Aimmune Therapeutics, Inc.
Form 424B4
August 06, 2015
Table of Contents

Filed Pursuant to Rule 424(b)(4)
Registration Nos. 333-205501 and 333-206122

PROSPECTUS

10,000,000 Shares

Common Stock

This is Aimmune Therapeutics, Inc. s initial public offering. We are selling 10,000,000 shares of our common stock.

The initial public offering price of our common stock is $16.00 per share. Our shares will trade on The NASDAQ Global Select Market under the symbol AIMT.

We are an emerging growth company under applicable Securities and Exchange Commission rules and will be subject to reduced public company reporting requirements.

Investing in our common stock involves risks that are described in the Risk Factors section beginning on page 11 of this prospectus.

	Per Share	Total
Public offering price	$ 16.00	$ 160,000,000
Underwriting discounts and commissions(1)	$ 1.12	$ 11,200,000
Proceeds, before expenses, to us	$ 14.88	$ 148,800,000

(1) We refer you to Underwriting beginning on page 154 for additional disclosure regarding total underwriting compensation.

The underwriters may exercise their option to also purchase up to an additional 1,499,999 shares from us, at the initial public offering price, less the underwriting discount, for 30 days the date of this prospectus.

Certain of our existing institutional investors, including investors affiliated with certain of our directors, have agreed to purchase an aggregate of 1,562,500 shares of our common stock in this offering at the initial public offering price and on the same terms as the other purchasers in this offering.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The shares will be ready for delivery on or about August 11, 2015.

BofA Merrill Lynch **Credit Suisse** **Piper Jaffray**

The date of this prospectus is August 5, 2015.

Table of Contents

TABLE OF CONTENTS

Neither we nor the underwriters have authorized anyone to provide you with information that is different from that contained in this prospectus or in any free writing prospectus we may authorize to be delivered or made available to you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are offering to sell shares of common stock and seeking offers to buy shares of common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date on the front of this prospectus, regardless of the time of delivery of this prospectus or any sale of shares of our common stock.

Neither we nor any of the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. You are required to inform yourself about, and to observe any restrictions relating to, this offering and the distribution of this prospectus.

Aimmune Therapeutics, Inc. , CODIT and our logo are some of our trademarks used in this prospectus. This prospectus also includes trademarks, tradenames and service marks that are the property of other organizations. Solely for convenience, our trademarks and tradenames referred to in this prospectus appear without the ® and symbol, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the right of the applicable licensor to these trademarks and tradenames.

Table of Contents

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before deciding to invest in our common stock, you should read this entire prospectus carefully, including the sections of this prospectus entitled Risk Factors and Management s Discussion and Analysis of Financial Condition and Results of Operations and our financial statements and related notes contained elsewhere in this prospectus. Unless the context otherwise requires, references in this prospectus to the company, Aimmune, we, us and our refer to Aimmune Therapeutics, Inc.

Aimmune Therapeutics, Inc.

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. It is estimated that over 30 million people in the United States and Europe have a food allergy, with peanut allergy being the most prevalent and most commonly associated with severe outcomes and life-threatening events. Our therapeutic 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 ARC001, our recently completed Phase 2 study of our lead CODIT product candidate, AR101, all of the 23 patients who completed the AR101 treatment regimen were desensitized to a clinically meaningful level of peanut protein of at least 443 mg, a level that substantially exceeds the amount of peanut protein typically encountered in an accidental exposure, which we believe to be approximately 100 mg or less. We intend to initiate a Phase 3 registration trial of AR101 in early 2016 and Phase 2 studies of other CODIT product candidates for two additional food allergies in 2016. AR101 has been granted Fast-Track designation and Breakthrough Therapy designation by the U.S. Food and Drug Administration, or FDA, and, if our planned Phase 3 trial is successful, we intend to file a Biologics License Application with the FDA and a Marketing Authorization Application with the European Medicines Agency. We have worldwide commercial rights to all of our product candidates and, if approved, intend to commercialize in the United States and Europe with our own specialty sales force.

Food allergies are a severe and growing health problem in the United States, Europe and throughout the developed world. Peanut is the most common food allergy, and we estimate that there are over five million people in the United States and Europe with peanut allergy, including over two million children. The prevalence of peanut allergy in children in the United States is estimated to have increased at a constant annual growth rate of approximately 10% between 1997 and 2008, and experts believe it has continued to rise since 2008. Food-related allergic reactions are estimated to result in approximately 200,000 emergency room visits and over 10,000 hospital admissions each year in the United States.

There are currently no approved medical therapies to cure food allergies or prevent their effects. Avoidance is the primary method of managing a food allergy and successfully practicing avoidance can be virtually impossible, as allergic reactions can often be triggered by trace amounts of food proteins, or allergens. For example, of the over two million people with peanut allergy in the United States, 40% to 50% are sensitive to an exposure of 100 mg or less of peanut protein, the equivalent of less than half of a peanut kernel. For patients exposed to allergens, treatment options are limited. Epinephrine is used as a rescue medication, but its effectiveness is dependent on several factors, such as availability, the promptness of administration and sufficient dosage to counteract the effects of the allergic reaction. The stress of practicing avoidance and the limited availability of effective treatment options can result in a fear of a fatal accidental exposure, substantially diminishing the quality of life of patients and their families. This fear can lead

to psychological traumas

including fear of eating, social difficulties and severe anxiety. In addition, parents of food-allergic children often attempt to prevent accidental exposures by limiting their child s participation in everyday activities.

We believe our CODIT system and product candidates, if approved, have the potential to reduce the dangers posed to food-allergic patients, such as accidental exposures resulting in anaphylactic reactions, emergency room visits or hospitalization. We expect that this potential protection from accidental exposures will reduce the stress and anxiety of patients and their families and enable patients to live more normal lives.

Our Lead Proprietary Product Candidate

Our lead CODIT product candidate, AR101, is a proprietary product designed to desensitize patients to a level of peanut protein that we believe substantially exceeds the amount typically encountered in an accidental exposure using a gradual up-dosing and maintenance dosing regimen. Based on our clinical development to date, including our ARC001 study, we believe AR101 has the following key attributes:

Proprietary Biologic Product: Our proprietary formulation is a complex mixture of naturally occurring proteins and pharmaceutical-grade ingredients that we developed to enable the convenient dosing of consistent amounts of peanut protein with well-defined relative concentrations of specific peanut allergens.

Clinically Meaningful and Reliable Desensitization: In ARC001, 23 of the 23 peanut allergic patients who completed the AR101 treatment regimen achieved clinically meaningful desensitization to peanut allergens. ARC001 and independent scientific research have indicated that clinically meaningful desensitization can be attained through an oral immunotherapy treatment regimen, independent of gender, age and other demographics.

Rapid and Predictable Onset of Action: In ARC001, a clinically meaningful level of protection was typically achieved by patients in the AR101 treatment group after only 22 weeks of dosing. Independent scientific research has also shown that continued maintenance dosing pursuant to an oral immunotherapy treatment regimen can confer increased protection over time.

Attractive Safety Profile: In ARC001, most patients tolerated AR101 well, experiencing only mild, intermittent side effects commonly associated with food allergies, during the up-dosing phase of treatment. The most frequent of these side effects included gastrointestinal symptoms ranging from itching of the lips to vomiting, hives, throat itching or discomfort and nasal congestion. Once patients are desensitized and on maintenance dosing, we believe that they are likely to experience few or no side effects.

Convenient Oral Administration: AR101 is designed to be provided to patients as a convenient, orally administered, once daily therapy that is mixed with common age-appropriate foods.

Direct, Targeted Mechanism of Action: Oral administration of AR101 enables the allergen to interact directly with immune cells in the gastrointestinal tract responsible for mediating the allergic reaction to peanuts. Oral desensitization works by gradually shifting the balance of the immune system to dampen the allergic response in the case of accidental exposure.

Compatibility with Current Clinical Practice and Infrastructure: The AR101 up-dosing regimen is similar to existing, widely adopted regimens for the treatment of non-food allergies, such as pollen and pet dander. We believe this feature will facilitate adoption by allergists and reimbursement by payors if AR101 is approved.

Table of Contents

CODIT Support Services: We intend to provide physician education, patient guidance and other support services to facilitate the administration of AR101, if approved.

In June 2015, we presented our ARC001 Phase 2 data as a late-breaking abstract at the European Academy of Allergy and Clinical Immunology Congress. In ARC001, all patients who completed the up-dosing regimen in the AR101 treatment group were desensitized to a cumulative dose of 443 mg of peanut protein, the equivalent of approximately two peanut kernels, as compared to five of the 26 patients who received placebo. In addition, 18 of the 23 patients who completed the up-dosing regimen in the AR101 treatment group were desensitized to a cumulative dose of 1,043 mg of peanut protein, the equivalent of approximately four peanut kernels, as compared to none of the 26 patients who received placebo. Our ongoing open label Phase 2 study, ARC002, is evaluating, among other things, the long-term safety and tolerability of a regimen of daily maintenance doses of AR101 and its effect on desensitization.

Regulatory Status of AR101

In September 2014, the FDA granted AR101 Fast-Track designation for oral immunotherapy of peanut sensitive adults and children and in June 2015, the FDA granted AR101 Breakthrough Therapy designation for oral immunotherapy of peanut sensitive children and adolescents (ages 4 through 17). These designations are intended to facilitate the development and to expedite the review of drugs and biologics that are intended for the treatment of serious or life-threatening diseases or conditions and, in the case of a Fast-Track designation, that demonstrate the potential to address unmet medical needs for the disease or condition or, in the case of a Breakthrough Therapy designation, where preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Sponsors of products under development with a Fast-Track designation or Breakthrough Therapy designation may have greater interactions with the FDA, including the involvement of more senior staff members, and the FDA may initiate review of sections of a Fast-Track product s marketing application before the application is complete. A product that receives these designations may be eligible for accelerated approval and priority review, if relevant criteria are met.

Key Advantages of Our CODIT System

Our CODIT system for the treatment of food allergies leverages and improves upon the extensive independent scientific research supporting oral immunotherapy, or OIT. Based on our clinical development to date, including our ARC001 study, we believe that our CODIT system will have the following key attributes:

Standardized Products: Our proprietary biologic product candidates are derived from natural food products and are designed to contain precisely defined dosages of well-characterized food proteins so that each dosage is consistent for total protein and relative allergen content. In addition, we expect each of our product candidates, if approved, to be provided to patients as a convenient, orally administered, once daily therapy.

Safe and Well-Defined Treatment Regimens: We intend to demonstrate the safety and efficacy of each CODIT product candidate in large scale, well-controlled clinical trials. In addition, we expect each CODIT product candidate to feature clearly defined clinical protocols with gradual up-dosing and practical maintenance dosing regimens designed to enhance safety, tolerability and efficacy.

Clinically Meaningful Desensitization: We expect each approved CODIT product candidate to provide patients with protection from food allergens at a level that exceeds the amount typically encountered in an accidental exposure.

Table of Contents

Compatibility with Clinical Practice: We expect our protocols for each CODIT product candidate to be similar to treatment regimens currently utilized by allergists for non-food allergies.

Tailored Support Services: We intend to provide physician education, patient guidance and other support services to facilitate the administration of each approved CODIT product candidate.

Regulatory Approval: We believe regulatory approval of our CODIT product candidates, if obtained, will validate the extensive existing scientific research supporting oral desensitization and could lead to widespread adoption of our system.

Additional Pipeline Product Candidates

We intend to leverage the expertise gained in our development of AR101 to develop CODIT product candidates for a range of additional food allergies. We are in the process of developing formulations for CODIT product candidates for the treatment of two additional food allergies. We currently anticipate that we will initiate Phase 2 studies of two additional CODIT product candidates in 2016.

Our Strategy

Our goal is to build a biopharmaceutical company that develops and commercializes proprietary therapies to improve the lives of food-allergic patients and their families. We intend to achieve this goal by pursuing the following key strategic objectives:

Complete development and obtain approval of AR101 in the United States and Europe for the treatment of peanut allergy.

Commercialize AR101 in the United States and Europe through our own specialty sales force.

Leverage the CODIT system to develop additional proprietary product candidates for the treatment of food allergies.

Strategically pursue collaborations to develop and commercialize product candidates.

Our History and Leadership

We were formed after a 2011 conference where leading researchers, clinicians, patient advocates and regulators in the field of food allergies concluded that oral desensitization had a strong scientific basis but required greater standardization and validation for widespread adoption. With the support of Food Allergy Research and Education (FARE), a leading patient advocacy organization, we were founded to pursue the development and commercialization of standardized oral desensitization medical therapies for the treatment of food allergies. To execute on this vision, we have assembled a team of experienced biotechnology and pharmaceutical executives who have collectively contributed to the development and regulatory approval of over 30 drugs and biologics. We believe that the quality of our team will strongly influence our ability to develop a new class of CODIT products to address the unmet medical

needs of food-allergic patients. Our Chief Executive Officer, Dr. Stephen Dilly, was previously Chief Executive Officer at APT Pharmaceuticals, Inc., Senior Vice President, Head of Development, Chief Medical Officer at Chiron BioPharmaceuticals, a division of Chiron Corporation, and Vice President of Medical Affairs at Genentech, Inc. Other members of our management team have held senior positions at Bristol-Myers Squibb Company, Chiron Corporation, GlaxoSmithKline plc, Novartis AG, Onyx Pharmaceuticals, Inc., Pfizer Inc., Roche Holding AG and Teva Pharmaceutical Industries Limited. We also have leading financial investors such as Adage Capital, Aisling Capital, funds affiliated with Fidelity Management & Research Company, Foresite Capital, Longitude Capital, Palo Alto Investors and RA Capital.

Table of Contents

Risks Associated With Our Business

Our business is subject to numerous risks, as more fully described in the section entitled Risk Factors immediately following this prospectus summary. These risks include, among others:

- 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 never generated any revenue from product sales and may never be profitable.
- Even if this offering is successful, we will require substantial additional financing to achieve our goals.
- We are substantially dependent on the success of our lead product candidate, 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.
- The clinical drug development and 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 harm our business and our results of operations.
- We use peanut flour from a single supplier as the source material for AR101 and are exposed to a number of sole supplier risks.

Corporate Information

We were founded on June 24, 2011 as a Delaware corporation under the name Allergen Research Corporation. In May 2015, we changed our name to Aimmune Therapeutics, Inc. Our principal executive offices are located at 8000 Marina Blvd, Suite 300, Brisbane, CA 94005, and our telephone number is (650) 614-5220. Our website address is www.aimmune.com. The information on, or that can be accessed through, our website is not part of this prospectus. We have included our website address as an inactive textual reference only.

Implications of Being an Emerging Growth Company

We are an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. We will remain an emerging growth company until the earlier of (1) the last day of the year following the fifth anniversary of the consummation of this offering, (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. An emerging growth company may take advantage

of specified reduced reporting requirements and is relieved of certain other significant requirements that are otherwise generally applicable to public companies. As an emerging growth company:

- we will present only two years of audited consolidated financial statements, plus unaudited condensed consolidated financial statements for any interim period, and related management s discussion and analysis of financial condition and results of operations;

- we will avail ourselves of the exemption from the requirement to obtain an attestation and report from our auditors on the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002, or Sarbanes Oxley;

Table of Contents

we will provide less extensive disclosure about our executive compensation arrangements; and

we will not require shareholder non-binding advisory votes on executive compensation or golden parachute arrangements.

However, we are choosing to opt out of the extended transition periods available under the JOBS Act for complying with new or revised accounting standards. Section 107 of the JOBS Act provides that our decision to opt out of the extended transition periods for complying with new or revised accounting standards is irrevocable.

Table of Contents

THE OFFERING

Issuer	Aimmune Therapeutics, Inc.
Common stock offered by us	10,000,000 shares.
Common stock to be outstanding after the offering	40,679,538 shares.
Underwriters option to purchase additional shares	1,499,999 shares.
Use of proceeds	We estimate that the net proceeds from this offering will be approximately $145.3 million, or approximately $167.6 million if the underwriters exercise their option to purchase additional shares in full, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We currently expect to use the net proceeds from this offering to fund the continued clinical development of AR101, including to fund our planned Phase 3 registration trial through data readout, to fund the development of additional product candidates and for working capital and general corporate purposes. See Use of Proceeds on page 57 for a more complete description of the intended use of proceeds from this offering.
Risk factors	See Risk Factors beginning on page 11 and other information included in this prospectus for a discussion of factors that you should consider carefully before deciding to invest in our common stock.
NASDAQ Global Select Market symbol	AIMT

The number of shares of common stock to be outstanding after this offering is based on 30,679,538 shares of common stock outstanding as of March 31, 2015, and excludes the following:

- 189,853 shares of common stock issuable upon the exercise of outstanding stock options as of March 31, 2015, having a weighted-average exercise price of $0.14 per share;

4,078,078 shares of common stock reserved for issuance pursuant to future awards under our 2013 Stock Plan, as amended, as of March 31, 2015. Of such shares, 3,228,100 shares of common stock are issuable upon the exercise of outstanding stock options that have been granted between March 31, 2015 and July 20, 2015, having a weighted-average exercise price of $3.56 per share;

4,681,544 shares of common stock reserved for issuance pursuant to future awards under our 2015 Equity Incentive Award Plan, as well as any automatic increases in the number of shares of our common stock reserved for future issuance under this plan, which will become effective prior to the consummation of this offering; and

390,128 shares of common stock reserved for issuance pursuant to future awards under our Employee Stock Purchase Plan, as well as any automatic increases in the number of shares of our

Table of Contents

common stock reserved for future issuance under this plan, which will become effective prior to the consummation of this offering.

In addition, unless we specifically state otherwise, all information in this prospectus assumes:

a 1-for-1.317 split of our outstanding common stock and preferred stock, which we have effected;

the automatic conversion of all outstanding shares of our convertible preferred stock at March 31, 2015 into an aggregate of 25,051,257 shares of common stock immediately prior to the consummation of this offering;

the filing and effectiveness of our amended and restated certificate of incorporation in Delaware and the adoption of our amended and restated bylaws, each of which will occur immediately prior to the consummation of this offering;

no exercise of outstanding stock options subsequent to March 31, 2015; and

no exercise of the underwriters option to purchase additional shares of common stock.

We refer to our Series A and Series B convertible preferred stock collectively as convertible preferred stock in this prospectus, as well as for financial reporting purposes and in the financial tables included in this prospectus, as more fully explained in Note 6 to our unaudited interim condensed financial statements included in this prospectus.

Indications of Interest

Certain of our existing institutional investors, including investors affiliated with certain of our directors, have agreed to purchase an aggregate of 1,562,500 shares of our common stock in this offering at the initial public offering price and on the same terms as the other purchasers in this offering.

Table of Contents

SUMMARY FINANCIAL DATA

The following tables present summary financial data for our business. You should read this data together with our financial statements and related notes appearing elsewhere in this prospectus and the information under the captions Selected Financial Data and Management s Discussion and Analysis of Financial Condition and Results of Operations.

We derived the following statement of operations data for the years ended December 31, 2013 and 2014 from our audited financial statements appearing elsewhere in this prospectus. The statement of operations data for the three months ended March 31, 2014 and 2015 and the balance sheet data as of March 31, 2015 have been derived from our unaudited interim condensed financial statements appearing elsewhere in this prospectus and are not necessarily indicative of results to be expected for the full year. The unaudited interim condensed financial statements have been prepared on the same basis as the audited financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to present fairly our financial position as of March 31, 2015 and the results of operations for the three months ended March 31, 2014 and 2015. Our historical results are not necessarily indicative of our future results.

	Year Ended December 31,		Three Months Ended March 31,	
	2013	2014	2014	2015
			(unaudited)	
	(in thousands, except share and per share data)			
Statement of Operations Data:				
Operating expenses:				
Research and development	$ 3,495	$ 8,181	$ 1,199	$ 2,069
General and administrative	1,263	2,951	401	1,372
Total operating expenses	4,758	11,132	1,600	3,441
Loss from operations	(4,758)	(11,132)	(1,600)	(3,441)
Other income (expense), net				
Interest income	24	12	7	
Interest expense	(91)			
Total other income (expense), net	(67)	12	7	
Net loss	$ (4,825)	$ (11,120)	$ (1,593)	$ (3,441)
Net loss per share, basic and diluted[1]	$ (1.65)	$ (3.80)	$ (0.54)	$ (0.81)
Weighted-average shares used in computing net loss per share, basic and diluted[1]	2,926,665	2,928,896	2,926,665	4,258,877
Pro forma net loss per share, basic and diluted (unaudited)[1]		$ (0.69)		$ (0.15)
		16,192,863		22,467,561

Shares used in computing pro forma net loss per share, basic and diluted (unaudited)[1]	

(1) See Note 10 to our audited financial statements and Note 7 to our unaudited interim condensed financial statements included elsewhere in this prospectus for an explanation of the calculations of our net loss per share, basic and diluted, pro forma net loss per share, basic and diluted, and the shares used in computing the net loss per share, basic and diluted, and pro forma net loss per share, basic and diluted.

Table of Contents

The table below presents our balance sheet data as of March 31, 2015:

on an actual basis;

on a pro forma basis to give effect to: (i) the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 25,051,257 shares of common stock immediately prior to the consummation of this offering; and (ii) the filing and effectiveness of our amended and restated certificate of incorporation, which will occur immediately prior to the consummation of this offering; and

on a pro forma as adjusted basis to give further effect to the sale of 10,000,000 shares of common stock in this offering at the initial public offering price of $16.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

	As of March 31, 2015		
	Actual	Pro Forma (unaudited) (in thousands)	Pro Forma as Adjusted
Balance Sheet Data:			
Cash and cash equivalents	$ 65,313	$ 65,313	$ 210,613
Working capital	64,065	64,065	209,365
Total assets	65,895	65,895	211,195
Convertible preferred stock	83,811		
Accumulated deficit	(20,958)	(20,958)	(20,958)
Total stockholders equity	64,239	64,239	209,539

Table of Contents

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 this prospectus, 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 $4.8 million and $11.1 million for the years ended December 31, 2013 and 2014, respectively, and $1.6 and $3.4 million for the three months ended March 31, 2014 and 2015, respectively. At December 31, 2014 and March 31, 2015, our accumulated deficit was $17.5 million and $21.0 million, respectively. 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.

Even if this offering is successful, 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 March 31, 2015, we had capital resources consisting of cash and cash equivalents of $65.3 million. 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.

Table of Contents

We believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will allow us to fund our planned operations for the 24 months following the date of this offering, 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 additional 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

Table of Contents

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;
- 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

Table of Contents

U.S. Food and Drug Administration, or 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;
- 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;

Table of Contents

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 you 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.

Table of Contents

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 obtain, if any, 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.

Table of Contents

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;

Table of Contents

- 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

Table of Contents

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 have not identified a significant variation in protein signature between lots. However, 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.

Table of Contents

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.

Table of Contents

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 you 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;

Table of Contents

- 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 you 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;

Table of Contents

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 June 30, 2015, we had 21 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.

Table of Contents

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.

We will incur significant legal, accounting and other expenses as a public company, 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.

After this offering, we will be 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 require 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) of the last day of the year following the fifth anniversary of the consummation of this offering, (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.

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 at 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 the material weakness, including implementing new procedures for review of account reconciliations and

manual journal entries and restricting check writing and wire transfer authority. We intend to implement further segregation of duties and to establish formal written policies for our accounting function by the

end of the year. However, we cannot assure you 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 you 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 will be required to evaluate and determine the effectiveness of our internal control over financial reporting and, beginning with our second annual report following this offering, which will be 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;

Table of Contents

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;

Table of Contents

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;

Table of Contents

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.

Table of Contents

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, our contract manufacturer s 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.

Table of Contents

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, production, and quality control. 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

Table of Contents

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;

Table of Contents

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.

Table of Contents

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 you that they will result in any issued patents in the U.S. or foreign countries. Even if any such patents issue, we cannot assure you 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.

Table of Contents

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 you 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.

Table of Contents

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.

46

Table of Contents

Risks Related to Our Common Stock and This Offering

Our stock price may be volatile and you may not be able to resell shares of our common stock at or above the price you paid.

The trading price of our common stock following this offering could be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include those discussed in this Risk Factors section and others such as:

- 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.

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, liquid and orderly market for our common stock may not develop, and you may not be able to resell your common stock at or above the public offering price.

Prior to this offering, there has been no public market for shares of our common stock, and an active public market for our shares may not develop or be sustained after this offering. We and the representatives of the underwriters will determine the initial public offering price of our common stock through negotiation. This price will not necessarily reflect the price at which investors in the market will be willing to buy and sell our shares following this offering. In addition, an active trading market may not develop following the consummation of this offering or, if it is developed, may not be sustained. Further, certain of our existing institutional investors, including investors affiliated with certain of our directors, have agreed to purchase an aggregate of 1,562,500 shares of our common stock in this offering at the initial public offering price and on the same terms as the other purchasers in this offering and, as a result, fewer shares may be actively traded in the public market because these stockholders may be restricted from selling the shares by restrictions under applicable securities laws and the lock-up agreements described in the Shares Eligible for Future Sale and Underwriting sections of this prospectus, which would reduce the liquidity of the market for our common stock. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. 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 will be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not currently have and may never obtain research coverage by securities and industry analysts. If no or few securities or industry analysts commence coverage of us, the trading price for our stock would be negatively impacted. In the event we obtain securities or industry analyst coverage, 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

Table of Contents

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) the last day of the year following the fifth anniversary of the consummation of this offering, (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 and other legal restrictions on resale discussed in this prospectus lapse, the trading price of our common stock could decline. Based upon the number of shares outstanding as of March 31, 2015, upon the closing of this offering, we will have outstanding a total of 40,679,538 shares of common stock, assuming no exercise of the underwriters option to purchase additional shares. Of these shares, approximately 9,625,840 shares of our common stock sold in this offering, plus any shares sold upon exercise of the underwriters option to purchase additional shares, will be freely tradable, without restriction, in the public market immediately following this offering, subject to the lock-up agreements described below.

