Aimmune Therapeutics, Inc.
Form 10-Q
November 04, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2015

OR

o 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: 001-37519

AIMMUNE THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

| Delaware | 45-2748244 |
| --- | --- |
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |

8000 Marina Blvd #300

Brisbane, California 94005

(Address of principal executive offices including zip code)

Registrant's telephone number, including area code: (650) 614-5220

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 x No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No o

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

| | |
|---|---|
| Large accelerated filer o | Accelerated filer o |
| Non-accelerated filer x (do not check if a smaller reporting company) | Smaller reporting company o |

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

As of October 31, 2015 the registrant had 42,249,431 shares of common stock, $0.0001 par value per share, outstanding.

Aimmune Therapeutics, Inc.

Quarterly Report on Form 10-Q

For the Quarter Ended September 30, 2015

INDEX

PART I. – FINANCIAL INFORMATION

Item 1. Financial Statements

AIMMUNE THERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share amounts)

| | September 30, 2015 (unaudited) | December 31, 2014 |
|---|---|---|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | $ 112,661 | $ 2,269 |
| Short-term investments | 103,946 | — |
| Prepaid expenses | 1,180 | 106 |
| Total current assets | 217,787 | 2,375 |
| Long-term investments | 2,784 | — |
| Property and equipment, net | 1,829 | 87 |
| Restricted cash | 100 | 40 |
| Other assets | 314 | 29 |
| Total assets | $ 222,814 | $ 2,531 |
| Liabilities and Stockholders' Equity | | |
| Current liabilities: | | |
| Accounts payable | $ 1,014 | $ 478 |
| Accrued liabilities | 1,848 | 1,259 |
| Other current liabilities | 238 | 67 |
| Total current liabilities | 3,100 | 1,804 |
| Other liabilities | 826 | 56 |
| Total liabilities | 3,926 | 1,860 |
| Commitments and contingencies (Note 5) | | |
| Stockholders' equity: | | |
| Series A convertible preferred stock, par value $0.0001 per share—0 and 13,263,967 shares authorized as of September 30, 2015 (unaudited) and December 31, 2014, respectively; 0 and 13,263,967 shares issued and outstanding as of September 30, 2015 (unaudited) and December 31, 2014, respectively; aggregate liquidation preference of $0 and $16,989 as of September 30, 2015 (unaudited) and December 31, 2014, respectively | — | 16,928 |
| Series B convertible preferred stock, par value $0.0001 per share—0 shares | — | — |

| | | |
|---|---|---|
| authorized as of September 30, 2015 (unaudited) and December 31, 2014; 0 shares issued and outstanding as of September 30, 2015 (unaudited) and December 31, 2014; aggregate liquidation preference of nil as of September 30, 2015 (unaudited) and December 31, 2014 | | |
| Common stock, par value $0.0001 per share—50,046,000 and 32,925,000 shares authorized as of September 30, 2015 (unaudited) and December 31, 2014, respectively; 42,249,431 and 4,252,248 shares issued and outstanding as of September 30, 2015 (unaudited) and December 31, 2014, respectively (including 770,786 and 788,873 shares subject to repurchase, legally issued and outstanding as of September 30, 2015 (unaudited) and December 31, 2014, respectively) | 4 | — |
| Additional paid-in capital | 256,211 | 1,260 |
| Accumulated other comprehensive loss | (2) | — |
| Accumulated deficit | (37,325) | (17,517) |
| Total stockholders' equity | 218,888 | 671 |
| Total liabilities and stockholders' equity | $ 222,814 | $ 2,531 |

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

AIMMUNE THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE LOSS

(In thousands, except share and per share amounts)

(Unaudited)

| | Three Months Ended | | Nine Months Ended | |
|---|---|---|---|---|
| | September 30, | | September 30, | |
| | 2015 | 2014 | 2015 | 2014 |
| Operating expenses | | | | |
| Research and development | $3,850 | $2,469 | $9,050 | $5,470 |
| General and administrative | 5,174 | 660 | 10,792 | 2,028 |
| Total operating expenses | 9,024 | 3,129 | 19,842 | 7,498 |
| Loss from operations | (9,024) | (3,129) | (19,842) | (7,498) |
| Other income (expense), net | | | | |
| Interest income | 33 | — | 34 | 12 |
| Net loss | $(8,991) | $(3,129) | $(19,808) | $(7,486) |
| Other comprehensive loss, net of tax: | | | | |
| Unrealized losses on investments | (2) | — | (2) | — |
| Comprehensive loss | $(8,993) | $(3,129) | $(19,810) | $(7,486) |
| | | | | |
| Net loss per common share, basic and diluted | $(0.36) | $(1.07) | $(1.73) | $(2.56) |
| Weighted average shares used in computing net loss per share, | | | | |
| basic and diluted | 25,149,428 | 2,926,665 | 11,446,922 | 2,926,665 |

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

AIMMUNE THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS

(In thousands)

(Unaudited)

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2015 | 2014 |
| Cash flows from operating activities: | | |
| Net loss | $(19,808) | $(7,486) |
| Adjustments to reconcile net loss to net cash used in operating activities | | |
| Depreciation | 60 | 15 |
| Stock-based compensation | 2,751 | 48 |
| Investment premium amortization, net | 57 | — |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses | (1,072) | (121) |
| Other assets | (285) | (3) |
| Accounts payable | 536 | 586 |
| Accrued liabilities | 590 | 423 |
| Other | 73 | — |
| Net cash used in operating activities | (17,098) | (6,538) |
| Cash flows from investing activities: | | |
| Purchase of property and equipment | (1,091) | (51) |
| Purchase of investments | (106,790) | — |
| Restricted cash | (60) | (40) |
| Net cash used in investing activities | (107,941) | (91) |
| Cash flows from financing activities: | | |
| Proceeds from issuance of common stock, net of issuance costs | 168,117 | — |
| Net proceeds from issuance of Series B convertible preferred stock, net of issuance costs | 79,779 | — |
| Repurchase of Series A convertible preferred stock | (12,874) | — |
| Net cash proceeds from exercise of stock options, including early exercise | 440 | — |
| Repurchases of common stock subject to early exercise | (31) | — |
| Net cash provided by financing activities | 235,431 | — |
| Net increase (decrease) in cash and cash equivalents | 110,392 | (6,629) |
| Cash and cash equivalents at the beginning of the period | 2,269 | 11,951 |
| Cash and cash equivalents at the end of the period | $112,661 | $5,322 |
| Supplemental schedule of non-cash investing and financing activities: | | |
| Conversion of convertible preferred stock to common stock at closing of initial public offering | $83,833 | $— |
| Capital expenditures and interest funded through long term lease obligation | $711 | $— |

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

AIMMUNE THERAPEUTICS, INC.

NOTES TO UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2015

1. Formation and Business of the Company

Aimmune Therapeutics, Inc. ("Aimmune Therapeutics" or the "Company"), formerly known as Allergen Research Corporation, is a clinical-stage biopharmaceutical company advancing a new therapeutic approach, including the development of proprietary candidates, for the treatment of peanut and other food allergies. The Company is headquartered in Brisbane, California and was incorporated in the state of Delaware on June 24, 2011.

Since inception, the Company has incurred net losses and negative cash flows from operations. During the nine months ended September 30, 2015, the Company incurred a net loss of $19.8 million and used $17.1 million of cash in operations. As of September 30, 2015, the Company had an accumulated deficit of $37.3 million and the Company does not expect to experience positive cash flows in the near future. The Company has financed operations to date primarily through private placements of equity securities and its initial public offering ("IPO") of common stock in August 2015. The Company's ability to continue to meet its obligations and to achieve its business objectives is dependent upon a number of factors, which include raising additional capital, obtaining U.S. Food and Drug Administration ("FDA") and European Medicines Agency ("EMA") approval and commercializing in the United States and Europe, generating sufficient revenue and its ability to continue to control expenses, if necessary, to meet its obligations as they become due for the foreseeable future. Failure to obtain FDA and EMA approval, commercialize its lead product candidate, manage discretionary expenditures or raise additional financing, as required, may adversely impact the Company's ability to achieve its intended business objectives.

Initial Public Offering

On August 5, 2015, the Company's registration statement on Form S-1 (File No. 333-205501) relating to its IPO of common stock became effective. The IPO closed on August 11, 2015 at which time the Company issued 11,499,999 shares of its common stock at a price of $16.00 per share, which included 1,499,999 shares sold pursuant to the exercise of the underwriters' option to purchase additional shares. The Company received proceeds of approximately $168 million, net of underwriting discounts and commissions, and offering expenses. In addition, upon the Company's IPO, all outstanding shares of convertible preferred stock converted by their terms into approximately 25.1 million shares of common stock. As of September 30, 2015, the Company had 42,249,431 shares of common stock outstanding. See Note 6, "Stockholders' Equity."

Stock Split

On July 30, 2015, the Company effected a 1-for-1.317 stock split of the Company's common stock and convertible preferred stock. The par value of the authorized stock was not adjusted as a result of the stock split. In addition, the Company increased the number of authorized shares of common stock to 55,051,264 and the number of authorized shares of preferred stock to 25,051,264. All issued and outstanding common stock, convertible preferred stock, stock options and per share amounts contained in the accompanying condensed consolidated financial statements and notes to the condensed consolidated financial statements have been retroactively adjusted to give effect to the stock split for all periods presented. In conjunction with the Company's IPO, the Company filed its amended and restated certificate of incorporation that authorized 290,000,000 shares of common stock, $0.0001 par value per share, and 10,000,000

shares of preferred stock, $0.0001 par value per share.

2. Summary of Significant Accounting Policies

Basis of Preparation

The accompanying condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and applicable rules and regulations of the Securities and Exchange Commission ("SEC") regarding interim financial reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. GAAP have been condensed or omitted, and accordingly the balance sheet as of December 31, 2014 has been derived from audited consolidated financial statements at that date but does not include all of the information required by U.S. GAAP for complete financial statements. These condensed consolidated financial statements have been prepared on the same basis as our annual financial statements and, in the opinion of management, reflect all adjustments (consisting only of normal recurring adjustments) that are necessary for a fair presentation of our financial information. The results of operations for the three and nine months ended September 30, 2015 are not necessarily indicative of the results to be expected for the year ending December 31, 2015 or for any other interim period or for any other future year. The company operates in one reportable segment.

The accompanying condensed consolidated financial statements and related financial information should be read in conjunction with the audited consolidated financial statements and the related notes thereto for the year ended December 31, 2014 included in our Registration Statement on Form S-1 filed with the SEC.

Basis of Consolidation

The accompanying condensed consolidated financial statements of the Company include the accounts of its wholly-owned subsidiary. All significant intercompany transactions have been eliminated.

Use of Estimates

The preparation of the accompanying condensed consolidated financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements, and the reported amounts of costs and expenses during the reporting period. The Company bases its estimates and assumptions on historical experience when available and on various factors that it believes to be reasonable under the circumstances. The Company evaluates its estimates and assumptions on an ongoing basis. The Company's actual results could differ from these estimates under different assumptions or conditions.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less from the date of purchase to be cash equivalents. Cash equivalents consist primarily of money market funds and certain available-for-sale investments with maturities of three months or less.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents and certain investments in money market funds, agency securities, corporate securities, and commercial paper. Bank deposits are primarily held by a single financial institution and these deposits may exceed insured limits. The Company is exposed to credit risk in the event of default by the financial institution holding its cash and cash equivalents and issuers of investments that are recorded on the condensed consolidated balance sheets. The Company mitigates its risk by investing in high-grade instruments and limiting the concentration in any one issuer, which limits the Company's exposure.

Investments

The Company's available-for-sale investments consist primarily of money market funds, agency securities, corporate securities, and commercial paper. Investments with original maturities of greater than 90 days but less than one (1) year are classified as short-term available-for-sale securities on the condensed consolidated balance sheets. Investments with original maturities greater than one (1) year are classified as long-term available-for-sale securities on the condensed consolidated balance sheets.

The Company's investments in available-for-sale securities are reported at fair value. Unrealized gains and losses related to changes in the fair value of securities are recognized in accumulated other comprehensive loss, net of tax, on our condensed consolidated balance sheets. Changes in the fair value of available-for-sale securities impact the statements of operations only when such securities are sold or an other-than-temporary impairment is recognized. Realized gains and losses on the sale of securities are determined by specific identification of each security's cost basis. The Company regularly reviews its investment portfolio to determine if any security is other-than-temporarily

impaired, which would require us to record an impairment charge in the period any such determination is made. In making this judgment, the Company evaluates, among other things, the duration and extent to which the fair value of a security is less than its cost, the financial condition of the issuer and any changes thereto, and its intent to sell, or whether it is more likely than not that the Company will be required to sell the security before recovery of its amortized cost basis. The Company's assessment on whether a security is other-than-temporarily impaired could change in the future due to new developments or changes in assumptions related to any particular security.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets. Maintenance and repairs are charged to operations as incurred. Upon sale or retirement of assets, the cost and related accumulated depreciation are removed from the balance sheet and the resulting gain or loss, if any, is reflected in operations.

The useful lives of property and equipment are as follows:

| | |
|---|---|
| Furniture and office equipment | 4 years |
| Computer equipment | 3 years |
| Buildings | 25 years |
| Fixtures | 10 years |

Impairment of Long-Lived Assets

The Company evaluates its long-lived assets, including property and equipment, for impairment whenever events or changes in circumstances indicate that the carrying value of these assets may not be recoverable. Recoverability of these assets is measured by comparison of the carrying amount of each asset to the future undiscounted cash flows expected to result from the use of the asset and its eventual disposition. If the asset is considered to be impaired, the amount of any impairment is measured as the difference between the carrying value and the fair value of the impaired assets. The Company has not recorded impairment of any long-lived assets in the periods presented.

Leases

The Company entered into lease agreements for its previous corporate headquarters in San Mateo, California through July 2017. In March 2015, the Company entered into a lease for its current corporate headquarters in Brisbane, California. In May 2015, the Company ceased use of its San Mateo facility and moved into its current facility. In August 2015, the Company entered into an amendment to the Brisbane, California facility lease. Pursuant to the amendment, the Company will lease an additional 11,655 square feet of office space, and the term of the existing office space has been extended so that it is coterminous with the new space.

These leases are classified as operating leases. Rent expense is recognized on a straight-line basis over the terms of the leases and, accordingly, the Company records the difference between cash rent payments and the recognition of rent expense as a deferred rent liability. Incentives granted under the Company’s facilities leases are deferred and recognized as adjustments to rental expense on a straight-line basis over the term of the lease.

In June 2015, the Company signed a lease for a manufacturing facility in Clearwater, Florida. The Company was considered the deemed owner for accounting purposes. See Note 5, “Commitments and Contingencies.”

Research and Development

The Company expenses research and development costs as incurred. The Company records accrued liabilities for estimated costs of research and development activities conducted by third-party service providers, which include the conduct of pre-clinical studies and clinical trials and contract manufacturing activities. These costs are a significant component of the Company’s research and development expenses. The Company accrues for these costs based on factors such as estimates of the work completed and in accordance with agreements established with its third-party service providers under the service agreements. The Company makes significant judgments and estimates in determining the accrued liabilities balance in each reporting period. As actual costs become known, the Company adjusts its accrued liabilities. The Company has not experienced any material differences between accrued costs and actual costs incurred. However, the status and timing of actual services performed, number of patients enrolled and the

rate of patient enrollments may vary from the Company's estimates, resulting in adjustments to expense in future periods. Changes in these estimates that result in material changes to the Company's accruals could materially affect the Company's results of operations.

Stock-based Compensation

Stock-based awards issued to employees, including stock options, are measured at fair value on the grant date using the Black-Scholes option-pricing model and recognized as expense on a straight-line basis over the employee's requisite service period (generally the vesting period). Because noncash stock compensation expense is based on awards ultimately expected to vest, it is reduced by an estimate for future forfeitures. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from estimates. There were 3,980,328 and 1,635,679 stock options granted during the nine months ended September 30, 2015 and 2014, respectively.

Income Taxes

The Company uses the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of reported assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company must then assess the likelihood that the resulting deferred tax assets will be realized. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. Due to the Company's lack of earnings history, the net deferred tax assets have been fully offset by a valuation allowance.

The Company has adopted Financial Accounted Standards Board Accounting Standards Codification 740, Income Taxes, regarding how uncertain tax positions should be recognized, measured, presented, and disclosed in the financial statements. As of September 30, 2015 and December 31, 2014, the Company does not have any unrecognized tax benefits.

Comprehensive Income or Loss

Comprehensive income or loss is defined as the change in equity during a period from transactions and other events, excluding changes resulting from investments from owners and distributions to owners. Other comprehensive loss includes net loss and unrealized losses on available-for-sale investments.

Offering Costs

Offering costs represent underwriting, legal, accounting and other direct costs related to the Company's IPO. These costs were deferred until completion of the IPO, at which time they were reclassified to additional paid-in capital as a reduction of the proceeds.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, or FASB, issued Auditing Standards Update, or ASU, No. 2014-09, Revenue from Contracts with Customers (Topic 606), which provides a framework for addressing revenue recognition issues and, upon its effective date, replaces almost all existing revenue recognition guidance, including industry-specific guidance, in current U.S. generally accepted accounting principles ("U.S. GAAP"). The ASU provides a five-step analysis of transactions to determine when and how revenue is recognized. The ASU will require many companies to use more judgment than under current U.S. GAAP. For public business entities, ASU 2014-09 is effective for annual periods beginning after December 15, 2017, however early adoption is permitted for annual periods beginning after December 15, 2016. Public business entities will be required to apply the new revenue standard to interim reporting periods beginning in the first interim period within the year of adoption.

