development programs may be delayed or the perception of us in the business and financial communities could be adversely affected. All of the risks relating to product development, marketing approval, and commercialization described in this Quarterly Report on Form 10-Q apply to the activities of our collaborators.

We may in the future decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of any product candidates we may develop. These relationships, or those like them, 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 could face significant competition in seeking appropriate collaborators, and the negotiation process is time-consuming and complex. Our ability to reach a definitive collaboration agreement will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator's evaluation of several factors. If we license rights to any product candidates we or our collaborators may develop, 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 may seek to establish additional collaborations. If we are not able to establish collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans.***

To realize the full potential of our PROTAC platform and accelerate the development of additional PROTAC programs, we plan to continue to selectively pursue collaborations with leading biopharmaceutical companies with particular experience, including development and commercial expertise and capabilities. We face significant competition in attracting appropriate collaborators to advance the development of any product candidates for which we may seek a collaboration. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or other regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, the terms of any existing collaboration agreements, and industry and market conditions generally. The collaborator may also have the opportunity to collaborate on other product candidates or technologies for similar indications and will have to evaluate whether such a collaboration could be more attractive than one with us.

Collaborations are complex and time-consuming to negotiate, document and execute. In addition, consolidation among large pharmaceutical companies has reduced the number of potential future collaborators. Any collaboration we enter into may limit our ability to enter into future agreements on particular terms or covering similar target indications with other potential collaborators.

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

revenue from product sales, which could have an adverse effect on our business, prospects, financial condition and results of operations.

***We rely and expect to continue to rely on agreements with Yale University to supplement our internal research and development program. If Yale decides to discontinue or devote less resources to such research, our research efforts could be diminished.***

Our set of arrangements with Yale University, or Yale, provide us with access to certain of Yale's intellectual property and to Professor Crews' laboratory in a manner that we believe closely aligns our scientific interests with those of Yale. We are a party to both a license agreement and a sponsored research agreement with Yale. While Yale has contractual obligations to us, it is an independent entity and is not under our control or the control of our officers or directors. The license agreement is structured to provide Yale with license maintenance fees, development and regulatory milestone payments, royalties on net sales of products, and a portion of sublicense income that we receive. Upon the scheduled expiration of the Yale research agreement in April 2021, the research agreement may not be renewed, or any renewal could be on terms less favorable to us than those contained in the existing agreement. Furthermore, either we or Yale may terminate the research agreement for convenience following a specified notice period. If Yale decides to not renew or to terminate the Yale research agreement or decides to devote fewer resources to such activities, our research efforts would be diminished, while our royalty obligations to Yale would continue unmodified, which could have a material adverse effect on our business and financial condition.

Our license agreement with Yale also provides that so long as Professor Crews serves as a member of our board of directors or scientific advisory board or has a similar advisory arrangement, has a consulting arrangement with us, or his laboratory is performing sponsored research for us, and so long as he is an employee or faculty member (including emeritus faculty member) at Yale, any future invention by Professor Crews' laboratory in the license agreement's field is included in the licensed intellectual property. If Professor Crews were to leave Yale or no longer be meaningfully involved with us, we would no longer have access to future inventions in the license agreement's field from Yale.

Additionally, the license granted under the license agreement terminates after a specified period following a qualifying change of control, unless we elect or our successor or assignee elects to continue the agreement. If the license is terminated after such a change of control, royalty payments would continue to be paid on certain licensed products.

***We expect to rely on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.***

We expect to rely on third-party clinical research organizations, or CROs, to conduct our planned Phase 1 clinical trial programs for ARV-110 and ARV-471 and any other clinical trials and currently do not plan to independently conduct any clinical trials of ARV-110 and ARV-471 or of our other product candidates. Agreements with these third parties might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, that 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 in the applicable IND. Moreover, the FDA requires compliance with standards, commonly referred to as good clinical practices, or GCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected.

Furthermore, these third parties may 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 product candidates.

***We rely on third-party contract manufacturing organizations for the manufacture of both drug substance and finished drug product for our product candidates for preclinical testing and clinical trials and expect to continue to do so for commercialization. This reliance on third parties may increase the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.***

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely on and expect to continue to rely on third-party contract manufacturing organizations, or CMOs, for both drug substance and finished drug product. This reliance on third parties may increase the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

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

- reliance on the third party for regulatory, compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

We have only limited technology transfer agreements in place with respect to our product candidates, and these arrangements do not extend to commercial supply. We acquire many key materials on a purchase order basis. As a result, we do not have long term committed arrangements with respect to our product candidates and other materials. If we receive marketing approval for any of our product candidates, we will need to establish an agreement for commercial manufacture with a third party.

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

Our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. As a result, we may not obtain access to these facilities on a priority basis or at all. 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 or a second source for bulk drug substance. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers. 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 manufacturer or be able to reach agreement with any alternative manufacturer.

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

## Risks Related to the Commercialization of Our Product Candidates

***Even if any of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.***

If any of our product candidates receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, current cancer

treatments, such as chemotherapy and radiation therapy, are well established in the medical community, and doctors may continue to rely on these treatments. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant revenue from product sales 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:

- the efficacy and potential advantages compared to alternative treatments;
- the prevalence and severity of any side effects, in particular compared to alternative treatments;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing, sales and distribution support;
- the availability of third-party coverage and adequate reimbursement;
- the timing of any marketing approval in relation to other product approvals;
- support from patient advocacy groups; and
- any restrictions on the use of our products together with other medications.