The lock-up agreements pertaining to this offering will expire 180 days from the date of this prospectus. Merrill Lynch, Pierce, Fenner & Smith Incorporated and Credit Suisse Securities (USA) LLC, however, may, in their sole discretion, permit our officers, directors and other stockholders who are subject to these lock-up agreements to sell shares prior to the expiration of the lock-up agreements. After the lock-up agreements expire, as of March 31, 2015, up to an additional 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. After this offering, the holders of approximately 25.1 million shares of our common stock, or approximately 61.6% of our total outstanding common stock as of March 31, 2015 will be 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.

As of July 24, 2015, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 89.2% of our outstanding voting stock and, upon the

closing of this offering, that same group will hold approximately 68.3% of our outstanding voting stock (assuming no exercise of the underwriters option to purchase additional shares and no exercise of outstanding options). Certain of our existing institutional investors, including investors affiliated with certain of our directors, have agreed to purchase an aggregate of 1,562,500 shares of our common stock in this offering at the initial public offering price. Additionally, at our request, the underwriters have reserved approximately 1% of the shares offered by this prospectus for sale, at the initial public offering price, to some of our directors, officers, employees, business associates and related persons in this offering. If such investors and our officers and directors purchase all of these shares, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates will beneficially own approximately 72.1% of our outstanding voting stock upon the closing of this offering (based on the initial public offering price of $16.00 per share, and assuming no exercise of the underwriters option to purchase additional shares and no exercise of outstanding options). Therefore, even after this offering these stockholders will 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 you may feel are in your best interest as one of our stockholders.

We have broad discretion to determine how to use the funds raised in this offering, and may use them in ways that may not enhance our operating results or the price of our common stock.

Our management will have broad discretion over the use of proceeds from this offering, and we could spend the proceeds from this offering in ways our stockholders may not agree with or that do not yield a favorable return, if at all. We currently intend to use our net proceeds from this offering to fund the continued clinical development of AR101, including to fund our planned Phase 3 registration trial through data readout, to fund the development of additional product candidates and for working capital and general corporate purposes. However, our use of these proceeds may differ substantially from our current plans. If we do not invest or apply the proceeds of this offering in ways that improve our operating results, we may fail to achieve expected financial results, which could cause our stock price to decline.

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 that will be in effect immediately prior to the consummation of this offering will 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 will 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;

Table of Contents

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 will provide 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 will provide that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our 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

Table of Contents

addition, as permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws to be effective immediately prior to the completion of this offering 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 March 31, 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 since March 31, 2015 and could experience ownership changes in the future, including in connection with this offering 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.

Table of Contents

We do not currently intend to pay dividends on our common stock, and, consequently, your ability to achieve a return on your 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. Therefore, you are not likely to receive any dividends on your common stock for the foreseeable future. Since we do not intend to pay dividends, your ability to receive a return on your investment 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.

Table of Contents

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as aim, anticipate, assume, believe, contemplate, continue, could, due, estimate, expect, goal, intend, predict, potential, positioned, seek, should, target, will, would, and other similar expressions that are pr indicate future events and future trends, or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- our expectations regarding the potential market size and the size of the patient populations for AR101 and our future product candidates, if approved for commercial use;
- clinical and regulatory development plans with respect to AR101 and our future product candidates;
- timing of commencement of future clinical trials and research and development programs;
- our ability to develop, acquire and advance product candidates into, and successfully complete, clinical trials;
- our intention and our ability to establish collaboration partnerships;
- the timing or likelihood of regulatory filings and approvals for AR101 and our future product candidates;
- our ability to commercialize AR101 and our future product candidates;
- our commercialization, marketing and manufacturing capabilities;
- the pricing and reimbursement of AR101 and our future product candidates, if approved;
- the implementation of our business model and strategic plans for our business, product candidates and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates, including the projected terms of patent protection;

estimates of our expenses, future revenue, capital requirements, our needs for additional financing and our ability to obtain additional capital;

our use of proceeds from this offering;

our financial performance;

developments and projections relating to our competitors and our industry, including competing therapies; and

other risks and uncertainties, including those listed under the caption Risk Factors.

These forward-looking statements are based on management s current expectations, estimates, forecasts and projections about our business and the industry in which we operate and management s beliefs and

Table of Contents

assumptions and are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this prospectus may turn out to be inaccurate. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Risk Factors and elsewhere in this prospectus. Potential investors are urged to consider these factors carefully in evaluating the forward-looking statements. These forward-looking statements speak only as of the date of this prospectus. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future. You should, however, review the factors and risks we describe in the reports we will file from time to time with the SEC after the date of this prospectus. See Where You Can Find More Information.

Table of Contents

INDUSTRY AND MARKET DATA

This prospectus contains estimates, projections and other information concerning our industry, our business, and the markets for our product candidates, including data regarding the estimated food-allergic patient population and the prevalence and severity of peanut allergy, as well as data regarding market research, estimates and forecasts prepared by our management. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires.

Table of Contents

USE OF PROCEEDS

We estimate that the net proceeds from the sale of 10,000,000 shares of common stock in this offering will be approximately $145.3 million at the initial public offering price of $16.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters exercise their option to purchase additional shares in full, we estimate that net proceeds will be approximately $167.6 million after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

We currently expect to use our net proceeds from this offering as follows:

- approximately $80.0 million to $90.0 million to fund the continued clinical development of AR101, including to fund our planned Phase 3 registration trial through data readout;
- approximately $30.0 million to $35.0 million to fund the development of additional product candidates; and
- the remainder, if any, for working capital and general corporate purposes.

However, due to the uncertainties inherent in the clinical development and regulatory approval process, it is difficult to estimate with certainty the exact amounts of the net proceeds from this offering that may be used for the above purposes. As such, our management will retain broad discretion over the use of the net proceeds from this offering. The amounts and timing of our expenditures will depend upon numerous factors, including (i) the time and cost necessary to implement our anticipated Phase 3 registration trial of AR101; (ii) the time and cost associated with clinical trials and pre-clinical development of other product candidates; (iii) our ability to obtain regulatory approval for and subsequently commercialize AR101 or any other product candidates we develop; and (iv) the time and cost necessary to develop clinical supplies and a commercial-scale manufacturing process for AR101.

We believe that our existing cash and cash equivalents, together with the net proceeds from this offering, will be sufficient to fund our planned operations for the 24 months following the date of this offering. Following this offering, we will require substantial capital in order to commercialize AR101 and complete the clinical development of any additional product candidate. For additional information regarding our potential capital requirements, see Even if this offering is successful, 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 under the heading Risk Factors.

Pending the use of the proceeds from this offering, we intend to invest the net proceeds in interest-bearing, investment-grade securities, certificates of deposit or government securities.

Table of Contents

DIVIDEND POLICY

We have never declared or paid cash dividends on our capital stock. We intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to dividend policy will be made at the discretion of our board of directors.

Table of Contents

CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of March 31, 2015:

- on an actual basis;
- on a pro forma basis to give effect to: (i) the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 25,051,257 shares of common stock immediately prior to the consummation of this offering and (ii) the filing and effectiveness of our amended and restated certificate of incorporation, which will occur immediately prior to the consummation of this offering; and
- on a pro forma as adjusted basis to give further effect to the sale of 10,000,000 shares of common stock in this offering at the initial public offering price of $16.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this information together with our audited financial statements and related notes appearing elsewhere in this prospectus and the information set forth under the headings Selected Financial Data and Management s Discussion and Analysis of Financial Condition and Results of Operations.

	As of March 31, 2015		
	Actual	Pro Forma	Pro Forma As Adjusted
		(unaudited)	
	(in thousands, except per share data)		
Cash and cash equivalents	$ 65,313	$ 65,313	$ 210,613
Stockholders (deficit) equity:			
Convertible preferred stock, $0.0001 par value per share, 25,248,814 shares authorized; 25,051,257 shares issued and outstanding, actual; no shares authorized, issued and outstanding, pro forma and pro forma as adjusted	83,811		
Preferred stock, $0.0001 par value per share, no shares authorized, issued and outstanding, actual; 10,000,000 shares authorized, no shares issued and outstanding, pro forma and pro forma as adjusted			
Common stock, $0.0001 par value per share, 50,046,000 shares authorized, 5,628,281 shares issued and outstanding, actual; 290,000,000 shares authorized, 30,679,538 shares issued and outstanding, pro forma, and 290,000,000 shares authorized, 40,679,538 shares issued and outstanding, pro forma as adjusted		3	4
Additional paid-in capital	1,386	85,194	230,493
Accumulated deficit	(20,958)	(20,958)	(20,958)

Total stockholders equity	64,239	64,239	209,539
Total capitalization	$ 64,239	$ 64,239	$ 209,539

The outstanding share information in the table above excludes the following:

189,853 shares of common stock issuable upon the exercise of outstanding stock options as of March 31, 2015, having a weighted-average exercise price of $0.14 per share;

Table of Contents

4,078,078 shares of common stock reserved for issuance pursuant to future awards under our 2013 Stock Plan, as amended, as of March 31, 2015. Of such shares, 3,228,100 shares of common stock are issuable upon the exercise of outstanding stock options that have been granted between March 31, 2015 and July 20, 2015, having a weighted-average exercise price of $3.56 per share;

4,681,544 shares of common stock reserved for issuance pursuant to future awards under our 2015 Equity Incentive Award Plan, as well as any automatic increases in the number of shares of our common stock reserved for future issuance under this plan, which will become effective prior to the consummation of this offering; and

390,128 shares of common stock reserved for issuance pursuant to future awards under our Employee Stock Purchase Plan, as well as any automatic increases in the number of shares of our common stock reserved for future issuance under this plan, which will become effective prior to the consummation of this offering.

Table of Contents

DILUTION

If you invest in our common stock in this offering, your interest will be immediately diluted to the extent of the difference between the initial public offering price per share of our common stock in this offering and the net tangible book value per share of our common stock after this offering. As of March 31, 2015, we had a historical net tangible book value of $64.2 million, or $11.41 per share of common stock. Our net tangible book value represents total tangible assets less total liabilities all divided by the number of shares of common stock outstanding on March 31, 2015. Our pro forma net tangible book value as of March 31, 2015, before giving effect to this offering, was $64.2 million, or $2.09 per share of our common stock. Pro forma net tangible book value, before the issuance and sale of shares in this offering, gives effect to:

- the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 25,051,257 shares of common stock immediately prior to the consummation of this offering; and
- the filing and effectiveness of our amended and restated certificate of incorporation, which will occur immediately prior to the consummation of this offering.

After giving effect to the sale of shares of common stock in this offering at the initial public offering price of $16.00 per share and after deducting the underwriting discounts and commissions and estimated offering expenses, our pro forma as adjusted net tangible book value as of March 31, 2015 would have been approximately $209.5 million, or $5.15 per share. This represents an immediate increase in pro forma as adjusted net tangible book value of $3.06 per share to existing stockholders and an immediate dilution of $10.85 per share to new investors. The following table illustrates this per share dilution:

Initial public offering price per share	$	16.00
Historical net tangible book value per share as of March 31, 2015	11.41	
Pro forma decrease in net tangible book value per share	(9.32)	
Pro forma net tangible book value per share as of March 31, 2015	2.09	
Increase in pro forma net tangible book value per share attributable to new investors	3.06	
Pro forma as adjusted net tangible book value per share after this offering		5.15
Dilution per share to new investors participating in this offering		$10.85

If the underwriters fully exercise their option to purchase additional shares, pro forma as adjusted net tangible book value after this offering would increase to approximately $5.50 per share, and there would be an immediate dilution of approximately $0.35 per share to new investors.

To the extent that outstanding options with an exercise price per share that is less than the pro forma as adjusted net tangible book value per share, before giving effect to the issuance and sale of shares in this offering, are exercised, new investors will experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the

issuance of these securities could result in further dilution to our stockholders.

Table of Contents

The following table shows, as of March 31, 2015, on a pro forma as adjusted basis, after giving effect to the pro forma adjustments described above, the number of shares of common stock purchased from us, the total consideration paid to us and the average price paid per share by existing stockholders and by new investors purchasing common stock in this offering at the initial public offering price of $16.00 per share, before deducting the underwriting discounts and commissions and estimated offering expenses payable by us (in thousands, except share and per share amounts and percentages):

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders[1]	30,679,538	75.4%	$ 95,391,149	37.4%	$ 3.11
Investors participating in this offering[1]	10,000,000	24.6	160,000,000	62.6	$ 16.00
Total	40,679,538	100%	$ 255,391,149	100%	

(1) Certain of our existing institutional investors have agreed to purchase an aggregate of 1,562,500 shares of our common stock in this offering at the initial public offering price. The presentation in this table regarding ownership by existing stockholders does not give effect to any purchases in this offering by such investors. See the footnotes to the beneficial ownership table in Principal Stockholders for more details.

The number of shares of common stock to be outstanding after this offering is based on the number of shares outstanding as of March 31, 2015 and excludes the following:

189,853 shares of common stock issuable upon the exercise of outstanding stock options as of March 31, 2015, having a weighted-average exercise price of $0.14 per share;

4,078,078 shares of common stock reserved for issuance pursuant to future awards under our 2013 Stock Plan, as amended, as of March 31, 2015. Of such shares, 3,228,100 shares of common stock are issuable upon the exercise of outstanding stock options that have been granted between March 31, 2015 and July 20, 2015 having a weighted-average exercise price of $3.56 per share;

4,681,544 shares of common stock reserved for issuance pursuant to future awards under our 2015 Equity Incentive Award Plan, as well as any automatic increases in the number of shares of our common stock reserved for future issuance under this plan, which will become effective prior to the consummation of this offering; and

390,128 shares of common stock reserved for issuance pursuant to future awards under our Employee Stock Purchase Plan, as well as any automatic increases in the number of shares of our common stock reserved for future issuance under this plan, which will become effective prior to the consummation of

this offering.

Table of Contents

SELECTED FINANCIAL DATA

The selected statement of operations data for the years ended December 31, 2013 and 2014 and the selected balance sheet data as of December 31, 2013 and 2014 are derived from our audited financial statements included elsewhere in this prospectus. The selected statement of operations data for the three months ended March 31, 2014 and 2015 and the selected balance sheet data as of March 31, 2015 are derived from our unaudited interim condensed financial statements included elsewhere in this prospectus. The unaudited interim condensed financial information has been prepared on the same basis as the annual financial information and, in the opinion of management, reflects all adjustments, consisting only of normal recurring adjustments, that we consider necessary for a fair presentation of the financial information set forth in those statements.

Our historical results are not necessarily indicative of the results to be expected in the future, and our interim unaudited results are not necessarily indicative of the results to be expected for the full year. You should read the following selected financial data together with the section of this prospectus entitled Management s Discussion and Analysis of Financial Condition and Results of Operations and our financial statements and the related notes included in this prospectus.

	Year Ended December 31,		Three Months Ended March 31,	
	2013	2014	2014	2015
			(unaudited)	
	(in thousands, except share and per share data)			
Statement of Operations Data:				
Operating expenses:				
Research and development	$ 3,495	$ 8,181	$ 1,199	$ 2,069
General and administrative	1,263	2,951	401	1,372
Total operating expenses	4,758	11,132	1,600	3,441
Loss from operations	(4,758)	(11,132)	(1,600)	(3,441)
Other income (expense), net				
Interest income	24	12	7	
Interest expense	(91)			
Total other income (expense), net	(67)	12	7	
Net loss	$ (4,825)	$ (11,120)	$ (1,593)	$ (3,441)
Net loss per share, basic and diluted[(1)]	$ (1.65)	$ (3.80)	$ (0.54)	$ (0.81)
Weighted-average shares used in computing net loss per share, basic and diluted[(1)]	2,926,665	2,928,896	2,926,665	4,258,877
Pro forma net loss per share, basic and diluted (unaudited)[(1)]		$ (0.69)		$ (0.15)

Shares used in computing pro forma net loss per share, basic and diluted (unaudited)[1]	16,192,863	22,467,561

(1) See Note 10 to our audited financial statements and Note 7 to our unaudited interim condensed financial statements included elsewhere in this prospectus for an explanation of the calculations of our net loss per share, basic and diluted, pro forma net loss per share, basic and diluted, and the shares used in computing the net loss per share, basic and diluted, and pro forma net loss per share, basic and diluted.

Table of Contents

	As of December 31, 2013	2014	As of March 31, 2015 (unaudited)
		(in thousands)	
Balance Sheet Data:			
Cash and cash equivalents	$ 11,951	$ 2,269	$ 65,313
Working capital	11,552	571	64,065
Total assets	12,156	2,531	65,895
Convertible preferred stock	16,928	16,928	83,811
Accumulated deficit	(6,397)	(17,517)	(20,958)
Total stockholders equity	11,637	671	64,239

Table of Contents

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 together with the section entitled Selected Financial Data and our financial statements and related notes included elsewhere in this prospectus. This discussion and other parts of this prospectus contain forward-looking statements that involve risks and uncertainties, such as our plans, objectives, expectations, intentions and beliefs. 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 identified below and those discussed in the section entitled Risk Factors included elsewhere in this prospectus.

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. It is estimated that over 30 million people in the United States and Europe have a food allergy, with peanut allergy being the most prevalent and most commonly associated with severe outcomes and life-threatening events. Our therapeutic 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 ARC001, our recently completed Phase 2 study of our lead CODIT product candidate, AR101, all of the 23 patients who completed the AR101 treatment regimen were desensitized to a clinically meaningful level of peanut protein of at least 443 mg, a level that substantially exceeds the amount of peanut protein typically encountered in an accidental exposure, which we believe to be approximately 100 mg or less. Our ARC002 study, an open label Phase 2 follow on study of patients who participated in ARC001, is ongoing. We intend to initiate a Phase 3 registration trial of AR101 and Phase 2 studies of other CODIT product candidates for two additional food allergies in 2016. AR101 has been granted Fast-Track designation and Breakthrough Therapy designation by the U.S. Food and Drug Administration, or FDA, and, 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 European Medicines Agency, or 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 $4.8 million and $11.1 million for the years ended December 31, 2013 and 2014, respectively, and $1.6 and $3.4 million for the three months ended March 31, 2014 and 2015, respectively. As of December 31, 2014 and March 31, 2015, our accumulated deficit was $17.5 million and $21.0 million, respectively. 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.

Since our inception and through March 31, 2015, we have funded our operations primarily through 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 March 31, 2015, we had $65.3 million in cash and cash equivalents. We believe that our existing cash and cash equivalents, together with the net proceeds from this offering, will be sufficient to fund our planned operations for the 24 months following the date of this offering, 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,

Table of Contents

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 have no manufacturing facilities and all of our manufacturing activities are contracted out to third parties. 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.

Critical Accounting Policies and Significant Judgments and Estimates

Our management s discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management s judgments and estimates.

Research and Development Costs

We record accrued expenses for estimated costs of our 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. We record the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced, and we include these costs in accrued liabilities in the consolidated balance sheets and within research and development expense in the statement of operations and comprehensive loss. These costs are a significant component of our research and development expenses. We record accrued expenses for these costs based on the estimated amount of work completed and in accordance with agreements established with these third parties.

We estimate the amount of work completed through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fee to be paid for such services. We make significant judgments and estimates in determining the accrued balance in each reporting period. As actual costs become known, we adjust our accrued estimates. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed, the number of patients enrolled and the rate of patient enrollment may vary from our estimates and could result in us reporting

amounts that are too high or too low in any particular period. Our accrued expenses are dependent, in part, upon the receipt of timely and accurate reporting from clinical research organizations and other third-party service providers. To date, there have been no material differences from our accrued expenses to actual expenses.

Table of Contents

Stock-Based Compensation

We recognize compensation costs related to stock options granted to employees and directors based on the estimated fair value of the awards on the date of grant, net of estimated forfeitures. We estimate the grant date fair value using the Black-Scholes option-pricing model. The grant date fair value of the stock-based awards is generally recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective awards.

We recorded stock-based compensation expense related to options granted of $0.1 million in each of the years ended December 31, 2013 and 2014, and $16,000 and $26,000 for the three months ended March 31, 2014 and 2015, respectively.

In determining the fair value of the stock-based awards, we use the Black-Scholes option-pricing model and assumptions discussed below. Each of these inputs is subjective and generally requires significant judgment to determine.

Expected Term. The expected term represents the period that stock-based awards are expected to be outstanding. We used the simplified method to determine the expected term, which is calculated as the mid-point between the vesting date and the end of the contractual term of the options.

Expected Volatility. Since we are not yet a public company and do not have any trading history for our common stock, the expected volatility was estimated based on the average historical volatilities of common stock of comparable publicly traded entities over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on their similar size, stage in the life cycle or area of specialty. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available.

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 term of the option.

Expected Dividend. We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero.

The following table presents the weighted-average assumptions used to estimate the fair value of options granted:

	Year Ended December 31,	
	2013	**2014**
Weighted-average exercise price of options granted	$ 0.14	$ 0.14
Expected volatility	85.52%	79.62%
Risk-free interest rate	1.56%	1.51%
Dividend yield	0.00%	0.00%

Expected term (in years)	4.76	4.65

No stock options were granted during the three months ended March 31, 2014 and 2015 and, as such, no weighted average assumptions for estimating fair value of options granted during such periods are available. Between March 31, 2015 and July 20, 2015, 3,228,100 shares of common stock issuable upon the exercise of outstanding stock options have been granted with a weighted-average exercise price of $3.56 per share.

In addition to the Black-Scholes assumptions, we estimate our forfeiture rate based on an analysis of our actual forfeitures and will continue to evaluate the adequacy of the forfeiture rate based on actual forfeiture experience, analysis of employee turnover behavior and other factors. The impact from any forfeiture rate adjustment would be recognized in full in the period of adjustment, and if the actual number of future forfeitures differs from our estimates, we might be required to record adjustments to stock-based compensation in future periods.

Table of Contents

See Note 7 to our audited financial statements included elsewhere in this prospectus for information concerning certain of the specific assumptions used in applying the Black-Scholes option-pricing model to determine the estimated fair value of employee stock options granted in 2013 and 2014. In addition to the assumptions used in the Black-Scholes option-pricing model, we must also estimate a forfeiture rate to calculate the stock-based compensation expense for our awards. We will continue to use judgment in evaluating the expected volatility, expected terms and forfeiture rates utilized for our stock-based compensation expense calculations on a prospective basis.

As of March 31, 2015, we had $86,000 of unrecognized compensation expense related to unvested stock options, which is expected to be recognized over an estimated weighted-average period of 2.2 years. For stock option awards subject to ratable vesting, we recognize compensation cost on a straight-line basis over the service period for the entire award. In future periods, our stock-based compensation expense is expected to increase as a result of recognizing our existing unrecognized stock-based compensation for awards that will vest and as we issue additional stock-based awards to attract and retain our employees.

Common Stock Valuation

Historically, for all periods prior to this offering, the fair value of the shares of common stock underlying our share-based awards were estimated on each grant date by our board of directors. In order to determine the fair value of our common stock underlying option grants, our board of directors considered, among other things, contemporaneous valuations of our common stock prepared by an unrelated third-party valuation firm at March 31, 2013, May 31, 2014, February 28, 2015, May 18, 2015 and July 6, 2015 in accordance with the guidance provide by the American Institute of Certified Public Accountants Practice Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. Given the absence of a public trading market for our common stock, our board of directors exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of our common stock, including our stage of development; progress of our research and development efforts; the rights, preferences and privileges of our preferred stock relative to those of our common stock; equity market conditions affecting comparable public companies and the lack of marketability of our common stock.

The unrelated third-party valuations were prepared using the Probability Weighted Expected Return Method, or PWERM, to arrive at the estimated fair value of our common stock. The PWERM is a scenario-based analysis that estimates the value per share of common stock based on the probability-weighted present value of expected future equity values for the common stock, under various possible future liquidity event scenarios, including initial public offering, sale of the company, dissolution and staying private. The PWERM utilized in each of the March 31, 2013, May 31, 2014, February 28, 2015, May 18, 2015 and July 6, 2015 valuations was based on several assumptions applicable at the time of the valuation, including the likelihood of successfully completing our then-planned clinical trials, the likelihood of receiving necessary regulatory approvals to commercialize AR101 and the likely timeframe of the relative liquidity event scenarios based, in part, on the occurrence of the preceding assumptions. The company valuation used in the exit scenarios utilized in the PWERM were derived from a combination of input from the company s management, valuations for comparable companies in comparable exit scenarios (initial public offering or sale) and comparable public company analysis. The results of the PWERM were then gauged for appropriateness by comparing them against results from the market and income approach, however, neither the market or income approach was relied upon to determine the company valuation in the exit scenarios.

After the completion of this offering, our board of directors will determine the fair value of each share of underlying common stock based on the closing price of our common stock as reported on the date of grant.

68

Table of Contents

The table below shows the intrinsic value of our outstanding vested and unvested options as of March 31, 2015 based upon the initial public offering price of $16.00 per share.

	Number of shares underlying options	Intrinsic value (in thousands, except share data)
Total vested options outstanding	140,495	$ 2,228
Total unvested options outstanding	49,358	$ 783
Total options outstanding	189,853	$ 3,011

Income Taxes

We recognize deferred income taxes for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes. We periodically evaluate the positive and negative evidence bearing upon realizability of our deferred tax assets. Based upon the weight of available evidence, which includes our historical operating performance, reported cumulative net losses since inception and difficulty in accurately forecasting our future results, we maintained a full valuation allowance on the net deferred tax assets. We intend to maintain a full valuation allowance on the federal and state deferred tax assets until sufficient positive evidence exists to support reversal of the valuation allowance.