In August 2014, the FASB issued ASU No. 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. ASU 2014-15 requires management to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. In doing so, companies will have reduced diversity in the timing and content of footnote disclosures than under today's guidance. ASU 2014-15 is effective for the Company in the first quarter of 2016 with early adoption permitted. We do not believe the impact of adopting ASU 2014-15 on our consolidated financial statements will be material.

3. Fair Value Measurements

The carrying amounts of certain of the Company's financial instruments, including cash equivalents and accounts payable approximated their fair values due to their short maturities. Assets and liabilities recorded at fair value on a recurring basis in the balance sheets, as well as assets and liabilities measured at fair value on a non-recurring basis or disclosed at fair value, are categorized based upon the level of judgment associated with inputs used to measure their fair values. The accounting guidance for fair value provide a framework for measuring fair value, and requires certain disclosures about how fair value is determined. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The accounting guidance also establishes a three-level valuation hierarchy that prioritizes the inputs to valuation techniques used to measure fair value based upon whether such inputs are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions made by the reporting entity. The three-level hierarchy for the inputs to valuation techniques is briefly summarized as follows:

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

Level 2—Inputs are observable, unadjusted quoted prices in active markets for similar assets or liabilities, unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and

Level 3—Unobservable inputs that are significant to the measurement of the fair value of the assets or liabilities that are supported by little or no market data.

The Company's valuation techniques used to measure the fair value of money market funds and certain marketable equity securities were derived from quoted prices in active markets for identical assets or liabilities. The valuation techniques used to measure the fair value of the Company's debt instruments and all other financial instruments, all of which have counterparties with high credit ratings, were valued based on quoted market prices or model driven valuations using significant inputs derived from or corroborated by observable market data.

In accordance with fair value accounting requirements, companies may choose to measure eligible financial instruments and certain other items at fair value. The Company has not elected the fair value option for any eligible financial instruments.

The following table sets forth the Company's financial instruments that were measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

| | September 30, 2015 (unaudited) | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| Cash and cash equivalents: | | | | |
| Cash and money market funds | $61,417 | $— | $ — | $61,417 |
| Agency securities | — | 12,999 | — | 12,999 |
| Corporate securities | — | 8,250 | — | 8,250 |
| Commercial paper | — | 29,995 | — | 29,995 |
| Total cash and cash equivalents | $61,417 | $51,244 | $ — | $112,661 |
| Available-for-sale investments: | | | | |
| Agency securities | $— | $37,905 | $ — | $37,905 |
| Corporate securities | — | 41,851 | — | 41,851 |
| Commercial paper | — | 26,974 | — | 26,974 |
| Total available-for-sale investments | $— | $106,730 | $ — | $106,730 |

| | December 31, 2014 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| Cash and cash equivalents: | | | | |
| Cash and money market funds | $2,269 | $ — | $ — | $2,269 |
| Agency securities | — | — | — | — |
| Corporate securities | — | — | — | — |

| | | | | |
|---|---|---|---|---|
| Commercial paper | — | — | — | — |
| Total cash and cash equivalents | $2,269 | $ — | $ — | $2,269 |
| Available-for-sale investments: | | | | |
| Agency securities | $— | $ — | $ — | $— |
| Corporate securities | — | — | — | — |
| Commercial paper | — | — | — | — |
| Total available-for-sale investments | $— | $ — | $ — | $— |

Available-for-sale investments are carried at fair value and are included in the tables above. The aggregate market value, cost basis, and gross unrealized gains and losses of available-for-sale investments by security type, classified in cash equivalents, short-term investments, and long-term investments, as of September 30, 2015 are as follows (in thousands):

| | Amortized Cost | Gross unrealized gains | Gross unrealized losses | Total fair value |
|---|---|---|---|---|
| Agency securities | $50,889 | $ 15 | $ — | $50,904 |
| Corporate securities | 50,118 | 9 | (26) | 50,101 |
| Commercial paper | 56,969 | — | — | 56,969 |
| Total available-for-sale investments | $157,976 | $ 24 | $ (26) | $157,974 |

There were no available-for-sale investments as of December 31, 2014. There were no gross realized gains or losses on sales of available-for-sale securities for the nine months ended September 30, 2015. The net adjustment to unrealized holding gains (losses) on available-for-sale securities included in other comprehensive loss totaled approximately $2,000 for the nine months ended September 30, 2015.

Contractual maturities of debt investment securities as of September 30, 2015 are as follows (in thousands):

| | Total Fair Value |
|---|---|
| Maturing within one year | $103,946 |
| Maturing in one to five years | 2,784 |
| Total available-for-sale investments | $106,730 |

There were no investment securities as of December 31, 2014. Expected maturities will differ from contractual maturities because the issuers of the securities may have the right to prepay obligations without prepayment penalties.

At each reporting date, the Company performs separate evaluations of impaired debt securities to determine if the unrealized losses are other-than-temporary.

For debt securities, management determines whether it intends to sell or if it is more likely than not that it will be required to sell impaired securities. This determination considers current and forecasted liquidity requirements, regulatory and capital requirements and securities portfolio management. For all impaired debt securities for which there was no intent or expected requirement to sell, the evaluation considers all available evidence to assess whether it is likely the amortized cost value will be recovered. The Company conducts a regular assessment of its debt securities with unrealized losses to determine whether securities have other-than-temporary impairment considering, among other factors, the nature of the securities, credit rating or financial condition of the issuer, the extent and duration of the unrealized loss, expected cash flows of underlying collateral, market conditions and whether the Company intends to sell or it is more likely than not the Company will be required to sell the debt securities.

Based on the Company’s analysis, the Company did not identify any other-than-temporary losses for the nine months ended September 30, 2015. The Company does not consider unrealized losses on its other debt securities to be credit-related. These unrealized losses relate to changes in interest rates and market spreads subsequent to purchase. A substantial portion of securities that have unrealized losses are US corporate securities that are highly-rated. The Company has not made a decision to sell securities with unrealized losses and believes it is more likely than not it would not be required to sell such securities before recovery of its amortized cost.

4. Balance Sheet Components

Property and Equipment, Net

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

| | September 30, 2015 (unaudited) | December 31, 2014 |
|---|---|---|
| Furniture and equipment | $ 219 | $ 58 |
| Computer equipment | 254 | 67 |
| Construction in progress | 1,454 | — |
| Property and equipment, gross | 1,927 | 125 |
| Less: accumulated depreciation | (98) | (38) |
| Property and equipment, net | $ 1,829 | $ 87 |

Depreciation expense for the three months ended September 30, 2015 and 2014 was $30,000 and $9,000, respectively, and for the nine months ended September 30, 2015 and 2014, was $60,000 and $15,000, respectively.

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

| | September 30, 2015 (unaudited) | December 31, 2014 |
|---|---|---|
| Compensation and benefits | $ 896 | $ 645 |
| Research and development | 281 | 542 |
| Professional and consulting | 657 | 71 |
| Other | 14 | 1 |
| Total | $ 1,848 | $ 1,259 |

5. Commitments and Contingencies

Facility Leases

In May 2015, the Company ceased use of its previous corporate headquarters and accrued a liability for approximately $121,000 as of June 30, 2015, net of estimated sublease payments. In September 2015, the Company revised its estimate for actual sublease payments which resulted in a complete reduction of the liability previously accrued. The reduction of the liability is reflected within rent expense for the period ended September 30, 2015.

In March 2015, the Company signed a new facility lease for its corporate headquarters in Brisbane, California. The new lease, which has been classified as an operating lease, commenced on May 1, 2015 with an initial term of 51 months. In August 2015, the Company entered into an amendment to the lease. Pursuant to the amendment, the

Company will lease an additional 11,655 square feet of office space. The term for the new space is 72 months from the delivery of the premises to the Company, which is expected to occur near the end of 2015. In addition, the term of the existing office space has been extended so that it is coterminous with the new space. The amendment required a total security deposit of approximately $304,000. As of the commencement of the amendment, future aggregate minimum lease payments for the combined space are as follows (in thousands):

| Year Ended December 31, | |
|---|---|
| 2015 | $190 |
| 2016 | 1,010 |
| 2017 | 1,602 |
| 2018 | 1,650 |
| and after | 5,265 |
| Total | $9,717 |

The Company is responsible for operating expenses over base operating expenses as defined in the headquarters lease agreement.

In June 2015, the Company signed a facility lease for a manufacturing facility in Clearwater, Florida. The initial term of the lease is for 120 months. For accounting purposes, due to the nature and extent of the Company's involvement with the construction of this manufacturing facility, it was considered to be the owner of the assets during the construction period through the lease commencement date, even though the lessor is responsible for funding and repairing components of the building shell and constructing a portion of the related building infrastructure. Construction to this building commenced in July 2015 and as of September 30, 2015, the Company has incurred approximately $188,000 of construction and equipment costs related to the building which is recorded in Construction in progress. The Company also recorded $687,500 to Construction in progress for costs incurred by the lessor and recognized a corresponding amount included within other liabilities within the accompanying condensed consolidated balance sheet. The agreement calls for a security deposit of $35,000. The new lease calls for future aggregate minimum lease payments as of the commencement of the lease as follows (in thousands):

| Year Ended December 31, | |
|---|---|
| 2015 | $38 |
| 2016 | 151 |
| 2017 | 156 |
| 2018 | 160 |
| and after | 1,198 |
| Total | $1,703 |

The Company is responsible for operating expenses including real estate taxes as defined in the manufacturing facility lease agreement.

Rent expense under operating leases for the three months ended September 30, 2015 and 2014 was $87,000 and $41,000, respectively, and for the nine months ended September 30, 2015 and 2014 was $342,000 and $90,000, respectively.

Purchase Commitments

The Company purchases peanut flour, the source material for AR101, from the Golden Peanut Company pursuant to a long term exclusive commercial supply agreement. Pursuant to the agreement, the Company's purchase obligation commences with the first delivery of peanut flour for commercial use, which it currently anticipates will not occur prior to 2018. Assuming the Company starts its purchase obligation of peanut flour for commercial use in 2018, which is not assured, the aggregate purchase commitment under this agreement is $1.2 million over a term of five years.

Indemnifications

The Company indemnifies each of its officers and directors for certain events or occurrences, subject to certain limits, while the officer or director is or was serving at the Company's request in such capacity, as permitted under Delaware law and in accordance with its certificate of incorporation and bylaws. The term of the indemnification period lasts as long as an officer or a director may be subject to any proceeding arising out of acts or omissions of such officer or director in such capacity. The maximum amount of potential future indemnification is unlimited; however, the Company currently holds director and officer liability insurance. This insurance allows the transfer of risk associated with the Company's exposure and may enable it to recover a portion of any future amounts paid. The Company

believes that the fair value of these indemnification obligations is minimal. Accordingly, it has not recognized any liabilities relating to these obligations for any period.

Legal

During the normal course of business, the Company may be a party to legal claims that may not be covered by insurance. Management does not believe that any such claims would have a material impact on the Company's consolidated financial statements.

6. Stock-based Awards

In January 2013, the Company adopted its Stock Plan (the "2013 Plan") and in July 2015, the Company adopted a new Stock Plan (the "2015 Plan"). 4,681,544 shares of the Company's common stock are initially reserved under the 2015 Plan for the issuance of stock options and restricted stock to employees, directors, and consultants under terms and provisions established by the Board of Directors and approved by the Company's stockholders. Upon consummation of the Company's IPO, the 2013 Plan was terminated and no further shares are reserved for issuance under the 2013 Plan. As of September 30, 2015 and December 31, 2014 there were 4,548,306 and 639,625 and shares available for future grant, respectively. Under the terms of the 2015 Plan, options may be granted at an exercise price not less than fair market value. For employees holding more than 10% of the voting rights of all classes of stock, the exercise prices for incentive stock options may not be less than 110% of fair market value, as determined by the Board of Directors. The terms of options granted under the Plan may not exceed ten years. All options issued to date have had a ten-year life. To date, options granted generally vest in three ways: 1) over four years at a rate of 25% upon the first anniversary of the issuance date and 1/48$^{th}$ per month thereafter, 2) over two years at a rate of 1/24$^{th}$ per month, and 3) over four years at a rate of 1/48$^{th}$ per month. The 2015 Plan contains certain change of control provisions and the employment offer letters of certain employees provide for varied acceleration of vesting in the event of a change of control and/or termination without cause. It also contains a net exercise provision and allows for cashless exercise upon the class of shares subject to the option becoming publicly traded in an established securities market.

The 2013 Plan allowed employees to exercise a stock option in exchange for cash before the requisite service is provided (e.g., before the award is vested under its original terms); however, such arrangements permit the Company to subsequently repurchase such shares at the exercise price if the vesting conditions are not satisfied. Such an exercise is not substantive for accounting purposes. Therefore, the payment received by the Company for the exercise price is recognized as an early exercise liability on the balance sheets and will be transferred to common stock and additional paid-in capital as such shares vest. As of September 30, 2015 and December 31, 2014, 770,786 and 788,873 unvested shares were legally issued and outstanding, respectively. In connection with these unvested shares, the Company has recorded an early exercise liability as of September 30, 2015 of $271,000, of which $156,000 is included in other current liabilities and $115,000 is included in other non-current liabilities in the Company's Balance Sheet. These shares are excluded from basic net loss per share until the Company's repurchase right lapses and the shares are no longer subject to the repurchase feature.

Activity under the Plan is set forth below:

| | | Options Outstanding | | |
|---|---|---|---|---|
| | Shares Available for Grant | Number of Options and Unvested Shares | Weighted Average Exercise Price | Weighted Average Remaining Contractual Life (in years) | Aggregate Intrinsic Value (in thousands) |
| Balance, December 31, 2014 | 639,625 | 2,566,559 | $0.14 | 9.19 | |
| Additional shares authorized | 7,908,194 | | | | |
| Shares retired upon adoption of 2015 Plan | (230,978) | | | | |
| Options granted | (3,980,328) | 3,980,328 | $5.47 | | |

| | | | | | |
|---|---|---|---|---|---|
| Options exercised and shares vested | | (1,464,016) | $0.16 | | |
| Options repurchased | 211,793 | (211,793 ) | $0.14 | | |
| Options cancelled | — | — | | | |
| Balances – September 30, 2015 | 4,548,306 | 4,871,078 | $4.49 | 9.59 | $ 101,441 |
| Options vested and expected to vest as of September 30, 2015 (unaudited) | | 4,489,667 | $4.73 | 9.17 | $ 92,439 |
| Options exercisable as of September 30, 2015 (unaudited) | | 3,967,049 | $4.82 | 9.59 | $ 81,316 |

The aggregate intrinsic values of options outstanding, exercisable, and vested and expected to vest were calculated as the difference between the exercise price of the options and the market price for shares of the Company's common stock as of September 30, 2015. The 2013 Plan provided for early exercise, therefore, all the Company's outstanding stock options issued under that plan are exercisable.

Stock Options Granted

Stock options granted during the three months ended September 30, 2015 and 2014 had a weighted-average grant-date fair value of $11.05and $0.09, respectively. Stock options granted during the nine months ended September 30, 2015 and 2014 had a weighted-average grant-date fair value of $5.77 and $0.09, respectively. The fair value is being expensed over the vesting period of the options, which is either four years or two years on a straight-line basis as the services are being provided. No tax benefits were

realized from options during the periods. The Company issued one grant totaling 213,354 options to a non-employee during the three and nine-months ended September 30, 2015. The fair value of the non-employee options was measured using the Black-Scholes option-pricing model reflecting the same assumptions as applied to employee options, other than the expected life, which is assumed to be the remaining contractual life of the option.

As of September 30, 2015 and December 31, 2014 total unrecognized stock-based compensation expense was $17,503,000 and $120,000, which is expected to be recognized over the weighted-average remaining vesting period of 3.47 years and 2.43 years respectively.

The fair value of employee stock options was estimated using the Black-Scholes pricing model, with the following weighted-average assumptions (unaudited):

| | Three Months Ended | | Nine Months Ended | |
|---|---|---|---|---|
| | September 30, | | September 30, | |
| | 2015 | 2014 | 2015 | 2014 |
| Expected volatility | 71.22% | 79.62% | 74.47% | 79.62% |
| Risk free interest rate | 1.79 % | 1.51 % | 1.72 % | 1.51 % |
| Dividend yield | — | — | — | — |
| Expected term (in years) | 5.95 | 4.65 | 5.98 | 4.65 |

Determining Fair Value of Stock Options

The fair value of each grant of stock options was determined by the Company using the methods and assumptions discussed below. The determination of each of these inputs is subjective and generally requires significant judgment.

Expected volatility—The expected stock price volatility assumption was determined by examining the historical volatilities of a group of industry peers, as the Company did not have any trading history for the Company's common stock. The Company will continue to analyze the historical stock price volatility and expected term assumptions as more historical data for the Company's common stock becomes available.

Expected term—The expected term of stock options represents the weighted average period the stock options are expected to be outstanding. The Company's option grants are considered "plain vanilla." Therefore, the Company has opted to use the simplified method for estimating the expected term as provided by the Securities and Exchange Commission. The simplified method calculates the expected term as the average time- to-vesting and the contractual life of the options.