***If we are unable to establish sales and marketing capabilities, we may not be successful in commercializing our product candidates if and when they are approved.***

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of biopharmaceutical products. To achieve commercial success for any product for which we obtain marketing approval, we will need to establish sales, marketing and distribution capabilities, either ourselves or through collaboration or other arrangements with third parties.

We currently expect that we would build our own focused, specialized sales and marketing organization to support the commercialization in the United States of product candidates for which we receive marketing approval and that can be commercialized with such capabilities. There are risks involved with establishing our own sales and marketing capabilities. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. These efforts may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

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

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

If we are unable to establish our own sales and marketing capabilities and enter into arrangements with third parties to perform these services, our revenue from product sales and our profitability, if any, are likely to be lower than if we were to market and sell any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to market and sell our product candidates or may be unable to do so on terms that are acceptable to us. We likely will have little control over such third parties, and any of these third parties may fail to devote the necessary resources and attention to sell and market our products 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.

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

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future 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 drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. 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 product candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues, if any, we are able to generate from the sale of the product 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 product candidates successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government healthcare programs, 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, government authorities and 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. Coverage and reimbursement may not be available for any product that we commercialize and, even if these are available, the level of reimbursement may not be satisfactory. Reimbursement may affect the demand for, or the price of, any product candidate for which we obtain marketing approval. Obtaining and maintaining adequate reimbursement for our products may be difficult. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and adequate reimbursement are not available or reimbursement 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 coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or similar regulatory authorities outside of the United States. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, intellectual property, manufacture, sale and distribution expenses. Interim reimbursement levels for new drugs, 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 drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs 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 drugs 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 adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

***Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products 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 products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- termination of clinical trials;
- withdrawal of marketing approval, recall, restriction on the approval or a “black box” warning or contraindication for an approved drug;

- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- injury to our reputation and significant negative media attention;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.

As a preclinical company, we do not currently hold product liability insurance coverage. We will need to purchase product liability insurance coverage as we initiate our clinical trials, as we expand our clinical trials, and if we commence commercialization of our product candidates. 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.

## Risks Related to Our Intellectual Property

***If we are unable to obtain and maintain patent protection for our technology and products or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired, and we may not be able to compete effectively in our market.***

Our commercial success depends in part on our ability to obtain and maintain patent and other proprietary protection in the United States and other countries with respect to our proprietary technology and products. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and product candidates. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Moreover, the patent applications we own, co-own or license may fail to result in issued patents in the United States or in other foreign countries.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after 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 owned, co-owned or licensed patents or pending patent applications, or that we were the first inventors 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. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Moreover, we may be subject to a third-party preissuance submission of prior art to the USPTO or in addition to interference proceedings, may become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or other post-grant proceedings challenging our or our licensors' patent rights or the patent rights of others. 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 products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Our owned, co-owned and licensed patent estate consists principally of patent applications, many of which are at an early stage of prosecution. Even if our owned, co-owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned, co-owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

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

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

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These changes include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The USPTO developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first-inventor-to-file provisions, became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition. Furthermore, for applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications.

Additionally, the U.S. Supreme Court has ruled on several patent cases in recent years limiting where a patentee may file a patent infringement suit, narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations, and there are other open questions under patent law that courts have yet to decisively address. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained.

Depending on decisions by Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways and could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. In addition, the European patent system is relatively stringent in the type of amendments that are allowed during prosecution, but, the complexity and uncertainty of European patent laws has also increased in recent years. Complying with these laws and regulations could limit our ability to obtain new patents in the future that may be important for our business.

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

Competitors may infringe our issued patents, the patents of our licensors, or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive, time-consuming and unpredictable. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court may decide that a patent of ours or our licensors is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Even if we successfully assert our patents, a court may not award remedies that sufficiently compensate us for our losses.

***We may need to license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.***

A third party may hold intellectual property, including patent rights, that are important or necessary to the development of our products. It may be necessary for us to use the patented or proprietary technology of a third party to commercialize our own technology or products, in which case we would be required to obtain a license from such third party. A license to such intellectual property may not be available or may not be available on commercially reasonable terms, which could have a material adverse effect on our business and financial condition.

The licensing and acquisition of third-party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. We may not be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire.

***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, and the ability of our collaborators, to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, reexamination, and *inter partes* review proceedings before the USPTO and oppositions and other comparable proceedings in foreign jurisdictions.

We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including interference, derivation, reexamination or *inter partes* review proceedings before the USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. 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. There may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our drug candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents.

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

***If we fail to comply with our obligations in our current and future intellectual property licenses and funding arrangements with third parties, we could lose rights that are important to our business.***

We are party to a license agreement with Yale that provides us with the foundational intellectual property rights for our PROTAC protein degradation technology. This license agreement imposes diligence, development and commercialization timelines and milestone payment, royalty, insurance and other obligations on us. If we fail to comply with our obligations, including achieving specified milestone events, Yale may have the right to terminate this license, in which event we might not be able to develop, manufacture or market any product that is covered by the intellectual property we in-license from Yale and may face other penalties. Such an occurrence would materially adversely affect our business prospects. For a variety of purposes, we will likely enter into additional licensing and funding arrangements with third parties that may also impose similar obligations on us.