As of December 31, 2014, we had generated net operating loss, or 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. 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 Internal Revenue Code of 1986, as amended, or 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 have experienced multiple ownership changes under Section 382 of the Code and, as a result, our federal and state NOL carryforwards and tax credits are subject to limitation.

We record unrecognized tax benefits as liabilities and adjust these liabilities when our judgment changes as a result of the evaluation of new information not previously available. Because of the complexity of some of these uncertainties, the ultimate resolution may result in a payment that is materially different from our current estimate of the unrecognized tax benefit liabilities. These differences will be reflected as increases or decreases to income tax expense in the period in which new information is available. As of December 31, 2013 and 2014 and March 31, 2015, we did not have any unrecognized tax benefits.

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;

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;

Table of Contents

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 absolute dollars 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.

Interest Income (Expense)

Interest income consists of interest earned on our cash and cash equivalents. Interest expense consists of interest expense on amounts borrowed under a convertible note.

Results of Operations

Comparison of the Three Months Ended March 31, 2014 and 2015

	Three Months Ended March 31,			
	2014	2015	$ Change	% Change
	(unaudited)			
	(in thousands, except percentages)			
Operating expenses:				
Research and development	$ 1,199	$ 2,069	$ 870	73%
General and administrative	401	1,372	971	242%

Total operating expenses	1,600	3,441	1,841	115%
Income (Loss) from operations	(1,600)	(3,441)	(1,841)	115%
Other income (expense), net				
Interest income	7		(7)	*
Interest expense				
Total other income (expense), net	7		(7)	*
Net loss and comprehensive loss	$ (1,593)	$ (3,441)	$ (1,848)	116%

* Percentage not meaningful.

Table of Contents

Research and Development Expenses

The following table summarizes our research and development expenses incurred during the three months ended March 31, 2014 and 2015:

	Three Months Ended March 31,			
	2014	2015	$ Change	% Change
	(unaudited)			
	(in thousands, except percentages)			
Clinical development and regulatory	$ 405	$ 971	$ 566	140%
Contract manufacturing	416	669	253	61%
Compensation and related personnel costs	355	330	(25)	(7)%
Other research and development costs		50	50	*
Facility costs	23	49	26	113%
Total research and development	$ 1,199	$ 2,069	$ 870	73%

* Percentage not meaningful.

Research and development expenses were $2.1 million for the three months ended March 31, 2015, an increase of $0.9 million, from $1.2 million for the three months ended March 31, 2014. This increase was primarily attributable to a $0.6 million increase in clinical development expenses mainly associated with our ongoing trials and a $0.3 million increase in contract manufacturing costs of our clinical product candidates. The decrease in compensation and related personnel costs was due to departure of certain executives in our clinical development function. We have subsequently filled these positions and we expect to incur additional compensation and related personnel costs in connection with our ongoing open label Phase 2 study of AR101, ARC002.

General and Administrative Expenses

The following table summarizes our general and administrative expenses incurred during the three months ended March 31, 2014 and 2015:

	Three Months Ended March 31,			
	2014	2015	$ Change	% Change
	(unaudited)			
	(in thousands, except percentages)			
Compensation and related personnel costs	$ 179	$ 646	$ 467	261%
Outside professional services	93	548	455	489%
Facility costs	37	58	21	57%
Other general and administrative	92	120	28	30%

Total general and administrative	$ 401	$ 1,372	$ 971	242%

General and administrative expenses were $1.4 million for the three months ended March 31, 2015, an increase of $1.0 million, from $0.4 million for the three months ended March 31, 2014. This increase was primarily due to a $0.5 million increase in compensation expenses primarily related to our additional administrative and executive personnel and severance payments to certain former executives, and $0.5 million in professional fees incurred in connection with financial consulting, public relations and communications activities.

Table of Contents

Comparison of the Years Ended December 31, 2013 and 2014

	Year Ended December 31,			
	2013	2014	$ Change	% Change
	(in thousands, except percentages)			
Operating expenses:				
Research and development	$ 3,495	$ 8,181	$ 4,686	134%
General and administrative	1,263	2,951	1,688	134%
Total operating expenses	4,758	11,132	6,374	134%
Income (Loss) from operations	(4,758)	(11,132)	(6,374)	134%
Other income (expense), net				
Interest income	24	12	(12)	*
Interest expense	(91)		91	*
Total other income (expense), net	(67)	12	79	*
Net loss and comprehensive loss	$ (4,825)	$ (11,120)	$ (6,295)	130%

* Percentage not meaningful.

Research and Development Expenses

The following table summarizes our research and development expenses incurred during the years ended December 31, 2013 and 2014:

	Year Ended December 31,			
	2013	2014	$ Change	% Change
	(in thousands, except percentages)			
Clinical development and regulatory	$ 2,228	$ 4,565	$ 2,337	105%
Contract manufacturing	114	1,834	1,720	*
Compensation and related personnel costs	1,101	1,559	458	42%
Facility costs	52	149	97	187%
Other research and development costs		74	74	*
Total research and development	$ 3,495	$ 8,181	$ 4,686	134%

* Percentage not meaningful.

Research and development expenses were $8.2 million for the year ended December 31, 2014, an increase of $4.7 million, from $3.5 million for the year ended December 31, 2013. This increase was primarily attributed to a $2.3 million increase in clinical development expenses mainly associated with ongoing trials, a $1.7 million increase in contract manufacturing costs of our clinical product candidates, a $0.5 million increase in compensation expenses primarily related to hiring of additional research and development staff and a $0.2 million increase in facility costs and other research and development costs.

Table of Contents

General and Administrative Expenses

The following table summarizes our general and administrative expenses incurred during the years ended December 31, 2013 and 2014:

	Year Ended December 31,			
	2013	2014	$ Change	% Change
	(in thousands, except percentages)			
Compensation and related personnel costs	$ 533	$ 1,716	$ 1,183	222%
Outside professional services	405	786	381	94%
Other general and administrative	225	274	49	22%
Facility costs	100	175	75	75%
Total general and administrative	$ 1,263	$ 2,951	$ 1,688	134%

General and administrative expenses were $3.0 million for the year ended December 31, 2014, an increase of $1.7 million, from $1.3 million for the year ended December 31, 2013. This increase was primarily due to a $1.2 million increase in compensation expenses primarily related to our additional administrative and executive personnel, and $0.4 million in professional fees incurred in connection with public relations and communications activities.

Interest Expense

Interest expense was nil for the year ended December 31, 2014, a decrease of $91,000 from the year ended December 31, 2013. The interest expense in 2013 was primarily attributable to the conversion of a convertible note payable into Series A preferred stock and expensing the remaining unamortized conversion discount on the convertible note.

Liquidity, Capital Resources and Plan of Operations

Since our inception and through March 31, 2015, we have funded our operations primarily through 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 March 31, 2015, we had $65.3 million in cash and cash equivalents. We believe that our existing cash and cash equivalents, together with the net proceeds from this offering, will be sufficient to fund our planned operations for the 24 months following the date of this offering, 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.

Table of Contents

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 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 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

Comparison of the Three Months Ended March 31, 2014 and 2015

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

	Three Months Ended March 31,	
	2014	2015
	(unaudited)	
	(in thousands)	
Net cash provided by (used in)		
Operating activities	$ (1,949)	$ (3,993)
Investing activities	(5)	(44)
Financing activities		67,081
Net change in cash and cash equivalents	$ (1,954)	$ 63,044

Table of Contents

Net Cash Used In Operating Activities

Net cash used in operating activities was $4.0 million for the three months ended March 31, 2015, an increase of $2.1 million, from $1.9 million for the three months ended March 31, 2014. This increase was primarily due to 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 consisted primarily of investment in equipment.

Net Cash Provided By Financing Activities

Net cash provided by financing activities for the three months ended March 31, 2015 consisted primarily of the proceeds of $79.8 million from the issuance of the Series B convertible preferred stock, net of offering costs, and $0.2 million from the exercise of stock options, offset in part by $12.9 million from the repurchase of shares of Series A from certain investors.

As of March 31, 2015, we had cash and cash equivalents of $65.3 million, including the net proceeds we received from the issuance of Series B convertible preferred stock in January and February 2015.

Comparison of the Years Ended December 31, 2013 and 2014

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

	Year Ended December 31,	
	2013	2014
	(in thousands)	
Net cash provided by (used in)		
Operating activities	$ (4,362)	$ (9,777)
Investing activities	(69)	(96)
Financing activities	16,164	191
Net change in cash and cash equivalents	$ 11,733	$ (9,682)

Net Cash Used In Operating Activities

Net cash used in operating activities was $9.8 million for the year ended December 31, 2014, an increase of $5.4 million, from $4.4 million for the year ended December 31, 2013. This increase was primarily due to 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 consisted primarily of investment in equipment.

Net Cash Provided By Financing Activities

Net cash provided by financing activities was $0.2 million for the year ended December 31, 2014, a decrease of $16.0 million, from $16.2 million for the year ended December 31, 2013. The net cash provided by financing activities in 2014 was primarily from the exercise of stock options and the net cash provided by financing activities in 2013 was primarily from the sale of preferred stock.

As of December 31, 2014, we had cash and cash equivalents of approximately $2.3 million.

Table of Contents

Contractual Obligations and Other Commitments

The following table summarizes our contractual obligations as of December 31, 2014:

	Payments due by periods				
	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
			(in thousands)		
Operating leases[1][2]	$ 423	$ 167	$ 170	$ 86	$
Other purchase commitments[3]					
Total contractual obligations	$ 423	$ 167	$ 170	$ 86	$

(1) In March 2015, we signed a new facility lease for our corporate headquarters and research facilities in Brisbane, California. The new headquarters lease calls for future aggregate non-cancellable lease payments of $2.0 million over a period of 51 months, which have not been reflected in the table above.
(2) In June 2015, we signed a new facility lease for a manufacturing facility Clearwater, Florida. The new manufacturing facility lease calls for future aggregate lease payments of $1.7 million over a period of 10 years, which have not been reflected in the table above.
(3) We purchase 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, our purchase obligation commences with the first delivery of peanut flour for commercial use, which we currently anticipate will not occur prior to 2018. Assuming that our first delivery for commercial use occurs in 2018, which is not assured, the aggregate purchase commitment under this agreement would be $1.2 million over the following five years.

We enter into agreements in the normal course of business with contract research organizations for clinical trials and with vendors for pre-clinical studies and other services and products for operating purposes which are cancelable at any time by us, generally upon 30 days prior written notice. These payments are not included in this table of contractual obligations.

Except for the new facility lease described above, our contractual obligations as of March 31, 2015 have not materially changed from December 31, 2014.

Off-Balance Sheet Arrangements

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

Material Weakness

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 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 implementing new procedures for review of account reconciliations and manual journal entries and restricting check writing and wire transfer authority. We intend to implement further segregation of duties and to establish formal written policies for our accounting function by the end of the year. However, we cannot assure you that these measures will be sufficient to remediate or prevent future material weaknesses or significant deficiencies from occurring. See Risk Factors Risks Related to our Business We identified a material weakness in our internal control

Table of Contents

over financial reporting at 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 fail to establish and maintain effective control over financial reporting, our ability to accurately and timely report our financial results could be adversely affected.

Quantitative and Qualitative Disclosures about Market Risk

As of March 31, 2015, we had cash and cash equivalents of $65.3 million, which consisted primarily of bank and money market deposits. Such interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations of interest income have not been significant. We had no outstanding debt as of March 31, 2015.

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.

JOBS Act Accounting Election

We are an emerging growth company, as defined in the JOBS Act of 2012. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards, and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Recent Accounting Pronouncements

In May 2014, the FASB issued ASU 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. ASU 2014-09 is effective for annual periods beginning after December 15, 2016, for public business entities. On April 29, 2015, the FASB issued for comment a proposed ASU, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date.* The proposed ASU would permit both public and nonpublic organizations to adopt the new revenue standard early, but not before the original public organization effective date (that is, annual periods beginning after December 15, 2017).

In June 2014, the FASB issued ASU 2014-10, *Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation*. ASU 2014-10 simplifies the accounting guidance by removing all incremental financial reporting requirements for development stage entities. The amendments related to the elimination of the inception-to-date information and other disclosure requirements of Topic 915 should be applied retrospectively and are effective for annual reporting periods beginning after December 15, 2014 and interim periods therein. We have elected to early adopt this guidance and, accordingly, there is no inception to date information presented in our financial statements.

In August 2014, the FASB issued ASU 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 first quarter of 2016 with early adoption permitted. We do not believe the impact of adopting ASU 2014-15 on our financial statements will be material.

Table of Contents

BUSINESS

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. It is estimated that over 30 million people in the United States and Europe have a food allergy, with peanut allergy being the most prevalent and most commonly associated with severe outcomes and life-threatening events. Our therapeutic 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 ARC001, our recently completed Phase 2 study of our lead CODIT product candidate, AR101, all of the 23 patients who completed the AR101 treatment regimen were desensitized to a clinically meaningful level of peanut protein of at least 443 mg, a level that substantially exceeds the amount of peanut protein typically encountered in an accidental exposure, which we believe to be approximately 100 mg or less. We intend to initiate a Phase 3 registration trial of AR101 in early 2016 and Phase 2 studies of other CODIT product candidates for two additional food allergies in 2016. AR101 has been granted Fast-Track designation and Breakthrough Therapy designation by the U.S. Food and Drug Administration, or FDA, and, 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 European Medicines Agency, or 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.

Our CODIT system for the treatment of food allergies leverages and improves upon the extensive independent scientific research demonstrating that food-allergic patients can be desensitized to clinically meaningful levels of a food allergen by orally administering them increasing amounts of such allergen over a period of months. Based on our clinical development to date, including our ARC001 study, we believe that our CODIT system will have the following key attributes:

Standardized Products: Our proprietary biologic product candidates are derived from natural food products and are designed to contain precisely defined dosages of well-characterized food proteins so that each dosage is consistent for total protein and relative allergen content. In addition, we expect each of our product candidates, if approved, to be provided to patients as a convenient, orally administered, once daily therapy.

Safe and Well-Defined Treatment Regimens: We intend to demonstrate the safety and efficacy of each CODIT product candidate in large scale, well-controlled clinical trials. In addition, we expect each CODIT product candidate to feature clearly defined clinical protocols with gradual up-dosing and practical maintenance dosing regimens designed to enhance safety, tolerability and efficacy.

Clinically Meaningful Desensitization: We expect each approved CODIT product candidate to provide patients with protection from food allergens at a level that exceeds the amount typically encountered in an accidental exposure.

Compatibility with Clinical Practice: We expect our protocols for each CODIT product candidate to be similar to treatment regimens currently utilized by allergists for non-food allergies.

Tailored Support Services: We intend to provide physician education, patient guidance and other support services to facilitate the administration of each approved CODIT product candidate.

Regulatory Approval: We believe regulatory approval of our CODIT product candidates, if obtained, will validate the extensive existing scientific research supporting oral desensitization and could lead to widespread adoption of our system.

Table of Contents

Food allergies are a severe and growing health problem in the United States, Europe and throughout the developed world. Peanut is the most common food allergy, and we estimate that there are over five million people in the United States and Europe with peanut allergy, including over two million children. The prevalence of peanut allergy in children in the United States is estimated to have increased at a constant annual growth rate of approximately 10% between 1997 and 2008, and experts believe it has continued to rise since 2008. Food-related allergic reactions are estimated to result in approximately 200,000 emergency room visits and over 10,000 hospital admissions each year in the United States.

There are currently no approved medical therapies to cure food allergies or prevent their effects. Avoidance is the primary method of managing a food allergy and successfully practicing avoidance can be virtually impossible, as allergic reactions can often be triggered by trace amounts of food proteins, or allergens. For example, of the over two million people with peanut allergy in the United States, 40% to 50% are sensitive to an exposure of 100 mg or less of peanut protein, the equivalent of less than half of a peanut kernel. For patients exposed to allergens, treatment options are limited. Epinephrine is used as a rescue medication, but its effectiveness is dependent on several factors, such as availability, the promptness of administration and sufficient dosage to counteract the effects of the allergic reaction. The stress of practicing avoidance and the limited availability of effective treatment options can result in a fear of a fatal accidental exposure, substantially diminishing the quality of life of patients and their families. This fear can lead to psychological traumas, including fear of eating, social difficulties and severe anxiety. In addition, parents of food-allergic children often attempt to prevent accidental exposures by limiting their child s participation in everyday activities.

We believe our CODIT system and product candidates, if approved, have the potential to reduce the dangers posed to food-allergic patients, such as accidental exposures resulting in anaphylactic reactions, emergency room visits or hospitalization. For instance, at high levels of accidental exposure, we believe the severity of an allergic response could potentially be reduced from a severe event requiring the use of epinephrine to a non-life-threatening warning sign, such as itching of the mouth or pruritus. We expect that this potential protection from accidental exposures will reduce the stress and anxiety of patients and their families and enable patients to live more normal lives.

Our lead CODIT product candidate, AR101, is a proprietary product designed to desensitize patients to a level of peanut protein that we believe substantially exceeds the amount typically encountered in an accidental exposure using gradual up-dosing and practical maintenance dosing regimens. Based on our clinical development to date, including our ARC001 study, we believe AR101 has the following key attributes:

Proprietary Biologic Product: Our proprietary formulation is a complex mixture of naturally occurring proteins and pharmaceutical-grade ingredients that we developed to enable the convenient dosing of consistent amounts of peanut protein with well-defined relative concentrations of specific peanut allergens.

Clinically Meaningful and Reliable Desensitization: In ARC001, 23 of the 23 peanut allergic patients who completed the AR101 treatment regimen achieved clinically meaningful desensitization to peanut allergens. ARC001 and independent scientific research have indicated that clinically meaningful desensitization can be attained through an oral immunotherapy treatment regimen, independent of gender, age and other demographics.

Rapid and Predictable Onset of Action: In ARC001, a clinically meaningful level of protection was typically achieved by patients in the AR101 treatment group after only 22 weeks of dosing. Independent scientific research has also shown that continued maintenance dosing pursuant to an oral immunotherapy treatment regimen can confer increased protection over time.

Attractive Safety Profile: In ARC001, most patients tolerated AR101 well, experiencing only mild, intermittent side effects commonly associated with food allergies during the up-dosing phase of treatment. The most frequent of these side effects included gastrointestinal symptoms ranging from itching of the lips

to vomiting, hives, throat itching or discomfort and nasal congestion. Once patients are desensitized and on maintenance dosing, we believe that they are likely to experience few or no side effects.

Convenient Oral Administration: AR101 is designed to be provided to patients as a convenient, orally administered, once daily therapy that is mixed with common age-appropriate foods.

Direct, Targeted Mechanism of Action: Oral administration of AR101 enables the allergen to interact directly with the immune cells in the gastrointestinal tract responsible for mediating the allergic reaction to peanuts. Oral desensitization works by gradually shifting the balance of the immune system to dampen the allergic response in the case of accidental exposure.

Compatibility with Current Clinical Practice and Infrastructure: The AR101 up-dosing regimen is similar to existing, widely adopted regimens for the treatment of non-food allergies, such as pollen and pet dander. We believe this feature will facilitate adoption by allergists and reimbursement by payors if AR101 is approved.

CODIT Support Services: We intend to provide physician education, patient guidance and other support services to facilitate the administration of AR101, if approved.

In June 2015, we presented our ARC001 Phase 2 data as a late-breaking abstract at the European Academy of Allergy and Clinical Immunology Congress, or EAACI. In ARC001, all patients who completed the up-dosing regimen in the AR101 treatment group were desensitized to a cumulative dose of 443 mg of peanut protein, the equivalent of approximately two peanut kernels, as compared to five of the 26 patients who received placebo. In addition, 18 of the 23 patients who completed the up-dosing regimen in the AR101 treatment group were desensitized to a cumulative dose of 1,043 mg of peanut protein, the equivalent of approximately four peanut kernels, as compared to none of the 26 patients who received placebo. Our ongoing open label Phase 2 study, ARC002, is evaluating, among other things, the long-term safety and tolerability of a regimen of daily maintenance doses of AR101 and its effect on desensitization.

We believe the consistency and reliability of patients responses to AR101, if confirmed in future studies and if AR101 is approved for its intended use, will result in patients and their caregivers feeling less stress and anxiety about the possibility of an accidental exposure and allow them to lead more normal lives. We intend to initiate a Phase 3 registration trial of AR101 in early 2016 and Phase 2 studies of CODIT product candidates for two additional food allergies in 2016. The FDA has granted AR101 Fast-Track designation for oral immunotherapy of peanut sensitive adults and children and Breakthrough Therapy designation for oral immunotherapy of peanut sensitive children and adolescents (ages 4-17) and, if our planned Phase 3 registration trial is successful, we intend to file a BLA with the FDA and a MAA with the EMA.

We were formed after a 2011 conference where leading researchers, clinicians, patient advocates and regulators in the field of food allergies concluded that oral desensitization had a strong scientific basis but required greater standardization and validation for widespread adoption. With the support of Food Allergy Research and Education (FARE), a leading patient advocacy organization, we were founded to pursue the development and commercialization of standardized oral desensitization medical therapies for the treatment of food allergies. To execute on this vision, we have assembled a team of experienced biotechnology and pharmaceutical executives who have collectively contributed to the development and regulatory approval of over 30 drugs and biologics. We believe that the quality of

our team will strongly influence our ability to develop a new class of CODIT products to address the unmet medical needs of food-allergic patients. Our Chief Executive Officer, Dr. Stephen Dilly, was previously Chief Executive Officer at APT Pharmaceuticals, Inc., Senior Vice President, Head of Development, Chief Medical Officer at Chiron BioPharmaceuticals, a division of Chiron Corporation, and Vice President of Medical Affairs at Genentech, Inc. Other members of our management team have held senior positions at Bristol-Myers Squibb Company, Chiron Corporation, GlaxoSmithKline plc, Novartis AG, Onyx Pharmaceuticals, Inc., Pfizer Inc., Roche Holding AG and Teva Pharmaceutical Industries Limited. We also have leading financial investors such as Adage Capital, Aisling Capital, funds affiliated with Fidelity Management & Research Company, Foresite Capital, Longitude Capital, Palo Alto Investors and RA Capital.

Table of Contents

Our Strategy

Our goal is to build a biopharmaceutical company that develops and commercializes proprietary therapies to improve the lives of food-allergic patients and their families. We intend to achieve this goal by pursuing the following key strategic objectives:

Complete development and obtain approval of AR101 in the United States and Europe for the treatment of peanut allergy: In early 2016, we intend to initiate a Phase 3 registration trial of AR101 in patients with peanut allergy to support the submission of a BLA in the United States and a MAA in the European Union.

Commercialize AR101 in the United States and Europe through our own specialty sales force: We own worldwide commercial rights to our product candidates. If AR101 is approved for the treatment of peanut allergy, we intend to commercialize our lead product candidate by developing a specialty sales force targeting a subset of the approximately 4,500 practicing allergists in the United States as well as allergy-focused clinicians in the five largest European markets. We anticipate that this sales force could also support the commercialization of additional CODIT product candidates, if approved.

Leverage the CODIT system to develop additional proprietary product candidates for the treatment of food allergies: Leveraging the expertise we have gained developing AR101, we intend to initiate Phase 2 studies for two additional CODIT product candidates for food allergies in 2016.

Strategically pursue collaborations: We intend to evaluate opportunities to work with partners that meaningfully enhance our capabilities with respect to the development and commercialization of our product candidates. In addition, working with key opinion leaders and academic researchers, we intend to evaluate the potential to develop other approaches to treating food allergies.

Food Allergy Overview

Food Allergies are a Significant and Growing Health Problem

Food allergies are a significant and growing health problem in the United States, Europe and throughout the developed world. It is estimated that over 30 million people in the United States and Europe have a food allergy, including over 11 million children. According to a study published in JAMA Pediatrics, the economic cost of food allergies in the United States is estimated to equal approximately $25 billion per year, of which approximately $4 billion is associated with direct medical expenses. Food allergies are a particularly urgent issue for children because of the greater prevalence of food allergies in that age group and because of the increased risk of accidental exposures leading to a serious allergic reaction. A recent large scale study concluded that approximately 8% of children in the United States have a food allergy and that approximately 39% of that group had a history of at least one severe allergic reaction. We estimate that over 50% of patients with peanut allergy experience a severe allergic reaction each year.

Peanut is the most common type of food allergy. Among children with food allergies in the United States, approximately 25% are allergic to peanuts, with other common food allergies being milk (21%), shellfish (17%), tree

nut (13%) and egg (10%). We estimate that there are over five million people in the United States and Europe with peanut allergy, including over two million children. The prevalence of peanut allergy in children in the United States is estimated to have increased at a constant annual growth rate of approximately 10% between 1997 and 2008, and experts believe it has continued to rise since 2008.

Risks Associated with Allergic Reactions

Allergic reactions to food are painful, frightening and potentially deadly. Symptoms of an allergic reaction include hives, swelling, vomiting, abdominal pain, wheezing, breathlessness and lowered blood

pressure. Severe and potentially life-threatening reactions are referred to as anaphylaxis and such reactions require urgent medical attention and often result in treatment at hospital emergency departments. Food-related allergic reactions are estimated to result in approximately 200,000 emergency room visits and over 10,000 hospital admissions each year in the United States.

Allergic reactions, including severe allergic reactions, can be triggered by exposure to minute quantities of the relevant food allergen. For example, of the over two million people with peanut allergy in the United States, 40% to 50% are sensitive to an exposure of 100 mg or less of peanut protein, the equivalent of less than half of a peanut kernel. In addition, people with peanut allergy are often sensitive to as little as 10 mg of peanut protein, the equivalent of approximately 1/25th of a peanut kernel. As a result, accidental exposure arising from contamination of a food source or the inaccurate or confusing labeling of food products occurs regularly and can result in severe allergic reactions.