Expected dividend—The expected dividend assumption was based on the Company's history and expectation that it will not declare dividend payout for the near future.

Risk-free interest rate—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected terms.

Fair value of common stock—Prior to the Company's IPO, the fair value of the shares of common stock underlying the stock options was the responsibility of and determined by the Company's board of directors. Because there was no

public market for the Company's common stock, the board of directors determined fair value of common stock at the time of grant of the option by considering a number of objective and subjective factors including independent third-party valuations of the Company's common stock, sales of convertible preferred stock to unrelated third parties, operating and financial performance, the lack of liquidity of capital stock and general and industry specific economic outlook, amongst other factors. Following the IPO, the market traded price of the shares of common stock underlying the stock options is the fair value of the Company's stock as reported on the NASDAQ Global Select Market on the grant date.

Stock-based compensation expense, net of estimated forfeitures, is reflected in the statements of operations (in thousands, unaudited):

| | Three Months Ended | | Nine Months Ended | |
|---|---|---|---|---|
| | September 30, | | September 30, | |
| | 2015 | 2014 | 2015 | 2014 |
| Research and development | $300 | $ 5 | $396 | $ 14 |
| General and administrative | 1,462 | 12 | 2,355 | 34 |
| Total stock-based compensation expense | $1,762 | $ 17 | $2,751 | $ 48 |

During the three and nine months ended September 30, 2015, the Company recorded $0 and approximately $562,000 of stock compensation expense related to the acceleration of certain former executives' stock options.

7. Net Loss per Share

The following table sets forth the computation of the Company's basic and diluted net loss per share during the three and nine months ended September 30, 2015 and 2014(in thousands, except share and per share data, unaudited):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2015 | 2014 | 2015 | 2014 |
| Numerator: | | | | |
| Net loss | $(8,991) | $(3,129) | $(19,808) | $(7,486) |
| Denominator: | | | | |
| Shares used in computing net loss per share, basic and diluted | 25,149,428 | 2,926,665 | 11,446,922 | 2,926,665 |
| Net loss per share basic and diluted | $(0.36) | $(1.07) | $(1.73) | $(2.56) |

The following common stock equivalents were excluded from the computation of diluted net loss per share for the periods presented because their inclusion would have been antidilutive (unaudited):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2015 | 2014 | 2015 | 2014 |
| Convertible preferred stock | 11,436,443 | 13,263,967 | 22,289,679 | 13,263,967 |
| Stock options | 1,198,209 | 3,501,939 | 4,871,078 | 3,501,939 |

8. Subsequent Events

Executive Retirement

On October 6, 2015, the Company's Chief Operating Officer informed the Company of his decision to retire from his position effective October 31, 2015. In connection with his separation from the Company, the Company entered into a transition and separation agreement whereby he has agreed to provide transition consulting services to the Company through October 31, 2016, on an as needed basis. In addition, he will receive nine months of his base salary, company subsidized COBRA coverage until the earlier of the end of July 31, 2016 or the date on which he becomes eligible for coverage by another employer, and accelerated vesting of his outstanding equity awards that would have vested had he continued to provide service to the Company for the six (6)-month period following his termination date. His

outstanding equity awards will continue to vest in accordance to their terms after giving effect to the accelerated vesting while he provides consulting services to the Company. The Company did not record any termination charges during the nine months ended September 30, 2015 related to the retirement.

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

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our unaudited condensed consolidated financial statements and related notes included in Part I, Item 1 of this Quarterly Report on Form 10-Q and with our audited financial statements and related notes thereto for the year ended December 31, 2014, included in our prospectus dated August 5, 2015, filed with the Securities and Exchange Commission pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, or the Prospectus. This discussion and other parts of this report contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section of this report titled "Risk Factors." Except as may be required by law, we assume no obligation to update these forward-looking statements or the reasons that results could differ from these forward-looking statements.

Overview

We are a clinical-stage biopharmaceutical company advancing a new therapeutic approach, including the development of proprietary product candidates, for the treatment of peanut and other food allergies. This approach, which we refer to as Characterized Oral Desensitization Immunotherapy, or CODIT™, is a system designed to desensitize patients to food allergens using rigorously characterized biologic products, defined treatment protocols and tailored support services. In January 2015, we successfully completed ARC001, a Phase 2 study of our lead CODIT product candidate, AR101, for the treatment of peanut allergy. The ARC002 study, an open label, follow-on study to the initial ARC001 trial is ongoing, and we plan to report data from this trial in the first quarter of 2016.

We are planning to initiate enrollment in a Phase 3 registration trial of AR101 at the beginning of 2016. In addition, we intend to initiate two Phase 2 studies of CODIT product candidates in 2016.

AR101 has been granted Breakthrough Therapy and Fast-Track designations by the U.S. Food and Drug Administration, or FDA. In Europe, we received approval from the European Medicines Agency, or EMA, for our pediatric investigation plan (PIP), a required component of the EMA regulatory approval process, for AR101 for the treatment of peanut allergy. If our planned Phase 3 trial is successful, we intend to file a Biologics License Application, or BLA, with the FDA and a Marketing Authorization Application, or MAA, with the EMA. We have worldwide commercial rights to all of our product candidates and, if approved, we intend to commercialize in the United States and Europe with our own specialty sales force.

Since commencing our operations in 2011, substantially all of our efforts have been focused on research, development and the advancement of our lead CODIT product candidate, AR101. We have not generated any revenue from product sales and, as a result, we have incurred significant losses. We incurred a net loss of $9.0 million and $3.1 million for the three months ended September 30, 2015 and 2014, respectively, and $19.8 million and $7.5 million for the nine months ended September 30, 2015 and 2014, respectively. As of September 30, 2015 our accumulated deficit was $37.3 million. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase as we continue our development of, seek regulatory approval for, and begin to commercialize, AR101 and as we develop other product candidates.

We do not expect to generate revenue from product sales unless and until we successfully complete development of, obtain regulatory approval for, and begin to commercialize one or more of our product candidates, which we expect will take a number of years and is subject to significant uncertainty. Accordingly, we anticipate that we will need to raise additional capital to fund our future operations. Until such time that we can generate substantial revenue from

product sales, if ever, we expect to finance our operating activities through a combination of equity offerings and debt financings and we may seek to raise additional capital through strategic collaborations. However, we may be unable to raise additional funds or enter into such arrangements when needed on favorable terms, or at all, which would have a negative impact on our financial condition and could force us to delay, limit, reduce or terminate our development programs or commercialization efforts or grant to others rights to develop or market product candidates that we would otherwise prefer to develop and market ourselves. Failure to receive additional funding could cause us to cease operations, in part or in full. Furthermore, even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital due to favorable market conditions or strategic considerations.

We currently utilize contract manufacturers for all of our manufacturing activities. We entered into a lease for a manufacturing facility in Clearwater, Florida, but do not expect manufacturing operations by our contract manufacturer to commence at that facility until late-2016. Additionally, we currently utilize third-party clinical research organizations, or CROs, to carry out our clinical trials and we do not yet have a sales organization. We expect to significantly increase our investment in costs relating to our manufacturing process and sales organization as we prepare for the filing of a BLA with the FDA and a MAA with the EMA and prepare for a possible commercial launch of AR101.

Recent Developments

In August 2015, we completed our initial public offering, or IPO, of our common stock pursuant to which we issued 11,499,999 shares of our common stock at a price of $16.00 per share, which included 1,499,999 shares sold pursuant to the exercise of the underwriters' option to purchase additional shares. We received proceeds of approximately $168 million from the IPO, net of underwriting discounts and commissions, and offering expenses.

Components of Results of Operations

Research and Development Expenses

The largest component of our total operating expenses has historically been our investment in research and development activities. Research and development expenses consist primarily of:

- costs incurred to conduct research, such as the discovery and development of our product candidates;
- costs related to production of clinical supplies, including fees paid to contract manufacturers and allocated facility expenses;
- fees paid to clinical consultants, clinical trial sites and vendors, including clinical research organizations in conjunction with implementing and monitoring our clinical trials and acquiring and evaluating clinical trial data, including all related fees, such as for investigator grants, patient screening fees, laboratory work and statistical compilation and analysis;
- salaries and related costs, including stock-based compensation expense, for personnel in our research and development functions; and
- costs related to compliance with drug development regulatory requirements.

We recognize all research and development costs as they are incurred. Clinical trial costs, contract manufacturing and other development costs incurred by third parties are expensed as the contracted work is performed.

We expect our research and development expenses to increase in the future as we advance our product candidates into and through clinical trials and pursue regulatory approval of our product candidates in the United States and Europe. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming. The actual probability of success for our product candidates and technology platforms may be affected by a variety of factors including: the quality of our product candidates, early clinical data, investment in our clinical program, competition, manufacturing capability and commercial viability. We may never succeed in achieving regulatory approval for any of our product candidates. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of our product candidates.

General and Administrative Expenses

General and administrative expenses include personnel costs, expenses for outside professional services and other allocated expenses. Personnel costs consist of salaries, bonuses, severance, benefits and stock-based compensation. Outside professional services consist of legal, accounting and audit services and other consulting fees. Allocated expenses consist of rent expense related to our office facility. We expect to incur additional expenses as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the Securities and Exchange Commission, and those of The NASDAQ Global Select Market, additional insurance expenses, investor relations activities and other administrative and professional services.

18

Results of Operations

Comparison of the three months ended September 30, 2015 and 2014

| | Three Months Ended September 30, | | | |
|---|---|---|---|---|
| | 2015 | 2014 | $ Change | % Change |
| | (in thousands, except percentages) | | | |
| Operating expenses: | | | | |
| Research and development | $3,850 | $2,469 | $1,381 | 56 % |
| General and administrative | 5,174 | 660 | 4,514 | 684 % |
| Total operating expenses | 9,024 | 3,129 | 5,895 | 188 % |
| Loss from operations | (9,024) | (3,129) | (5,895) | 188 % |
| Other income (expense), net | | | | |
| Interest income | 33 | — | 33 | 0 % |
| Other expense | — | — | — | — |
| Net loss | $(8,991) | $(3,129) | $(5,862) | 187 % |

Research and Development Expenses

The following table summarizes our research and development expenses incurred during the three months ended September 30, 2015 and 2014:

| | Three Months Ended September 30, | | | |
|---|---|---|---|---|
| | 2015 | 2014 | $ Change | % Change |
| | (in thousands, except percentages) | | | |
| Clinical development and regulatory | $1,412 | $1,582 | $(170) | (11)% |
| Contract manufacturing | 692 | 424 | 268 | 63 % |
| Compensation and related personnel costs | 1,562 | 396 | 1,166 | 294 % |
| Other research and development costs | 57 | 13 | 44 | 338 % |
| Facility costs | 127 | 54 | 73 | 135 % |
| Total research and development | $3,850 | $2,469 | $1,381 | 56 % |

Research and development expenses were $3.9 million for the three months ended September 30, 2015, an increase of $1.4 million, from $2.5 million for the three months ended September 30, 2014. This increase was primarily attributable to a $1.2 million increase in compensation and related personnel costs to support continued AR101

development, including $0.3M increase in stock-based compensation, a $0.3 million increase in contract manufacturing and other costs associated with AR101 development, partially offset by a $0.2 million decrease in clinical development expenses associated with our Phase 2 clinical trial which was completed in January, 2015. We expect to incur additional research and development costs in connection with our ongoing ARC002 study and our planned ARC003 study.

General and Administrative Expenses

The following table summarizes our general and administrative expenses incurred during the three months ended September 30, 2015 and 2014:

| | Three Months Ended September 30, | | | | |
|---|---|---|---|---|---|
| | 2015 | 2014 | $ Change | % Change | |
| | (in thousands, except percentages) | | | | |
| Compensation and related personnel costs | $2,642 | $378 | $2,264 | 599 | % |
| Outside professional services | 1,955 | 179 | 1,776 | 992 | % |
| Facility costs | 297 | 48 | 249 | 519 | % |
| Other general and administrative | 280 | 55 | 225 | 409 | % |
| Total general and administrative | $5,174 | $660 | $4,514 | 684 | % |

General and administrative expenses were $5.2 million for the three months ended September 30, 2015, an increase of $4.5 million, from $0.7 million for the three months ended September 30, 2014. This increase was primarily due to a $2.3 million increase in compensation expenses related to additional administrative and executive personnel, including $1.5 million in stock-based compensation, and a $1.8 million increase in consulting services incurred for financial consulting and market research to inform our commercial strategy and support our growth. We expect to incur additional general and administrative costs associated with being a publicly traded company following our IPO in August 2015 and the hiring of additional personnel.

Comparison of the nine months ended September 30, 2015 and 2014

| | Nine Months Ended September 30, | | | | |
|---|---|---|---|---|---|
| | 2015 | 2014 | $ Change | % Change | |
| | (in thousands, except percentages) | | | | |
| Operating expenses: | | | | | |
| Research and development | $9,050 | $5,470 | $3,580 | 65 | % |
| General and administrative | 10,792 | 2,028 | 8,764 | 432 | % |
| Total operating expenses | 19,842 | 7,498 | 12,344 | 165 | % |
| Loss from operations | (19,842) | (7,498) | (12,344) | 165 | % |
| Other income (expense), net | | | | | |
| Interest income | 34 | 12 | 22 | 183 | % |
| Other expense | — | — | — | — | |
| Net loss | $(19,808) | $(7,486) | $(12,322) | 165 | % |

Research and Development Expenses

The following table summarizes our research and development expenses incurred during the nine months ended September 30, 2015 and 2014:

| | Nine Months Ended September 30, | | | | |
|---|---|---|---|---|---|
| | 2015 | 2014 | $ Change | % Change | |
| | (in thousands, except percentages) | | | | |
| Clinical development and regulatory | $3,507 | $2,745 | $ 762 | 28 | % |
| Contract manufacturing | 2,140 | 1,406 | 734 | 52 | % |
| Compensation and related personnel costs | 3,010 | 1,197 | 1,813 | 151 | % |

| | | | | | |
|---|---|---|---|---|---|
| Other research and development costs | 74 | 13 | 61 | 469 | % |
| Facility costs | 319 | 109 | 210 | 193 | % |
| Total research and development | $9,050 | $5,470 | $3,580 | 65 | % |

Research and development expenses were $9.1 million for the nine months ended September 30, 2015, an increase of $3.6 million, from $5.5 million for the nine months ended September 30, 2014. This increase was primarily attributable to a $1.8 million increase in compensation and related personnel costs to support continued AR101 development, including $0.4 million in stock-based compensation, a $0.8 million increase in clinical development and regulatory expenses mainly associated with our AR101 development program, and a $0.7 million increase in AR101 contract manufacturing costs. We expect to incur additional research and development costs in connection with our ongoing ARC002 study and our planned ARC003 study.

General and Administrative Expenses

The following table summarizes our general and administrative expenses incurred during the nine months ended September 30, 2015 and 2014:

| | Nine Months Ended September 30, | | | | |
|---|---|---|---|---|---|
| | 2015 | 2014 | $ Change | % Change | |
| | (in thousands, except percentages) | | | | |
| Compensation and related personnel costs | $4,745 | $1,152 | $3,593 | 312 | % |
| Outside professional services | 4,818 | 529 | 4,289 | 811 | % |
| Facility costs | 585 | 121 | 464 | 383 | % |
| Other general and administrative | 644 | 226 | 418 | 185 | % |
| Total general and administrative | $10,792 | $2,028 | $8,764 | 432 | % |

General and administrative expenses were $10.8 million for the nine months ended September 30, 2015, an increase of $8.8 million, from $2.0 million for the nine months ended September 30, 2014. This increase was primarily due to a $4.3 million increase in consulting services incurred for financial consulting, corporate communications activities, and market research to inform our commercial strategy and support our growth, and a $3.6 million increase in compensation expenses primarily related to additional administrative and executive personnel, including $2.3 million of stock-based compensation expense. We expect to incur additional general and administrative costs associated with being a publicly traded company following our IPO in August 2015 and the hiring of additional personnel.

Liquidity and Capital Resources

Prior to our IPO, our operations were financed primarily by net proceeds from the sale and issuance of convertible preferred stock. In January and February 2015, we received net proceeds of $79.8 million from the sale of our Series B convertible preferred stock, of which $12.9 million was used to repurchase outstanding shares of our Series A convertible preferred stock.

As of September 30, 2015, we had cash and cash equivalents and short-term investments of $216.6. In August 2015, we completed our IPO pursuant to which we issued 11,499,999 shares of our common stock at a price to the public of $16.00 per share, which included the exercise in full of the underwriters' option to purchase additional shares. We received proceeds of approximately $168 million, net of underwriting discounts and commissions, and offering expenses. We believe that our existing capital resources will be sufficient to fund our planned operations for the 24 months following our IPO, including through data readout of our planned Phase 3 registration trial for AR101.

We do not expect to generate revenue from product sales unless and until we successfully complete development of, obtain regulatory approval for and begin to commercialize one or more of our product candidates, which we expect will take a number of years and is subject to significant uncertainty. Accordingly, we anticipate that we will need to raise additional capital to fund our future operations. Until such time that we can generate substantial revenue from product sales, if ever, we expect to finance our operating activities through a combination of equity offerings and debt financings and we may seek to raise additional capital through strategic collaborations. However, we may be unable to

raise additional funds or enter into such arrangements when needed on favorable terms, or at all, which would have a negative impact on our financial condition and could force us to delay, limit, reduce or terminate our development programs or commercialization efforts or grant to others rights to develop or market product candidates that we would otherwise prefer to develop and market ourselves. Failure to receive additional funding could cause us to cease operations, in part or in full. Furthermore, even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital due to favorable market conditions or strategic considerations.