Termination of any of our current or future in-licenses would reduce or eliminate our rights under these agreements and m ay result in our having to negotiate new or reinstated agreements with less favorable terms or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology. Any of the foregoing could prevent us from commercializing our other product candidates, which could have a material adverse effect on our operating results and overall financial condition.

In addition to the above risks, intellectual property rights that we license in the future may include sublicenses under intellectual property owned by third parties, in some cases through multiple tiers. The actions of our licensors may therefore affect our rights to use our sublicensed intellectual property, even if we are in compliance with all of the obligations under our license agreements. Should our licensors or any of the upstream licensors fail to comply with their obligations under the agreements pursuant to which they obtain the rights that are sublicensed to us, or should such agreements be terminated or amended, our ability to develop and commercialize our product candidates may be materially harmed.

Further, we do not have the right to control the prosecution, maintenance and enforcement of all of our licensed and sublicensed intellectual property, and even when we do have such rights, we may require the cooperation of our licensors and upstream licensors, which may not be forthcoming. For example, under the Yale license, any patent applications and issued patents under the agreement remain the property of Yale, and Yale has the right to choose patent counsel. Our business could be adversely affected if we or our licensors are unable to prosecute, maintain and enforce our licensed and sublicensed intellectual property effectively.

***We may be subject to claims by third parties asserting that our employees, consultants, contractors or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.***

We employ individuals who were previously employed at universities as well as other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We have received confidential and proprietary information from collaborators, prospective licensees and other third parties. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these employees or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. We may not be successful in defending these claims, and 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. Even if we are successful, litigation could result in substantial cost and reputational loss and be a distraction to our management and other employees.

In addition, while it is our policy to require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Such assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

***Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.***

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

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

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and patent offices in foreign countries in several stages over the lifetime of the patent. The USPTO and patent offices in foreign countries require compliance with a number of procedural, documentary, fee payment and other requirements during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of a patent or patent rights in the relevant jurisdiction. Non-compliance 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. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

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

In addition 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. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and 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 of 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, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

***If we are not able to obtain patent term extensions in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of our marketing exclusivity for our product candidates, our business may be impaired.***

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, one of the U.S. patents covering each of such product candidates or the use thereof may be eligible for a patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or Hatch-Waxman Act. The period of extension may be up to five years beyond the expiration date of a patent, but cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. The Hatch-Waxman Act allows a maximum of one patent to be extended per FDA-approved product. Similar patent term extension also may be available in certain foreign countries upon regulatory approval of our product candidates. Nevertheless, we may not be granted patent term extension either in the United States or in any foreign country because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request.

If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product may be shortened and our competitors may obtain approval of competing products following our patent expiration sooner, and our revenue could be reduced, possibly materially.

***We only have limited geographical protection with respect to certain patents and we may not be able to protect our intellectual property rights throughout the world.***

Filing, prosecuting and defending patents covering 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 can be less extensive than those in the United States. In-licensing patents covering our product candidates in all countries throughout the world may similarly be prohibitively expensive, if such opportunities are available at all. And in-licensing or

filing, prosecuting and defending patents even in only those jurisdictions in which we develop or commercialize our product candidates may be prohibitively expensive or impractical. Competitors may use our and our licensors' technologies in jurisdictions where we have not obtained patent protection or licensed patents to develop their own products and, further, may export otherwise infringing products to territories where we and our licensors have patent protection, but enforcement is not as strong as that in the United States or the European Union. These products may compete with our product candidates, and our or our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

In addition, we may decide to abandon national and regional patent applications while they are still pending. The grant proceeding of each national or regional patent is an independent proceeding which may lead to situations in which applications may be rejected by the relevant patent office, while substantively similar applications are granted by others. For example, relative to other countries, China has a heightened detailed description requirement for patentability. Furthermore, generic drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' patents, requiring us or our licensors to engage in complex, lengthy and costly litigation or other proceedings. Generic drug manufacturers may develop, seek approval for and launch generic versions of our products. It is also quite common that depending on the country, the scope of patent protection may vary for the same product candidate or technology.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or regulations in the United States and the European Union, and many companies have encountered significant difficulties in protecting and defending proprietary rights in such jurisdictions. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets or other forms of intellectual property, which could make it difficult for us to prevent competitors in some jurisdictions from marketing competing products in violation of our proprietary rights generally.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, are likely to result in substantial costs and divert our efforts and attention from other aspects of our business, and additionally could put our or our licensors' patents at risk of being invalidated or interpreted narrowly, could increase the risk of our or our licensors' patent applications not issuing, or could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, while damages or other remedies may be awarded to the adverse party, which may be commercially significant. If we prevail, damages or other remedies awarded to us, 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. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets. If we or our licensors encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition in those jurisdictions.

In some jurisdictions, compulsory licensing laws compel patent owners to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors are forced to grant a license to third parties under patents relevant to our business, or if we or our licensors are prevented from enforcing patent rights against third parties, our competitive position may be substantially impaired in such jurisdictions.

### Risks Related to Regulatory Approval and Marketing of Our Product Candidates and Other Legal Compliance Matters

***The regulatory approval process of the FDA is lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain marketing approval for our product candidates, our business will be substantially harmed.***

The time required to obtain approval by the FDA is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have

not obtained marketing approval for any product candidate and it is possible that none of our existing product candidates, or any product candidates we may seek to develop in the future will ever obtain marketing approval.