Causes of Allergic Reactions

Food allergies occur when the immune system responds to a harmless food as if it were a threat. The human gastrointestinal tract contains immune cells whose purpose is to identify and mount a response against proteins deemed to be foreign and unsafe. These cells come into contact with a large amount and variety of food proteins. In a non-allergic person, a tolerance for food proteins develops early in life, and the immune cells do not mount a response when food proteins are detected. In contrast, in an allergic patient, the immune system is sensitized to one or more food proteins, or allergens. As a result of this sensitization, the immune system produces antibodies, known as IgE antibodies, which are directed against a particular allergen, such as a specific peanut protein. The IgE antibodies link with mast cells and basophils, which are other immune cells. When an IgE antibody linked to these immune cells encounters the allergen it is directed against, the immune cells are activated and release histamine and other inflammatory mediators into the blood. These mediators then provoke the symptoms of an allergic reaction.

The development and progression of food allergies is highly variable. It is unknown why some people develop food allergies while others do not. For certain types of allergies, such as milk and egg, patients may outgrow their allergies, but for others, such as peanuts, tree nuts and shellfish, most patients remain allergic for life. In addition, a person s sensitivity appears to vary over time based on a range of factors. It is not unusual for a person s first allergic reaction to be mild and their second allergic reaction to be severe or life-threatening.

Challenges in the Current Treatment and Management of Food Allergies

There are currently no approved medical therapies to cure food allergies or prevent their symptoms. The most common practices are strict avoidance of food allergens and emergency treatment of allergy symptoms in the event of an accidental exposure. These options have substantial limitations and the burdens of practicing avoidance and stress caused by the limited availability of effective treatment options for accidental exposure can have a substantial negative impact on the quality of life of food-allergic patients and their families. For example, food-allergic patients and their caregivers often have difficulties managing their social and day-to-day lives, and live with an ongoing fear of accidental exposure and anaphylaxis. One study found that children with peanut allergy reported a poorer quality of life than children with insulin-dependent diabetes mellitus. A separate study found that the parents of peanut-allergic children reported more disruption in their family s lives than the parents of children with rheumatological disease.

Limitations of Practicing Avoidance of Food Allergens

Successfully practicing avoidance can be very difficult and requires careful reading of food labels, care in the storage and preparation of foods, awareness of product recalls for mislabeling and contamination, and oftentimes avoidance of

cuisines where the food allergen is known to be common. In addition, activities such as attending a sporting event, traveling by airplane or visiting public spaces become difficult and stressful for food-allergic patients and their families. Practicing avoidance can be particularly difficult on food-allergic children as

Table of Contents

parents often attempt to prevent accidental exposures by limiting their child s participation in everyday activities, including social activities, eating outside the home and sometimes even choosing to home school their child because such food-allergic children may not have the awareness or self-regulation skills to practice avoidance by themselves.

Limitations of Emergency and Symptomatic Treatments

Due to a lack of approved symptomatic or disease-modifying food allergy treatments, food-allergic patients typically must carry rescue medication to treat severe and possibly life-threatening allergic reactions. The most widely used treatment is epinephrine (also known as adrenaline) which is administered using an auto-injector, such as an EpiPen or Auvi-Q. Epinephrine blunts certain symptoms of the allergic reaction by increasing heart rate and blood pressure and dilating airways, but it does not treat the allergic reaction itself. While epinephrine is useful as a rescue medication, it is not always administered properly or quickly enough and may not be sufficient to counteract the effects of the allergic reaction.

Limitations of Current Desensitization Treatments

Emergency and symptomatic remedies are reactive treatments and often ineffective in the chronic management of food allergies. The most commonly practiced proactive therapy for food and other allergies is desensitization therapy. Desensitization therapy consists of repeated administrations of increasing quantities of an allergen to an allergic patient in order to decrease the immune response to that allergen. The most common form of desensitization therapy is subcutaneous injections for patients with environmental allergies. While desensitization therapy has had significant success in the treatment of environmental allergies, it has been less successful in the treatment of food allergies. Four different desensitization therapy approaches to food allergies have been researched:

Subcutaneous Injections: Involves the subcutaneous injection of the food allergen. This approach has been shown to induce desensitization in some patients but has had an unacceptably high incidence of adverse events and research on this approach has largely been abandoned.

Sublingual Immunotherapy: Involves the administration of increasing amounts of food extract under a patient s tongue. This approach has been shown to be safe, but it appears to induce only a modest degree of desensitization.

Epicutaneous Desensitization: Involves the use of a patch that causes allergens to be absorbed by the skin. Clinical trials are ongoing to explore the potential viability of this approach.

Oral Immunotherapy: Involves the administration of increasing doses of a food-based product on a daily basis over a period of months. This approach has the potential to produce a high degree of desensitization but adoption has been hampered by lack of standardization for products and protocols.

We believe the most effective form of desensitization therapy is oral immunotherapy, or OIT.

Immunology of Oral Desensitization

Oral desensitization works by gradually shifting the balance of the immune system to dampen the allergic response in the case of accidental exposure.

The initial step in an immune response is the presentation of an allergenic protein by an antigen presenting cell, such as a dendritic cell, and subsequent recognition of the allergenic protein by T-cells. T-cells proliferate into Th2 cells upon antigen recognition and secrete a set of proteins called inflammatory cytokines,

such as IL-5 and IL-13, which are important in cell signaling. Secretion of this group of cytokines results in B-cell maturation and production of IgE antibodies. IgE antibody cross-linking at the surface of mast cells results in the mast cells releasing histamines, proteoglycans and other molecules, which elicit symptoms of an allergic reaction.

In oral desensitization, very low levels of allergen insufficient to trigger an IgE-mediated allergic reaction induce regulatory T-cells, which dampen the Th2 immune response and induce B-cells to produce IgG4 antibodies. IgG4 antibodies compete with IgE antibodies for mast cell binding and inhibit IgE antibody cross-linking at the surface of the mast cells. As such, when IgG4 antibodies are bound to mast cells, they act to dampen the symptoms of an allergic reaction.

The following provides an overview of the immunology of allergies.

Oral Desensitization in Practice

In an OIT treatment regimen, the initial administration of a particular dose of the food allergen will typically be provided in an allergist s office and the subsequent administrations will be done at home. The highest level of dosing administration will vary depending on the patient and the protocol, but generally the goal is to achieve desensitization to a level of food allergen greater than the amount a patient might be exposed to in an accidental exposure. Once the highest dosing level is attained, the patient will continue to be administered a maintenance dose on a regular basis. Over time, this regular administration has been shown to result in the patient being desensitized to an amount of food substantially greater than the maintenance dose.

Numerous clinical trials at leading academic research centers have shown that OIT can desensitize patients to a range of food allergies, including peanut, egg and milk. While OIT generally does not cure a patient of their allergy, it can provide protection from food allergens at a level that exceeds the amount typically encountered in an accidental exposure. For many patients, this protection meaningfully decreases their stress and anxiety and enables them to lead a more normal life.

Table of Contents

While OIT has been shown to be effective, it has not been widely adopted and is currently available only from a limited number of academic research centers and specialized allergy clinics. These institutions have access to compounding pharmacies to produce the doses of food-based product necessary for the therapy and also have the resources to provide the required patient support. However, because no OIT protocol or product has been validated in a large scale clinical trial or approved by the FDA, the treatment regimen and food source used in OIT treatment is determined by the allergist based on their experience and review of the scientific literature, which can lead to varying results. While studies have shown that most patients tolerate OIT well, the incidence of severe adverse events associated with OIT treatment has historically been high enough to raise concerns in the medical community that it is not safe enough to be a standard part of an allergist s practice. We believe these safety concerns along with complexity and lack of standardization have limited the adoption of OIT by community-based allergists. As a result, we believe that a widely adoptable OIT approach must feature:

Standardized Products: The product used must be well-defined and be manufactured to the same standards as other pharmaceutical-grade products.

Safe and Well-Defined Treatment Regimens: The safety and efficacy of the treatment approach must be demonstrated in a large scale, well-controlled clinical trial and the treatment regimen must be clearly established so that allergists can be confident that they are administering the product appropriately.

Clinically Meaningful Desensitization: The treatment must result in the patient attaining protection from food allergens at a level that exceeds the amount typically encountered in an accidental exposure.

Compatibility with Clinical Practice: The treatment must be compatible with existing practices of allergists and must enable allergists to reliably, conveniently and safely use oral desensitization as part of their regular clinical practice.

Availability of Support Services: Physicians, parents and patients should have access to support services to guide them through the treatment regimen.

Regulatory Approval: The treatment approach must be reviewed and approved by independent regulatory authorities in order to appeal to patients, parents, allergists and payors.

Our Solution

Our CODIT system for the treatment of food allergies leverages and improves upon the extensive independent scientific research supporting OIT. Based on our clinical development to date, including our ARC001 study, we believe that our CODIT system has the potential to be widely adopted by allergists and to appeal to patients and parents as a result of the following key attributes:

Standardized Products: Our proprietary biologic product candidates are derived from natural food products and are designed to contain precisely defined dosages of well-characterized food proteins so that each dosage is consistent for total protein and relative allergen content. In addition, we expect each of our product candidates, if approved, to be provided to patients as a convenient, orally administered, once daily therapy.

Safe and Well-Defined Treatment Regimens: We intend to demonstrate the safety and efficacy of each CODIT product candidate in large scale, well-controlled clinical trials. In addition, we expect each CODIT product candidate to feature clearly defined clinical protocols with gradual up-dosing and practical maintenance dosing regimens designed to enhance safety, tolerability and efficacy.

Table of Contents

Clinically Meaningful Desensitization: We expect each approved CODIT product candidate to provide patients with protection from food allergens at a level that exceeds the amount typically encountered in an accidental exposure.

Compatibility with Clinical Practice: We expect our protocols for each CODIT product candidate to be similar to treatment regimens currently utilized by allergists for non-food allergies.

Tailored Support Services: We intend to provide physician education, patient guidance and other support services to facilitate the administration of each approved CODIT product candidate.

Regulatory Approval: We believe regulatory approval of our CODIT product candidates, if obtained, will validate the extensive existing scientific research supporting oral desensitization and could lead to widespread adoption of our system.

We believe our CODIT system and product candidates, if approved, have the potential to reduce the dangers posed to food-allergic patients, such as accidental exposures resulting in anaphylactic reactions, emergency room visits or hospitalization. We expect that this potential protection from accidental exposures will reduce the stress and anxiety of patients and their families and enable patients to live more normal lives.

AR101 for Peanut Allergy

Overview

We are developing our lead CODIT product candidate, AR101, for the treatment of peanut allergy in children and adults. AR101 is intended to desensitize patients to a level of peanut protein that substantially exceeds the amount typically encountered in an accidental exposure. Patients successfully treated with AR101 will still need to avoid the consumption of peanuts and foods containing peanuts, but we believe that protection from accidental exposure will significantly improve the lives of food-allergic patients and their families.

We believe AR101, if approved, will provide allergists with a safe and practical means of providing oral desensitization treatment to their patients with peanut allergy. AR101 is designed to be taken orally once daily after having been mixed with a common age-appropriate food. As with OIT, patients would start with a very low dose of AR101 and gradually increase their dose over time. The initial assessment of patients and each initial increase in dosage would occur at an allergist s office. 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. Based on independent scientific research, we anticipate that with continued maintenance dosing, patients level of desensitization will increase over time. In order to maintain desensitization, patients would need to continue to take a daily 300 mg maintenance dose; however, based on experience with OIT, we do not believe that the occasional failure to take a maintenance dose will significantly affect desensitization.

Table of Contents

Our up-dosing and maintenance dosing regimens are set forth below:

For patients in the up-dosing phase of the AR101 treatment regimen, AR101 would be provided in a series of color coded pharmaceutical grade capsules of various dose levels. These capsules can be easily opened and the contents mixed with food. For patients who have reached the 300 mg maintenance dose level, AR101 would be provided in an easy to open sachet. We are in the process of evaluating additional delivery forms for AR101 for the maintenance phase including caplets that could be swallowed.

AR101 Product Characteristics

We believe the following characteristics of AR101 could enable it, if approved, to achieve widespread market acceptance and distinguish it from existing treatments and potentially competing products in development:

Proprietary Biologic Product: Our proprietary formulation is a complex mixture of naturally occurring proteins and pharmaceutical-grade ingredients that we developed to enable the convenient dosing of consistent amounts of peanut protein with well-defined relative concentrations of peanut specific allergens.

Clinically Meaningful and Reliable Desensitization: Based on the results of ARC001, we believe that patients who successfully complete the AR101 up-dosing regimen will be desensitized to a level of peanut protein that substantially exceeds the amount typically found in a peanut-contaminated food product. In addition, even if such patients have an allergic reaction, based on the results of ARC001, we believe it is likely to be less severe as a result of treatment with AR101. ARC001 and independent scientific research have indicated that clinically meaningful desensitization can be attained through an oral immunotherapy treatment regimen, independent of gender, age and other demographics.

Rapid and Predictable Onset of Action: In ARC001, a clinically meaningful level of protection was typically achieved by patients in the AR101 treatment group after only 22 weeks of dosing. Independent scientific research has also shown that continued maintenance dosing pursuant to an oral immunotherapy treatment regimen can confer increased protection over time.

Attractive Safety Profile: In ARC001, most patients tolerated AR101 well, experiencing only mild, intermittent side effects commonly associated with food allergies during the up-dosing phase of treatment. The most frequent of these side effects included gastrointestinal symptoms ranging from itching of the lips to vomiting, hives, throat itching or discomfort and nasal congestion. We believe that many of these side effects are associated with the increases in dosage amounts during the initial up-dosing phase of the treatment regimen. Once patients are desensitized and on maintenance dosing, we believe that they are likely to experience few or no side effects. Of the 29 patients

87

treated with AR101, 23 completed the AR101 treatment regimen, with six patients discontinuing treatment due to gastrointestinal side effects that occurred in the first two to four weeks, which were resolved, in each case, within one to three weeks after cessation of treatment.

Convenient Oral Administration: AR101 is designed to be provided to patients as a convenient, orally administered, once daily therapy that is mixed with common age-appropriate foods. Compared to subcutaneous, epicutaneous or sublingual administration, we believe our CODIT system represents a more convenient and practical method of dosing, particularly in young patients.

Direct, Targeted Mechanism of Action: Oral administration of AR101 enables the allergen to interact directly with immune cells in the gastrointestinal tract responsible for mediating the allergic reaction to peanuts. Oral desensitization works by gradually shifting the balance of the immune system to dampen the allergic response in the case of accidental exposure.

Compatibility with Current Clinical Practice and Infrastructure: The AR101 up-dosing regimen involves a series of visits to an allergist. This process is similar in many ways to existing regimens for the treatment of non-food allergies, such as pollen and pet dander, which we believe will facilitate adoption by allergists and reimbursement by payors if AR101 is approved.

CODIT Support Services: We intend to provide physician education, patient guidance and other support services to facilitate the administration of AR101, if approved.

Phase 2 Clinical Trials ARC001

Clinical Trial Design

Our first clinical trial, ARC001, was a randomized, multi-center, double blind, placebo controlled Phase 2 trial of AR101 for the treatment of peanut allergy. Fifty-five patients with confirmed peanut allergy ranging in age from four to 21 years old participated in the trial, which was conducted at eight leading academic medical research centers in the United States. Of the fifty-five patients, 29 received AR101 and 26 received placebo. Patients were required to have experienced a prior allergic reaction that was attributed to peanuts, have elevated levels of anti-peanut protein antibodies in their blood and/or tested positive for peanut allergy on a skin prick test, and failed a double blind placebo controlled food challenge, or DBPCFC, at a dosage level of 100 mg of peanut protein or less. A DBPCFC is generally considered the gold standard method of measuring a patient s sensitivity to peanuts or other foods. A DBPCFC is performed in a clinical setting in two sessions that are usually on two separate days. On each day, the patient is orally administered escalating doses of either a suspected allergenic food or a placebo over time and monitored to see if an allergic reaction is elicited. For example, in the entry DBPCFC for ARC001, patients were administered challenge does of 3 mg, 10 mg, 30 mg and 100 mg of peanut protein 20 to 30 minutes apart in one session and a series of placebo doses on the same schedule in the other session. Neither the patient nor the clinicians overseeing the DBPCFC knew what substance was being administered in a given session. If the patient developed a moderate or stronger allergic reaction after being administered a dose of peanut protein, then such patient was deemed to have failed the food challenge at that dosage level. While in our clinical trials we screened patients for peanut allergy using a DBPCFC because of its sensitivity, we do not anticipate that a DBPCFC will be a requirement for prescribing AR101 as DBPCFCs are not widely used a diagnostic tool in current clinical practice.

88

Table of Contents

The table below shows the escalation of challenge doses in a peanut DBPCFC along with the corresponding cumulative exposure attained at each dose level:

Dose #	Challenge Dose Amount (mg)	Cumulative Exposure (mg)
1	3	3
2	10	13
3	30	43
4	100	143
5	300	443
6	600	1,043
7	1,000	2,043

We selected failure at a challenge dose of 100 mg or less on a DBPCFC as an inclusion criteria for ARC001 to enable the study of AR101 in patients with more severe allergies. In addition, because a patient s sensitivity to peanut protein can fluctuate significantly based on various factors, we believed that using a lower maximum tolerated dose would reduce the likelihood that patients in the trial would pass the exit DBPCFC at 300 mg solely due to natural variations in their sensitivity.

The table below shows the baseline demographics of patients participating in ARC001:

	Active AR101	Placebo
Intent To Treat	29 patients	26 patients[(1)]
Gender	20 male; 9 female	16 male; 10 female
Median Age (min, max)	7 years (4 to 21)	8 years (4 to 14)
Median Peanut Specific IgE (min, max)	64.3 (0.8 to >100)	100.0 (3.5 to >100)
Median Wheal (min, max)	14 mm (5 to 30)	13 mm (5 to 26)
Median Max Tolerated Dose, Cumulative (min, max)	13 mg (3 to 43)	28 mg (3 to 43)

(1) The placebo group initially contained 27 patients, with one patient withdrawing from the study prior to the commencement of treatment.

In ARC001, 29 patients received AR101 and 26 patients received placebo. On the first day of the study, patients were up-dosed to a dose of 3 mg or 6 mg at the clinical site. Patients then took a daily 3 mg or 6 mg dose at home for two weeks and returned to the clinical site to be up-dosed to the next dose level, either 6 mg or 12 mg dose. This process continued with doses of 12 mg, 20 mg, 40 mg, 80 mg, 120 mg, 160 mg, 200 mg, 240 mg and, finally, 300 mg. If a patient had an allergic reaction at a particular level, the allergist could maintain the patient at that dose for a longer period of time or reduce the dose for a period of time before resuming up-dosing. In addition, if a patient s schedule did not allow him or her to visit an allergist s office exactly two weeks after an up-dosing, the patient was permitted to remain on the current dose until he or she was able to visit an allergist. Even with this flexibility, the median completion time for the patients in the AR101 group was not significantly longer than the scheduled completion time.

After patients had been taking the 300 mg dose for two weeks, they were administered a DBPCFC with a maximum challenge dose of 600 mg.

Table of Contents

The trial design for ARC001 is set forth below:

Clinical Trial Results and Key Metrics

As the tables below show, ARC001 met the primary endpoint of passing a DBPCFC at a 300 mg challenge dose and met an additional endpoint of passing a DBPCFC at a 600 mg challenge dose.

Primary Endpoint = Pass 300 mg (443 mg cumulative) Challenge at Exit (p<0.0001)				
	Active AR101 (29 patients)		**Placebo (26 patients)**	
	Patients	**%**	**Patients**	**%**
Responder	23	79%	5	19%
Non-responder	6[(1)]	21%	21	81%

Additional Endpoint = Pass 600 mg (1,043 mg cumulative) Challenge at Exit (p<0.0001)				
	Active AR101 (29 patients)		**Placebo (26 patients)**	
	Patients	**%**	**Patients**	**%**
Responder	18	62%	0	0%
Non-responder	11[(2)]	38%	26	100%

(1) All were early discontinuations.

(2) Includes the 6 early discontinuations.

Statistical significance is denoted in the table above by reference to the p-values in the Primary Endpoint and Additional Endpoint. The p-value is a measure that states the probability that a comparable or better result would be produced purely by chance. A p-value <0.0001 in the chart means that if the drug was only as effective as the placebo, there would be less than a 0.01% chance that a comparable or better result would be produced purely by chance. A p-value £0.05 is a commonly used criterion for statistical significance. When evaluating the potential efficacy of a drug product, the FDA reviews a statistical analysis to determine whether the results of the clinical trial demonstrated that the drug product was efficacious, and a showing of statistical significance in favor of the tested criterion supports the finding of efficacy.

Table of Contents

In ARC001, 23 of the 29 patients in the AR101 treatment group completed the trial. All 23 patients who completed the trial passed an exit DBPCFC at a 300 mg challenge dose as compared with five of the 26 patients who received placebo (p£0.0001). In addition, 18 of the 23 patients in the AR101 treatment group that completed the trial passed an exit DBPCFC at a 600 mg challenge dose compared to none of the 26 patients who received placebo (p£0.0001). Those patients who passed the DBPCFC at a 300 mg challenge dose had received a cumulative dose of 443 mg of peanut protein, the equivalent of approximately two peanut kernels, and those patients who passed the DBPCFC at a 600 mg challenge dose had received a cumulative dose of 1,043 mg of peanut protein, the equivalent of approximately four peanut kernels. We believe these results suggest that AR101 has the potential to provide patients with peanut allergy protection from accidental exposure to peanut protein even when taking into account natural variations in sensitivity. Consistent with independent academic research, our results in ARC001 indicate that clinically meaningful desensitization can be attained independent of gender, age and other demographics.

The charts below illustrate the efficacy results from ARC001:

Table of Contents

In addition, we believe that AR101 may lessen the severity of a patient s reaction to an accidental exposure. As the charts below indicate, patients in the placebo group had significantly more severe reactions to exposure to peanut protein in the exit DBPCFCs compared to patients in the AR101 group at the same challenge dose level.

These results are corroborated by the use of epinephrine during the entry and exit DBPCFCs. During the entry DBPCFCs, four patients in each of the AR101 group and the placebo group had an allergic reaction severe enough to require the use of epinephrine. In contrast, in the exit DBPCFCs, only two patients in the AR101 group needed epinephrine, while eleven patients in the placebo group were administered epinephrine, including three who required two doses. The epinephrine use in the placebo group was caused by severe reactions starting at doses as low as 30 mg, while in the active group, both uses were triggered by moderate reactions at the highest challenge dose of 600 mg.

The results of ARC001 also indicate that AR101 was well-tolerated. Among patients in the AR101 treatment group, there was only one incident of anaphylactic reaction of moderate severity that was treated with epinephrine, and there were no other serious or severe adverse events related to treatment with AR101 in the study. Six of the 29 patients in the AR101 treatment group dropped out of the trial. Four patients dropped out of the trial because of moderate gastrointestinal side effects, such as abdominal discomfort and vomiting, and two dropped out of the trial because of a combination of gastrointestinal side effects and compliance issues. This drop-out rate was consistent with prior academic OIT studies. The patients in ARC001 who discontinued treatment prematurely all began to have gastrointestinal symptoms at the 3 mg or 12 mg dose level and generally dropped out of the study early. Their gastrointestinal issues resolved without significant medical intervention within one to three weeks. One of the patients was diagnosed with eosinophilic esophagitis, or EoE, a condition in which a certain type of white blood cell accumulates in the esophagus. EoE is an immune condition that can be triggered by exposure to food allergens. The standard of care for EoE is simply to avoid exposure to the triggering food allergen, which allows the condition to resolve. Once this patient ceased ingesting AR101, the patient s EoE symptoms resolved within three weeks. No patients in the placebo group dropped out and there were no incidents of anaphylaxis or other severe or serious adverse events related to treatment in the placebo group.

Table of Contents

Phase 2 Clinical Trials ARC002

Patients who completed ARC001 were eligible to participate in our Phase 2 follow-on study, ARC002, an open label study designed to evaluate the long-term safety, efficacy and tolerability of AR101. In ARC002, those patients who had been in the AR101 treatment group for ARC001 were maintained on a 300 mg maintenance dose for three months and then administered a DBPCFC with a the maximum challenge dose of 1,000 mg, resulting in a maximum cumulative dose of 2,043 mg. After administration of this DBPCFC, the patients could choose to continue with a 300 mg maintenance dose or to up-titrate to a higher dose level. Patients who had been in the placebo group in ARC001 began ARC002 by going through the same up-titration regimen that had been administered to the active group in ARC001 and then were placed on a 300 mg maintenance dose for three months. As with the original active group, they were administered DBPCFCs at the end of both the up-titration period and the three month maintenance period. They then could choose to either stay at a daily dose of 300 mg or begin an up-titration regimen. Independent scientific research has shown that continued maintenance dosing can confer increased protection over time.

Based on independent scientific research, we believe that chronic administration of AR101 will generally be safe and well-tolerated. Those patients in the AR101 treatment group who completed ARC001 reported mild and intermittent sides effects generally related to gastrointestinal issues. These side effects appear to be the result of the increasing dose levels during the initial part of the treatment regimen. Once patients are desensitized and on maintenance dosing, we believe that they are likely to experience few or no side effects.