Our future funding requirements will depend on many factors, including the following:

- the time and cost necessary to initiate and complete our anticipated Phase 3 registration program for AR101;
- the time and cost associated with clinical trials and pre-clinical development of other product candidates;
- our ability to obtain regulatory approval for and subsequently commercialize AR101 or any other product candidates we develop;
- the time and cost necessary to develop clinical supplies and a commercial-scale manufacturing process for AR101;
- sales and marketing costs associated with AR101, if approved, including the cost and timing of developing our sales and marketing capabilities;

- the amount of sales and other revenue from AR101, if approved;
- our ability to achieve sufficient market acceptance, coverage and reimbursement from third-party payors and adequate market share for our product candidates;
- the costs associated with any additional clinical trials of AR101;
- the cash requirements of any future acquisitions or discovery of product candidates;
- the time and cost necessary to respond to technological and market developments;
- our ability to attract, hire and retain qualified personnel; and
- our ability to obtain and maintain intellectual property protection for AR101 and the associated costs of such activities, including for filing, prosecuting, defending and enforcing any patents for AR101.

Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate:

- clinical trials or other development activities for AR101 or any future product candidate;
- our research and development activities; or
- our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize AR101 or any future product candidate.

Cash Flows

The following table summarizes our cash flows for the periods indicated:

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2015 | 2014 |
| Net cash provided by (used in): | | |
| Operating activities | $(17,098) | $(6,538) |
| Investing activities | (107,941) | (91) |
| Financing activities | 235,431 | — |
| Net change in and cash equivalents | $110,392 | $(6,629) |

Net Cash Used In Operating Activities

Net cash used in operating activities was $17.1 million for the nine months ended September 30, 2015, an increase of $10.6 million, from $6.5 million for the nine months ended September 30, 2014. This increase was primarily due to higher net loss from operations resulting from increased research and development expenses and general and administrative expenses.

Net Cash Used In Investing Activities

Cash used in investing activities during the nine months ended September 30, 2015 consisted primarily of $106.8 million in purchases of investments in conjunction with the proceeds received in the Company’s IPO, and certain costs associated with the manufacturing facility in Clearwater, Florida and office furniture and equipment purchases for our Brisbane, California office. Cash used in investing activities during the nine months ended September 30, 2014 consisted primarily of additional investment in equipment.

Net Cash Provided By Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2015 consisted primarily of the proceeds of $168 million from the issuance of common stock in the Company's IPO, net of offering costs, $79.8 million from the issuance of the Series B convertible preferred stock, net of offering costs, , offset in part by $12.9 million from the repurchase of shares of our Series A convertible preferred stock from certain investors.

As of September 30, 2015, we had cash and cash equivalents of $112.7 million, including the net proceeds we received from the issuance common stock in the Company's IPO in August 2015 and issuance of Series B convertible preferred stock in January and February 2015.

Contractual Obligations and Other Commitments

In June 2015, we signed a facility lease for a manufacturing facility in Clearwater, Florida. The lease calls for future aggregate lease payments of $1.7 million over a period of 10 years.

In March 2015, the Company signed a facility lease for its corporate headquarters in Brisbane, California. The lease commenced on May 1, 2015 with an initial term of 51 months. In August 2015, the Company entered into an amendment to the lease. Pursuant to the amendment, the Company will lease an additional 11,655 square feet of office space. The term for the new space is 72 months from the delivery of the premises to the Company, which is expected to occur near the end of 2015. In addition, the term of the existing office space has been extended so that it is coterminous with the new space. The amended lease calls for future aggregate payments of $9.7 million over 6 years.

Off-Balance Sheet Arrangements

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

Item 3. Quantitative and Qualitative Disclosures about Market Risk

As of September 30, 2015, we had cash and cash equivalents and investments of $219.4 million which consisted primarily of money market funds, agency securities, corporate securities, and commercial paper. Such interest-earning instruments carry a degree of interest rate risk. However, historical fluctuations of interest income have not been significant.

We do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate exposure. We have not historically been exposed to material risks due to changes in interest rates. A hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our consolidated financial statements. We had no outstanding debt as of September 30, 2015.

Item 4. Controls and Procedures

Evaluation of disclosure controls and procedures.

As required by Rule 13a-15(b) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), our management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of September 30, 2015. Based on the evaluation of our disclosure controls and procedures, our Chief Executive Officer and Chief Financial Officer have concluded that, as of September 30, 2015, our disclosure controls and procedures were not effective at the reasonable assurance level as a result of the material weakness described below.

Material Weakness

In connection with the audit of our financial statements for the years ended December 31, 2013 and 2014, we identified control deficiencies in the design and operation of our internal control over financial reporting that aggregated to a material weakness. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. The material weakness identified in our internal control over financial reporting related to our lack of written policies regarding our accounting function, lack of oversight of account reconciliations, lack of independent review of manual journal entries and inadequate segregation of duties for check writing and wire transfers. We have taken certain actions to remediate this material weakness, including implementation of new procedures for review of account reconciliations and manual journal entries, restriction of check writing and wire transfer authority, segregation of duties, and establishment of formal written policies for our accounting function.

Changes in internal control over financial reporting.

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended September 30, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting other than noted above.

Inherent Limitations on Effectiveness of Controls

Internal control over financial reporting may not prevent or detect all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Also, projections of any evaluation of effectiveness of internal control to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

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

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in the Prospectus and this Quarterly Report on Form 10-Q, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could have a material adverse effect on our business, results of operations, financial condition, prospects and stock price. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

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

We have a limited operating history, have incurred significant losses since our inception and anticipate that we will continue to incur losses for the foreseeable future. We have only one product candidate in clinical trials and no product sales, which, together with our limited operating history, make it difficult to assess our future viability.

We are a clinical-stage biopharmaceutical company with a limited operating history. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. To date, we have focused primarily on developing our CODIT system and our lead product candidate, AR101, which is currently our only product in clinical development, and researching additional product candidates. We are not profitable and have incurred losses each year since our inception in June 2011. We have only a limited operating history upon which you can evaluate our business and prospects. In addition, we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the pharmaceutical industry. We have not generated any revenue from product sales and, as a result, we have incurred significant losses. We incurred a net loss of $11.1 million and $4.8 million for the years ended December 31, 2014 and 2013, respectively, and $19.8 and $7.5 million for the nine months ended September 30, 2015 and 2014, respectively. At September 30, 2015, our accumulated deficit was $37.3 million. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase as we continue our development of, seek regulatory approval for and begin to commercialize AR101, and as we develop other product candidates. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

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

Since commencing our operations in 2011, substantially all of our efforts have been focused on research, development and the advancement of AR101. As of September 30, 2015, we had capital resources consisting of cash and cash equivalents and investments of $219.4 million. In August 2015, we completed our initial public offering, or IPO, of our common stock pursuant to which we received proceeds of approximately $168 million, net of underwriting discounts and commissions, and offering expenses. We believe that we will continue to expend substantial resources

for the foreseeable future as we continue clinical development, seek regulatory approval for and prepare for the commercialization of AR101, and as we develop other product candidates.

These expenditures will include costs associated with research and development, conducting nonclinical studies and clinical trials, obtaining regulatory approvals, manufacturing and supply, sales and marketing and general operations. In addition, other unanticipated costs may arise. Because the outcome of any clinical trial and/or regulatory approval process is highly uncertain, we may not be able to accurately estimate the actual amounts necessary to successfully complete the development, regulatory approval process and commercialization of AR101 or any other product candidates.

We believe that our existing capital resources will allow us to fund our planned operations for 24 months from the date of our IPO, including through data readout of our planned Phase 3 registration trial for AR101. However, our operating plan may change as a result of many factors, including factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity, debt financings or other sources, such as strategic collaborations. Such financing may result in dilution to stockholders, imposition of debt covenants and repayment obligations or other restrictions that may affect our business. If we raise additional capital through strategic collaborations agreements, we may have to relinquish valuable rights to our product candidates including possible future revenue streams. In addition, any fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. Furthermore, even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital due to favorable market conditions or strategic considerations.

Our future funding requirements will depend on many factors, including, but not limited to:

- the time and cost necessary to initiate and complete our anticipated Phase 3 registration trial for AR101;
- the time and cost associated with clinical trials and pre-clinical development of other product candidates;
- our ability to obtain regulatory approval for and subsequently commercialize AR101 or any other product candidates we develop;
- the time and cost necessary to develop clinical supplies and a commercial-scale manufacturing process for AR101;
- sales and marketing costs associated with AR101, if approved, including the cost and timing of developing our sales and marketing capabilities;
- the amount of sales and other revenue from AR101, if approved;
- our ability to achieve sufficient market acceptance, coverage and reimbursement from third-party payors and adequate market share for our product candidates;
- the costs associated with any additional clinical trials of AR101;
- the cash requirements of any future acquisitions or discovery of product candidates;
- the time and cost necessary to respond to technological and market developments;
- our ability to attract, hire and retain qualified personnel; and
- our ability to obtain and maintain intellectual property protection for AR101 or any future product candidate and the associated costs of such activities, including for filing, prosecuting, defending and enforcing any patents for AR101 or any future product candidate.

Additional funds may not be available when we need them, on terms that are acceptable to us, or at all.

If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate:

- clinical trials or other development activities for AR101 or any future product candidate;
- our research and development activities; or
- our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize AR101 or any future product candidate.

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

Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside of our control and may be difficult to predict, including:

- the timing and cost of, and level of investment in, research, development and commercialization activities relating to our product candidates, which may change from time to time;
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coverage and reimbursement policies with respect to our product candidates, if approved, and potential future drugs that compete with our product candidates;

- the cost of manufacturing our product candidates, which may vary depending on the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we may incur to acquire, develop or commercialize additional product candidates and technologies;
- the level of demand for our products, if approved, which may vary significantly;
- future accounting pronouncements or changes in our accounting policies; and
- the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners.

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

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

Risks Related to Our Business

We are substantially dependent on the success of AR101 which will require significant additional clinical testing before we can seek regulatory approval and potentially launch commercial sales, and which may not be successful in clinical trials, receive regulatory approval or be successfully commercialized, even if approved.

To date, we have invested substantially all of our efforts and financial resources in the research and development of our CODIT system and AR101, which is currently our only product candidate in clinical development. Before seeking marketing approval from regulatory authorities for the sale of AR101, we must conduct extensive clinical trials to demonstrate the safety, purity and potency of the product in humans. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA, or comparable foreign regulatory authorities, and we may never receive such regulatory approval. We cannot be certain that AR101 will be successful in clinical trials. Further, AR101 may not receive regulatory approval even if it is successful in clinical trials. If we do not receive regulatory approvals for AR101, we may not be able to continue our operations. Our prospects, including our ability to finance our operations and generate revenue, will depend largely on the successful development, regulatory approval and commercialization of AR101. We do not expect that such commercialization will occur for at least the next two years, if ever. The clinical and commercial success of AR101 will depend on a number of factors, including the following:

- the results from our planned Phase 3 registration trial of AR101, and from ARC002, our ongoing open label Phase 2 clinical trial of AR101;
- the frequency and severity of adverse effects of AR101;
- the ability of third-party manufacturers to manufacture supplies of AR101 and to develop, validate and maintain a commercial-scale manufacturing process that is compliant with current good manufacturing practices, or cGMP;
- our ability to maintain our exclusive supply relationship with the Golden Peanut Company;
- our ability to demonstrate AR101's safety and efficacy to the satisfaction of the FDA and foreign regulatory authorities;
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whether we are required by the FDA to conduct additional clinical trials prior to the approval to market AR101 and whether the FDA may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the receipt of necessary marketing approvals from the FDA and foreign regulatory authorities;
- whether the FDA may require implementation of a Risk Evaluation and Mitigation Strategy, or REMS, as a condition of approval or post-approval;
- whether the FDA may restrict the use of our products to a narrow population;
- our ability to successfully commercialize AR101, if approved for marketing and sale by the FDA or foreign regulatory authorities, whether alone or in collaboration with others;
- our success in educating physicians and patients about the benefits, administration and use of AR101;

- acceptance of AR101 as safe and effective by patients and the medical community;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing treatments;
- achieving and maintaining compliance with all regulatory requirements applicable to AR101;
- the effectiveness of our own or any future collaborators' marketing, pricing, coverage and reimbursement, sales and distribution strategies and operations;
- our ability to obtain issued patents that cover AR101 and to enforce such patents and other intellectual property rights in and to AR101;
- our ability to avoid third-party intellectual property claims; and
- a continued acceptable safety profile of AR101 following approval.

Many of these factors are beyond our control. Accordingly, we cannot assure our stockholders that we will ever be able to generate revenue through the sale of AR101. If we are not successful in commercializing AR101, or are significantly delayed in doing so, our business will be materially harmed.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and we may encounter substantial delays in our clinical trials. Furthermore, results of earlier studies may not be predictive of future studies' results.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials and of similar academic research studies. For example, the positive results generated to date in our Phase 2 clinical trial of AR101 do not ensure that our planned Phase 3 registration trial will demonstrate similar results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through initial clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier studies, and we cannot be certain that we will not face similar setbacks. Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval or commercial acceptance for our product candidates.

In addition, we do not know whether our anticipated Phase 3 registration trial of AR101 or clinical trials of other product candidates will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. Clinical trials can be delayed or terminated for a variety of reasons, including delay or failure to:

- obtain regulatory approval to commence a clinical trial;
- reach agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among CROs and clinical trial sites;
- obtain institutional review board, or IRB, or foreign equivalent approval at each site;
- recruit suitable patients to participate in a clinical trial;
- have patients complete a clinical trial or return for post-treatment follow-up;
- ensure that clinical sites observe clinical trial protocols, operate in accordance with good clinical practice standards, or continue to participate in a clinical trial;
- address any patient safety concerns that arise during the course of a clinical trial, particularly with respect to the double-blind, placebo-controlled food challenges;
- address any conflicts with new or existing laws or regulations;
- initiate or add a sufficient number of clinical trial sites; or
- manufacture sufficient quantities of product candidate for use in clinical trials.

28

For example, subsequent to filing our IND for AR101, the FDA put the Phase 2 clinical trial on clinical hold in order to obtain additional information regarding our manufacturing process and to request certain changes to the design of the clinical trial. Specifically, the FDA requested information regarding the procedures used to ensure that the drug product was not contaminated, the procedures used to ensure the uniformity and consistency of the drug product, our acceptance procedures for the drug product and the placebo, and procedures to ensure correct dosing. In addition, the FDA requested changes to the clinical trial relating to the stopping rules for the trial, withdrawal criteria for the trial, exclusion criteria for patients, the appearance of the drug and the placebo and the drug lots used in the trial. We provided the FDA with the information it requested and made agreed upon changes to the clinical trial. However, complying with the FDA's request resulted in an approximately two month delay in initiation of the trial.

We rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and, while we have agreements governing their committed activities, we have limited influence over their actual performance and, as a result, may be subject to unanticipated delays. We anticipate that we will conduct our clinical trials, at least in part, at leading academic allergy research centers in the United States and Europe. The number and capacity of such sites is limited and our ability to access the sites may be affected by the number and size of other trials occurring at the same time, including trials sponsored by our competitors. If adequate capacity at these sites is not available, the initiation and pace of our clinical trials may be adversely affected.

Conducting clinical trials in foreign countries, as we intend to do for our Phase 3 registration trial of AR101, presents additional risks that may delay completion of our clinical trials. These risks include the failure of physicians or enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes and political and economic risks relevant to such foreign countries. In addition, the FDA may determine that our clinical trial results obtained in foreign subjects are not representative of the U.S. patient population and are thus not supportive of a Biologics License Application, or BLA, approval in the United States.

Patient enrollment is a significant factor in the timing of clinical trials and is affected by many factors, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, the design of the clinical trial, safety, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating.

In addition, certain sub-groups of patients may be more difficult to recruit than others. For example, in our planned Phase 3 registration trial of AR101, we currently intend to recruit a significant number of patients over the age of 26. We have not enrolled patients in this age group before and believe they may be more difficult to recruit than younger patients. If we are not able to recruit sufficient numbers of patients over the age of 26 into our Phase 3 registration trial, any approval that we may obtain will not include an indication for patients over the age of 26. If we are not able to recruit patients to participate in our clinical trials in a timely manner, our business and results of operations could be adversely affected.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such studies are being conducted, by an independent Safety Review Board for such clinical trial or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, failure to pass inspections of the clinical trial operations or trial site by the FDA or other regulatory authorities, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using the product, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. For example, the protocols for our clinical trials require that patients participate in food challenges where they receive increasing amounts of the food to which they are allergic. In our clinical trials, participation in these food challenges

has resulted in allergic reactions severe enough to require treatment with epinephrine. It is possible that patients could have allergic reactions severe enough to require hospitalization or even cause death. In such event, we could be required to suspend or terminate our clinical trials.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates may be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences could have a material adverse effect on our business, results of operations, financial condition, prospects and stock price. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

In our clinical trials, we utilize an oral food challenge procedure designed to trigger an allergic reaction, which could be severe or life threatening.