Our product candidates could fail to receive marketing approval for many reasons, including the following:

- the FDA may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA that a product candidate is safe and effective for its proposed indication;
- results of clinical trials may not meet the level of statistical significance required by the FDA for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA may disagree with our interpretation of data from preclinical studies or clinical trials;
- data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA to the FDA or other submission or to obtain marketing approval in the United States;
- the FDA may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA may significantly change in a manner rendering our clinical data insufficient for approval.

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

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

***Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of some or all of our product candidates. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.***

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, export and import are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by the EMA and similar regulatory authorities outside of the United States. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not submitted an application for or received marketing approval for any of our product candidates in the United States or in any other jurisdiction.

As a company, we do not have experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party clinical research organizations or other third-party consultants or vendors to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. New cancer drugs frequently are indicated only for patient populations that have not responded to an existing therapy or have relapsed.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

***Failure to obtain marketing approval in foreign jurisdictions would prevent our product candidates from being marketed abroad and may limit our ability to generate revenue from product sales.***

In order to market and sell our products in the European Union and many other jurisdictions, we, and any collaborators, must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The marketing approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. We, and any collaborators, may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA.

In many countries outside the United States, a product candidate must also be approved for reimbursement before it can be sold in that country. In some cases, the price that we intend to charge for our products, if approved, is also subject to approval. Obtaining non-U.S. regulatory approvals and compliance with non-U.S. regulatory requirements could result in significant delays, difficulties and costs for us and any collaborators and could delay or prevent the introduction of our product candidates in certain countries. In addition, if we or any collaborators fail to obtain the non-U.S. approvals required to market our product candidates outside the United States or if we or any collaborators fail to comply with applicable non-U.S. regulatory requirements, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business, financial condition, results of operations and prospects may be adversely affected.

Additionally, on June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the European Union, commonly referred to as Brexit. On March 29, 2017, the United Kingdom formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. Since a significant proportion of the regulatory framework in the United Kingdom is derived from European Union directives and regulations, the withdrawal could materially impact the regulatory regime with respect to the approval of our product candidates in the United Kingdom or the European Union. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the United Kingdom and/or the European Union and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or European Union for our product candidates, which could significantly and materially harm our business.

***Even if we, or any collaborators, obtain marketing approvals for our product candidates, the terms of approvals and ongoing regulation of our products may limit how we, or they, manufacture and market our products, which could materially impair our ability to generate revenue.***

Once marketing approval has been granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation. We, and any collaborators, must therefore comply with requirements concerning advertising and promotion for any of our product candidates for which we or they obtain marketing approval. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, we, and any collaborators will not be able to promote any products we develop for indications or uses for which they are not approved.

In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We, our third-party manufacturers, any collaborators and their third-party manufacturers could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMPs.

Accordingly, assuming we, or any collaborators, receive marketing approval for one or more of our product candidates, we, and any collaborators, and our respective third-party manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control.

If we, and any collaborators, are not able to comply with post-approval regulatory requirements, we, and any collaborators, could have the marketing approvals for our products withdrawn by regulatory authorities and our, or any collaborators', ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

***Any product candidate for which we, or any collaborators, obtain marketing approval could be subject to post-marketing restrictions or withdrawal from the market and we, or any collaborators, may be subject to substantial penalties if we, or they, fail to comply with regulatory requirements or if we, or they, experience unanticipated problems with our products when and if any of them are approved.***

Any product candidate for which we, or any collaborators, obtain marketing approval, as well as the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA, EMA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including the requirement to implement a risk evaluation and mitigation strategy. New cancer drugs frequently are indicated only for patient populations that have not responded to an existing therapy or have relapsed. If any of our product candidates receives marketing approval, the accompanying label may limit the approved use of our drug in this way, which could limit sales of the product.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product, including the adoption and implementation of risk evaluation and mitigation strategies. The FDA and other agencies, including the Department of Justice, or the DOJ, closely regulate and monitor the post-approval marketing and promotion of drugs to ensure they are marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and DOJ impose stringent restrictions on manufacturers' communications regarding off-label use, and if we do not market our products for their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug, and Cosmetic Act and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs may lead to investigations and enforcement actions alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown side effects or other problems with our products or their manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions and warnings on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;

- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of our products;
- product seizure;
- injunctions or the imposition of civil or criminal penalties; or
- litigation involving patients using our products.

Non-compliance with European Union requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with the European Union's requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs applicable to drug manufacturers or quality assurance standards applicable to medical device manufacturers, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We, any contract manufacturers we may engage in the future, our collaborators and their contract manufacturers will also be subject to other regulatory requirements, including submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements regarding the distribution of samples to clinicians, recordkeeping, and costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product such as the requirement to implement a risk evaluation and mitigation strategy.