AR101 Historical Clinical Development Program

Our development of AR101 leveraged the substantial pre-existing independent scientific research on peanut allergy and OIT. In connection with our IND submission, we licensed data from studies conducted at three leading academic research institutions. These studies demonstrated the potential of using OIT to desensitize peanut allergic patients. The results of the studies are as follows:

- In a placebo controlled study conducted jointly at Duke University and the University of Arkansas, 16 out of 17 patients were successfully up-dosed to a daily dose of 2,400 mg of peanut protein over the course of a year. At the end of the study, the 16 patients in the active group who completed treatment passed a DBPCFC at a mean level of 5,000 mg of peanut protein while the nine patients in the placebo group passed at a mean level of 280 mg of peanut protein (p=0.0001).

- For the purposes of creating a safety database, the results of the above study were combined with results from an open label crossover study of the placebo patients from the above study and also with an open label OIT study conducted at Stanford University. This safety analysis covered a total of 53 patients who received OIT treatment with peanut flour. The analysis concluded that the therapy was generally well-tolerated and no specific safety concerns were noted.

We have also leveraged academic studies that have shown that the daily administration of a relatively low maintenance dose can enable patients to attain and sustain a significant degree of desensitization. For example, in one study, 29 children with peanut allergy completed an OIT up-dosing regimen and then received a 300 mg daily maintenance dose of peanut protein for 12 months. At the end of that period, 27 of the patients were desensitized to exposure of 3,900 mg of peanut protein and the remaining two were desensitized to exposure of 2,100 mg of peanut protein. Two other studies have also shown that 300 mg maintenance doses can result in consistent desensitization to exposure many times the level of the maintenance dose.

Our clinical trial designs were developed following a review of the academic study protocols described above as well as protocols used in clinical practice. Many of the protocols used in clinical practice have maximum dose levels of several thousand milligrams of peanut protein and use aggressive dose escalation rates to reach the maximum dose levels quickly. We believe that, as a result, patients under these protocols sometimes

receive too much peanut protein too soon and consequently suffer anaphylaxis, contributing to the perception that OIT is not safe. In designing our clinical trials, we have incorporated low initial dose levels, a more gradual escalation of the dosing and much lower maintenance dose levels. We believe that this approach provides for an improved protocol and has the potential to enable patients to safely attain a clinically significant level of desensitization in a reasonable time frame.

We also believe that a successful oral desensitization treatment regimen requires a well-characterized and precisely manufactured drug product. Independent scientific research has shown that the quantity of peanut protein and the relative concentrations of key peanut proteins can vary widely between the different commercially available peanut products that could potentially be used as a source for oral desensitization therapy. These variations could significantly impact the reliability and safety of an oral desensitization treatment regimen. In order to reduce the potential for variability, we have chosen to use peanut flour solely from the Golden Peanut Company, or GPC, as the basis for AR101. This flour has been used in most of the leading academic studies of peanut allergy OIT and, based on our own testing, shows little variation in the level of peanut protein in different batches of the company s flour, including between batches produced in different years. In order to develop AR101 as an FDA-approvable biological product, we took the further step of precisely characterizing the protein signature of GPC flour. Independent scientific research has identified numerous peanut proteins that are the allergens that cause allergic reactions to peanuts. Three of these proteins appear to be the most significant and representative of the levels of the other proteins. Our characterization of AR101 is based on precisely measuring total protein amount and the concentrations of those three key proteins.

We filed an Investigational New Drug application for AR101 in April 2013 for use in oral desensitization therapy for peanut allergy in children and adults. In June 2013, the FDA placed our proposed Phase 2 clinical trial on hold in order to obtain additional information regarding our manufacturing process and to request certain changes to the trial design. 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. The FDA lifted the clinical hold in August 2013.

Because there are no robust animal models of peanut allergy, we did not conduct any pre-clinical efficacy studies of AR101. In addition, because AR101 is based on a food product, the FDA did not require us to submit any pre-clinical toxicology data.

AR101 Development and Commercialization Plan

We have developed AR101 in close consultation with the FDA and the EMA. In September 2014, the FDA granted AR101 Fast-Track designation for oral immunotherapy of peanut sensitive adults and children and in June 2015, the FDA granted AR101 Breakthrough Therapy designation for oral immunotherapy of peanut sensitive children and adolescents (ages 4 through 17). These designations are intended to facilitate the development and to expedite the review of drugs and biologics that are intended for the treatment of serious or life-threatening diseases or conditions and, in the case of a Fast-Track designation, that demonstrate the potential to address unmet medical needs for the disease or condition or, in the case of a Breakthrough Therapy designation, where preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Sponsors of products under development with a Fast-Track designation or Breakthrough Therapy designation may have greater

interactions with the FDA, including the involvement of more senior staff members, and the FDA may initiate review of sections of a Fast-Track product s marketing application before the application is complete. A product that receives these designations may be eligible for accelerated approval and priority review, if relevant criteria are met.

We have had several formal communications and meetings with the FDA relating to the clinical development of AR101 and its manufacture, and we participated in two end-of-Phase 2 meetings with the FDA in July 2015. We have had two country level scientific advice meetings with European regulatory authorities and have received positive preliminary feedback on our Pediatric Investigation Plan for AR101 from the EMA.

We anticipate initiating ARC003, a Phase 3 registration trial of AR101, in early 2016. ARC003 will be a randomized, double blind, placebo-controlled study of AR101 for the treatment of peanut allergy in children and adults. We anticipate that ARC003 will enroll approximately 500 patients, including 400 patients between the ages of 4 and 17 and approximately 100 patients between the ages of 18 and 55. The study protocol will largely be a combination of the protocols for ARC001 and ARC002. Patients will be randomized at a three to one ratio between the AR101 group and a placebo group. Patients in ARC003 will be up-dosed to a daily 300 mg dose over a period of five to six months and then maintained at that dose level for approximately six months. At the end of the maintenance period, patients will be administered a DBPCFC. The primary endpoint of the study will be desensitization to cumulative exposure to 1,043 mg of peanut protein, and secondary endpoints will include desensitization to cumulative exposure of 443 mg of peanut protein and desensitization to cumulative exposure of 2,043 mg of peanut protein. Subgroup analysis will also be performed. We anticipate conducting the study at approximately 35 sites in the United States and approximately 15 sites in Europe. Assuming we are able to initiate the study in early 2016, we anticipate completing the study in 2017. Based on our discussions with regulatory authorities, we anticipate that ARC003, if it meets its primary endpoint, will be sufficient to support the filing of a BLA with the FDA and an MAA with the EMA.

If AR101 is approved by the FDA and the EMA for the treatment of peanut allergy, we intend to commercialize it by developing a specialty sales force targeting a subset of the approximately 4,500 practicing allergists in the United States as well as allergy-focused clinicians in the five largest European markets.

Additional Food Allergy Research and Development

We intend to leverage the expertise gained in our development of AR101 to develop CODIT product candidates for a range of additional food allergies. A critical part of our process is transforming natural food products into biopharmaceuticals. This process requires identifying the key proteins that need to be in the product, developing characterizations methods for those proteins, creating usable formulations and ensuring the stability of those formulations.

We are in the process of developing formulations for CODIT product candidates for the treatment of two additional food allergies. We currently anticipate that we will initiate Phase 2 studies of two additional CODIT product candidates in 2016. We expect to conduct these studies at leading academic allergy research centers in the United States and Europe. As there are a limited number of such sites and their capacity to conduct clinical trials is limited, the timing of the initiation of the Phase 2 studies may be affected by the available capacity of the sites.

Based on existing scientific research, we believe that once a significant level of desensitization to the allergens in certain foods has been achieved, it may be possible to re-introduce that food into the patients diet in a controlled manner. The level of desensitization necessary to allow for reintroduction of those foods into the diet is likely to be much higher than is necessary to reduce the risk from accidental exposure. Therefore, the CODIT treatment regimen to reintroduce food may be significantly longer. In addition, the development pathway for those therapies may be different from the one used for AR101.

We are also researching potential CODIT product candidates for several other food allergies and for the treatment of two or more food allergies at once. We also believe that AR101 and our other potential future CODIT product candidates could potentially be used in conjunction with certain drugs on the market and in development for

environmental allergies and asthma. We believe that using these drugs in combination with our CODIT product candidates, if approved, could allow for a quicker up-dosing regimen or for the treatment of highly sensitive patients. We are currently evaluating potential clinical approaches to studying these drug combinations.

Table of Contents

Manufacturing

We currently do not own manufacturing facilities and have limited personnel with manufacturing experience. We contract with third-party manufacturers to produce the food product and final biologic product for our product candidates and to package our product candidates. We plan to continue to rely on contract manufacturers for the production of supply for our clinical trials, and if we receive marketing approval for a product candidate, for commercial supply.

Our product candidates are manufactured in accordance with stringent manufacturing processes. Our processes are designed to ensure that that the total protein content of each formulation and the relative concentrations of particular proteins are consistent. Through our contract manufacturers, we are capable of producing dosages with protein content as small as 0.5 mg and have developed advanced analytical methods to ensure each dose contains precisely defined amounts of multiple well-characterized allergenic proteins. Our formulations are also designed to ensure that the drug product is acceptably stable and can be easily mixed with food.

AR101 is currently produced for us by a contract manufacturer using our proprietary process. This process involves several blending and characterization steps intended to ensure that each dose contains a precise amount of peanut flour containing a specific concentration of peanut protein. Because peanut flour is a sensitizing agent, AR101 must be produced on a manufacturing line that is physically separated from other manufacturing lines and that has its own ventilation system. The manufacturing line that we have used to produce the clinical supply for our planned Phase 3 trial will not be adequate to produce commercial supplies of AR101. In June 2015, we leased space in a building proximate to our current contract manufacturer s existing facility and intend to establish a commercial scale manufacturing line for AR101 in that space. We are currently in the process of negotiating a supply agreement with our contract manufacturer pursuant to which the manufacturer would use our manufacturing line to produce commercial supplies of AR101 for us. Producing commercial quantities of AR101 will require us to scale up our existing manufacturing process and institute rigorous quality control and assurance procedures. In addition, we will need to engage a new provider of packaging services. Contract manufacturers often encounter difficulties involving production yields, quality control and quality assurance, as well as shortages of qualified personnel. Qualifying manufacturers and providers of packaging services is a lengthy process. If at any time, one or more of our qualified contract organizations were not able to manufacture or package our drug product candidate or provide other requisite services, our business and financial condition could be materially adversely affected.

Our third-party suppliers, their facilities and all lots of product candidates used in our clinical trials are required to be in compliance with current Good Manufacturing Practices, or cGMP. The cGMP regulations include requirements relating to organization and personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports, and returned or salvaged products. The manufacturing facilities for our products must meet cGMP requirements to the FDA s satisfaction before any product is approved and we can manufacture commercial products. Our third-party manufacturers are also subject to periodic inspections of facilities by the FDA and other authorities, which may include the evaluation of procedures and operations used in the testing and manufacture of our products to assess compliance with applicable regulations.

Suppliers

Our lead product candidate, AR101, contains peanut flour and pharmaceutical-grade ingredients. We source the peanut flour from GPC, a wholly-owned subsidiary of Archer Daniels Midland. We chose to use peanut flour from GPC as the basis for AR101 because its peanut flour has been used in most of the leading academic studies of peanut allergy OIT and because we believe that the widespread use of GPC peanut products in the United States may make

their peanut flour representative of the type of peanut protein that patients are

most likely to encounter in an accidental exposure. The other ingredients in AR101, such as diluents, glidants and lubricants, are sourced from established producers of pharmaceutical grade ingredients. In order to develop AR101 as an FDA-approvable biological product, we took the further step of precisely characterizing the protein signature of GPC flour. Independent scientific research has identified numerous peanut proteins that are the allergens that cause allergic reactions to peanuts. Three of these proteins appear to be the most significant and representative of the levels of the other proteins. Our characterization of AR101 is based on precisely measuring total protein amount and the concentrations of those three key proteins.

We purchase standard food-grade peanut flour from GPC pursuant to a long term exclusive commercial supply agreement. Under the terms of the agreement, we are obligated to purchase peanut flour exclusively from GPC provided that GPC is able to supply us in a timely manner with the quantity of peanut flour that we require. GPC is not allowed to sell peanut flour of the type (or equivalent to the type) we use to any third party in United States, Mexico, Canada, the European Union or Japan for use in OIT for peanut allergy provided that we are in compliance with our exclusive purchase obligation and meet specified annual purchase commitments. 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. We may terminate the agreement at any time for any reason upon providing 60 days written notice to GPC, and 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. Either party may terminate the agreement if the other party fails to cure their material breach within 30 days of receiving notice of such breach from the non-breaching party or if the other party fails to perform their obligations under the agreement for a continuous period of 90 days due to a force majeure event or an insolvency or bankruptcy-related events.

Intellectual Property

We have filed patent applications in the United States and international patent applications pursuant to the Patent Cooperation Treaty relating to the manufacture, formulation and stability of AR101 and anticipate filing similar applications with respect to our other product candidates. We have received an allowance from the USPTO with respect to one of our patent applications but none of our patent applications has yet resulted in an issued patent. There is no assurance that any patents will be issued as a result of the allowance or from any of our patent applications. Even if patents do issue, there can be no assurance that the scope of the claims contained in the patents will be broad enough to provide protection from potentially competing products. If issued, our patents relating to AR101 are projected to expire between 2033 and 2034 without taking into account any potential patent term extensions. Our patent applications seek protection relating to our formulations and methods of manufacture. We do not own or license, and 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.

In addition to patents, we rely upon unpatented trade secrets, know-how, and continuing technological innovation to develop and maintain our competitive position. We protect our proprietary information, in part, using confidentiality agreements with our commercial partners, collaborators, employees and consultants and invention assignment agreements with our employees. We also have confidentiality agreements or invention assignment agreements with our commercial partners and selected consultants. Despite these measures, any of our intellectual property and proprietary rights could be challenged, invalidated, circumvented, infringed or misappropriated, or such intellectual property and proprietary rights may not be sufficient to permit us to take advantage of current market trends or otherwise to provide competitive advantages. For more information, please see Risk Factors Intellectual Property.

Sales and Marketing

Subject to regulatory approval, we intend to commercialize AR101 in the United States and Europe by developing a specialty sales force targeting a subset of the approximately 4,500 practicing allergists in the United States as well as allergy-focused clinicians in the five largest European markets. We anticipate that this sales force could also support the commercialization of additional CODIT product candidates, if approved. We intend

to focus our sales efforts on patients with more severe food allergies, particularly children. While in our clinical trials we have screened patients for peanut allergy using a DBPCFC because of its sensitivity, we do not anticipate that a DBPCFC will be a requirement for prescribing AR101 as DBPCFCs are not widely used a diagnostic tool in current clinical practice. We anticipate that our CODIT system for food allergies will encompass providing a range of services to patients and their physicians including telephone and e-mail support for patients, physician awareness and education activities, reimbursement assistance, benefit navigation and co-pay and patient assistance programs. Based on the estimated direct medical expenses associated with peanut allergy and the estimated number of people with peanut allergy in the United States, we believe the potential market opportunity for approved peanut allergy treatments in the United States could exceed one billion dollars annually.

Competition

Our industry is highly competitive and subject to rapid and significant technological change. While we believe that our development experience and scientific knowledge provide us with competitive advantages, we may face competition from large pharmaceutical and biotechnology companies, smaller pharmaceutical and biotechnology companies, specialty pharmaceutical companies, generic drug companies, academic institutions, government agencies and research institutions and others.

Many of our potential competitors may have significantly greater financial, technical and human resources than we have. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Our commercial opportunity could be reduced or eliminated if our competitors develop or market products or other novel technologies that are more effective, safer or less costly than any that will be commercialized by us, or if they obtain regulatory approval for their product candidates more rapidly than we may obtain approval for ours. Our success will be based in part on our ability to identify, develop and manage a portfolio of drugs that are safer, more efficacious and/or more cost-effective than alternative therapies.

Currently there are no approved medical therapies for the treatment of food allergies. We are aware that DBV Technologies S.A., or DBV, is developing treatments for peanut allergy and other food allergies based on a patch technology that epicutaneously delivers food allergens to the patient with the goal of desensitizing the patient to the allergens. DBV completed a Phase 2 study for the treatment of peanut allergy in 2014. If AR101 and/or any future product candidate of ours is approved, they may face competition from DBV s product candidates, if approved.

In addition, we may face competition from allergists who decide to provide OIT and other desensitization therapies to their patients using their own formulations of food allergens and treatment protocols rather than adopting our product candidates or we may face competition from companies that develop their own OIT products or other desensitization therapy products.

In the future, we may face competition from competitors seeking to use AR101 as a reference product while developing a biosimilar product candidate using the FDA s abbreviated approval pathway for biosimilar products. The abbreviated regulatory pathway, created pursuant to the Biologics Price Competition and Innovation Act of 2009, or BPCIA, establishes legal authority for the FDA to review and approve biosimilar biologics. To be considered a 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. We believe that the concentrations of relevant proteins in the peanut flour we source pursuant to our exclusive contract with the GPC are significantly different from the concentrations of proteins found in other commercially available sources of protein 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. 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.

Table of Contents

Under the BPCIA, a reference product may be eligible for a 12-year period of exclusivity starting from the date that the product is first licensed by the FDA pursuant to the approval of a BLA, during which time no approval of a biosimilar product under the abbreviated approval pathway may be made effective. 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.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of coverage and adequate reimbursement from third-party payors. Third-party payors include government payor programs at the federal and state levels, including Medicare and Medicaid, managed care providers, private health insurers and other organizations. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved drug products for a particular indication. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor s decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

The cost of pharmaceuticals continues to generate substantial governmental and third-party payor interest. We expect that the pharmaceutical industry will experience pricing pressures due to the trend toward managed healthcare, the increasing influence of managed care organizations and possible legislative proposals. Third-party payors are increasingly challenging the prices charged for medical products and services and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. If these third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products for branded prescription drugs. Adoption of such controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceuticals such as the drug candidates that we are developing and could adversely affect our net revenue and results.

Different pricing and reimbursement schemes exist in each country. In the European Community, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Some

Table of Contents

jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular drug candidate to currently available treatment approaches. Other member states allow companies to set their own prices for medicines, but monitor and control company profits. The downward pressure on healthcare costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country. There can be no assurance that any country that has price controls or reimbursement limitations for drug products will allow favorable reimbursement and pricing arrangements for any of our products.

Significant uncertainty also surrounds the reimbursement of allergists for administering the anticipated treatment regimen for AR101 and our other products candidates. In the United States, it is not certain whether the existing reimbursement codes that can be appropriately used for AR101 up-dosing sessions will adequately compensate clinicians for the time spent on these 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. In markets outside of the United States, we will need to evaluate clinician compensation mechanisms in each market to determine whether any action needs to be taken to ensure appropriate payment of physicians for administration of the treatment regimens.

Healthcare Reform

In the United States and certain foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system that could affect our future results of operations as we begin to directly commercialize our products.

In particular, there have been and continue to be a number of initiatives at the U.S. federal and state level that seek to reduce healthcare costs. Initiatives to reduce the federal deficit and to reform healthcare delivery are increasing cost-containment efforts. We anticipate that Congress, state legislatures and the private sector will continue to review and assess alternative benefits, controls on healthcare spending through limitations on the growth of private health insurance premiums and Medicare and Medicaid spending, the creation of large insurance purchasing groups, price controls on pharmaceuticals and other fundamental changes to the healthcare delivery system. Any proposed or actual changes could limit or eliminate our spending on development projects and affect our ultimate profitability.

In March 2010, the Affordable Care Act was signed into law, which has the potential to substantially change the way healthcare is financed by both governmental and private insurers. The Affordable Care Act, among other things, established: an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents; revised the methodology by which rebates owed by manufacturers for covered outpatient drugs under the Medicaid Drug Rebate Program are calculated; increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; extended the Medicaid Drug Rebate program to utilization of certain injectable outpatient drugs, as well as prescriptions of individuals enrolled in Medicaid managed care organizations; and required manufacturers to offer 50% point-of-sale discounts on 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 the future, there may continue to be additional proposals relating to the reform of the United States healthcare system, some of which could further limit the prices we are able to charge for our products candidates, or the amounts of reimbursement available for our product candidates. If future legislation were to impose direct governmental price controls and access restrictions, it could have a significant adverse impact on our business. Managed care

organizations, as well as Medicaid and other government agencies, continue to seek price

discounts. Some states have implemented, and other states are considering, price controls or patient access constraints under the Medicaid program, and some states are considering price-control regimes that would apply to broader segments of their populations that are not Medicaid-eligible. Due to the volatility in the current economic and market dynamics, we are unable to predict the impact of any unforeseen or unknown legislative, regulatory, payor or policy actions, which may include cost containment and healthcare reform measures. Such policy actions could have a material adverse impact on our profitability.

Government Regulation

Government Regulation in the United States

Government authorities in the United States at the federal, state and local level, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacturing, labeling, packaging, promotion, advertising, storage, distribution, marketing, post-approval monitoring and reporting, and export and import of biologics such as those we are developing. We, along with third-party contractors, will be required to navigate the various pre-clinical, clinical and commercial requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources.

Overview of Biologics Regulation in the United States

In the United States, our product candidates are regulated by the FDA as biologics under the Federal Food, Drug, and Cosmetic Act, or the FDCA, the Public Health Service Act, or PHSA, and regulations implemented by the FDA. Section 351(i)(1) of the PHSA defines a biological product (biologic) as a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product applicable to the prevention, treatment, or cure of a disease or condition of human beings. The process required by the FDA before biologic product candidates may be marketed in the United States generally involves the following:

- completion of pre-clinical laboratory tests and animal studies performed in accordance with the FDA s Good Laboratory Practices, or GLP, regulations;
- submission to the FDA of an IND which must become effective before human clinical trials may begin and must be updated annually;
- approval by an independent Institutional Review Board, or IRB, or ethics committee at each clinical site before the trial is initiated;
- performance of adequate and well-controlled clinical trials to establish the safety, purity and potency of the proposed biologic product candidate for its intended purpose;

preparation, and submission to, the FDA of a BLA after completion of clinical trials;

a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;

satisfactory completion of an FDA Advisory Committee review, if applicable;

satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMP requirements, and to assure that the facilities, methods and controls are adequate to preserve the biological product s continued safety, purity and potency; and

FDA review and approval of the BLA prior to any commercial marketing or sale of the product in the United States.

Pre-clinical Studies and Investigational New Drug Application

Prior to beginning the first clinical trial with a product candidate, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical trials. The IND also generally includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. Because there are no robust animal models of peanut allergy, we did not conduct any pre-clinical efficacy studies of AR101. In addition, because AR101 is based on a food product, the FDA did not require us to submit any pre-clinical toxicology data.

Clinical Trials

An IND must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to the proposed clinical trials. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trials can begin. Accordingly, submission of an IND may or may not result in the FDA allowing clinical trials to commence.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with Good Clinical Practices, or GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each clinical protocol and any subsequent protocol amendments must be submitted to the FDA as part of the IND, and an IRB at each site where the study is to be conducted must also approve the study. The IRB must monitor the study until completed. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries. Clinical trials typically are conducted in three or four sequential phases, but the phases may overlap or be combined.

Phase 1. The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to evaluate the safety, dosage tolerance, metabolism and pharmacologic actions of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.

Phase 2. The investigational product is administered to a limited patient population to evaluate dosage tolerance and optimal dosage, identify possible adverse side effects and safety risks and preliminarily evaluate efficacy.

Phase 3. The investigational product is administered to an expanded patient population, generally at geographically dispersed clinical study sites to generate enough data to statistically evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the investigational product, and to provide an adequate basis for product licensure.

Phase 4. In some cases, the FDA may condition approval of a BLA for a product candidate on the sponsor s agreement to conduct additional clinical trials after approval. In other cases, a sponsor may voluntarily conduct additional clinical trials after approval to gain more information about the product. Such post-approval studies are typically referred to as Phase 4 clinical trials.

The FDA, the IRB, or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial. We may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate. Concurrent with clinical trials, companies may complete additional in vitro studies and develop additional information about the biological characteristics of the product candidate, and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the safety, purity and potency of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

Review and Approval of a Biologics License Application

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, detailed information regarding the investigational product is submitted to the FDA in the form of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent pre-clinical and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product s chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of the product, or from a number of alternative sources, including studies initiated by investigators. Under federal law, the submission of most BLAs is subject to an application user fee, and the sponsor of an approved BLA is also subject to annual product and establishment user fees. These fees are typically increased annually. A waiver of user fees may be obtained under certain limited circumstances.

Once a BLA has been submitted, the FDA s goal is to review the application within ten months after it accepts the application for filing, or, if the application relates to an unmet medical need in a serious or life-threatening indication, six months after the FDA accepts the application for filing. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product s continued safety, purity and potency.

Before approving a BLA, the FDA typically will inspect the facility or facilities at which the product is manufactured. The FDA will not approve the application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP requirements. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The FDA is required to refer an application for a novel product to an advisory committee or explain why such referral was not made. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its substance will be produced, the FDA may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the product with specific

Table of Contents

prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter may require additional clinical data and/or an additional pivotal Phase 3 trial or trials, and/or other significant, expensive and time-consuming requirements related to clinical trials, pre-clinical trials or manufacturing. Even if such additional information is submitted, the FDA may ultimately decide that the BLA does not satisfy the criteria for approval. The FDA may also approve the BLA with a Risk Evaluation and Mitigation Strategy (REMS) plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications, or a commitment to conduct one or more post-market studies or clinical trials, and may limit further marketing of the product based on results of these post-marketing studies. Such post-market testing may include Phase 4 trials and surveillance to further assess and monitor the product s safety and effectiveness after commercialization. In addition, once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing regulatory standards is not maintained or if problems occur after the product reaches the marketplace. New government requirements, including those resulting from new legislation, may also be established, or the FDA s policies may change, which could delay or prevent regulatory approval of our products under development.