In accordance with our food allergy clinical trial protocols, we utilize a double-blind, placebo-controlled food challenge procedure. This consists of giving the offending food protein to patients in order to assess the sensitivity of their food allergy, and thus the safety and efficacy of our product candidates versus placebo. The food challenge protocol is meant to induce objective symptoms of an allergic reaction. These oral food challenge procedures can potentially trigger anaphylaxis, a potentially life-threatening systemic allergic reaction. Even though these procedures are well-controlled, standardized and performed in highly specialized centers with intensive care units, there are inherent risks in conducting a clinical trial of this nature. Such risks may dissuade patients, particularly children, or their parents from participating in our clinical trials. In addition, an uncontrolled allergic reaction could potentially lead to serious or even fatal reactions and any such serious clinical event could potentially adversely affect our clinical development timelines, including a complete clinical hold on our food allergy clinical trials. For instance, we are aware of one clinical trial for a peanut allergy treatment that was terminated by its safety monitoring committee because of severe adverse events arising from the administration of food challenges. We may also become liable to subjects who participate in our clinical trials and experience any such serious or fatal reactions. Any of the foregoing could have a material adverse effect on our business, results of operations, financial condition, prospects and stock price.

The regulatory approval process is lengthy, time-consuming and inherently unpredictable, and we may experience significant delays in obtaining regulatory approval of AR101, if at all, which would delay the commercialization of AR101, adversely impact our ability to generate revenue, and harm our business and our results of operations.

To gain approval to market a biologic product candidate, such as AR101, we must provide the FDA and foreign regulatory authorities with clinical, non-clinical and manufacturing data that adequately demonstrates to the satisfaction of such regulatory authority the safety, purity, potency and effectiveness of the product for the intended indication applied for in the BLA or other relevant regulatory filing. We have not previously submitted a BLA to the FDA, or similar approval filings to comparable foreign regulatory authorities. A BLA or other relevant regulatory filing must include extensive nonclinical and clinical data and supporting information to establish that the product candidate is safe, pure and potent for each desired indication. The BLA or other relevant regulatory filing must also include significant information regarding the chemistry, manufacturing and controls for the product.

The FDA or any foreign regulatory bodies can delay, limit or deny approval to market AR101 for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA or the applicable foreign regulatory body that AR101 is safe, pure and potent for the proposed indication;
- the FDA or the applicable foreign regulatory authority may disagree with the interpretation of data from clinical trials;
- our inability to demonstrate that the clinical and other benefits of AR101 outweigh any safety or other perceived risks;
- the FDA or the applicable foreign regulatory authority may require additional nonclinical studies or clinical trials;
- the CROs that we retain to conduct our clinical trials may take actions outside of our control that materially adversely impact our clinical trials;
- the FDA or the applicable foreign regulatory authority may not approve or disagree with the formulation, labeling and/or the specifications of AR101;
- if our BLA, if and when submitted, is reviewed by an advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional nonclinical studies or

clinical trials, limitations on approved labeling or distribution and use restrictions;

- the FDA or the applicable foreign regulatory authority may require development of a REMS as a condition of approval or post-approval;
- our inability to demonstrate that the manufacturing process for AR101 is adequately controlled to ensure that all product produced meets required quality standards;
- the FDA or the applicable foreign regulatory authority may fail to approve the third-party manufacturers or testing laboratories with which we contract; or
- the potential for approval policies or regulations of the FDA or the applicable foreign regulatory authorities to significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of drugs and biologics in development, only a small percentage successfully complete the FDA or other regulatory approval processes and are commercialized. In addition, the FDA has never approved a drug based on efficacy as measured by a double-blind, placebo controlled food challenge, which is the testing mechanism for determining the desensitization efficacy of AR101.

Even if we eventually complete clinical testing and receive approval of a BLA or foreign marketing authorization for AR101, the FDA or the applicable foreign regulatory authority may grant approval contingent on the performance of costly additional clinical trials. The FDA or the applicable foreign regulatory authority may also approve AR101 for a more limited indication and/or a narrower patient population than we originally request, and the FDA or applicable foreign regulatory authority may not approve the labeling that we believe is necessary or desirable for the successful commercialization of AR101. Any delay in obtaining, or inability to obtain, applicable regulatory approval or a regulatory approval for a more limited indication and/or narrower patient population would delay, prevent, or limit commercialization of AR101 and would materially adversely impact our business and prospects.

If we do not receive marketing approval for AR101 or are otherwise not successful in commercializing AR101, or are significantly delayed in doing so, our business will be materially harmed and we may need to curtail or cease operations. We currently have no products approved for sale, and we may never obtain regulatory approval to commercialize AR101.

If we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, the commercialization of AR101 or any future product candidates may be delayed, and our business will be harmed.

We sometimes estimate for planning purposes the timing of the accomplishment of various scientific, clinical, regulatory and other product development objectives. These milestones may include our expectations regarding the commencement or completion of scientific studies, clinical trials, the submission of regulatory filings, or commercialization objectives. From time to time, we may publicly announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial, the initiation of other clinical programs, receipt of marketing approval, or a commercial launch of a product. The achievement of many of these milestones may be outside of our control. All of these milestones are based on a variety of assumptions which may cause the timing of achievement of the milestones to vary considerably from our estimates, including:

- our available capital resources or capital constraints we experience;
- the rate of progress, costs and results of our clinical trials and research and development activities,
- including the extent of scheduling conflicts with participating clinicians and collaborators, and our
- ability to identify and enroll patients who meet clinical trial eligibility criteria;
- our receipt of approvals by the FDA and other regulatory authorities and the timing thereof;
- other actions, decisions or rules issued by regulators;
- our ability to access sufficient, reliable and affordable supplies of materials used in the manufacture
- of our product candidates;
- the efforts of our collaborators with respect to the commercialization of our products; and
- the securing of, costs related to, and timing issues associated with, product manufacturing as well as
- sales and marketing activities.

If we fail to achieve announced milestones in the timeframes we expect, the commercialization of AR101 and any future product candidates may be delayed, and our business and results of operations may be harmed.

We rely exclusively on the Golden Peanut Company to provide the source material for AR101 and are exposed to a number of sole supplier risks.

The source material for AR101 is a specific type of peanut flour, which we purchase from the Golden Peanut Company, or GPC, pursuant to a long-term exclusive commercial supply agreement. In order to develop AR101 as an FDA-approvable biological product we were required to precisely characterize the protein signature of the flour. We believe the flour produced by GPC has a distinct protein signature that is significantly different from the protein signatures of other commercially available peanut flours and, as a result, it is unlikely that we could use any other peanut flours as the source material for AR101. If GPC became unwilling or unable to supply us with peanut flour, our business and operating results would be materially adversely affected.

In addition, our agreement with GPC does not require GPC to provide us with peanut flour with a specific protein signature. We have tested multiple lots of GPC peanut flour produced in several different years and generally have not identified significant variations in the protein signature between lots. We can provide no assurance that natural variations or variations in GPC's manufacturing process will not result in alterations in the protein signature in GPC's peanut flour that would make it unsuitable for use in AR101. If such variations occurred, we would not be able to manufacture AR101 and our business and operating results would be materially adversely affected.

Our agreement with GPC restricts it from selling peanut flour of the type (or equivalent to the type) we use to any third party in the United States, Canada, Mexico, the European Union or Japan for use in oral immunotherapy, or OIT, for peanut allergy. The agreement remains in effect until five years after the first delivery to us of peanut flour for commercial use and includes an option for us to extend the term for an additional five years, however GPC may terminate the agreement upon 60 days' written notice if we fail to meet our minimum annual purchase commitment and fail to pay an amount equal to GPC's standard price for the unpurchased quantity within the notice period. GPC may also terminate the agreement if we fail to cure a material breach within 30 days of receiving notice of such breach from GPC or if we fail to perform our obligations under the agreement for a continuous period of 90 days due to a force majeure event or an insolvency or bankruptcy-related events. If GPC were to make sales despite the restrictions set forth in the agreement, or terminate the agreement as a result of any of the foregoing or if we were to otherwise lose exclusivity, we could face additional competition from pharmaceutical and biotechnology companies, with considerably more resources and experience than we have, that are researching and selling products designed to treat food allergies or allergies in general.

AR101 may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. To date, patients treated with AR101 have experienced drug-related side effects, which mainly include gastrointestinal issues ranging from itching of the lips to vomiting. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our clinical trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the clinical trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

In addition, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of subjects and limited duration of exposure in our clinical trials, we cannot be assured that rare and severe adverse effects of AR101 will not be uncovered when a significantly larger number of patients are exposed to the drug. Further, we have not designed our clinical trials to determine the effect and safety consequences of taking AR101 over a multi-year period.

Although we have monitored the subjects in our studies for certain safety concerns and we have not seen evidence of significant safety concerns in our clinical trials, patients treated with AR101 may experience adverse reactions. For instance, in independent research studies, patients receiving OIT for peanut allergy have suffered severe anaphylactic reactions. While we have developed AR101 and its associated treatment regimen in a manner which we believe reduces the risk of adverse reactions, we can provide no assurance that patients administered AR101 will not also suffer severe anaphylactic reactions, including reactions leading to death. For example, in our ARC001 clinical trial, one patient had an allergic reaction that was attributed to AR101 that was severe enough to require the administration

of epinephrine and six patients in our ARC001 clinical trial who received AR101 and who did not achieve desensitization dropped out of the clinical trial early in the treatment regimen due to gastrointestinal side effects. It is possible that the FDA may ask for additional data regarding such matters.

If safety problems are identified prior to approval of AR101, the FDA or other regulatory agencies may not approve AR101, may limit the population it is used in or may require warnings on the label. If AR101 is ultimately approved and we or others later identify undesirable side effects caused by AR101, the FDA or other regulatory agencies may require that we amend the labeling of AR101, require additional warnings, create a medication guide outlining the risks of such side effects for distribution to patients, order us to recall AR101 or even withdraw marketing approval for AR101. In addition, we could be sued and held liable for harm caused to patients and our reputation may suffer. Each of these events could prevent us from achieving or maintaining market acceptance of AR101, if approved, and could have a material adverse effect on our business, results of operations, financial condition, prospects and stock price.

The potential efficacy of AR101, if approved, is dependent upon patient compliance with the prescribed dosing regimen and failure to adhere to the dosing regimen could increase the potential of a patient experiencing an adverse allergic reaction.

The AR101 treatment regimen, if approved, would require that patients start with a very low dose of AR101 and gradually increase their dose over time. Based on our existing clinical data, we anticipate it will take patients between five and six months to reach a daily dose level of 300 mg of peanut protein. Patients would then continue on a daily 300 mg maintenance dose.

In order to maintain desensitization, patients would need to continue to take a daily 300 mg maintenance dose. The potential efficacy of AR101, if approved, is dependent upon patients complying with the prescribed dosing regimen, including the continued maintenance dosing. Based on our studies and independent studies, we do not believe that the occasional failure to take a dose will affect desensitization. However, in the event a patient fails to follow the prescribed dosing regimen, halts or skips treatment and then restarts the dosing regimen, the likelihood of an adverse allergic reaction to the allergen is greatly increased, as any level of desensitization previously achieved may have dissipated. Further, patients will be required to continue to practice avoidance to peanut exposure and if patients begin to achieve desensitization, it is possible that they may become less vigilant in practicing avoidance and further increase their risk of an accidental exposure. As a result, a lack of patient compliance and the resulting increased likelihood for adverse safety events could have a material adverse effect on our ability to obtain and maintain, if approved, the regulatory approval necessary to commercialize AR101.

Failure to do so would significantly harm our business, results of operations, financial condition, prospects and stock price. In addition, if patients drop out of our clinical trial due to the strict dosing regimen, the likelihood that we will be able to demonstrate clinically meaningful desensitization will be decreased.

We intend to rely on third parties to manufacture our clinical and commercial drug supply of AR101 and to manufacture nonclinical, clinical and commercial supplies of any future product candidate.

We do not currently have, nor do we currently plan to acquire, the infrastructure or internal capability to produce our clinical or commercial supply of AR101, and we lack the internal resources and the capability to manufacture any product candidates on a nonclinical, clinical or commercial scale. The FDA and other comparable foreign regulatory authorities must, pursuant to inspections that will be conducted before and after we submit our BLA or relevant foreign regulatory submission, approve our contract manufacturers to manufacture AR101 or any future product candidates.

We do not directly control the manufacturing of, and are completely dependent on, contract manufacturers for compliance with cGMP for manufacture of our products and product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or foreign regulatory authorities, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no direct control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Furthermore, all of our contract manufacturers are engaged with other companies to supply and/or manufacture materials or products for such companies, which exposes our manufacturers to regulatory risks for the production of such materials and products. As a result, failure to meet the regulatory requirements for the production of those materials and products may generally affect the regulatory clearance of our contract manufacturers' facilities. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws its approval in the future, we may need to find alternative manufacturing facilities, which would negatively impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

We intend to rely on a single manufacturer for each of the production of the drug product used in AR101 and the packaging of AR101. If one of these manufacturers encountered financial difficulties and was unable to continue operating or was acquired by a third party and changed strategic direction, our ability to obtain supplies of AR101 or future product candidates could be materially adversely affected.

We have not yet entered into an agreement with a third-party manufacturer to produce commercial quantities of AR101 and any failure to reach such an agreement and commence the development process for AR101 in a timely manner would delay commercialization of AR101.

We intend to rely on a third-party manufacturer to develop a commercial-scale manufacturing process for AR101. While we have identified a potential manufacturing partner for the commercial supply of AR101 we have not yet entered into agreements with respect to that supply. Aspects of our manufacturing process for AR101 are complex and our existing manufacturing process will need to be scaled up to meet our anticipated commercial requirements. If we and our third-party manufacturer are not able to successfully develop a commercial manufacturing process or do so in a timely manner, we will not be able to initiate commercialization of AR101 within our estimated timeline, if at all. We anticipate that we will initially be dependent on a single contract manufacturer for the production of AR101 and that during such time, our commercialization efforts will be substantially dependent on this single contract manufacturer's ability to scale up the manufacturing process for AR101. In addition, we will need to make a substantial investment in property and equipment in order to support the commercial production of AR101. Any delay in making that investment and acquiring the necessary infrastructure could delay commercial production of AR101.

We rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for or commercialize AR101 or any future product candidates.

We do not have the ability to independently conduct clinical trials. We rely and plan to continue to rely on medical institutions, clinical investigators, contract laboratories, collaborative partners and other third parties, such as CROs, to conduct clinical trials on our product candidates. The third parties with whom we contract for execution of our clinical trials play a significant role in the conduct of these studies and the subsequent collection and analysis of data. However, these third parties are not our employees, and except for contractual duties and obligations, we have limited ability to control the amount or timing of resources that they devote to our programs. Although we rely on these third parties to conduct our clinical trials, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities.

The FDA and foreign regulatory authorities require us and our third-party contractors to comply with regulations and standards, including regulations commonly referred to as good clinical practices, or GCPs, which are regulations and guidelines enforced by the FDA and foreign regulatory authorities for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the clinical trial subjects are adequately informed of the potential risks of participating in clinical trials. Regulatory authorities enforce these GCPs through periodic inspections of clinical trial sponsors, principal investigators and clinical trial sites. If we or any of our third-party contractors fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure our stockholders that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations.

In addition, certain of our clinical trials must be conducted with product produced under current good manufacturing practice, or cGMP, regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. In addition, the execution of clinical trials, and the subsequent compilation and analysis of the data produced, requires coordination among various parties. In order for these functions to be carried out effectively and efficiently, it is imperative that these parties communicate and coordinate with one another. Moreover, these third parties may also have relationships with other commercial entities, some of which may compete with us. In addition, our agreements with third parties may typically be terminated by such third

parties upon as little as 30 days' prior written notice or, in certain cases, under certain other circumstances, including our insolvency. If the third parties conducting our clinical trials do not perform their contractual duties or obligations, experience work stoppages, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical trial protocols or GCPs, or for any other reason, we may need to enter into new arrangements with alternative third parties, which could be difficult, costly or impossible, and our clinical trials may be extended, delayed or terminated or may need to be repeated. If any of the foregoing were to occur, we may not be able to obtain regulatory approval for or commercialize the product candidate being tested in such studies.

Even if AR101 or any future product candidates obtain regulatory approval, they may never achieve market acceptance or commercial success, which will depend, in part, upon the degree of acceptance among clinicians, patients, patient advocacy groups, healthcare payors and the general medical community.

Even if we obtain FDA or other regulatory approvals, AR101 or any future product candidates may not achieve market acceptance among clinicians, patients, patient advocacy groups, healthcare payors and the general medical community. With respect to AR101, which we intend to market as a means of obtaining protection from accidental exposure to peanut protein and not as a cure for peanut allergy, we anticipate that clinicians will continue to recommend that their patients strictly avoid foods that may contain any amount of peanut protein and continue to carry epinephrine auto-injectors even if the patients have been successfully desensitized with AR101. As a result, if we are unable to persuade clinicians, patients and caregivers that AR101 has therapeutic value when used in conjunction with the practice of avoidance, our sales will be adversely affected.

In addition, we may face challenges in gaining market acceptance as a result of our therapeutic approach, which exposes patients to the exact allergen that poses a risk of causing a severe allergic reaction.