***Regulatory reform may limit the FDA's ability to engage in oversight and implementation activities in the normal course, and that could negatively impact our business.***

The Trump Administration has taken several executive actions, including the issuance of a number of executive orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. On January 30, 2017, President Trump issued an executive order, applicable to all executive agencies, including the FDA, that requires that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This executive order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the executive order requires agencies to identify regulations to offset any incremental cost of a new regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within the Office of Management and Budget on February 2, 2017, the administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. It is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

***Our relationships with health care providers, physicians and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other health care laws and regulations, which could expose us to civil, criminal and administrative sanctions, contractual damages, reputational harm and diminished future profits and earnings.***

Health care providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any drugs for which we obtain marketing approval. Our future arrangements with third-party payors, health care providers and physicians may expose us to broadly applicable state and federal fraud and abuse and other health care laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any drugs for which we obtain marketing approval. These include the following:

- *Anti-Kickback Statute,* which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, paying, or receiving remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchasing, ordering, leasing, arranging for, or recommending the purchasing, ordering, or leasing of, any good or service for which payment may be made, in whole or in part, under a federal health care program such as Medicare or Medicaid;
- *False Claims Act*—the federal civil and criminal false claims laws, including the civil False Claims Act, and Civil Monetary Penalties Law, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, false or fraudulent claims for payment or knowingly making, using or causing to made or used a false record or statement material to a false or fraudulent claim or to avoid, decrease or conceal an obligation to pay money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government;
- *HIPAA*—the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit, among other things, executing a scheme to defraud any health care benefit program or making false statements relating to health care matters, and apply regardless of the payor (e.g., public or private);
- *HIPAA and HITECH*—HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, which impose obligations on HIPAA covered entities and their business associates, including mandatory contractual terms and required implementation of administrative, physical and technical safeguards to maintain the privacy and security of individually identifiable health information;
- *Transparency Requirements*—the federal physician transparency requirements known as the Physician Payments Sunshine Act, under the Patient Protection and Affordable Care Act, as amended by the Health Care Education Reconciliation Act, or the Affordable Care Act (ACA), which requires manufacturers of drugs, medical devices, biological and medical supplies covered by Medicare, Medicaid, or State Children's Health Insurance Program (CHIP) to report annually to the Centers for Medicare & Medicaid Services, or CMS, within the United States Department of Health and Human Services, information related to payments and other transfers of value made by that entity to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and
- *Analogous State, Local and Foreign Laws*—analogous state, local and foreign fraud and abuse laws and regulations, such as state anti-kickback and false claims laws, which may be broader than similar federal laws, can apply to claims involving health care items or services regardless of payor, and are enforced by many different federal and state agencies as well as through private actions.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and require drug manufacturers to report information related to payments and other transfers of value to physicians and other health care providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable health care laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other health care laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and/or administrative penalties, damages, fines, individual imprisonment, disgorgement, exclusion from government funded health care programs, such as Medicare and Medicaid, contractual damages, reputational harm, administrative burdens, diminished

profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations. If any of the physicians or other health care providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded health care programs.

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

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

The collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the EU, including personal health data, is subject to the EU General Data Protection Regulation, or the GDPR, which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EU, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with any European activities.

***Current and future legislation may increase the difficulty and cost for us and any collaborators to obtain marketing approval of and commercialize our product candidates and affect the prices we, or they, may obtain.***

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. The pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by legislative initiatives. Current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any FDA approved product.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

In March 2010, then-President Obama signed into law the ACA. Among the provisions of the ACA of importance to our business and our product candidates are the following:

- an annual, non-deductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of federal healthcare fraud and abuse laws, including the civil False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (and 70% starting January 1, 2019) point-of-sale discounts off negotiated prices;
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report certain financial arrangements with physicians and teaching hospitals;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes include the Budget Control Act of 2011, which, among other things, led to aggregate reductions to Medicare payments to providers of up to 2% per fiscal year that started in 2013 and, due to subsequent legislative amendments to the statute, will stay in effect through 2027 unless additional congressional action is taken, and the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain marketing approval or the frequency with which any such product candidate is prescribed or used. Further, there have been several recent U.S. congressional inquiries and proposed state and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products.

We expect that these healthcare reforms, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product and/or the level of reimbursement physicians receive for administering any approved product we might bring to market. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

With enactment of the Tax Cuts and Jobs Act of 2017, which was signed by the President on December 22, 2017, Congress repealed the "individual mandate." The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, will become effective in 2019. According to the Congressional Budget Office, the repeal of the individual mandate will cause 13 million fewer Americans to be insured in 2027 and premiums in insurance markets may rise. Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, among other things, amends the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to reduce the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." Further, each chamber of the Congress has put forth multiple bills designed to repeal or repeal and replace portions of the ACA. Although none of these measures has been enacted by Congress to date, Congress may consider other legislation to repeal and replace elements of the ACA. The Congress will likely consider other legislation to replace elements of the ACA, during the next Congressional session.

The Trump Administration has also taken executive actions to undermine or delay implementation of the ACA. In January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. In October 2017, the President signed a second Executive Order allowing for the use of association health plans and short-term health insurance, which may provide fewer health benefits than the plans sold through the ACA exchanges. At the same time, the Trump Administration announced that it will discontinue the payment of cost-sharing reduction, or CSR, payments to insurance companies until Congress approves the appropriation of funds for such CSR payments. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. A bipartisan bill to appropriate funds for CSR payments was introduced in the Senate, but the future of that bill is uncertain. We will continue to evaluate the effect that the ACA and its possible repeal and replacement could have on our business.

The costs of prescription pharmaceuticals has also been the subject of considerable discussion in the United States, and members of Congress and the Trump Administration have stated that they will address such costs through new legislative and administrative measures. To date, there have been several recent U.S. congressional inquiries and proposed and enacted state and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. At the federal level, the Trump Administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. While any proposed measures will require authorization through additional legislation to become effective, Congress and the Trump Administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs.