Expedited Review and Approval Programs

A sponsor may seek approval of its product candidate under programs designed to accelerate FDA s review and approval of new drugs and biological products that meet certain criteria. Specifically, new drugs and biological products are eligible for Fast-Track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for that disease or condition. For a Fast-Track product, the FDA may consider sections of the BLA for review on a rolling basis before the complete application is submitted if relevant criteria are met. A Fast-Track designated product candidate may also qualify for priority review, under which the FDA sets the target date for FDA action on the BLA at six months after the FDA accepts the application for filing. Priority review is granted when there is evidence that the proposed product would be a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious condition. If criteria are not met for priority review, the application is subject to the standard FDA review period of 10 months after FDA accepts the application for filing. Priority review designation does not change the scientific or medical standard for approval or the quality of evidence necessary to support approval.

Under the accelerated approval program, the FDA may approve a BLA on the basis of either a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Post-marketing studies or completion of ongoing studies after marketing approval are generally required to verify the biologic s clinical benefit in relationship to the surrogate endpoint or ultimate outcome in relationship to the clinical benefit. In September 2014, the FDA granted AR101 Fast-Track designation.

In 2012, Congress enacted the Food and Drug Administration Safety and Innovation Act, or FDASIA. This law established a new regulatory scheme allowing for expedited review of products designated as Breakthrough Therapies. A product may be designated as a Breakthrough Therapy if it is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to Breakthrough Therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving

more senior staff in the review process; assigning a cross disciplinary project lead for the review team; and taking other steps to design the clinical trials in an efficient manner.

Table of Contents

Post-Approval Requirements

Biologics manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data. Manufacturers of biologics and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and state agencies for compliance with cGMP requirements, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

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

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates the marketing, labeling, advertising, and promotion of biologics. A company may make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may

prescribe legally available products for uses that are not described in the product s labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturers communications on the subject of off-label use of their products.

Table of Contents

Abbreviated Licensure Pathway of Biological Products as Biosimilar or Interchangeable

The Patient Protection and Affordable Care Act, or PPACA, signed into law on March 23, 2010, included the BPCIA, which amended the PHSA and established a regulatory scheme authorizing the FDA to approve biosimilars and interchangeable biosimilars. To date, only one biosimilar has been licensed under the BPCIA, although numerous biosimilars have been approved in Europe. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.

Under the BPCIA, a manufacturer may submit an application for licensure of a biologic product that is biosimilar to or interchangeable with a previously approved biological product or reference product. In order for the FDA to approve a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and proposed biosimilar product in terms of safety, purity, and potency. 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.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years after the date that the reference product is first licensed by the FDA. In addition, the approval of an application for a biosimilar product may not be made effective by the FDA until 12 years after the date that the reference product is first licensed by the FDA. These exclusivity provisions have been subject to various interpretations that have not yet been fully addressed by the FDA. In addition, even if a product is considered to be a reference product eligible for exclusivity, another company could market a competing version of that product if the FDA approves a full BLA for such product containing the sponsor s own pre-clinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed interchangeable by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

Other Healthcare Laws in the United States

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare & Medicaid Services, other divisions of the United States Department of Health and Human Services (e.g., the Office of Inspector General), the United States Department of Justice and individual United States Attorney offices within the Department of Justice, and state and local governments. The laws we are subject to include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, physician payment transparency and privacy and security laws and regulations.

The federal Anti-Kickback Statute prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. The Anti-Kickback Statute is subject to evolving interpretations. In the past, the government has enforced the Anti-Kickback Statute to reach large settlements with healthcare companies based on sham consulting and other financial arrangements with physicians. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order 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 federal False Claims Act. The majority of states also have anti-kickback laws which establish similar prohibitions and in some cases may apply to items or services reimbursed by any third-party payor, including commercial insurers.

106

Table of Contents

Additionally, the civil False Claims Act prohibits knowingly presenting or causing the presentation of a false, fictitious or fraudulent claim for payment to the United States government. Actions under the False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Violations of the False Claims Act can result in very significant monetary penalties and treble damages. The federal government is using the False Claims Act, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical and biotechnology companies throughout the country, for example, in connection with the promotion of products for unapproved uses and other sales and marketing practices. The government has obtained multi-million and multi-billion dollar settlements under the False Claims Act in addition to individual criminal convictions under applicable criminal statutes. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating healthcare providers and manufacturers compliance with applicable fraud and abuse laws.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, also created federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

There has also been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, among other things, imposed new reporting requirements on drug manufacturers for payments made by them to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year (or up to an aggregate of $1 million per year for knowing failures), for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Drug manufacturers are required to submit reports to the government by the 90th day of each calendar year. Certain states also mandate implementation of compliance programs, impose restrictions on drug manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians.

We may also be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and their respective implementing regulations, including the final omnibus rule published on January 25, 2013, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA s privacy and security standards directly applicable to business associates, defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney s fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts.

Government Regulation in Europe

In the European Economic Area, or EEA, (which is composed of the 28 Member States of the European Union plus Norway, Iceland and Liechtenstein), medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA.

Table of Contents

There are two types of MAs:

- The Community MA, which is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the EMA, and which is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, and medicinal products indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU. Under the Centralized Procedure the maximum timeframe for the evaluation of a marketing authorization application is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP). Accelerated evaluation might be granted by the CHMP in exceptional cases, when the authorization of a medicinal product is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. Under the accelerated procedure the standard 210 days review period is reduced to 150 days.

- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member States through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure.

Under the above described procedures, before granting the MA, the EMA 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.

Employees

As of June 30, 2015, we had 21 full-time employees. Of these employees, fifteen are engaged in research and development. Our employees are not represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Facilities

We lease approximately 11,500 square feet of office space in Brisbane, California under a lease that expires in 2019 and approximately 20,000 square feet of manufacturing space in Clearwater, Florida pursuant to a lease that expires in 2025. We believe that our existing facilities and other available properties will be sufficient for our needs for the foreseeable future.

Legal Proceedings

We are not currently party to any material legal proceedings.

108

Table of Contents

MANAGEMENT

Executive Officers and Directors

The following table sets forth information regarding our executive officers, directors and key employees as of the date of this prospectus:

Name	Age	Position(s)
Executive Officers and Employee Directors		
Stephen G. Dilly, M.B.B.S., Ph.D.	56	President, Chief Executive Officer and Director
Warren L. DeSouza.	46	Chief Financial Officer
Howard V. Raff, Ph.D.	64	Chief Operating Officer
Robert M. Elfont, M.D., Ph.D.	57	Chief Medical Officer
Mary M. Rozenman, Ph.D.	34	Senior Vice President, Corporate and Commercial Development
Key Employees		
Michael S. Holfinger, Ph.D.	52	Vice President, Manufacturing
Joseph W. Suttner.	49	Vice President, Clinical Operations
Non-Employee Directors		
Patrick G. Enright	53	Director
Kathryn E. Falberg.	55	Director
Mark T. Iwicki	48	Director
Mark D. McDade	60	Chairman of the Board
Stacey D. Seltzer.	39	Director

Executive Officers and Employee Directors

Stephen G. Dilly, M.B.B.S., Ph.D. has served as our Chief Executive Officer since April 2014 and as a member of our board of directors since April 2013. Dr. Dilly was Chief Executive Officer of PhotoThera, Inc., a medical device company, from January 2012 to December 2012. Since April 2010, Dr. Dilly has served as an independent director of Sangamo Biosciences, Inc., a biopharmaceutical company, where he also currently serves as chair of the clinical review committee. From 2006 to December 2011, Dr. Dilly served as President and Chief Executive Officer and a member of the board of directors of APT Pharmaceuticals, Inc., a drug development company. From 2007 to 2009, he was a member of the board of directors of Avigen, Inc., a biopharmaceutical company, which merged with MediciNova, Inc. in December 2009. From 2003 to 2006, he served as Chief Medical Officer and Senior Vice President of Development of Chiron BioPharma, a biotechnology company which was later acquired by Novartis International AG. From 1998 to 2003, Dr. Dilly held various management positions at Genentech, Inc., a biotechnology company, including Vice President of Development Sciences from 2002 to 2003 and Vice President of Medical Affairs from 1998 to 2001. From 1988 to 1998, Dr. Dilly held various management positions in drug development with SmithKline Beecham, PLC, a healthcare company in the U.K. During his career, Dr. Dilly has been closely associated with the development and launch of marketed drugs for many therapeutic areas, including Kytril, Paxil, Kredex, Requip, TNKase, Xolair, Avastin, Raptiva, Tarceva, Lucentis and Cubicin. Dr. Dilly received an M.B.B.S., the equivalent of an M.D., from the University of London in the U.K. and a Ph.D. in cardiac physiology from University of London. We believe that Dr. Dilly is qualified to serve on our board of directors due to his extensive management experience in the life science industry and drug development experience.

Warren L. DeSouza has served as our Chief Financial Officer since April 2015. Mr. DeSouza served as a consultant on financial matters to Onyx Pharmaceuticals, Inc., or Onyx, a biopharmaceutical company, from August 2013 to January 2014, during which the company was acquired by Amgen, Inc. From January 2005 to August 2013, Mr. DeSouza served as Vice President, Finance for Onyx, where he led accounting, SEC reporting,

purchasing, tax, treasury and risk management. From 2002 to 2005, Mr. DeSouza served as a senior manager at Deloitte & Touche LLP, an accounting firm. From 1990 to 2002, Mr. DeSouza was a senior manager at Arthur Andersen LLP, an accounting firm. Mr. DeSouza received a B.B.A. from the University of Notre Dame and is a certified public accountant (inactive).

Howard V. Raff, Ph.D. has served as our Chief Operating Officer since July 2012. From 2007 to March 2012, Dr. Raff served as Chief Operating Officer for APT Pharmaceuticals, Inc., a pharmaceutical company. Dr. Raff was Vice President of Development Management for Chiron Corporation, a biotechnology company, from 1995 until its acquisition by Novartis International AG, a pharmaceutical company, in 2006. Dr. Raff also served as the head of west coast operations for The Biologics Consulting Group, a regulatory consulting firm in product development and regulatory strategy for biologics, drugs and medical devices, and spent 11 years in discovery research and development for Bristol-Myers Squibb, a pharmaceutical company. Dr. Raff has been involved with the development and approval of several drugs in the U.S. and Europe, including CTLA4-lg, Proleukin, Menjugate vaccine and Cubicin. Dr. Raff received a B.S. in Zoology from the University of Illinois and an M.S. and Ph.D. in Immunology and Microbiology from Washington State University.

Robert M. Elfont, M.D., Ph.D has served as our Chief Medical Officer since March 2014. From April 2012 to March 2014, Dr. Elfont served as Chief Medical Officer for PhotoThera, Inc., a medical device company. From December 2009 to March 2014, he was a consultant for Strategic Clinical Development, LLC, a life sciences consulting company, of which he was a founder. From 2008 to December 2009, Dr. Elfont served as Associate Vice President of Clinical Development and Acting Chief Medical Officer at Avigen, Inc., a biopharmaceutical company. During 2007, he served as Vice President of Clinical Development for Medivation, Inc., a biopharmaceutical company. From 2005 to 2007, Dr. Elfont was Clinical Research and Licensing Liaison, Neuroscience, at Roche Pharmaceuticals, a biotechnology company. Dr. Elfont also served as Medical Director, Early Clinical Development for Pfizer, Inc., a biopharmaceutical company, from 2002 to 2005, and as Medical Director for Teva Neuroscience, Inc., a pharmaceutical company. Prior to that, Dr. Elfont was an assistant professor of neurology at Johns Hopkins University School of Medicine and Drexel University College of Medicine. Dr. Elfont received an A.B. in Biology and English from the University of Pennsylvania and an M.D. and Ph.D. in Neuroanatomy from the University of Rochester School of Medicine and Dentistry. Dr. Elfont is Board-certified in neurology.

Mary M. Rozenman, Ph.D. has served as our Senior Vice President, Corporate and Commercial Development, since February 2015. From February 2013 to January 2015, Dr. Rozenman was Vice President at Longitude Capital Management Co., LLC, a venture investment company, where she focused on biotechnology investments in therapeutics, diagnostics and research and development tools and services. From February 2008 to January 2013, Dr. Rozenman was at McKinsey & Company, a management-consulting company, where she most recently served as Associate Principal. Dr. Rozenman previously served as an observer on the boards of directors of Esperion Therapeutics, Inc., a biopharmaceutical company, and CardioDx, Inc., a molecular diagnostics company. Dr. Rozenman received a B.A. in Biochemistry and Russian Literature from Columbia University and a Ph.D. in Organic Chemistry and Chemical Biology from Harvard University.

Key Employees

Michael S. Holfinger, Ph.D. has served as our Vice President, Manufacturing and Supply Chain since March 2015. From June 2013 to March 2015, Dr. Holfinger was Vice President, Manufacturing and Supply Chain Management at Alexza Pharmaceuticals, Inc., a pharmaceutical company. From 2006 to June 2013, he served in various roles at Affymax, Inc., a biopharmaceutical company, including Executive Director, Senior Director and Director of API Manufacturing and Process Development and, most recently, Vice President, Manufacturing and CMC Development. Previously, Dr. Holfinger served as Senior Manager, API Support Team at Pfizer, Inc., a biopharmaceutical company,

from 2002 to 2006, and as Scientist, Research Scientist and Senior Research Scientist, Process Development for Pharmacia & Upjohn Company, LLC, a biopharmaceutical

company and a subsidiary of Pfizer, Inc., from 1992 to 2002. Dr. Holfinger received a B.S. in Chemistry and a B.S. in Applied Science, Paper Science and Engineering from Miami University and a Ph.D. Chemical Engineering from the University of Wisconsin-Madison.

Joseph W. Suttner has served as our Vice President, Clinical Operations since November 2012. From July 2012 to November 2012, he served as Director, Clinical Operations at PhotoThera, Inc., a medical device company. From March 2011 to June 2012, he served as Director, Clinical Operations at Ipsen, a pharmaceutical company. From 2007 to April 2011, Mr. Suttner served as Director, Clinical Development for Peplin, Ltd., a pharmaceutical company. Mr. Suttner received a B.A. in Liberal Arts from California State University-Long Beach and an M.B.A. from the University of Liverpool.

Non-Employee Directors

Patrick G. Enright has served as a member of our board of directors since April 2013. Since July 2007, Mr. Enright has served as a Managing Director of Longitude Capital, a venture capital firm, of which he is a founder. From 2002 through 2006, Mr. Enright was a Managing Director of Pequot Ventures, a venture capital investment firm, where he co-led the life sciences investment practice. He currently serves on the board of directors and as a member of the compensation committee of Jazz Pharmaceuticals, PLC, a biopharmaceutical company, where he also served as a member of the audit committee from 2009 to 2014. Mr. Enright also currently serves on the board of directors and as a member of the audit committee of Corcept Therapeutics Incorporated, a pharmaceutical company and Esperion Therapeutics, Inc., a pharmaceutical company. Mr. Enright received a B.S. in Biological Sciences from Stanford University and an M.B.A. from the Wharton School at the University of Pennsylvania. We believe that Mr. Enright is qualified to serve on our board of directors due to his experience serving on the board of directors of clinical-stage biotechnology companies and his investment experience in the life sciences industry.

Kathryn E. Falberg has served as a member of our board of directors since May 2015. Ms. Falberg served as Executive Vice President and Chief Financial Officer of Jazz Pharmaceuticals, PLC, a biopharmaceutical company, from March 2012 to March 2014, after serving as Senior Vice President and Chief Financial Officer since December 2009. From 1995 to 2001, Ms. Falberg was with Amgen Inc., a biotechnology company, where she served as Senior Vice President, Finance and Strategy and Chief Financial Officer, and before that as Vice President, Controller and Chief Accounting Officer and Vice President, Treasurer. Ms. Falberg currently serves as chair of the board of directors and chair of the audit committee of Halozyme Therapeutics, Inc., a biopharmaceutical company, Medivation, Inc., a biopharmaceutical company, and aTyr Pharma, Inc., a biotherapeutics company. She previously served on the board of directors of QLT Inc., a biotechnology company. Ms. Falberg received a B.A. in Economics and M.B.A. from the University of California, Los Angeles and is a certified public accountant (inactive). We believe Ms. Falberg is qualified to serve on our board of directors due to her extensive financial experience as a certified public accountant and principal financial officer of numerous public companies, as well as her experience as a director of numerous public companies in the life science industry.

Mark T. Iwicki has served as a member of our board of directors since May 2015. Mr. Iwicki served as President and Chief Executive Officer and a member of the board of directors of Civitas Therapeutics, Inc., a biopharmaceutical company, from January 2014 until its acquisition by Acorda Therapeutics, Inc., a biotechnology company, in September 2014. From December 2012 to January 2014, Mr. Iwicki served as President and Chief Executive Officer and director at Blend Therapeutics, Inc., a biopharmaceutical company. From 2007 to June 2012, Mr. Iwicki was President and Chief Executive Officer and director of Sunovion Pharmaceuticals, Inc., formerly Sepracor, Inc., a pharmaceutical company. From 1998 to 2007, Mr. Iwicki served as Vice President and Business Unit Head at Novartis Pharmaceuticals Corporation, a pharmaceuticals company. Mr. Iwicki has also held management positions at Astra Merck Inc. and Merck & Co., Inc., pharmaceutical companies. Mr. Iwicki received a B.A. in Business

Administration from Ball State University and an M.B.A. from Loyola University. We believe that Mr. Iwicki is qualified to serve on our board of directors due to his executive management and operational experience in the life science industry.

Table of Contents

Mark D. McDade has served as the Chairman of our board of directors since May 2015. He is currently the Executive Vice President, Chief Operating Officer at UCB S.A., a biopharmaceutical company, where he previously served as Executive Vice President, Established Brands, Solutions and Supply and Executive Vice President, Global Operations since joining in 2008. From 2002 to 2007, Mr. McDade served as Chief Executive Officer and a member of the board of directors of PDL BioPharma, Inc., a biotechnology company. From 2000 to 2002, Mr. McDade was Chief Executive Officer of Signature BioScience, Inc., a drug discovery company. From 1994 to 2000, Mr. McDade served as Chief Operating Officer and a director of Corixa Corporation, a biopharmaceutical company he co-founded. At Corixa, he most recently served as its President and Chief Operating Officer. Mr. McDade currently serves on the board of directors and as a member of the audit and conflicts committees for Phillips Edison Grocery Center REIT II, Inc., a real estate investment company. He has served on the board of directors of Five Prime Therapeutics, Inc., a biotechnology company, since 2006 and Dermira, Inc., biopharmaceutical company, since August 2014. He previously served on the board of directors of several public and private companies, including Cytokinetics, Inc., a biopharmaceutical company, PDL BioPharma, Inc., a biotechnology company, and Valentis, Inc., a biotechnology company. Mr. McDade received a B.A. in history from Dartmouth College and an M.B.A. from Harvard Business School. We believe that Mr. McDade is qualified to serve on our board of directors due to his executive management and leadership experience in the life science industry, as well as extensive experience as a director of public companies.

Stacey D. Seltzer has served as a member of our board of directors since January 2015. Ms. Seltzer is currently a partner at Aisling Capital, where she previously served as principal since joining in September 2008. From 2004 to 2008, Ms. Seltzer held various positions at Schering-Plough Corporation, a pharmaceutical company, including U.S. Schering-Plough Brand Lead for Zetia, Associate Director, U.S. Marketing, Senior Manager, Global Licensing and Management Associate. From 2001 to 2002, Ms. Seltzer served as Director of Business Development for Akceli, Inc., a biotechnology company. Ms. Seltzer serves on the board of directors of Miramar Labs, Inc., a privately-held medical device company. She previously served as a board observer for Agile Therapeutics, Inc., a pharmaceutical company, Durata Therapeutics, Inc., a pharmaceutical company, and Zeltiq Aesthetics, Inc. a medical equipment supplier. Ms. Seltzer received a B.S. and M.S. in Molecular Biophysics and Biochemistry from Yale University and an M.B.A. from the Wharton School at the University of Pennsylvania. We believe that Ms. Seltzer is qualified to serve on our board of directors due to her investment and management experience in the life science industry.

Board Composition

Director Independence

Our board of directors currently consists of six members. Our board of directors has determined that all of our directors, other than Dr. Dilly, qualify as independent directors in accordance with The NASDAQ Global Select Market listing requirements. Dr. Dilly is not considered independent because he is an employee of Aimmune Therapeutics, Inc. The NASDAQ Global Select Market s independence definition includes a series of objective tests, such as that the director is not, and has not been for at least three years, one of our employees and that neither the director nor any of his or her family members has engaged in various types of business dealings with us. In addition, as required by The NASDAQ Global Select Market rules, our board of directors has made a subjective determination as to each independent director that no relationships exists that, in the opinion of our board of directors, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In making these determinations, our board of directors reviewed and discussed information provided by the directors and us with regard to each director s business and personal activities and relationships as they may relate to us and our management. There are no family relationships among any of our directors or executive officers.

Classified Board of Directors

In accordance with our amended and restated certificate of incorporation to be in effect immediately prior to the consummation of this offering, our board of directors will be divided into three classes with

Table of Contents

staggered, three-year terms. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Effective upon the consummation of this offering, we expect that our directors will be divided among the three classes as follows:

- the Class I directors will be Dr. Dilly and Mr. Iwicki, and their terms will expire at the annual meeting of stockholders to be held in 2016;
- the Class II directors will be Mr. McDade and Ms. Seltzer, and their terms will expire at the annual meeting of stockholders to be held in 2017; and
- the Class III directors will be Mr. Enright and Ms. Falberg, and their terms will expire at the annual meeting of stockholders to be held in 2018.

Our amended and restated certificate of incorporation will provide that the authorized number of directors may be changed only by resolution of the board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control of our company.

Voting Arrangements

The election of the members of our board of directors is governed by the amended and restated voting agreement, as amended, that we entered into with certain holders of our common stock and certain holders of our convertible preferred stock and the related provisions of our amended and restated certificate of incorporation.

Pursuant to the voting agreement and these provisions the holders of our Series A convertible preferred stock, voting together as a single class, have the right to elect one (1) director to our board of directors, the holders of our Series B convertible stock, voting together as a single class, have the right to elect two (2) directors to our board of directors, the holders of our common stock, voting together as a single class, have the right to elect one (1) director to our board of directors and the holders of our common stock and any other class or series of voting stock (including our convertible preferred stock), voting together as a single class, have the right to elect the balance of the total number of our directors, which are designated as follows:

- one (1) member designated by Longitude Venture Partners II, L.P. (together with its affiliated funds) and elected by our Series A convertible preferred stock, for which Mr. Enright has been designated;
- one (1) member designated by Foresite Capital Fund II, L.P. (together with its affiliated funds) and elected by our Series B convertible preferred stock, which is currently vacant;

one (1) member designated by Aisling Capital III, L.P. (together with its affiliated funds) and elected by our Series B convertible preferred stock, for which Ms. Seltzer has been designated;

one (1) member designated and elected by the holders of a majority of the shares of our common stock, for which Dr. Dilly has been designated; and

three (3) members designated and elected by the holders of a majority of our voting capital stock, including our preferred stock and common stock, voting together as a single class on an as-converted basis, for which Kathryn E. Falberg, Mark T. Iwicki and Mark D. McDade have been designated.

Table of Contents

The holders of our common stock and convertible preferred stock who are parties to our voting agreement are obligated to vote for such designees indicated above. The provisions of this voting agreement will terminate upon the consummation of this offering and our certificate of incorporation will be amended and restated, after which there will be no further contractual obligations or charter provisions regarding the election of our directors. Our directors hold office until their successors have been elected and qualified or appointed, or the earlier of their death, resignation or removal.

Leadership Structure of the Board

Our bylaws and corporate governance guidelines provide our board of directors with flexibility to combine or separate the positions of chairman of the board of directors and Chief Executive Officer and/or the implementation of a lead director in accordance with its determination that utilizing one or the other structure would be in the best interests of our company. Mr. McDade currently serves as the Chairman of our board of directors. In that role, Mr. McDade presides over the executive sessions of the board of directors.

Our board of directors has concluded that our current leadership structure is appropriate at this time. However, our board of directors will continue to periodically review our leadership structure and may make such changes in the future as it deems appropriate.

Role of Board in Risk Oversight Process

Risk assessment and oversight are an integral part of our governance and management processes. Our board of directors encourages management to promote a culture that incorporates risk management into our corporate strategy and day-to-day business operations. Management discusses strategic and operational risks at regular management meetings, and conducts specific strategic planning and review sessions during the year that include a focused discussion and analysis of the risks facing us. Throughout the year, senior management reviews these risks with the board of directors at regular board meetings as part of management presentations that focus on particular business functions, operations or strategies, and presents the steps taken by management to mitigate or eliminate such risks.

Our board of directors does not have a standing risk management committee, but rather administers this oversight function directly through our board of directors as a whole, as well as through various standing committees of our board of directors that address risks inherent in their respective areas of oversight. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure, our audit committee is responsible for overseeing our major financial risk exposures and the steps our management has taken to monitor and control these exposures. The audit committee also monitors compliance with legal and regulatory requirements and considers and approves or disapproves any related person transactions. Our nominating and corporate governance committee monitors the effectiveness of our corporate governance guidelines. Our compensation committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking.

Board Committees

Audit Committee

Our audit committee oversees our corporate accounting and financial reporting process. Among other matters, the audit committee:

appoints our independent registered public accounting firm;

evaluates the independent registered public accounting firm s qualifications, independence and performance;

determines the engagement of the independent registered public accounting firm;

Table of Contents

- reviews and approves the scope of the annual audit and the audit fee;
- discusses with management and the independent registered public accounting firm the results of the annual audit and the review of our quarterly financial statements;
- approves the retention of the independent registered public accounting firm to perform any proposed permissible non-audit services;
- monitors the rotation of partners of the independent registered public accounting firm on our engagement team in accordance with requirements established by the SEC;
- is responsible for reviewing our financial statements and our management s discussion and analysis of financial condition and results of operations to be included in our annual and quarterly reports to be filed with the SEC;
- reviews our critical accounting policies and estimates; and
- reviews the audit committee charter and the committee s performance at least annually.