Many clinicians believe that previous oral immunotherapy approaches to the treatment of peanut allergy are too unsafe or unreliable to use in clinical practice. We are also susceptible to changes in the public perception of the safety and efficacy of desensitization treatments. For example, if a competitor's desensitization treatment similar to our own had significant safety issues, perceptions of our products could also be negatively impacted even if our product did not have similar safety issues. If we are unable to convince clinicians and their patients that AR101 is safe and reliable, our sales will be adversely affected.

Furthermore, market acceptance of AR101 or any future product candidates for which we receive approval depends on a number of factors, including:

- the efficacy of the product as demonstrated in clinical trials;
- the frequency and severity of any adverse effects and overall safety profile of the product;
- the clinical indication for which the product is approved including any limitations on the patient population for which it is indicated;
- acceptance by clinicians and patients of the product as a safe and effective treatment and their perceptions of the benefit of the product;
- the evaluation of our products by governmental health technology assessment organizations;
- the relative convenience and ease of administration of our products, including patients' acceptance of the need to take our product candidates mixed with food;
- patient and parent acceptance of our product's form factor and packaging;
- the willingness of patients to comply with a treatment regimen that requires daily administration of our product candidates on a chronic basis;
- the potential and perceived advantages of our product candidates over current treatment options or alternative treatments, including future alternative treatments;
- the cost of treatment in relation to alternative treatments and willingness to pay for our products, if approved, on the part of clinicians and patients;
- the availability of products and their ability to meet market demand, including a reliable supply for long-term daily treatment;
- the strength of our marketing and distribution organizations;
- the quality of our relationships with patient advocacy groups; sufficient third-party coverage or reimbursement for our product candidates; and
- sufficient third-party payments to clinicians for the procedures necessary to administer product candidates.

Any failure by our product candidates that obtain regulatory approval to achieve market acceptance or commercial success would adversely affect the results of our operations.

AR101, if approved, or any future product candidates may face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration.

The pharmaceutical market is highly competitive and dynamic, and is characterized by rapid and substantial technological development and product innovations. In particular, we compete in the segments of the pharmaceutical, biotechnology and other related markets that address the treatment of food allergies. As a result, we may face competition from many pharmaceutical and biotechnology companies, with considerably more resources and experience than we have, that are researching and selling products designed to treat food allergies or allergies in general. We are aware that DBV Technologies S.A. is developing a treatment for peanut allergy though we cannot predict the timing or success of such development. Many of our competitors have materially greater financial, manufacturing, marketing, research and drug development resources than we do. Large pharmaceutical and biotechnology companies in particular have extensive expertise in nonclinical and clinical testing and in obtaining regulatory approvals for drugs. In addition, academic institutions, government agencies and other public and private organizations conducting research may seek patent protection with respect to potentially competitive products or technologies. These organizations may also establish exclusive collaborative or licensing relationships with our competitors. Failure to effectively compete against future products approved for the treatment of peanut allergy could harm our business and results of operations.

In addition, we may face competition from clinicians who provide oral immunotherapy to patients using commercially available source material. If we are unable to convince clinicians, patients and caregivers, that our products have advantages over these self-developed approaches to oral immunotherapy, our business and results of operation could be materially adversely affected.

AR101 and any future product candidates are regulated as biological products, or biologics, which may subject them to competition sooner than anticipated.

With the enactment of the Biologics Price Competition and Innovation Act of 2009, or BPCIA, as part of the Affordable Care Act, an abbreviated pathway for the approval of biosimilar and interchangeable biological products was created. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as “interchangeable” based on its similarity to an existing brand product. To be considered biosimilar, a product candidate must be highly similar to the reference product notwithstanding minor differences in clinically inactive components. In addition, there can be no clinically meaningful differences between the product candidate and the reference product in terms of the safety, purity and potency of the product. For the FDA to approve a biosimilar product as interchangeable with a reference product, the agency must find that the biosimilar product can be expected to produce the same clinical results as the reference product, and (for products administered multiple times) that the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. We believe that the concentrations of relevant proteins in the peanut flour we source pursuant to our exclusive contract with GPC are significantly different from the concentrations of proteins found in other commercially available sources of peanut flour, and that a product candidate using different concentrations of such proteins or different proteins might not be considered “highly similar” to AR101 by the FDA. In that case, such a product candidate would not be eligible for the biosimilar approval pathway. However, there can be no guarantee that the FDA would agree with this interpretation. Indeed, the BPCIA is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement the BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological product candidates.

Under the BPCIA, no approval of an application for a biosimilar product may be made effective until 12 years after the original branded product is first licensed by the FDA pursuant to the approval of a BLA. We believe that if the FDA approves a BLA for AR101, AR101 should qualify for this 12-year period of market exclusivity, known as reference product exclusivity, such that no approval of a biosimilar version of our product could become effective prior to the expiration of that 12-year period. However, these exclusivity provisions have been subject to various interpretations that have not yet been fully addressed by the FDA, and there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider AR101 to be eligible for reference product exclusivity, potentially creating the opportunity for competition sooner than anticipated. In addition, even if AR101 were to receive reference product exclusivity, a competitor may seek approval of a product candidate under a full BLA rather than a biosimilar product application. In such a case, although the competitor would not enjoy the benefits of the abbreviated pathway for biosimilar approval created under the BPCIA, the FDA would not be precluded from making effective an approval of the competitor product pursuant to a BLA prior to the expiration of our 12-year period of marketing exclusivity.

In addition, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear. In particular, it is unclear at this juncture whether products deemed “interchangeable” by the FDA will, in fact, be readily substituted by pharmacies. Such substitution will depend on a number of marketplace and regulatory factors that are still developing.

We currently have no sales organization or distribution network. If we are unable to establish sales capabilities and a distribution network on our own or through third parties, we may not be able to market, sell and distribute AR101, if approved, or any future product candidates or generate product revenue.

We currently do not have a sales organization. In order to commercialize AR101, we will need to build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If AR101 receives regulatory approval, we expect to establish a specialty sales organization with technical expertise and supporting distribution capabilities to commercialize our product candidates, which will be expensive and time-consuming.

We have no prior experience in the marketing, sale and distribution of pharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain, and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. Further, given our lack of prior experience in marketing, selling and distributing pharmaceutical products, our estimates of the number of sales representatives needed to commercialize AR101 may be materially less than the actual number of sales representatives required. As such, we may be required to hire substantially more sales representatives to adequately support the commercialization of AR101, which could have a material adverse effect on our business, results of operations, financial condition, prospects and stock price.

We may choose to collaborate with third parties that have direct sales forces or established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize AR101. If we are not successful in commercializing AR101 or any future product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we would incur significant additional losses.

Any product candidate that we are able to commercialize may become subject to unfavorable pricing regulations, third-party coverage or reimbursement policies.

Significant uncertainty exists as to the coverage and reimbursement status of any drug candidates for which we obtain regulatory approval. Our ability to commercialize any products successfully in the United States will depend in part on the extent to which coverage and reimbursement for these products becomes available from third-party payors, including government health administration authorities, such as those that administer the Medicare and Medicaid programs, and private health insurers. Third-party payors decide which medications they will cover and establish reimbursement levels. A primary trend in the U.S. healthcare industry is cost containment. Government programs and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot assure our stockholders that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. Increasingly, third-party payors are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. If coverage and reimbursement are not available or are available only at limited levels, we may not be able to successfully commercialize any product candidate that we successfully develop.

There may be significant delays in obtaining coverage and reimbursement for approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including

research, development, manufacture, sale and distribution. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed and may be incorporated into existing payments for other services. Net prices for products 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 products from countries where they may be sold at lower prices than in the United States. In the United States, private third-party payors often rely upon Medicare coverage and reimbursement policies and payment limitations in setting their own coverage and reimbursement policies. Our inability to promptly obtain coverage, reimbursement and profitable payment rates from both government funded and private payors for new products that we develop could have a material adverse effect on our business, results of operations, financial condition, prospects and stock price.

In addition, the anticipated treatment regimen for AR101 and our other products candidates requires a clinician to see the patient every two weeks during the up-dosing portion of the regimen. These appointments may take significant time as the patient has to be monitored for two hours after receiving an increased dose. It is not certain whether the existing reimbursement codes that can be appropriately used for these visits adequately compensate clinicians for the time spent on the visits. We may decide to seek the creation of new codes and associated reimbursement rates to ensure that clinicians are adequately compensated; however, creation of new codes is a complicated and lengthy process and we may not be successful in any such efforts. If appropriate codes and compensation are not available, clinicians may be deterred from offering AR101 to their patients and our business and operating results would be adversely affected.

In addition, under the Medicare program, physician payments are updated on an annual basis according to a statutory formula. Because application of the statutory formula for the update factor would have resulted in a decrease in total physician payments for the past several years, Congress has intervened with interim legislation to prevent the reductions. In April 2015, however, the Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, was signed into law, which repealed and replaced the statutory formula for Medicare payment adjustments to physicians. MACRA provides a permanent end to the annual interim legislative updates that had previously been necessary to delay or prevent significant reductions to payments under the Medicare Physician Fee Schedule. MACRA extended existing payment rates through June 30, 2015, with a 0.5% update for July 1, 2015 through December 31, 2015, and for each calendar year through 2019, after which there will be a 0% annual update each year through 2025. In addition, MACRA requires the establishment of the Merit-Based Incentive Payment System (“MIPS”), beginning in 2019, under which physicians may receive performance based payment incentives or payment reductions based on their performance with respect to clinical quality, resource use, clinical improvement activities and meaningful use of electronic health records. MACRA also requires Centers for Medicare & Medicaid Services, or CMS, beginning in 2019, to provide incentive payments for physicians and other eligible professionals that participate in alternative payment models, such as accountable care organizations, that emphasize quality and value over the traditional volume-based fee-for-service model. It is unclear what impact, if any, MACRA will have on our business and operating results, but any resulting decrease in payment may result in reduced demand for our product candidates or additional pricing pressures.

Outside of the United States, the regulations that govern marketing approvals, pricing, coverage and reimbursement for new therapeutic products vary widely from country to country. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay or prevent our commercial launch of the product and negatively impact the revenue we are able to generate from the sale of the product in that country. We will need to evaluate clinician compensation mechanisms in each market outside of the United States to determine whether any action needs to be taken to allow for payment of physicians for administration of the treatment regimens.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of AR101 or any future product candidates, and our existing insurance coverage may not be sufficient to satisfy any liability that may arise.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. In addition, we may be sued if our product fails to protect a patient from exposure to a food allergen. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers

inherent in the product, negligence, strict liability and a breach of warranties.

Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources.

Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for AR101 or any future product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management's time and our resources;

- substantial monetary awards to clinical trial participants or patients;
- regulatory investigations, product recalls or withdrawals, or labeling, marketing or promotional restrictions;
- loss of revenue; and
- the inability to commercialize AR101 or any future product candidates.

Our inability to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims could prevent or inhibit the commercialization of AR101 or any future products we develop. We currently carry product liability insurance covering use in our clinical trials in the amount of $5.0 million in the aggregate. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions and deductibles, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses.

If and when we obtain approval for marketing AR101, we intend to expand our insurance coverage to include the sale of AR101. However, we may be unable to obtain this liability insurance on commercially reasonable terms, if at all.

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

As of September 30, 2015, we had 32 full-time employees. We will need to continue to expand our managerial, operational, finance, clinical, manufacturing, commercial and other resources in order to manage our operations, regulatory filings, manufacturing and supply activities, marketing and commercialization activities, clinical trials and develop and commercialize AR101 or any future product candidates. Our management, personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our growth strategy requires that we:

- expand our general and administrative, manufacturing, sales, marketing and clinical development organizations;
- identify, recruit, retain, incentivize and integrate additional employees;
- establish the infrastructure necessary to support international operations;
- manage our internal development efforts effectively while carrying out our contractual obligations to third parties; and
- continue to improve our operational, legal, financial and management controls, reporting systems and procedures.

We may be unable to successfully implement these tasks, which could have a material adverse effect on our business, results of operations, financial condition, prospects and stock price.

If we fail to attract and retain senior management, we may be unable to successfully develop AR101 or any future product candidates, conduct our clinical trials and commercialize AR101 or any future product candidates.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified personnel. In particular, we are highly dependent upon our senior management. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, completion of our planned clinical trial or the commercialization of AR101 or any future product candidates. Although we have entered into employment agreements with our senior management team, these agreements do not provide for a fixed term of service.

Although we have not historically experienced unique difficulties attracting and retaining qualified employees, we could experience such problems in the future. For example, competition for qualified personnel in the biotechnology and pharmaceuticals field is intense due to the limited number of individuals who possess the skills and experience required by our industry. We will need to hire additional personnel as we expand our clinical development and manufacturing activities. We may not be able to attract and retain quality personnel on acceptable terms or at all. In addition, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output.

We will incur significant costs as a result of operating as a public company, and our management will devote substantial time to new compliance initiatives. We may fail to comply with the rules that apply to public companies, including Section 404 of Sarbanes Oxley, which could result in sanctions or other penalties that would harm our business.

As a new public company, we will incur significant legal, accounting and other expenses that we have not previously incurred, including costs resulting from public company reporting obligations under the Exchange Act and regulations regarding corporate governance practices. The listing requirements of The NASDAQ Global Select Market require that we satisfy certain corporate governance requirements relating to director independence, distributing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct. Our management and other personnel will need to devote a substantial amount of time to ensure that we comply with all of these requirements. Moreover, the reporting requirements, rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

In addition, we expect that we will need to implement an enterprise resource planning, or ERP, system for our company. An ERP system is intended to combine and streamline the management of our financial, accounting, human resources, sales and marketing and other functions, enabling us to manage operations and track performance more effectively. However, an ERP system would likely require us to complete many processes and procedures for the effective use of the system or to run our business using the system, which may result in substantial costs. Additionally, during the conversion process, we may be limited in our ability to convert any business that we acquire to the ERP. Any disruptions or difficulties in implementing or using an ERP system could adversely affect our controls and harm our business, including our ability to forecast or make sales and collect our receivables. Moreover, such disruption or difficulties could result in unanticipated costs and diversion of management attention.

As a public company, we are subject to Section 404, or Section 404, of the Sarbanes-Oxley Act of 2002, or Sarbanes Oxley, and the related rules of the Securities and Exchange Commission, or SEC, which generally requires our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. Beginning with the second annual report that we will be required to file with the SEC, Section 404 requires an annual management assessment of the effectiveness of our internal control over financial reporting. However, for so long as we remain an emerging growth company as defined in the JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404. Once we are no longer an emerging growth company or, if prior to such date, we opt to no longer take advantage of the applicable exemption, we will be required to include an opinion from our independent registered public accounting firm on the effectiveness of our internal controls over financial reporting. We will remain an emerging growth company until the earlier of (1) December 31, 2020, (2) the last day of the year in which we have total annual gross revenue of at least $1.0 billion, (3) the last day of the year in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year or (4) the date on which we have issued more than $1.0 billion in nonconvertible debt securities during the prior three-year period.

To date, we have never conducted a review of our internal control for the purpose of providing the reports required by these rules. During the course of our review and testing, we may identify deficiencies and be unable to remediate them

before we must provide the required reports. For example, during the course of our audit for the years ended December 31, 2013 and 2014 we identified a material weakness in our internal control over financial reporting. If we are unable to remediate this weakness or if additional material weaknesses in our internal controls over financial reporting are identified, we may not detect errors on a timely basis and our financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company we will be required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from The NASDAQ Global Select Market or other adverse consequences that would materially harm our business. We anticipate that to meet these new reporting obligations, we will need to implement new finance and accounting systems.

We identified a material weakness in our internal control over financial reporting as of December 31, 2013 and December 31, 2014, and we may identify additional material weaknesses in the future that may cause us to fail to meet our reporting obligations or result in material misstatements of our financial statements. If we fail to remediate any material weaknesses or if we otherwise fail to establish and maintain effective control over financial reporting, our ability to accurately and timely report our financial results could be adversely affected.

In connection with the contemporaneous audit of our financial statements for the years ended December 31, 2013 and 2014, we identified control deficiencies in the design and operation of our internal control over financial reporting that constituted a material weakness. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis.

The material weakness identified in our internal control over financial reporting related to our lack of written policies regarding our accounting function, lack of oversight of account reconciliations, lack of control of manual journal entries and inadequate segregation of duties for check writing and wire transfers. We have taken certain actions to remediate this material weakness, including implementation of new procedures for review of account reconciliations and manual journal entries, restriction of check writing and wire transfer authority, segregation of duties, and establishment of formal written policies for our accounting function. However, we cannot assure our stockholders that these measures will be sufficient to remediate the material weakness that has been identified or prevent future material weaknesses or significant deficiencies from occurring. We also cannot assure our stockholders that we have identified all of our existing material weaknesses. Neither we nor our independent registered public accounting firm has performed an evaluation of our internal control over financial reporting during any period in accordance with the provisions of Sarbanes Oxley. In light of the control deficiencies and the resulting material weakness that were previously identified as a result of the limited procedures performed, we believe that it is possible that, had we and our independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes Oxley, additional material weaknesses and significant control deficiencies may have been identified.

If we identify future material weaknesses in our internal controls over financial reporting or fail to meet the demands that will be placed upon us as a public company, including the requirements of the Sarbanes Oxley, we may be unable to accurately report our financial results, or report them within the timeframes required by law or stock exchange regulations. Under Section 404, we are required to evaluate and determine the effectiveness of our internal control over financial reporting and, beginning with the annual report for the year ended December 31, 2016, provide a management report as internal control over financial reporting. Failure to comply with Section 404 could also potentially subject us to sanctions or investigations by the SEC or other regulatory authorities. We cannot assure that our existing material weakness will be remediated or that additional material weaknesses will not exist or otherwise be discovered, any of which could adversely affect our reputation, financial condition and results of operations.