In addition, on May 11, 2018, the Trump Administration issued a plan to lower drug prices. Under this blueprint for action, the Trump Administration indicated that the Department of Health and Human Services (HHS) will: take steps to end the gaming of regulatory and patent processes by drug makers to unfairly protect monopolies; advance biosimilars and generics to boost price competition; evaluate the inclusion of prices in drug makers' ads to enhance price competition; speed access to and lower the cost of new drugs by clarifying policies for sharing information between insurers and drug makers; avoid excessive pricing by relying more on value-based pricing by expanding outcome-based payments in Medicare and Medicaid; work to give Part D plan sponsors more negotiation power with drug makers; examine which Medicare Part B drugs could be negotiated for a lower price by Part D plans, and improving the design of the Part B Competitive Acquisition Program; update Medicare's drug-pricing dashboard to increase transparency; prohibit Part D contracts that include "gag rules" that prevent pharmacists from informing patients when they could pay less out-of-pocket by not using insurance; and require that Part D plan members be provided with an annual statement of plan payments, out-of-pocket spending, and drug price increases.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. Increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

***Governments outside of the United States tend to impose strict price controls, which may adversely affect our revenues from the sales of drugs, if any.***

In some countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take

considerable time after the receipt of marketing approval for a drug. To obtain reimbursement or pricing approval in some countries, we, or our collaborators, may be required to conduct a clinical trial that compares the cost-effectiveness of our drug to other available therapies. If reimbursement of our drugs is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

***We are subject to anti-corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures and legal expenses, which could adversely affect our business, results of operations and financial condition.***

Our operations are subject to anti-corruption laws, including the FCPA, the Bribery Act, and other anticorruption laws that apply in countries where we do business and may do business in the future. The FCPA, the Bribery Act, and these other laws generally prohibit us, our officers and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. We may in the future operate in jurisdictions that pose a high risk of potential FCPA or Bribery Act violations, and we may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the FCPA, the Bribery Act, or local anti-corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United States, United Kingdom, and authorities in the European Union, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations, which we collectively refer to as Trade Control Laws.

There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the FCPA, the Bribery Act, or other legal requirements, including Trade Control Laws. If we are not in compliance with the FCPA, the Bribery Act, and other anti-corruption laws or Trade Control Laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. The Securities and Exchange Commission, or SEC, also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions. Likewise, any investigation of any potential violations of the FCPA, the Bribery Act, other anti-corruption laws or Trade Control Laws by U.S., U.K. or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition.

***If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could significantly harm our business.***

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

We maintain workers' compensation insurance to cover costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, but 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 addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts, which could adversely affect our business, financial condition, results of operations or prospects. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

## Risks Related to Employee Matters and Managing Growth

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

We are highly dependent on the research, development and clinical expertise of our management and scientific teams. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. We also benefit from the research expertise of Professor Craig Crews, Ph.D., our scientific founder and Chief Scientific Advisor. Although we have entered into a consulting agreement with Professor Crews, he may terminate his relationship with us at any time. We do not maintain "key person" insurance for any of our executives or other employees.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be 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 marketing approval of and commercialize products. Competition to hire from this limited pool 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. 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.

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

As of September 30, 2018, we had 77 full-time employees, including 64 employees engaged in research and development. We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, manufacturing, 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. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA review process for ARV-110, ARV-471 and any product candidate we develop, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to advance development of and, if approved, commercialize ARV-110, ARV-471 and any product candidate we develop will depend, in part, on our ability to effectively manage any future growth. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, 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.

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

Our internal computer systems and those of any collaborators, contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other

similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed.

***Our employees, independent contractors, vendors, principal investigators, CROs and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading laws.***

We are exposed to the risk that our employees, independent contractors, vendors, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include:

- intentional, reckless or negligent conduct or disclosure of unauthorized activities to us that violate the regulations of the FDA or similar foreign regulatory authorities;
- healthcare fraud and abuse laws and regulations in the United States and abroad;
- violations of U.S. federal securities laws relating to trading in our common stock; and
- failures to reporting of financial information or data accurately.

In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations regulate a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Other forms of misconduct could involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct and implement other internal controls applicable to all of our employees, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

## Risks Related to Our Common Stock

***The price of our common stock is volatile and may fluctuate substantially, which could result in substantial losses for holders of our common stock.***

Our stock price is volatile. The stock market in general and the market for smaller biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by many factors, including:

- the degree of success of competitive products or technologies;
- results of preclinical studies and clinical trials, of our product candidates or those of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional technologies or product candidates;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;

- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

If any of the foregoing matters were to occur, or if our operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. In the past, following periods of volatility in the market price of a company’s securities, securities class-action litigation often has been instituted against that company. Such litigation, if instituted against us, could cause us to incur substantial costs to defend such claims and divert management’s attention and resources, which could seriously harm our business, financial condition, results of operations and prospects.