The current members of our audit committee are Kathryn E. Falberg, Mark T. Iwicki and Stacey D. Seltzer. Ms. Falberg serves as the chairperson of the committee. All members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and The NASDAQ Global Select Market. Our board of directors has determined that Ms. Falberg is an audit committee financial expert as defined under the applicable rules of the SEC and has the requisite financial sophistication as defined under the applicable rules and regulations of The NASDAQ Global Select Market. Under the rules of the SEC, members of the audit committee must also meet heightened independence standards. Our board of directors has determined that each of Ms. Falberg, Mr. Iwicki and Ms. Seltzer are independent under the applicable rules of the SEC and The NASDAQ Global Select Market. The audit committee operates under a written charter that satisfies the applicable standards of the SEC and The NASDAQ Global Select Market.

Compensation Committee

Our compensation committee oversees policies relating to compensation and benefits of our officers and employees. The compensation committee reviews and recommends corporate goals and objectives relevant to compensation of our executive officers (other than our Chief Executive Officer), evaluates the performance of these officers in light of those goals and objectives and approves the compensation of these officers based on such evaluations. The compensation committee also recommends to our board of directors the issuance of stock options and other awards under our stock plans (other than for our Chief Executive Officer). The compensation committee reviews the performance of our Chief Executive Officer and makes recommendations to our board of directors with respect to his compensation, and our board of directors retains the authority to make compensation decisions relative to our Chief Executive Officer. The compensation committee will review and evaluate, at least annually, the performance of the compensation committee and its members, including compliance by the compensation committee with its charter. The current members of our compensation committee are Patrick G. Enright, Kathryn E. Falberg and Mark D. McDade.

Mr. Enright serves as the chairman of the committee. Each of the members of our compensation committee is independent under the applicable rules and regulations of The NASDAQ Global Select Market, is a non-employee director as defined in Rule 16b-3 promulgated under the Exchange Act and is an outside director as that term is defined in Section 162(m) of the U.S. Internal Revenue Code of 1986, as amended, or Section 162(m). The compensation committee operates under a written charter that satisfies the applicable standards of the SEC and The NASDAQ Global Select Market.

Nominating and Corporate Governance Committee

The nominating and corporate governance committee is responsible for making recommendations to our board of directors regarding candidates for directorships and the size and composition of our board of directors.

Table of Contents

In addition, the nominating and corporate governance committee is responsible for overseeing our corporate governance policies and reporting and making recommendations to our board of directors concerning governance matters. The current members of our nominating and corporate governance committee are Patrick G. Enright, Mark D. McDade and Stacey D. Seltzer. Mr. McDade serves as the chairman of the committee. Each of the members of our nominating and corporate governance committee is an independent director under the applicable rules and regulations of The NASDAQ Global Select Market relating to nominating and corporate governance committee independence. The nominating and corporate governance committee operates under a written charter that satisfies the applicable standards of the SEC and The NASDAQ Global Select Market.

Compensation Committee Interlocks and Insider Participation

During the year ended December 31, 2014, our compensation committee consisted of Patrick G. Enright, Walter Flamenbaum, M.D. and Joon Yun, M.D. Each of Drs. Flamenbaum and Yun resigned from our board of directors in 2015. None of the members of our compensation committee has at any time been one of our officers or employees. None of our executive officers currently serves, or in the past fiscal year has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers on our board of directors or compensation committee.

Board Diversity

Upon consummation of this offering, our nominating and corporate governance committee will be responsible for reviewing with the board of directors, on an annual basis, the appropriate characteristics, skills and experience required for the board of directors as a whole and its individual members. In evaluating the suitability of individual candidates (both new candidates and current members), the nominating and corporate governance committee, in recommending candidates for election, and the board of directors, in approving (and, in the case of vacancies, appointing) such candidates, may take into account many factors, including but not limited to the following:

- personal and professional integrity;
- ethics and values;
- experience in corporate management, such as serving as an officer or former officer of a publicly held company;
- experience in the industries in which we compete;
- experience as a board member or executive officer of another publicly held company;
- diversity of expertise and experience in substantive matters pertaining to our business relative to other board members;

conflicts of interest; and

practical and mature business judgment.

Currently, our board of directors evaluates, and following the consummation of this offering will evaluate, each individual in the context of the board of directors as a whole, with the objective of assembling a group that can best maximize the success of the business and represent stockholder interests through the exercise of sound judgment using its diversity of experience in these various areas.

Table of Contents

Code of Business Conduct and Ethics

Prior to the consummation of this offering, we will adopt a code of business conduct and ethics that will apply to all of our employees, officers and directors, including those officers responsible for financial reporting. Following the consummation of this offering, the code of business conduct and ethics will be available on our website. We expect that any amendments to the code, or any waivers of its requirements, will be disclosed on our website.

Limitation on Liability and Indemnification Matters

Our amended and restated certificate of incorporation, which will become effective immediately prior to the consummation of this offering, will contain provisions that limit the liability of our directors for monetary damages to the fullest extent permitted by Delaware law. Consequently, our directors will not be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director s duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or
- any transaction from which the director derived an improper personal benefit.

Each of our amended and restated certificate of incorporation and amended and restated bylaws, which will become effective immediately prior to the consummation of this offering, will provide that we are required to indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law. Our amended and restated bylaws will also obligate us to advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under Delaware law. We have entered and expect to continue to enter into agreements to indemnify our directors, executive officers and other employees as determined by our board of directors. With specified exceptions, these agreements provide for indemnification for related expenses including, among other things, attorneys fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain directors and officers liability insurance.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against our directors and officers for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and our stockholders. Further, a stockholder s investment may be adversely affected to the extent that we pay the costs of settlement and damage.

Director Compensation

The following table presents the total compensation for each person who served as a non-employee member of our board of directors during the year ended December 31, 2014. Other than as set forth in the table

Table of Contents

below, in the year ended December 31, 2014 we did not grant any equity awards, or pay any other compensation to, any of the non-employee members of our board of directors. We reimburse our directors for travel and other necessary business expenses incurred in the performance of their services for us.

Dr. Dilly served as a non-employee member of our board of directors until his commencement of employment with us in April 2014. Dr. Walser served as a member of our board of directors during his employment with us, and following cessation of employment, as a non-employee member of our board of directors.

Director Compensation Table

The following table sets forth information for the year ended December 31, 2014 regarding the compensation awarded to, earned by or paid to our non-employee directors:

Name[1]	Fees Earned or Paid in Cash ($)	Total ($)
Patrick Enright	25,000	25,000
Walter Flamenbaum, M.D.[2]	70,000	70,000
Bryan Walser, M.D., J.D.[2][3]		
Joon Yun, M.D.[2][4]		

(1) The compensation that Dr. Dilly received during the fiscal year ended December 31, 2014 in his capacity as a director is reflected in the 2014 Summary Compensation Table below in accordance with SEC disclosure rules.

(2) Dr. Flamenbaum resigned from our Board in March 2015, Dr. Walser resigned from our Board in May 2015 and Dr. Yun resigned from our Board in April 2015.

(3) Dr. Walser did not receive any compensation for his role as a director. See the 2014 Summary Compensation Table below for information regarding his compensation as our former Chief Executive Officer and as a consultant to us.

(4) Dr. Yun was entitled to $25,000 cash compensation as a director. However, Dr. Yun requested that we not pay him his cash compensation.

As of December 31, 2014, (i) Patrick Enright held options to purchase 65,850 shares of our common stock; (ii) Dr. Bryan Walser held options to purchase 742,864 shares of our common stock, which he exercised in full; and (iii) Drs. Walter Flamenbaum and Joon Yun each held options to purchase 65,850 shares of our common stock. No other non-employee director held any outstanding equity awards as of December 31, 2014.

In July 2015, our board of directors approved a compensation policy for our non-employee directors to be effective in connection with the consummation of this offering, or the Post-IPO Director Compensation Program. Pursuant to the Post-IPO Director Compensation Program, our non-employee directors will receive cash compensation, paid quarterly in arrears, as follows:

Each non-employee director will receive an annual cash retainer in the amount of $35,000.

The chairperson of the board will receive additional annual cash compensation of $30,000 for such chairperson s service on the board.

The chairperson of the audit committee will receive additional annual cash compensation in the amount of $20,000 for such chairperson s service on the audit committee. Each non-chairperson member of the audit committee will receive additional annual cash compensation in the amount of $10,000 for such member s service on the audit committee.

Table of Contents

The chairperson of the compensation committee will receive additional annual cash compensation in the amount of $12,000 for such chairperson s service on the compensation committee. Each non-chairperson member of the compensation committee will receive additional annual cash compensation in the amount of $6,000 for such member s service on the compensation committee.

The chairperson of the nominating and corporate governance committee will receive additional annual cash compensation in the amount of $8,000 for such chairperson s service on the nominating and corporate governance committee. Each non-chairperson member of the nominating and corporate governance committee will receive additional annual cash compensation in the amount of $4,000 for such member s service on the nominating and corporate governance committee.

Under the Post-IPO Director Compensation Program, each non-employee director who is elected or appointed to our board of directors after the completion of this offering will automatically be granted an option to purchase 39,510 shares of our common stock upon the director s initial appointment or election to our board of directors, referred to as the Initial Grant. In addition, each non-employee director who is serving on our board of directors immediately following an annual stockholder s meeting will automatically be granted an annual option to purchase 19,755 shares of our common stock on the date of such annual stockholder s meeting, referred to as the Annual Grant. The Initial Grant will vest as to 1/36th of the shares subject to the Initial Grant each month following the applicable grant date, subject to continued service through each applicable vesting date. The Annual Grant will vest as to all of the shares subject to the Annual Grant on the earlier of the first anniversary of the applicable grant date or the next annual stockholders meeting, subject to continued service through the vesting date. All equity awards, including any Initial Grants and Annual Grants, held by our non-employee directors will vest in full immediately prior to the occurrence of a change in control.

Table of Contents

EXECUTIVE COMPENSATION

Overview

This section discusses the material components of the executive compensation program for our executive officers who are named in the 2014 Summary Compensation Table below. In 2014, our named executive officers and their positions were as follows:

Dr. Stephen G. Dilly, Chief Executive Officer;

Dr. Bryan Walser, Former Chief Executive Officer;

Dr. Howard Raff, Chief Operating Officer; and

Dr. Robert Elfont, Chief Medical Officer.

Dr. Walser served as our Chief Executive Officer through April 4, 2014. Dr. Dilly commenced employment with us in April 2014 and has served as our Chief Executive Officer since April 5, 2014.

2014 Summary Compensation Table

The following table shows information regarding the compensation of our named executive officers for services performed in the year ended December 31, 2014.

Name and Principal Position	Year	Salary($)	Bonus($)	Option Awards ($)[1]	Non-Equity Incentive Plan Compensation ($)	All Other Compensation ($)	Total($)
Dr. Stephen G. Dilly[2] *Chief Executive Officer*	2014	$ 262,500	$ 125,000	$ 57,181		$ 25,000[3]	$ 469,681
Dr. Bryan Walser[4] *Former Chief Executive Officer*	2014	$ 107,510				$ 406,994[5]	$ 514,504
Dr. Howard Raff. *Chief Operating Officer*	2014	$ 275,000	$ 55,000				$ 330,000
Dr. Robert Elfont[6] *Chief Medical Officer*	2014	$ 219,984	$ 55,000	$ 30,171			$ 305,155

(1)

Amounts reported in the Option Awards column represent the grant date fair values of stock options granted during 2014, calculated in accordance with ASC Topic 718. For a discussion of the assumptions used to calculate the value of our stock options, see Note 7 to our audited financial statements included elsewhere in this prospectus.

(2) Dr. Dilly commenced employment with us in April 2014.

(3) Represents cash director fees of $25,000 in respect of Dr. Dilly s service as a director prior to his commencement of employment with us during the year ended December 31, 2014.

(4) Dr. Walser s employment with us terminated on April 4, 2014.

(5) Represents (a) the following severance payments and benefits: (i) continued payment of Dr. Walser s base salary for twelve months following termination ($300,000), (ii) Company-paid COBRA coverage for up to twelve months following termination (valued at $10,494) and (iii) his target annual bonus for the year of termination ($90,000), and (b) consulting fees equal to $6,500.

(6) Dr. Elfont commenced employment with us in March 2014.

Table of Contents

Narrative Disclosure to Summary Compensation Table

2014 Salaries

The named executive officers receive a base salary to compensate them for services rendered to us. The base salary payable to each named executive officer is intended to provide a fixed component of compensation reflecting the executive s skill set, experience, role and responsibilities. The actual base salaries paid to each named executive officer for 2014 are set forth in the 2014 Summary Compensation Table above. For 2014, Dr. Dilly s annual base salary was $350,000, Dr. Walser s annual base salary was $300,000, Dr. Elfont s annual base salary was $265,000 and Dr. Raff s annual base salary was $275,000.

2014 Bonuses

During 2014, each of Drs. Dilly, Raff and Elfont were eligible to receive annual cash bonuses pursuant to their respective employment letters or Board approved compensation arrangements with the Company. The 2014 annual bonuses for Drs. Dilly, Elfont and Raff were targeted at 40%, 20% and 20% of their respective base salaries. The annual bonuses, which are determined by the board of directors, are discretionary and are not based on pre-determined Company or individual goals or metrics. Instead, the board determines individual bonus amounts at the end of each fiscal year based on a comprehensive assessment of the applicable executive s performance and the Company s operational and financial performance. In determining 2014 annual bonuses, the board considered each named executive officer s individual performance and the Company s financial and operational performance during 2014.

The actual 2014 annual bonuses paid to each of Drs. Dilly, Raff and Elfont for 2014 are set forth in the 2014 Summary Compensation Table above.

Dr. Walser, whose employment with us terminated on April 4, 2014, became entitled to his 2014 target annual bonus pursuant to the terms of his settlement agreement with the Company, described below under Executive Compensation Arrangements Bryan Walser Agreements.

Equity Compensation

We have historically granted stock options under our 2013 Stock Plan, as amended, to our named executive officers. Our stock options generally may be exercised in full at any time, subject to a right of repurchase upon a termination of the applicable executive s employment prior to the final vesting date of the underlying stock option.

During 2014, Drs. Dilly and Elfont received grants of stock options covering 563,672 shares and 299,002 shares of our common stock, respectively, under our 2013 Stock Plan. These stock options vest over a four-year period, with 25% of the shares subject to the option vesting on the first anniversary of the applicable vesting commencement date and one-forty-eighth of the shares subject to the option vesting on each monthly anniversary of the vesting commencement date thereafter, subject to the applicable executive officer s continued service through the vesting date. For additional information about the 2013 Stock Plan, please see 2013 Stock Plan below.

In April 2014, in connection with Dr. Walser s termination as our Chief Executive Officer, our board of directors modified his outstanding vested stock options to provide for such options to remain exercisable for six (6) months following his termination of employment with us.

In connection with this offering, we adopted the 2015 Equity Incentive Award Plan in order to facilitate the grant of cash and equity incentives to directors, employees (including our named executive officers) and consultants of our

company and certain of its affiliates and to enable our company and certain of its affiliates to obtain and retain services of these individuals, which is essential to our long-term success. We expect that the

Table of Contents

2015 Equity Incentive Award Plan will be effective on the date on the effective date of the registration statement of which this prospectus is a part, subject to approval of such plan by our stockholders. For additional information about the 2015 Equity Incentive Award Plan, please see 2015 Equity Incentive Award Plan below.

Other Elements of Compensation

Retirement Plan

We maintain a 401(k) retirement savings plan for the benefit of our employees, including our named executive officers, who satisfy certain eligibility requirements. Under the 401(k) plan, eligible employees may elect to defer a portion of their compensation, within the limits prescribed by the Internal Revenue Code, on a pre-tax or after-tax (Roth) basis through contributions to the 401(k) plan. We believe that providing a vehicle for tax-deferred retirement savings though our 401(k) plan adds to the overall desirability of our executive compensation package and further incentivizes our employees, including our named executive officers, in accordance with our compensation policies.

Employee Benefits and Perquisites

All of our full-time employees, including our named executive officers, are eligible to participate in our health and welfare plans, including medical, dental and vision benefits, medical flexible spending accounts, short-term and long-term disability insurance and life insurance. We do not provide our named executive officers with perquisites or other personal benefits, other than the retirement, health and welfare benefits that apply uniformly to all of our employees.

No Tax Gross-Ups

We are not required to make gross-up payments to cover our named executive officers personal income taxes that may pertain to any of the compensation or perquisites paid or provided by our company.

Table of Contents

Outstanding Equity Awards at Fiscal Year End

The following table sets forth specified information concerning the outstanding equity awards held by each of the named executive officers as of December 31, 2014.

			Option Awards				Stock Awards			
Name	Grant Date	Vesting Commencement Date	Number of Securities Underlying Unexercised Options (#) Exercisable[1]	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)[2]	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested ($)
Dr. Stephen G. Dilly *Chief Executive Officer*	8/22/2013	4/1/2013						31,746[3]	$ 4,580		
	12/5/2013	4/1/2013						23,810[3]	$ 3,435		
	9/30/2014	4/1/2014						563,672[4]	$ 81,319		
Dr. Bryan Walser *Former Chief Executive Officer*	8/22/2013	12/2/2011	742,864[5]			$ 0.14	8/21/2023				
Dr. Howard Raff *Chief Operating Officer*	8/22/2013	7/1/2012					8/21/2024	169,645[4]	$ 24,474		
Dr. Robert Elfont *Chief Medical Officer*	9/30/2014	3/1/2014	299,002[5]			$ 0.14	9/29/2024				

(1) Stock options are exercisable immediately, in whole or in part, conditioned upon the holder entering into a restricted stock purchase agreement with respect to any unvested shares.

(2) Based on the per share price of our common stock as of December 31, 2014 ($0.14 per share).

(3) Represents shares of Company common stock acquired upon the early exercise of stock options by the applicable holder. One-twenty-fourth of the shares are released from the Company s right of repurchase on each monthly anniversary of the vesting commencement date, subject to the applicable executive s continued service through the applicable vesting date.

(4) Represents shares of Company common stock acquired upon the early exercise of stock options by the applicable holder. One-fourth of the shares are released from the Company s right of repurchase on the first anniversary of the vesting commencement date and 1/48th of the shares are released from the Company s right of repurchase on each monthly anniversary of the vesting commencement date thereafter, subject to the applicable executive s continued service through the applicable vesting date.

(5) Represents stock options which vest as to as to 1/4th of the shares subject thereto on the first anniversary of the vesting commencement date, and as to 1/48th of the shares subject thereto on each monthly anniversary of the vesting commencement date thereafter, subject to the applicable executive s continued service through the applicable vesting date. The applicable holder may exercise the stock option in full at any time, subject to a right of repurchase upon a termination of his employment prior to the fourth anniversary of the grant date.

Executive Compensation Arrangements

Howard Raff Offer Letter

Under Dr. Raff s offer of employment letter with the Company, dated July 2, 2012, Dr. Raff receives an annual base salary of $275,000. In addition, Dr. Raff is eligible to participate in the Company s annual bonus plan, with an annual bonus targeted at 20% of his base salary, and customary benefit plans available to similarly situated executives. Dr. Raff is not entitled to any severance benefits under his offer of employment letter with the Company.

Robert Elfont Offer Letter

Under Dr. Elfont s offer of employment letter with the Company, dated February 24, 2014, Dr. Elfont receives an annual base salary of $265,000. In addition, Dr. Elfont is eligible to participate in the Company s annual bonus plan,

with an annual bonus targeted at 20% of his base salary, and customary benefit plans available to similarly situated executives. Dr. Elfont is not entitled to any severance benefits under his offer of employment letter with the Company.

Bryan Walser Agreements

In connection with his termination of employment in April 2014, we entered into a settlement agreement with Dr. Walser, or the Walser Agreement, pursuant to which he became entitled to receive certain severance payments and benefits. Pursuant to the Walser Agreement, upon his termination of employment with us, subject to his execution and non-revocation of a general release of claims, Dr. Walser became entitled to receive (i) continued payment of his base salary for twelve months following termination, (ii) Company-paid COBRA coverage for up to six months following termination and (iii) his target annual bonus for the year of termination. In addition, pursuant to the Walser Agreement we modified Dr. Walser s outstanding vested stock options to provide for such options to remain exercisable for six months following cessation of services to the Company.

In connection with Dr. Walser s termination of employment with the Company in April 2014, we entered into a consulting agreement with Dr. Walser, or the Walser Consulting Agreement, pursuant to which he provided consulting services to the Company from April 4, 2014 through October 4, 2014. Pursuant to the Walser Consulting Agreement, Dr. Walser was entitled to a consulting fee equal to $2,000 for each day during which he provided consulting services to us (or, if less, $250 per hour multiplied by the number of hours worked during such day), as well as reimbursement for ordinary and necessary business expenses incurred in connection with his performance of the consulting services. The Walser Consulting Agreement includes confidentiality restrictions effective during the term of Dr. Walser s consulting relationship with the Company, as well as non-solicit restrictions effective during the term of Dr. Walser s consulting relationship with the Company and for a period of two years thereafter.

Executive Employment Agreements

In connection with this offering, we have entered into executive employment agreements with each of our current executive officers, including our Chief Executive Officer. These agreements supersede the existing offer letters of employment for each of Drs. Elfont and Raff. The agreements are substantially similar other than the level of pay and benefits provided to each executive officer and specify that each executive officer is an at-will employee. The agreements provide for Drs. Dilly, Elfont and Raff be provided an annual base salary of $400,000, $331,250 and $300,000, respectively, and an annual target bonus of 40%, 30% and 30%, respectively, of base salary. Under the agreements, if an executive officer is terminated by us without cause or resigns for good reason , then in exchange for providing us a general release of claims, the executive officer is entitled to receive continued base salary payments for nine months or, in the case of Dr. Dilly, twelve months and reimbursement of premiums for continued healthcare coverage for nine months or, in the case of Dr. Dilly, twelve months. In addition, the vesting of equity awards, including stock options, held by each executive officer accelerates by six months and any vested stock options remain exercisable for twelve months after his termination of employment or resignation. If the termination or resignation occurs during the period commencing three months prior to a change in control and ending twelve months after a change in control, then, in lieu of the foregoing benefits, each executive officer is entitled to receive a cash lump sum payment equal to twelve months or, in the case of Dr. Dilly, eighteen months base salary, target bonus and reimbursement of continued healthcare coverage premiums. In addition, the vesting of each equity award, including stock option, held by each executive officer accelerates with respect to all of the shares subject thereto and any stock options remain exercisable for twelve months following such termination or resignation.

For the purposes of the employment agreements, cause means any of the following events: (a) the executive officer s theft, dishonesty or falsification of any employment or company records that is non-trivial in nature; (b) the executive officer s malicious or reckless disclosure of our confidential or proprietary information or any material breach by the

executive officer of his obligations under the proprietary information and invention assignment agreement with us; (c) the conviction of the executive officer of a felony (excluding motor vehicle

violations) or the commission of gross negligence or willful misconduct, where a majority of the non-employee members of our board of directors reasonably determines that such act or misconduct has (i) seriously undermined the ability of the board of directors or management to entrust the executive officer with important matters or otherwise work effectively with the executive officer, (ii) substantially contributed to our loss of significant revenues or business opportunities, or (iii) significantly and detrimentally affected our business or reputation; and/or (d) the willful failure or refusal by the executive officer to follow the reasonable and lawful directives of our board of directors, provided such willful failure or refusal continues after the executive officer s receipt of reasonable notice in writing of such failure or refusal and a reasonable opportunity of not less than 30 days to correct the problem.

The employment agreements provide that good reason means any of the following are undertaken without the executive officer s prior written consent: (a) a material diminution in the executive officer s authority, duties, or responsibilities which substantially reduces the nature or character of the executive officer s position with us; (b) a material reduction by us of the executive officer s base salary as in effect immediately prior to such reduction; (c) a relocation of the executive officer s principal office to a location that increases Executive s one-way commute by more than thirty-five (35) miles; or (d) any material breach by us of any provision of his employment agreement, in each case, subject to notice and cure requirements.

The employment agreements provide for change in control to have the same definition as in the Company s 2015 Equity Incentive Award Plan.

Equity Compensation Plans

2015 Equity Incentive Award Plan

In connection with this offering, we adopted the 2015 Equity Incentive Award Plan, or 2015 Plan, which will be effective on the effective date of the registration statement of which this prospectus is a part. The principal purpose of the 2015 Plan is to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards and cash-based performance bonus awards. The material terms of the 2015 Plan, as it is currently contemplated, are summarized below.

Share Reserve. Under the 2015 Plan, an aggregate of 4,681,544 shares of our common stock will be initially reserved for issuance pursuant to a variety of stock-based compensation awards, including stock options, stock appreciation rights, or SARs, restricted stock awards, restricted stock unit awards, deferred stock awards, dividend equivalent awards, stock payment awards and performance awards. The number of shares initially reserved for issuance or transfer pursuant to awards under the 2015 Plan will be increased by (i) the number of shares represented by awards outstanding under our 2013 Stock Plan that are forfeited or lapse unexercised following the effective date up to a maximum of 4,267,931 shares and (ii) an annual increase on the first day of each fiscal year beginning in 2016 and ending in 2025, equal to the lesser of (A) four percent (4.0%) of the shares of stock outstanding (on an as converted basis) on the last day of the immediately preceding fiscal year and (B) such smaller number of shares of stock as determined by our board of directors; provided, however, that no more than 35,000,000 shares of stock may be issued upon the exercise of incentive stock options.