If we are not successful in identifying, acquiring or commercializing additional product candidates, our ability to expand our business and achieve our strategic objectives would be impaired.

Although a substantial amount of our effort will focus on the continued clinical testing, potential approval and commercialization of AR101, an important element of our strategy is to expand our product portfolio by identifying, developing and commercializing additional therapies including therapies using our CODIT system. Other than AR101, none of our product candidates have been tested in human clinical trials and many of our potential product candidates are still in the discovery stage. In addition, while we intend to evaluate product candidates and technologies for the treatment of food allergies, we currently have no plans to acquire or in-license any specific product candidate. Our efforts to develop, acquire or in-license product candidates may be unsuccessful for many reasons, including:

- we may not be successful in identifying potential product candidates;
- we may not accurately assess the relative technical feasibility or commercial potential of potential product candidates and may not select the most promising product candidates for development, acquisition or in-licensing;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop, acquire or in-license may nevertheless be covered by third-parties' patents or other exclusive rights;
- the market for a product candidate may change over time so that such a product may become unreasonable to continue to develop;
- a product candidate may on further study be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;

- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by clinicians, patients, patient advocacy groups, healthcare payors or the general medical community.

If we fail to develop and successfully commercialize other product candidates, our business and future prospects may be harmed and our business will be more vulnerable to any problems that we encounter in developing and commercializing AR101.

Any collaboration arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize AR101 and potential future product candidates.

We may seek collaboration arrangements with pharmaceutical or biotechnology companies for the development or commercialization of AR101 and other product candidates depending on the merits of retaining commercialization rights for ourselves as compared to entering into collaboration arrangements. We will face, to the extent that we decide to enter into collaboration agreements, significant competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time-consuming to negotiate, document, implement and maintain. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements should we so chose to enter into such arrangements. The terms of any collaborations or other arrangements that we may establish may not be favorable to us.

Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial, 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;
- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of our current or future products or that results in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable current or future products;
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and

- a collaborator’s sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

If we engage in acquisitions, we will incur a variety of costs and we may never realize the anticipated benefits of such acquisitions.

Although we currently have no plans to do so, we may attempt to acquire businesses, technologies, services, products or product candidates that we believe are a strategic fit with our business. If we do undertake any acquisitions, the process of integrating an acquired business, technology, service, products or product candidates into our business may result in unforeseen operating difficulties and expenditures, including diversion of resources and management's attention from our core business. In addition, we may fail to retain key executives and employees of the companies we acquire, which may reduce the value of the acquisition or give rise to additional integration costs. Future acquisitions could result in additional issuances of equity securities that would dilute the ownership of existing stockholders. Future acquisitions could also result in the incurrence of debt, contingent liabilities or the amortization of expenses related to other intangible assets, any of which could adversely affect our operating results. In addition, we may fail to realize the anticipated benefits of any acquisition.

If we obtain approval to commercialize AR101 outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

If we or a collaborator seek to commercialize AR101 outside the United States, we expect that we will be subject to additional risks related to entering into these international markets or business relationships, including:

- different regulatory requirements for drug approvals in foreign countries;
- different approaches by reimbursement agencies regarding the assessment of the cost effectiveness of AR101;
- differing U.S. and foreign drug import and export rules;
- reduced protection for intellectual property rights in certain foreign countries;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- different reimbursement systems for food allergy medications and for clinicians treating food allergy patients;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- potential liability resulting from activities conducted on our behalf by distributors or other vendors we engage; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters.

Our business involves the use of hazardous materials and we and our third-party manufacturers and suppliers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or

eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and governmental authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage. Any of the foregoing risks could have a material adverse impact on our business.

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

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

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

Our corporate headquarters is located in the San Francisco Bay Area, which in the past has experienced severe earthquakes. We do not carry earthquake insurance. Earthquakes or other natural disasters could severely disrupt our operations, and could have a material adverse effect on our business, results of operations, financial condition, prospects and stock price.

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

Furthermore, our contract manufacturer and integral parties in our supply chain, are operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen and severe adverse events. In particular, the manufacturing facility is located in Florida, which in the past has experienced severe hurricanes. If hurricanes or other natural disasters were to affect our contract manufacturer or our supply chain, it could have a material adverse effect on our business, results of operations, financial condition, prospects and stock price.

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

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and 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 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 drug development programs. For example, the loss of clinical trial data from completed or ongoing clinical trials for any of our product candidates could result in delays in our regulatory 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 and the further development of our product candidates could be delayed.

Our product development programs for candidates may require substantial financial resources and may ultimately be unsuccessful.

In addition to the development of AR101, we are pursuing development of our other early-stage development programs. Our current early-stage development programs are still in the pre-clinical formulation phase and may not result in product candidates we can advance to the clinical development phase. None of our other potential product candidates have commenced clinical trials, and there are a number of FDA and foreign regulatory requirements that we must satisfy before we can commence these clinical trials. Satisfaction of these requirements will entail substantial time, effort and financial resources. We may never satisfy these requirements. Any time, effort and financial resources we expend on our other early-stage development programs may adversely affect our ability to continue development and commercialization of AR101 product candidates, and we may never commence clinical trials of such development programs despite expending significant resources in pursuit of their development. Even if we do commence clinical trials of our other potential product candidates, such product candidates may never be approved by the FDA or the foreign regulatory authorities.

Risks Related to Government Regulation

The regulatory approval process is highly uncertain and we may not obtain regulatory approval for the commercialization of AR101 or any future product candidates.

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of biologics are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country.

Neither we nor any future collaboration partner will be permitted to market AR101 or any future product candidate in the United States until we receive approval of a BLA from the FDA, and we will not be permitted to market AR101 in other countries until similar regulatory approvals are obtained in those countries. We have not submitted an application or obtained marketing approval for AR101 anywhere in the world and will not be able to do so until we complete additional clinical trials. Obtaining regulatory approval of a BLA in the United States and similar applications in other countries can be a lengthy, expensive and uncertain process. In addition, failure to comply with FDA and other applicable United States and foreign regulatory requirements may subject us to administrative or judicially imposed sanctions or other actions, including:

- warning letters;
- civil and criminal penalties;
- injunctions;
- withdrawal of regulatory approval of products;
- product seizure or detention;
- product recalls;
- total or partial suspension of production; and
- refusal to approve pending BLAs or supplements to approved BLAs.

Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we or our collaborators must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or other foreign regulatory authorities, that such product candidates are safe, pure and potent for their intended uses. The number of nonclinical studies and clinical trials that will be required for FDA approval varies depending on the product candidate, the disease or condition that the product candidate is designed to address, and the regulations applicable to any particular product candidate. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for our product candidates are promising, regulatory authorities may not agree that such data are sufficient to support approval. Administering product candidates to humans may produce undesirable side effects, which could interrupt, delay or halt clinical trials and result in the FDA or other regulatory authorities denying approval of a product candidate for any or all targeted indications.

Regulatory approval of a BLA or equivalent application in other territories is not guaranteed, and the approval process is expensive and may take several years. The FDA and foreign regulatory authorities also have substantial discretion in the approval process and we may be required to expend additional time and resources and any approval we may seek may be delayed or prevented. For example, the FDA or other regulatory authority may require us to conduct additional studies or studies for AR101 either prior to or post-approval, such as additional or safety or efficacy studies or studies in specific patient subpopulations, or it may object to elements of our clinical development program. Despite the time and expense exerted, failure can occur at any stage.

Regulatory authorities can delay, limit or deny approval of a drug candidate for many reasons, including, but not limited to, the following:

- a drug candidate may not be deemed safe or effective;
- the characterization of the active pharmaceutical ingredient and the data to demonstrate adequate control of the manufacturing process may be deemed insufficient;
- regulatory officials may not find the data from nonclinical studies and clinical trials sufficient;
- the regulatory authorities might not approve our third-party manufacturers' processes or facilities; or
- the regulatory authorities may change its approval policies or adopt new regulations.

If AR101 or any future product candidate fails to demonstrate safety and efficacy in clinical trials or does not gain regulatory approval, our business and results of operations will be materially and adversely harmed. Additionally, if the FDA or other regulatory authorities require that we conduct additional clinical trials, place limitations on AR101 in our label, delay approval to market AR101 or limit the use of AR101, our business and results of operations may be harmed.

Even if we receive regulatory approval for AR101 or any future product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, any product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Even if a drug is approved, regulatory authorities may still impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-marketing studies. Furthermore, any new legislation addressing drug safety issues could result in delays or increased costs to assure compliance.

If AR101 is approved it will be subject to ongoing regulatory requirements for labeling, packaging, storage, advertising, promotion, sampling, record-keeping and submission of safety and other post-marketing information, including both federal and state requirements in the United States and the requirements of the regulatory agencies in other countries. In addition, manufacturers and manufacturers' facilities are required to comply with extensive regulatory requirements, including ensuring that quality control and manufacturing procedures conform to current cGMP requirements. As such, we and our contract manufacturers are subject to continual review and periodic inspections to assess compliance with cGMP. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, quality control, and quality assurance. We will also be required to report certain adverse reactions and production problems, if any, to regulatory authorities, and to comply with requirements concerning advertising and promotion for our products. 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 label. As such, we may not promote our products for indications or uses for which they do not have regulatory approval.

If a regulatory authority discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, a regulatory authority may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory authority or enforcement authority may:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities; or
- seize or detain products or require a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenues from AR101. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected. Additionally, if we are unable to generate revenues from the sale of AR101 our potential for achieving profitability will be diminished and the capital necessary to fund our operations will be increased.

If approved, AR101 or any future products may cause or contribute to adverse medical events that we are required to report to regulatory authorities and if we fail to do so we could be subject to sanctions that would materially harm our business.

Some participants in our clinical trials have reported adverse effects after being treated with AR101. For example, in our ARC001 clinical trial, one patient had an allergic reaction that was attributed to AR101 that was severe enough to require the administration of epinephrine and six patients in our ARC001 clinical trial receiving AR101 dropped out of the trial early in the treatment regimen due to gastrointestinal side effects. If we are successful in completing the development of, obtaining approval for, and commercializing AR101 or any other products, FDA and foreign regulatory authority regulations require that we report certain

information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events we become aware of within the prescribed timeframe. We may also fail to appreciate that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our products. If we fail to comply with our reporting obligations, the FDA or a foreign regulatory authority could take action, including criminal prosecution, the imposition of civil monetary penalties, seizure of our products or delay in approval or clearance of future products.

Our failure to obtain regulatory approvals in foreign jurisdictions for AR101 would prevent us from marketing AR101 internationally.

In order to market any product in the European Economic Area, or EEA (which is composed of the 28 Member States of the European Union plus Norway, Iceland and Liechtenstein), and many other foreign jurisdictions, separate regulatory approvals are required. In the EEA, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. Before granting the MA, the European Medicines Agency or the competent authorities of the Member States of the EEA make an assessment of the risk benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

The approval procedures vary among countries and can involve additional clinical testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one or more foreign regulatory authorities does not ensure approval by regulatory authorities in other foreign countries or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not be able to file for foreign regulatory approvals or do so on a timely basis, and even if we do file we may not receive necessary approvals to commercialize our products in any market.

We may be subject to healthcare laws, regulation and enforcement.

Although we do not currently have any products on the market, once we begin commercializing our products, we will be subject to additional healthcare statutory and regulatory requirements and enforcement by the U.S. by the federal government and the states and by the governments of other countries where we conduct our business. The laws that will affect our ability to operate as a commercial organization include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the false claims laws;
- U.S. federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;
- U.S. federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them to have committed a violation;

- the U.S. federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information;
- the U.S. federal physician sunshine requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the Affordable Care Act, which requires certain manufacturers of drugs, devices, biologics, and medical supplies to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members;

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers;
- state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources;
- state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts; and
- European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to market our products and adversely impact our financial results.

Legislative or regulatory healthcare reforms in the United States may make it more difficult and costly for us to obtain regulatory clearance or approval of our product candidates and to produce, market and distribute our products after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval, manufacture, and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of our product candidates. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require:

- additional clinical trials to be conducted prior to obtaining approval;
- changes to manufacturing methods;
- recall, replacement or discontinuance of one or more of our products; and
- additional record keeping.

Each of these would likely entail substantial time and cost and could materially harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any future products could have a material adverse effect on our business, results of operations, financial condition, prospects and stock price.

In addition, the full impact of recent healthcare reform and other changes in the healthcare industry and in healthcare spending is currently unknown, and may adversely affect our business model. In the United States, the Affordable Care Act was enacted in 2010 with a goal of reducing the cost of healthcare and substantially changing the way healthcare is financed by both government and private insurers. The Affordable Care Act, among other things, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and

extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This included aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2024 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals.

It is likely that federal and state legislatures within the United States and foreign governments will continue to consider changes to existing healthcare legislation. We cannot predict the reform initiatives that may be adopted in the future or whether initiatives that have been adopted will be repealed or modified. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect the demand for any drug products for which we may obtain regulatory approval, our ability to set a price that we believe is fair for our products, our ability to obtain coverage and reimbursement approval for a product, our ability to generate revenues and achieve or maintain profitability, and the level of taxes that we are required to pay.

Neither a Fast-Track designation nor a Breakthrough Therapy designation by the FDA may actually lead to a faster development or regulatory review or approval process.

Even though we do have Fast-Track designation for AR101 for oral immunotherapy of peanut sensitive adults and children and Breakthrough Therapy designation for AR101 for oral immunotherapy of peanut sensitive children and adolescents (ages 4-17), we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast-Track designation or Breakthrough Therapy designation if it believes that the designation is no longer supported by data from our clinical development program or other sources.

Risks Related to Intellectual Property

If we are unable to obtain and maintain adequate intellectual property protection for AR101 or any future product candidates, we may not be able to compete effectively in our market.

Our commercial success depends in part on our ability to obtain and maintain proprietary or intellectual property protection in the United States and other countries for AR101 and any future product candidates. We intend to rely upon a combination of patents, trademarks, trade secrets and confidentiality agreements to protect our product candidates. Evaluating the strength of patents in the biotechnology and pharmaceutical fields involves complex legal and scientific questions and, as a result, the patent position of biopharmaceutical companies can generally be highly uncertain. Further, any disclosure to or misappropriation by third parties of our confidential or proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

The degree of patent protection we require to successfully commercialize our product candidates may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or maintain any competitive advantage. For instance, we do not currently own or license any issued patents, and we do not anticipate that we will be able to obtain a composition of matter patent over the active pharmaceutical ingredient in AR101 or for any other product candidates that are based on widely or readily available food products. Although we have filed patent applications that relate to the manufacture, formulation, stability and other aspects of AR101, none of these

patent applications have resulted in issued patents and we cannot assure our stockholders that they will result in any issued patents in the U.S. or foreign countries. Even if any such patents issue, we cannot assure our stockholders that they or any other patents we obtain will include any claims with a scope sufficient to protect AR101 or any other future product candidate or otherwise provide us with meaningful protection or competitive advantage.

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. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Furthermore, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally twenty years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. If we encounter delays in our clinical trials or other delays during the regulatory approval process, even if we obtain patents covering AR101 or other product candidates, the period of time during which we could exclusively market AR101 or such other product candidates under such patents would be reduced. As a result, any patents we obtain may not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing products similar or identical to our product candidates, including generic versions of such products.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and therefore, even if we acquire patent protection with respect to AR101 or other product candidates, third parties may challenge our patents in the courts or patent offices in the United States and abroad. Any issued patents we obtain could be narrowed, invalidated, held unenforceable or circumvented, any of which could limit our ability to prevent competitors and other third parties from developing and marketing similar products or limit the length of terms of patent protection we may obtain for our product candidates. Competitors or other third parties may also claim that they invented the inventions claimed in our patent applications, or any patents that may issue in the future, prior to us, or may file patent applications before we do. Further, our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets. Such challenges may also result in our inability to manufacture or commercialize our future products, including AR101, without infringing third-party patent rights. If the breadth or strength of protection provided by any patents we obtain with respect to AR101 or any future product candidates is successfully challenged, then our ability to commercialize AR101 or any future product candidates could be negatively affected, and we may face unexpected competition that could have a material adverse impact on our business.

Even if they are unchallenged, any patents issuing from our pending patent applications may not adequately protect our intellectual property or prevent others from designing around our claims to circumvent those patents by developing similar or alternative technologies or drugs in a non-infringing manner. For example, a third party may develop a competitive product that provides benefits similar to AR101 or a future product candidate but falls outside the scope of our patent protection. If the patent protection covering our product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our product candidates could be negatively affected, which would harm our business.

In addition, we may in the future be subject to claims by our former employees or consultants asserting an ownership right in our patents or patent applications, as a result of the work they performed on our behalf. Although we generally require all of our employees, consultants and advisors and any other third parties who have access to our proprietary know-how, information or technology to assign to their inventions to us, we cannot be certain that we have executed such agreements with all parties who may have contributed to our intellectual property, nor can we be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy.

We may become subject to claims alleging infringement of third-party patents or proprietary rights, the outcome of which could result in delay or prevent the development and commercialization of AR101 or any future product candidates or otherwise prevent us from competing effectively in our market.