***Our executive officers, directors and principal stockholders, if they choose to act together, have the ability to control or significantly influence all matters submitted to stockholders for approval.***

Our executive officers and directors, combined with our stockholders who owned more than 5% of our outstanding common stock prior to our initial public offering, in the aggregate, beneficially own shares representing more than a majority of our capital stock. As a result, if these stockholders were to choose to act together, they would be able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership control may:

- delay, defer or prevent a change in control;
- entrench our management and the board of directors; or
- impede a merger, consolidation, takeover or other business combination involving us that other stockholders may desire.

***Provisions in our corporate charter documents, under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.***

Provisions in our certificate of incorporation and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- provide for a classified board of directors such that only one of three classes of directors is elected each year;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from our board of directors;
- provide for advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a “poison pill” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal specified provisions of our charter or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

***An active trading market for our common stock may not develop***

Our shares of common stock began trading on the Nasdaq Global Select Market on September 27, 2018. Given the limited trading history of our common stock, there is a risk that an active trading market for our shares will not be sustained, which could put downward pressure on the market price of our common stock and therefore affect the ability of our stockholders to sell their shares.

***A significant portion of our total outstanding shares are eligible to be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is doing well.***

Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. As of November 01, 2018, we had 32,350,972 shares of our common stock outstanding. Of these shares, 24,658,748 shares are currently restricted as a result of securities laws or lock-up agreements but will become eligible to be sold at various times after the expiration of the applicable lock-up period. Moreover, holders of an aggregate of 19,697,928 shares of our common stock have rights, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. In September 2018, we registered all shares of common stock that we may issue under our equity compensation plans. These shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements entered into in connection with our initial public offering.

***We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.***

We are an "emerging growth company," or EGC, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. We will remain an EGC until the earlier of: (1) the last day of the fiscal year in which we have total annual gross revenue of $1.07 billion or more; (2) December 31, 2023; (3) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; and (4) the date on which we are deemed to be a large accelerated filer under the rules of the SEC, which means the last day of the first year in which the market value of our common stock that is held by non-affiliates exceeds $700 million as of June 30. For so long as we remain an EGC, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not EGCs. These exemptions include:

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- reduced disclosure obligations regarding executive compensation;
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved; and
- an exemption from compliance with the requirement of the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor's report on the financial statements.

We may choose to take advantage of some, but not all, of the available exemptions. We cannot predict whether investors will find our common stock less attractive if we rely on certain or all of 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.

In addition, the JOBS Act provides that an EGC may take advantage of an extended transition period for complying with new or revised accounting standards. This allows an EGC to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not EGCs.

***We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.***

As a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Global Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our board of directors.

We are evaluating these rules and regulations, and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404 of Sarbanes-Oxley, or Section 404, we will be required to furnish a report by our management on our internal control over financial reporting beginning with the annual report for our fiscal year ending December 31, 2019. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets and restrict our future access to the capital markets due to a loss of confidence in the reliability of our financial statements.

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

Our certificate of incorporation provides 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 owed by our directors, officers, other employees or stockholders to the company or our stockholders, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law or as to which the Delaware General Corporation Law confers jurisdiction on the Court of Chancery of the State of Delaware, or any action asserting a claim arising pursuant to our certificate of incorporation or our bylaws or governed by the internal affairs doctrine. This 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, other employees or other stockholders, which may discourage such lawsuits against us and our directors, officers, other employees or other stockholders. Alternatively, if a court were to find this provision in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

***Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.***

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements we may enter into may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

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

***Sale of Unregistered Securities***

Set forth below is information regarding equity securities sold or issued by us during the three months ended September 30, 2018 that were not registered under the Securities Act of 1933, as amended (the "Securities Act"). Also included is the consideration, if any, received by us for such equity securities and information relating to the section of the Securities Act, or rule of the Securities and Exchange Commission, under which exemption from registration was claimed.

In July 2018, we issued 110,116 of our series A preferred units in connection with the exercise of an outstanding warrant by CII at a price per unit of $0.6811, for an aggregate exercise price of $75,000.01. No underwriters were involved in the foregoing issuances of securities. The securities described in this paragraph (a) of Item 15 were issued to accredited investors in reliance upon the exemption from the registration requirements of the Securities Act, as set forth in Section 4(a)(2) or Regulation D under the Securities Act, relating to transactions by an issuer not involving any public offering.

On July 3, 2018, we issued an aggregate of 150,340 incentive units pursuant to our Incentive Share Plan to a new director. The incentive unit grants described in this paragraph were issued pursuant to written compensatory plans or arrangements with our employees, directors and consultants, in reliance on the exemption provided by Rule 701 promulgated under the Securities Act, or pursuant to Section 4(a)(2) under the Securities Act, relating to transactions by an issuer not involving any public offering. All recipients either received adequate information about us or had access, through employment or other relationships, to such information.

Immediately prior to the effectiveness of our registration statement on Form S-1 (File No. 333-227112), Arvinas Holding Company, LLC, or Arvinas LLC, our predecessor Company, converted from a Delaware limited liability company into Arvinas, Inc., a Delaware corporation, which we refer to as the Conversion. In connection with the Conversion, the series A preferred units of Arvinas LLC converted into shares of series A preferred stock, the series B preferred units of Arvinas LLC converted into shares of series B preferred stock, the series C preferred units of Arvinas LLC converted into shares of series C preferred stock, the common units of Arvinas LLC converted into shares of common stock and, the incentive units of Arvinas LLC converted into shares of common stock, and if such outstanding incentive units were subject to vesting at the time of the Conversion, the resulting shares of common stock continued to be subject to vesting to the same extent as such outstanding common shares were subject to time-based vesting prior to the Conversion.