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our drug candidates and use our proprietary technologies without infringing or otherwise violating the proprietary rights and intellectual property of third parties. The biotechnology and pharmaceutical industries are characterized by extensive and frequent litigation regarding patents and other intellectual property rights. Third parties, including our competitors may initiate legal proceedings against us or our collaborators alleging that we are infringing or otherwise violating their patent or other intellectual property rights. Given the vast number of patents in our field of technology, we cannot assure our stockholders that AR101 or any future product candidates we develop will not infringe existing patents or patents that may be granted in the future. Because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because pending patent claims can be revised before issuance, there may be applications now pending of which we are unaware that may later result in issued patents that may be infringed by the manufacture, use or sale of AR101 or any future product candidates. If a patent holder believes our drug product candidate infringes on its patent, the patent holder may sue us even if we have received patent protection for our technology.

If a patent infringement suit were brought against us or any future collaborators, we or they could be forced to stop or delay the research, development, manufacturing or sales of the product or product candidate that is the subject of the suit. Defending any such claims would cause us to incur substantial expenses of financial and other resources and, if unsuccessful, we could be forced to pay substantial damages, including treble damages and attorney's fees if we are found to have willfully infringed a third-party patent. Furthermore, we may be required to indemnify our collaborators against such claims.

We may choose to seek, or may be required to seek, a license from the third-party patent holder and would most likely be required to pay license fees or royalties or both, each of which could be substantial. These licenses may not be available on commercially reasonable terms, however, or at all. Even if we were able to obtain a license, the rights we obtain may be nonexclusive, which would provide our competitors access to the same intellectual property rights upon which we are forced to rely. Ultimately, we could be prevented from commercializing a product, or forced to redesign it, or to cease aspects of our business operations if, as a result of actual or threatened patent infringement claims, we or our collaborators are unable to enter into licenses on acceptable terms. Even if we are successful in defending against any infringement claims, litigation is expensive and time-consuming and is likely to divert management's attention and substantial resources from our core business, which could harm our business.

We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Competitors and other third parties may infringe, misappropriate or otherwise violate any patents we obtain or other intellectual property rights. To counter infringement or unauthorized use, we may be required to initiate infringement proceedings, which can be expensive and time-consuming. A court may disagree with our allegations, however, and may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the third-party technology in question. Further, such third parties could counterclaim that we infringe their intellectual property or that a patent we have asserted against them is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims challenging the validity, enforceability or scope of asserted patents are commonplace.

In addition, third parties may initiate their own legal proceedings against us to assert such challenges to our intellectual property rights. For example, we may be subject to a third-party submission of prior art to the United States Patent and Trademark Office, or USPTO, challenging the priority of an invention claimed within any patents we may obtain. Such third-party prior art submissions may also be made prior to a patent's issuance, precluding such issuance at all. We may become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others from whom we have obtained licenses to such rights. We may also become involved in similar opposition proceedings in the European Patent Office or similar offices in other jurisdictions regarding our intellectual property rights.

The outcome of any such proceeding is generally unpredictable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Patents may be unenforceable if someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. It is possible that prior art of which we and the patent examiner were unaware during prosecution exists, which could render any patents we obtain invalid. Moreover, it is also possible that prior art may exist that we are aware of but do not believe is relevant to patents we may obtain, but that could nevertheless be determined to render such patents invalid. An adverse result in any litigation or other proceeding to defend or enforce any patents we may obtain could put one or more of such patents at risk of being invalidated, held unenforceable, or interpreted narrowly. If a defendant were to prevail on a legal assertion of invalidity or unenforceability of any patents we obtain covering AR101 or future product candidates, we would lose at least part, and perhaps all, of any patent protection covering such product candidate, which would materially impair our competitive position.

Intellectual property litigation could cause us to spend considerable resources and would be likely to distract our personnel from their normal responsibilities.

Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time-consuming and is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments 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 adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can

because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating or from successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, including patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time consuming and inherently uncertain. Recent patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act, or Leahy-Smith Act, signed into law on September 16, 2011, could increase those uncertainties and costs. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior

art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. In addition, the Leahy-Smith Act has transformed the U.S. patent system into a "first-to-file" system. The first-to-file provisions, however, only became effective on March 16, 2013. Accordingly, it is not yet 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 make it more difficult to obtain patent protection for our technology and could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any patents we obtain, all of which could harm our business, results of operations and financial condition.

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

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

The USPTO and various foreign patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions to maintain patent applications and issued patents. In addition, periodic maintenance fees and various other governmental fees on patents and patent applications often must be paid to the USPTO and foreign patent agencies over the lifetime of the patents or for the prosecution of patent applications. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. 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. If we fail to maintain the patents and patent applications covering our products or procedures, we may not be able to stop a competitor from marketing products that are the same as or similar to our products, which would have a material adverse effect on our business.

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

Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The requirements for patentability differ, in varying degrees, from country to country. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patent and other intellectual property rights, especially those relating to life sciences. This could make it difficult for us to stop the infringement of any patents we obtain or the misappropriation of our other intellectual property rights. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws.

Proceedings to enforce our patent rights in foreign jurisdictions, regardless of whether successful, would result in substantial costs and divert our efforts and attention from other aspects of our business. 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 AR101 or any future products. 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 products in all of our expected significant foreign markets.

If we are unable to protect the confidentiality of our trade secrets and proprietary know-how or if competitors independently develop viable competing products, our business and competitive position may be harmed.

We rely on trade secrets and confidentiality agreements to protect our proprietary know-how and other confidential information related to our development processes and other elements of our technology for which patent protection may not be available or may be difficult to obtain or enforce. Although we require all of our employees to assign their inventions to us, and endeavor to execute confidentiality agreements with all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how and other confidential information related to such technology, we cannot be certain that we have executed such agreements with all parties who may have helped to develop our intellectual property or who had access to our proprietary information, nor can we be certain that our agreements will not be breached.

Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. We cannot guarantee that our trade secrets and other proprietary and confidential information will not be disclosed or that competitors will not otherwise gain access to our trade secrets. If any of the parties to these confidentiality agreements breaches or violates the terms of such agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Enforcing a claim that a third party illegally obtained and is using our trade secrets, like patent litigation, is expensive and time-consuming, and the outcome is unpredictable. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad.

Even if we are able to adequately protect our trade secrets and proprietary information, our trade secrets could otherwise become known or could be independently discovered by our competitors. Competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, in the absence of patent protection, we would have no right to prevent them, or those to whom they communicate, from using that technology or information to compete with us. If our trade secrets are not adequately protected so as to protect our market against competitors' products, our competitive position could be adversely affected, as could our business.

Risks Related to Our Common Stock

Our stock price may be volatile, and investors in our common stock could incur substantial losses.

The trading price of our common stock has been highly volatile and could be subject to wide fluctuations in response to various factors, including the following:

- results of, or delays in, our clinical trials;
- regulatory approval or our receipt of a complete response letter to AR101 and our other product candidates, or limitations to specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- severe adverse events in our trials or in our competitors' trials as a result of exposure to the peanut allergen;
- therapeutic innovations or new products developed by us or our competitors;
- adverse actions taken by regulatory authorities with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;
- changes or developments in laws or regulations applicable to AR101 and our other product candidates;
- any changes to our relationship with any manufacturers or suppliers;
- the success or failure of our efforts to acquire, license or develop additional product candidates;
- any intellectual property infringement actions in which we may become involved;
- announcements concerning our competitors or the pharmaceutical industry in general;
- achievement of expected product sales and profitability;
- manufacturing, supply or distribution delays or shortages;
- acquisitions or significant partnerships by us or our competitors;
- actual or anticipated fluctuations in our operating results;
- changes in financial estimates or recommendations by securities analysts;
- failure to meet financial projections that we or the investment community may provide;
- trading volume of our common stock;
- an inability to obtain additional funding;

· sales of our common stock by us, our executive officers and directors or our stockholders in the future;

- general economic and market conditions and overall fluctuations in the United States equity markets; and
- additions or departures of any of our key scientific or management personnel.

As a result of this volatility, investors may experience losses on their investment in our stock.

In addition, the stock markets in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme volatility that may have been unrelated to the operating performance of the issuer. These broad market fluctuations may adversely affect the trading price or liquidity of our common stock. In the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the issuer. If any of our stockholders were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit and the attention of our management would be diverted from the operation of our business, which could seriously harm our financial position. Any adverse determination in litigation could also subject us to significant liabilities.

An active market for our common stock may not be maintained

Prior to our IPO in August 2015, there had been no public market for shares of our common stock. Our stock only recently began trading on NASDAQ, but we can provide no assurance that we will be able to maintain an active trading market on NASDAQ or any other exchange in the future. If an active market for our common stock is not maintained, it may be difficult for our stockholders to sell shares without depressing the market price for the shares or at all. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses, applications or technologies using our shares as consideration.

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us or our business. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

We are an “emerging growth company” and as a result of the reduced disclosure and governance requirements applicable to emerging growth companies, our common stock may be less attractive to investors.

We are an “emerging growth company,” as defined in the JOBS Act, and, for so long as we remain an emerging growth company as defined in the JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (1) December 31, 2020, (2) the last day of the year in which we have total annual gross revenue of at least $1.0 billion, (3) the last day of the year in which we are deemed to be a “large accelerated filer” as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded

$700.0 million as of the last business day of the second fiscal quarter of such year or (4) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

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

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lock-up relating to our IPO or other legal restrictions on resale, the trading price of our common stock could decline. Upon the closing of the IPO, we had outstanding a total of 42,249,431 shares of common stock.

The lock-up agreements pertaining to our IPO will expire on February 1, 2016 following which, up to 31,106,458 shares of common stock will be eligible for sale in the public market, of which 9,190,769 shares are held by current directors, executive officers and their respective affiliates and may be subject to Rule 144 under the Securities Act of 1933, as amended, or the Securities Act.

If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline. The holders of approximately 25.1 million shares of our common stock are entitled to rights with respect to the registration of their shares under the Securities Act, subject to vesting schedules and to the lock-up agreements described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

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

Our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 70% of our outstanding common stock. Therefore, these stockholders have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that our stockholders may feel are in their best interest.

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

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

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- the required approval of at least 66 ⅔% of the shares entitled to vote to remove a director for cause, and the prohibition on removal of directors without cause;

- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;
- the ability of our board of directors to alter our bylaws without obtaining stockholder approval;
- the required approval of at least 66 ⅔% of the shares entitled to vote at an election of directors to adopt, amend or repeal our bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the

election and removal of directors;

- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by the chairman of the board of directors, the chief executive officer, the president or the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

In addition, these provisions would apply even if we were to receive an offer that some stockholders may consider beneficial.

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

Our amended and restated 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 or employees.

Our amended and restated 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, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine. 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 or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. 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.

We provide broad indemnity to our directors and officers. Claims for such indemnification may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law. In addition, as permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

- We will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.
- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.
- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.
    - We will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification.
- The rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.

We may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

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

Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership over a rolling three-year period, the corporation's ability to use its pre-change net operating loss, or NOL, carryforwards to offset its post-change taxable income may be limited. Limitations may also apply to the utilization of other pre-change tax attributes as a result of an ownership change. As of December 31, 2014, we had generated NOL carryforwards for federal income tax purposes of $11.9 million and for state income tax purposes of $11.9 million. These federal and state NOL carryforwards will begin to expire in 2031, if not utilized. As described above, our ability to utilize NOL carryforwards or other tax attributes, such as research tax credits, in any taxable year may

be limited if we have experienced an ownership change under Section 382 of the Code. Following the issuance of the Series B convertible preferred stock in January and February 2015, we performed a Section 382 analysis and believe that we experienced multiple ownership changes under Section 382 of the Code prior to June 30, 2015 and, as a result, such federal and state NOL carryforwards and our tax credits are subject to limitation. In addition, we may have experienced ownership changes in connection with our IPO and as a result of future changes in our stock ownership, some of which changes may be outside our control. As a result, if we earn net taxable income, our ability to use our pre-change NOL carryforwards to offset post-change taxable income may be subject to limitations. For these reasons, we may not be able to utilize a material portion of our NOL carryforwards and other tax attributes, which could adversely affect our future cash flows.

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

We do not currently intend to pay any cash dividends on our common stock for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Since we do not intend to pay dividends, our stockholders' ability to receive a return on their investment in our common stock will depend on any future appreciation in the market value of our common stock. There is no guarantee that our common stock will appreciate or even maintain the price at which our holders have purchased it.

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

a) Sales of Unregistered Securities

In the third quarter of 2015, prior to our IPO, the Company granted stock options under our 2013 and 2015 Plans covering an aggregate of 1,255,637 shares of common stock at a weighted average exercise price of $10.17.

b) Use of Proceeds from our Initial Public Offering of Common Stock

On August 5, 2015, our registration statements on Form S-1 (File No. 333-205501) relating to our IPO of common stock became effective.

There has been no material change in the planned use of proceeds from our IPO from that described in the related Prospectus.

c) Repurchases of Shares or of Company Equity Securities

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

57

Item 6. Exhibits

See the Exhibit Index on the page immediately following the signature page to this Quarterly Report on Form 10-Q for a list of the exhibits filed as part of this Quarterly Report, which Exhibit Index is incorporated herein by reference.

SIGNATURES

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

Aimmune Therapeutics, Inc.

Date: November 4, 2015 By: /s/ Stephen G. Dilly
Stephen G. Dilly, M.B.B.S., Ph.D.
President, Chief Executive Officer and Director
(Principal Executive Officer)

Aimmune Therapeutics, Inc.

Date: November 4, 2015 By: /s/ Warren L. DeSouza
Warren L. DeSouza
Chief Financial Officer and Corporate Secretary
(Principal Financial and Accounting Officer)

EXHIBIT INDEX

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| Exhibit Number | Exhibit Description | Incorporated by Reference | | | Filed Herewith |
|---|---|---|---|---|---|
| | | Form | Date | Number | |
| 3.1 | Amended and Restated Certificate of Incorporation. | 8-K | 8/11/2015 | 3.1 | |
| 3.2 | Amended and Restated Bylaws. | 8-K | 8/11/2015 | 3.2 | |
| 4.1 | Reference is made to Exhibits 3.1 through 3.2. | | | | |
| 4.2 | Form of Common Stock Certificate. | S-1/A | 7/27/2015 | 4.2 | |
| 10.1# | Transition and Separation Agreement, by and between, Howard Raff and the Company, effective as of October 15, 2015 | | | | X |
| 10.2 | First Amendment to the Office Facility Lease, dated August 26, 2015, by and between the Company and Diamond Marina LLC and Diamond Marina II LLC | 10-Q | 8/31/2015 | 10.2 | |
| 10.3(a)# | 2015 Equity Incentive Award Plan. | S-8 | 8/11/2015 | 99.2(a) | |
| 10.3(b)# | Form of Stock Option Grant Notice and Stock Option Agreement under the 2015 Equity Incentive Award Plan. | S-1/A | 7/27/2015 | 10.6(c) | |
| 10.3(c)# | Form of Restricted Stock Award Agreement and Restricted Stock Unit Award Agreement under the 2015 Equity Incentive Award Plan. | S-1/A | 7/27/2015 | 10.6(c) | |
| 10.4# | Aimmune Therapeutics, Inc. Employee Stock Purchase Plan. | S-8 | 8/11/2015 | 99.3 | |
| 10.5# | Non-Employee Director Compensation Program. | S-1/A | 7/27/2015 | 10.16 | |
| 10.6# | Form of Indemnification Agreement for directors and officers | S-1/A | 7/27/2015 | 10.7 | |
| 10.7# | Executive Employment Agreement, by and between the Company and Stephen G. Dilly, M.B.B.S., Ph.D. | S-1/A | 7/27/2015 | 10.8 | |
| 10.8# | Executive Employment Agreement, by and between the Company and Warren L. DeSouza. | S-1/A | 7/27/2015 | 10.9 | |
| 10.9# | Executive Employment Agreement, by and between the Company and Howard V. Raff. | S-1/A | 7/27/2015 | 10.10 | |
| 10.10# | Executive Employment Agreement, by and between the Company and Robert M. Elfont. | S-1/A | 7/27/2015 | 10.11 | |

| | | | | | |
|---|---|---|---|---|---|
| 10.11# | Executive Employment Agreement, by and between the Company and Mary M. Rozenman. | S-1/A | 7/27/2015 | 10.12 | |
| 31.1 | Certification of Chief Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a). | | | | X |
| 31.2 | Certification of Chief Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a). | | | | X |
| 32.1 | Certification required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350). | | | | X |
| 101.INS | XBRL Instance Document | | | | X |
| 101.SCH | XBRL Taxonomy Extension Schema Document | | | | X |
| 101.CAL | XBRL Taxonomy Extension Calculation Linkbase Document | | | | X |
| 101.DEF | XBRL Taxonomy Extension Definition Linkbase Document. | | | | X |
| 101.LAB | XBRL Taxonomy Extension Label Linkbase Document. | | | | X |
| 101.PRE | XBRL Taxonomy Extension Presentation Linkbase Document. | | | | X |

#Indicates management contract or compensatory plan.

*The certification attached as Exhibit 32.1 that accompanies this Quarterly Report on Form 10-Q is not deemed filed with the SEC and is not to be incorporated by reference into any filing of Aimmune Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-Q, irrespective of any general incorporation language contained in such filing.