***Use of Proceeds from Initial Public Offering of Common Stock***

In October 2018, we closed our initial public offering of an aggregate of 7,700,482 shares of common stock, including 200,482 additional shares of common stock at a subsequent closing upon the exercise in part by the underwriters of their option to purchase additional shares of common stock, at a public offering price of $16.00 per share. The aggregate gross proceeds to us from our IPO were $123.2 million. The offer and sale of all of the shares in the offering were registered under the Securities Act pursuant to registration statement on Form S-1 (File No. 333-227112), which was declared effective by the SEC on September 26, 2018. Goldman Sachs & Co. LLC, Citigroup Global Markets Inc. and Piper Jaffray & Co. acted as joint book-running managers for the offering and as representatives of the underwriters. The offering commenced on September 26, 2018 and did not terminate until the sale of all of the shares offered.

Aggregate net proceeds from the offering were approximately $111.0 million, after deducting underwriting discounts and commissions of $8.6 million and estimated offering expenses of approximately $3.6 million payable by us. None of the underwriting discounts and commissions or offering expenses were paid directly or indirectly to any directors or officers of ours or their associates or to persons owning 10% or more of any class of equity securities or to any affiliates of ours.

We had not used any of the net offering proceeds as of September 30, 2018 because the initial public offering closed on October 1, 2018. We have invested the net proceeds in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments and U.S. government securities. There has been no material change in our planned use of the net proceeds from the offering as described in our Prospectus.

**Item 6. Exhibits.**

| Exhibit Number | Description |
|---|---|
| 3.1 | Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-38672) filed with the SEC on October 1, 2018). |
| 3.2 | Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-38672) filed with the SEC on October 1, 2018). |
| 10.1 | 2018 Stock Incentive Plan (incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1/A (File No. 333-227112) filed with the SEC on September 14, 2018). |
| 10.2 | Form of Stock Option Agreement under 2018 Stock Incentive Plan (incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1/A (File No. 333-227112) filed with the SEC on September 14, 2018). |
| 10.3 | 2018 Employee Stock Purchase Plan, (incorporated by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1/A (File No. 333-227112) filed with the SEC on September 14, 2018). |
| 10.4 | Employment Agreement between the Registrant and John Houston, Ph.D., dated September 13, 2018 (incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1/A (File No. 333-227112) filed with the SEC on September 14, 2018). |
| 10.5 | Employment Agreement between the Registrant and Sean Cassidy, dated August 28, 2018 (incorporated by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1/A (File No. 333-227112) filed with the SEC on September 14, 2018). |
| 10.6 | Employment Agreement between the Registrant and Ian Taylor, Ph.D., dated August 28, 2018 (incorporated by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form S-1/A (File No. 333-227112) filed with the SEC on September 14, 2018). |
| 10.7 | Employment Agreement between the Registrant and Andrew Crew, Ph.D., dated August 28, 2018 (incorporated by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form S-1/A (File No. 333-227112) filed with the SEC on September 14, 2018). |
| 10.8 | Amended and Restated Consulting Agreement between the Registrant and Craig Crews, dated July 5, 2013, as amended on August 27, 2018 (incorporated by reference to Exhibit 10.14 to the Registrant's Registration Statement on Form S-1/A (File No. 333-227112) filed with the SEC on September 14, 2018). |
| 10.9 | Lease Agreement between the Registrant and Science Park Development Corporation, dated December 31, 2017, as amended by First Amendment to Lease, dated May 23, 2018, and second Amendment to Lease, dated September 4, 2018 (incorporated by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1/A (File No. 333-227112) filed with the SEC on September 14, 2018). |
| 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 |

* filed herewith

** furnished herewith

**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.

Arvinas, Inc.

Date: November 14, 2018

By: /s/ John Houston, Ph.D.

**John Houston, Ph.D.**
**President and Chief Executive Officer**
**(Principal Executive Officer)**

Date: November 14, 2018

By: /s/ Sean Cassidy

**Sean Cassidy**
**Chief Financial Officer and Treasurer**
**(Principal Financial and Accounting Officer)**

**Exhibit 31.1**

**CERTIFICATION PURSUANT TO**
**RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,**
**AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, John Houston, Ph.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Arvinas, Inc.;

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

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

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

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

   (b) 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 small registrant's internal control over financial reporting; and

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

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

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

Date: November 14, 2018

By: /s/ John Houston, Ph.D.

**John Houston, Ph.D.**
**President and Chief Executive Officer**
**(Principal Executive Officer)**

**Exhibit 31.2**

**CERTIFICATION PURSUANT TO**
**RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,**
**AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Sean Cassidy, certify that:

1. I have reviewed this Quarterly Report of Arvinas, Inc.;

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

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

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

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

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

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

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

Date: November 14, 2018

By: /s/ Sean Cassidy

**Sean Cassidy**
**Chief Financial Officer and Treasurer**
**(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**

In connection with the Quarterly Report of Arvinas, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: November 14, 2018

By: /s/ John Houston, Ph.D.

**John Houston**
**President and 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**

In connection with the Quarterly Report of Arvinas, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: November 14, 2018

By: /s/ Sean Cassidy

**Sean Cassidy**
**Chief Financial Officer and Treasurer**
**(Principal Financial and Accounting Officer)**