The following counting provisions will be in effect for the share reserve under the 2015 Plan:

- to the extent that an award terminates, expires or lapses for any reason or an award is settled in cash without the delivery of shares, any shares subject to the award at such time will be available for future

grants under the 2015 Plan;

to the extent shares are tendered or withheld to satisfy the grant, exercise price or tax withholding obligation with respect to any award under the 2015 Plan, such tendered or withheld shares will be available for future grants under the 2015 Plan;

Table of Contents

to the extent that shares of our common stock are repurchased by us prior to vesting so that shares are returned to us, such shares will be available for future grants under the 2015 Plan;

the payment of dividend equivalents in cash in conjunction with any outstanding awards will not be counted against the shares available for issuance under the 2015 Plan; and

to the extent permitted by applicable law or any exchange rule, shares issued in assumption of, or in substitution for, any outstanding awards of any entity acquired in any form of combination by us or any of our subsidiaries will not be counted against the shares available for issuance under the 2015 Plan.

Awards granted under the 2015 Plan upon the assumption of, or in substitution for, awards authorized or outstanding under a qualifying equity plan maintained by an entity with which the company enters into a merger or similar corporate transaction will not reduce the shares available for grant under the 2015 Plan.

Administration. The compensation committee of the company s board of directors is expected to administer the 2015 Plan. The board or compensation committee may delegate their duties and responsibilities to committees of directors and/or officers, subject to certain limitations that may be imposed under Section 162(m) of the Code, Section 16 of the Exchange Act and/or stock exchange rules. The plan administrator must consist of at least two members of our board of directors, each of whom is intended to qualify as an outside director, within the meaning of Section 162(m) of the Code, a non-employee director for purposes of Rule 16b-3 under the Exchange Act and an independent director within the meaning of the rules of the applicable stock exchange, or other principal securities market on which shares of our common stock are traded. The 2015 Plan provides that the board or compensation committee may delegate its authority to grant awards to employees other than executive officers and certain senior executives of the company to a committee consisting of one or more members of our board of directors or one or more of our officers, other than awards made to our non-employee directors, which must be approved by our full board of directors. Our board of directors may at any time remove the compensation committee as the administrator and revest in itself the authority to administer the 2015 Plan.

Subject to the terms and conditions of the 2015 Plan, the administrator has the authority to select the persons to whom awards are to be made, to determine the number of shares to be subject to awards and the terms and conditions of awards and to make all other determinations and to take all other actions necessary or advisable for the administration of the 2015 Plan. The administrator is also authorized to adopt, amend or rescind rules relating to administration of the 2015 Plan.

Eligibility. Options, SARs, restricted stock and all other stock-based and cash-based awards under the 2015 Plan may be granted to individuals who are then our officers, employees or consultants or are the officers, employees or consultants of certain of our subsidiaries. Such awards also may be granted to our directors. Only employees of our company or certain of our subsidiaries may be granted incentive stock options, or ISOs.

Awards. The 2015 Plan provides that the administrator may grant or issue stock options, SARs, restricted stock, restricted stock units, deferred stock, dividend equivalents, performance awards, stock payments and other stock-based and cash-based awards, or any combination thereof. Each award will be set forth in a separate agreement with the person receiving the award and will indicate the type, terms and conditions of the award.

Nonstatutory Stock Options, or NSOs, will provide for the right to purchase shares of our common stock at a specified price which may not be less than fair market value on the date of grant, and usually will become exercisable (at the discretion of the administrator) in one or more installments after the grant date, subject to the participant s continued employment or service with us and/or subject to the satisfaction of corporate performance targets and individual performance targets established by the administrator. NSOs may be granted for any term specified by the administrator that does not exceed ten years.

Table of Contents

Incentive Stock Options, or ISOs, will be designed in a manner intended to comply with the provisions of Section 422 of the Code and will be subject to specified restrictions contained in the Code. Among such restrictions, ISOs must have an exercise price of not less than the fair market value of a share of common stock on the date of grant, may only be granted to employees and must not be exercisable after a period of ten years measured from the date of grant. In the case of an ISO granted to an individual who owns (or is deemed to own) at least 10% of the total combined voting power of all classes of our capital stock, the 2015 Plan provides that the exercise price must be at least 110% of the fair market value of a share of common stock on the date of grant and the ISO must not be exercisable after a period of five years measured from the date of grant.

Restricted Stock may be granted to any eligible individual and made subject to such restrictions as may be determined by the administrator. Restricted stock, typically, may be forfeited for no consideration or repurchased by us at the original purchase price if the conditions or restrictions on vesting are not met. In general, restricted stock may not be sold or otherwise transferred until restrictions are removed or expire. Purchasers of restricted stock, unlike recipients of options, will have voting rights and will have the right to receive dividends, if any, prior to the time when the restrictions lapse, however, extraordinary dividends will generally be placed in escrow, and will not be released until restrictions are removed or expire.

Restricted Stock Units may be awarded to any eligible individual, typically without payment of consideration, but subject to vesting conditions based on continued employment or service or on performance criteria established by the administrator. Like restricted stock, restricted stock units may not be sold, or otherwise transferred or hypothecated, until vesting conditions are removed or expire. Unlike restricted stock, stock underlying restricted stock units will not be issued until the restricted stock units have vested, and recipients of restricted stock units generally will have no voting or dividend rights prior to the time when vesting conditions are satisfied.

Deferred Stock Awards represent the right to receive shares of our common stock on a future date. Deferred stock may not be sold or otherwise hypothecated or transferred until issued. Deferred stock will not be issued until the deferred stock award has vested, and recipients of deferred stock generally will have no voting or dividend rights prior to the time when the vesting conditions are satisfied and the shares are issued. Deferred stock awards generally will be forfeited, and the underlying shares of deferred stock will not be issued, if the applicable vesting conditions and other restrictions are not met.

Stock Appreciation Rights, or SARs, may be granted in connection with stock options or other awards, or separately. SARs granted in connection with stock options or other awards typically will provide for payments to the holder based upon increases in the price of our common stock over a set exercise price. The exercise price of any SAR granted under the 2015 Plan must be at least 100% of the fair market value of a share of our common stock on the date of grant. Except as required by Section 162(m) of the Code with respect to a SAR intended to qualify as performance-based compensation as described in Section 162(m) of the Code, there are no restrictions specified in the 2015 Plan on the exercise of SARs or the amount of gain realizable therefrom, although restrictions may be imposed by the administrator in the SAR agreements. SARs under the 2015 Plan will be settled in cash or shares of our common stock, or in a combination of both, at the election of the administrator.

Dividend Equivalents represent the value of the dividends, if any, per share paid by us, calculated with reference to the number of shares covered by the award. Dividend equivalents may be settled in cash or shares and at such times as determined by the compensation committee or board of directors, as applicable.

Table of Contents

Performance Awards may be granted by the administrator on an individual or group basis. Generally, these awards will be based upon specific performance targets and may be paid in cash or in common stock or in a combination of both. Performance awards may include phantom stock awards that provide for payments based upon the value of our common stock. Performance awards may also include bonuses that may be granted by the administrator on an individual or group basis and which may be payable in cash or in common stock or in a combination of both.

Stock Payments may be authorized by the administrator in the form of common stock or an option or other right to purchase common stock as part of a deferred compensation or other arrangement in lieu of all or any part of compensation, including bonuses, that would otherwise be payable in cash to the employee, consultant or non-employee director.

Change in Control. In the event of a change in control where the acquiror does not assume or replace awards granted, prior to the consummation of such transaction, awards issued under the 2015 Plan will be subject to accelerated vesting such that 100% of such awards will become vested and exercisable or payable, as applicable. In the event that within the twelve (12) month period immediately following a change in control, a the holder of an award under the 2015 Plan is terminated other than cause or by the leaves the company for good reason, then the vesting and, if applicable, exercisability of one hundred percent (100%) of the then-unvested shares subject to the outstanding awards shall accelerate upon the termination date. In addition, the administrator will also have complete discretion to structure one or more awards under the 2015 Plan to provide that such awards will become vested and exercisable or payable on an accelerated basis in the event such awards are assumed or replaced with equivalent awards but the individual s service with us or the acquiring entity is subsequently terminated within a designated period following the change in control event. The administrator may also make appropriate adjustments to awards under the 2015 Plan and is authorized to provide for the acceleration, cash-out, termination, assumption, substitution or conversion of such awards in the event of a change in control or certain other unusual or nonrecurring events or transactions. Under the 2015 Plan, a change in control is generally defined as:

the transfer or exchange in a single transaction or series of related transactions by our stockholders of more than 50% of our voting stock to a person or group;

a change in the composition of our board of directors over a two-year period such that 50% or more of the members of the board of directors were elected by at least two-thirds of the directors who were directors at the beginning of the two year period or whose election or nomination was so approved cease to constitute a majority of our board;

a merger, consolidation, reorganization or business combination in which we are involved, directly or indirectly, other than a merger, consolidation, reorganization or business combination which results in our outstanding voting securities immediately before the transaction continuing to represent a majority of the voting power of the acquiring company s outstanding voting securities and after which no person or group beneficially owns 50% or more of the outstanding voting securities of the surviving entity immediately after the transaction;

the sale, exchange or transfer of all or substantially all of our assets; or

stockholder approval of our liquidation or dissolution.

Adjustments of Awards. In the event of any stock dividend, stock split, combination or exchange of shares, merger, consolidation, spin-off, recapitalization, distribution of our assets to stockholders (other than normal cash dividends) or any other corporate event affecting the number of outstanding shares of our common stock or the share price of our common stock other than an equity restructuring (as defined below), the administrator will make appropriate, proportionate adjustments to:

the aggregate number and type of shares subject to the 2015 Plan;

Table of Contents

the number and kind of shares subject to outstanding awards and terms and conditions of outstanding awards (including, without limitation, any applicable performance targets or criteria with respect to such awards); and

the grant or exercise price per share of any outstanding awards under the 2015 Plan.

In the event of one of the adjustments described above or other corporate transactions, in order to prevent dilution or enlargement of the potential benefits intended to be made available under the 2015 Plan, the administrator has the discretion to make such equitable adjustments and may also:

provide for the termination or replacement of an award in exchange for cash or other property;

provide that any outstanding award cannot vest, be exercised or become payable after such event;

provide that awards may be exercisable, payable or fully vested as to shares of common stock covered thereby; or

provide that an award under the 2015 Plan cannot vest, be exercised or become payable after such event.

In the event of an equity restructuring, the administrator will make appropriate, proportionate adjustments to the number and type of securities subject to each outstanding award and the exercise price or grant price thereof, if applicable. In addition, the administrator will make equitable adjustments, as the administrator in its discretion may deem appropriate to reflect such equity restructuring, with respect to the aggregate number and type of shares subject to the 2015 Plan. The adjustments upon an equity restructuring are nondiscretionary and will be final and binding on the affected holders and the Company.

For purposes of the 2015 Plan, equity restructuring means a nonreciprocal transaction between us and our stockholders, such as a stock dividend, stock split, spin-off, rights offering or recapitalization through a large, nonrecurring cash dividend, that affects the number or kind of shares (or other securities) or the share price of our common stock (or other securities) and causes a change in the per share value of the common stock underlying outstanding stock-based awards granted under the 2015 Plan.

Foreign Participants, Claw-Back Provisions and Transferability. The plan administrator may modify award terms, establish subplans and/or adjust other terms and conditions of awards, subject to the share limits described above, in order to facilitate grants of awards subject to the laws and/or stock exchange rules of countries outside of the United States. All awards will be subject to the provisions of any claw-back policy implemented by the Company to the extent set forth in such claw-back policy and/or in the applicable award agreement. With limited exceptions for estate planning, domestic relations orders, certain beneficiary designations and the laws of descent and distribution, awards under the 2015 Plan are generally non-transferable prior to vesting unless otherwise determined by the plan administrator, and are exercisable only by the participant.

Amendment and Termination. Our board of directors or the compensation committee (with board approval) may terminate, amend or modify the 2015 Plan at any time and from time to time. However, we must generally obtain stockholder approval:

to increase the number of shares available under the 2015 Plan (other than in connection with the automatic annual increases and certain corporate events, in each case, as described above);

to reduce the price per share of any outstanding option or SAR granted under the 2015 Plan;

to cancel any outstanding option or SAR in exchange for cash or another award when the option or SAR price per share exceeds the fair market value of the underlying shares; or

to the extent required by applicable law, rule or regulation (including any applicable stock exchange rule).

Termination. The board of directors may terminate the 2015 Plan at any time. No incentive stock options may be granted pursuant to the 2015 Plan after the tenth anniversary of the effective date of the 2015 Plan, and no additional annual share increases to the 2015 Plan s aggregate share limit will occur from and after such anniversary. Any award that is outstanding on the termination date of the 2015 Plan will remain in force according to the terms of the 2015 Plan and the applicable award agreement.

We intend to file with the SEC a registration statement on Form S-8 covering the shares of our common stock issuable under the 2015 Plan.

2013 Stock Plan

We currently maintain the 2013 Stock Plan, as amended, or the 2013 Plan. The purposes of the 2013 Plan are to attract, retain and provide additional incentives to eligible employees, officers, directors and consultants and to promote the success of our business. The material terms of the 2013 Plan, as amended, are summarized below.

Share Reserve. The 2013 Plan reserved an aggregate of 6,969,545 shares of our common stock for issuance pursuant to awards of stock options, restricted stock purchase rights and restricted stock bonuses. The following counting provisions are in effect for the share reserve under the 2013 Plan:

to the extent that an award terminates, expires or is canceled for any reason, any shares subject to the award at such time will be available for future grants under the 2013 Plan; and

to the extent shares are subject to an award that is settled in cash or withheld or reacquired by the Company in satisfaction of tax withholding obligations, such shares will be available for future grants under the 2013 Plan.

Administration. The Company s board of directors administers the 2013 Plan. Subject to the terms and conditions of the 2013 Plan, the plan administrator has the authority to select the persons to whom awards are to be made, to determine the types of awards granted, the number of shares to be subject to awards and the terms and conditions of awards, and to adopt, amend or rescind rules relating to administration of the 2013 Plan.

Eligibility. Awards under the 2013 Plan may be granted to individuals who are then our officers, employees or consultants or are the officers, employees or consultants of certain of our parents and subsidiaries. Such awards also may be granted to our directors. Only employees of our company or certain of our subsidiaries may be granted ISOs.

Awards. The 2015 Plan provides that the administrator may grant or issue stock options, restricted stock purchase rights, restricted stock bonuses or any combination thereof. Each award will be set forth in a separate agreement with the person receiving the award and will indicate the type, terms and conditions of the award.

Nonstatutory Stock Options, or NSOs, provide for the right to purchase shares of our common stock at a specified price which may not be less than fair market value on the date of grant, and usually will become exercisable (at the discretion of the administrator) in one or more installments after the grant

date, subject to the participant s continued employment or service with us and/or subject to the satisfaction of corporate performance targets and individual performance targets established by the administrator. NSOs may be granted for any term specified by the administrator that does not exceed ten years.

Table of Contents

Incentive Stock Options, or ISOs, are intended to comply with the provisions of Section 422 of the Code and will be subject to specified restrictions contained in the Code. Among such restrictions, ISOs must have an exercise price of not less than the fair market value of a share of common stock on the date of grant, may only be granted to employees, and must not be exercisable after a period of ten years measured from the date of grant. In the case of an ISO granted to an individual who owns (or is deemed to own) at least 10% of the total combined voting power of all classes of our capital stock, the 2013 Plan provides that the exercise price must be at least 110% of the fair market value of a share of common stock on the date of grant and the ISO must not be exercisable after a period of five years measured from the date of grant.

Restricted Stock Bonuses may be awarded to any eligible individual and made subject to such restrictions as may be determined by the administrator. Restricted stock bonuses may not be sold or otherwise transferred until restrictions are removed or expire. Restricted stock bonuses may not be sold or otherwise transferred until vesting conditions are removed or expire. Recipients of restricted stock bonuses generally will have no dividend rights prior to the time when vesting conditions are satisfied.

Restricted Stock Purchase Rights represent the right to purchase shares of Company common stock for a per share purchase price determined by the administrator. Restricted stock purchase rights are exercisable during a specified period, typically thirty days following the grant date, established by the administrator. Like restricted stock bonuses, restricted stock purchase rights are typically subject to such vesting conditions based on continued employment or service or on performance criteria established by the administrator. Restricted stock purchase rights may not be sold or otherwise transferred until vesting conditions are removed or expire. Recipients of restricted stock purchase rights generally will have no dividend rights prior to the time when vesting conditions are satisfied.

Change in Control. In the event of a change in control of the Company, the board of directors may provide that (i) outstanding awards will vest and, if applicable, become exercisable in full, (ii) the acquiror will assume or replace awards granted, awards issued under the 2013 Plan; provided that any such awards that are not assumed or replaced will terminate upon such change in control; or (iii) outstanding awards will be cancelled in exchange for cash or other property.

280G Best Pay Provision. The 2013 Plan includes a Section 280G best pay provision, whereby if any accelerated vesting or other payments or benefits received by a participant in connection with a change in control of the Company would subject a participant to the excise tax under Section 4999 of the Code, the participant may elect to receive either (i) the full amount of such payments and benefits or (ii) a reduced amount of such payments or benefits that will not result in the imposition of the excise tax imposed by Section 4999 of the Code (whichever results in the greater after-tax benefit to the participant).

Adjustments of Awards. In the event of any change in Company common stock effected without receipt of consideration by the Company, the administrator will make appropriate, proportionate adjustments to:

the aggregate number and type of shares subject to the 2013 Plan;

the number and kind of shares subject to outstanding awards; and

the purchase or exercise price per share of any outstanding awards under the 2013 Plan.

Amendment and Termination. Our board of directors may terminate, amend or suspend the 2013 Plan at any time and from time to time. However, we must generally obtain stockholder approval:

to increase the number of shares available under the 2013 Plan (other than in connection with certain corporate events, as described above);

Table of Contents

to change the individuals eligible to receive incentive stock options; or

to the extent required by applicable law, rule or regulation (including any applicable stock exchange rule).

2015 Employee Stock Purchase Plan

In connection with this offering, we will adopt the 2015 Employee Stock Purchase Plan, which we refer to as our ESPP, which will be effective on the effective date of the registration statement of which this prospectus is a part. The ESPP is designed to allow our eligible employees to purchase shares of our common stock, at semi-annual intervals, with their accumulated payroll deductions. The ESPP is intended to qualify under Section 423 of the Code.

Plan Administration. Subject to the terms and conditions of the ESPP, our compensation committee will administer the ESPP. Our compensation committee can delegate administrative tasks under the ESPP to the services of an agent and/or employees to assist in the administration of the ESPP. The administrator will have the discretionary authority to administer and interpret the ESPP. Interpretations and constructions of the administrator of any provision of the ESPP or of any rights thereunder will be conclusive and binding on all persons. We will bear all expenses and liabilities incurred by the ESPP administrator.

Shares Available Under ESPP. The maximum number of our shares of our common stock which will be authorized for sale under the ESPP is equal to the sum of (a) 390,128 shares of common stock and (b) an annual increase on the first day of each year beginning in 2016 and ending in 2025, equal to the lesser of (i) one percent (1.0%) of the shares of common stock outstanding (on an as converted basis) on the last day of the immediately preceding fiscal year and (ii) such number of shares of common stock as determined by our board of directors; provided, however, no more than 8,000,000 shares of our common stock may be issued under the ESPP. The shares made available for sale under the ESPP may be authorized but unissued shares or reacquired shares reserved for issuance under the ESPP.

Eligible Employees. Employees eligible to participate in the ESPP for a given offering period generally include employees who are employed by us or one of our designated subsidiaries on the first day of the offering period, or the enrollment date. Our employees and any employees of our subsidiaries who customarily work less than five months in a calendar year or are customarily scheduled to work less than 20 hours per week will not be eligible to participate in the ESPP. Finally, an employee who owns (or is deemed to own through attribution) 5% or more of the combined voting power or value of all our classes of stock or of one of our subsidiaries will not be allowed to participate in the ESPP.

Participation. Employees will enroll under the ESPP by completing a payroll deduction form permitting the deduction from their compensation of at least 1% of their compensation but not more than the lesser of 15% of their compensation and $30,000 per offering period. Such payroll deductions are expressed as a whole number percentage and the accumulated deductions will be applied to the purchase of shares on each semi-annual purchase date. However, a participant may not purchase more than 10,000 shares in each offering period, and may not subscribe for more than $25,000 in fair market value of shares our common stock (determined at the time the option is granted) per calendar year falling in the offering period. The ESPP administrator has the authority to change these limitations for any subsequent offering period.

Offering. Under the ESPP, participants are offered the option to purchase shares of our common stock at a discount during a series of successive offering periods. The offering periods will commence and end on dates as determined by the ESPP administrator. However, in no event may an offering period be longer than 27 months in length.

132

Table of Contents

The option purchase price will be the lower of 85% of the closing trading price per share of our common stock on the first trading date of an offering period in which a participant is enrolled or 85% of the closing trading price per share on the semi-annual purchase date, which will occur on the last trading day of each offering period.

Unless a participant has previously canceled his or her participation in the ESPP before the purchase date, the participant will be deemed to have exercised his or her option in full as of each purchase date. Upon exercise, the participant will purchase the number of whole shares that his or her accumulated payroll deductions will buy at the option purchase price, subject to the participation limitations listed above.

A participant may cancel his or her payroll deduction authorization at any time prior to the end of the offering period. Upon cancellation, the participant will have the option to either (a) receive a refund of the participant s account balance in cash without interest or (b) exercise the participant s option for the current offering period for the maximum number of shares of common stock on the applicable purchase date, with the remaining account balance refunded in cash without interest. Following at least one payroll deduction, a participant may also decrease (but not increase) his or her payroll deduction authorization once during any offering period. If a participant wants to increase or decrease the rate of payroll withholding, he or she may do so effective for the next offering period by submitting a new form before the offering period for which such change is to be effective.

A participant may not assign, transfer, pledge or otherwise dispose of (other than by will or the laws of descent and distribution) payroll deductions credited to a participant s account or any rights to exercise an option or to receive shares of our common stock under the ESPP, and during a participant s lifetime, options in the ESPP shall be exercisable only by such participant. Any such attempt at assignment, transfer, pledge or other disposition will not be given effect.

Adjustments upon Changes in Recapitalization, Dissolution, Liquidation, Merger or Asset Sale. In the event of any increase or decrease in the number of issued shares of our common stock resulting from a stock split, reverse stock split, stock dividend, combination or reclassification of the common stock or any other increase or decrease in the number of shares of common stock effected without receipt of consideration by us, we will proportionately adjust the aggregate number of shares of our common stock offered under the ESPP, the number and price of shares which any participant has elected to purchase pursuant under the ESPP and the maximum number of shares which a participant may elect to purchase in any single offering period.

If there is a proposal to dissolve or liquidate us, then the ESPP will terminate immediately prior to the consummation of such proposed dissolution or liquidation, and any offering period then in progress will be shortened by setting a new purchase date to take place before the date of our dissolution or liquidation. We will notify each participant of such change in writing at least ten business days prior to the new exercise date. If we undergo a merger with or into another corporation or sale of all or substantially all of our assets, each outstanding option will be assumed or an equivalent option substituted by the successor corporation or the parent or subsidiary of the successor corporation. If the successor corporation refuses to assume the outstanding options or substitute equivalent options, then any offering period then in progress will be shortened by setting a new purchase date to take place before the date of our proposed sale or merger. We will notify each participant of such change in writing at least ten business days prior to the new exercise date.

Amendment and Termination. Our board of directors may amend, suspend or terminate the ESPP at any time. However, the board of directors may not amend the ESPP without obtaining stockholder approval within 12 months before or after such amendment to the extent required by applicable laws. The ESPP will terminate on the 10th anniversary of the date of its initial approval of our stockholders, unless earlier terminated.

We intend to file with the SEC a registration statement on Form S-8 covering our shares issuable under the ESPP.

Table of Contents

Rule 10b5-1 Sales Plans

Our directors and executive officers may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of common stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the director or officer when entering into the plan, without further direction from the director or executive officer. The director or executive officer may amend or terminate the plan in limited circumstances. Our directors and executive officers may also buy or sell additional shares of common stock outside of a Rule 10b5-1 plan when they are not in possession of material, nonpublic information.

Table of Contents

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a description of transactions since January 1, 2012 to which we have been a party, in which the amount involved exceeds $120,000, and in which any of our directors, executive officers or holders of more than 5% of our capital stock, or an affiliate or immediate family member thereof, had or will have a direct or indirect material interest.

Sales and Purchases of Securities

Convertible Promissory Note

In June 2012, we entered into an unsecured convertible promissory note in aggregate principal amount of $750,000 with Food Allergy & Research Education, Inc. The note provided for an annual interest rate of 3% and a due date of December 31, 2013, but could be extended by mutual agreement for an additional year. Under the terms of the note, under certain circumstances, the balance of the note, including any accrued interest, would convert into preferred stock upon the closing of a future preferred stock financing that met specified criteria. Such conversion would be at a 15% discount to the per share price of the preferred stock sold in the financing. In February 2013, as part of the issuance of Series A convertible preferred stock, the note, plus $14,000 of accrued interest converted into 694,364 shares of Series A convertible preferred stock at a rate of $1.10 per share in full payment for the note and accrued interest.

Series A Preferred Stock Financing

In February and April 2013, we issued an aggregate of 13,263,967 shares of our Series A convertible preferred stock at a price per share of either (i) $1.29 in cash or (ii) with respect to 694,364 shares of Series A convertible preferred stock issued to Food Allergy Research & Education, Inc. in exchange for the cancellation by Food Allergy Research & Education, Inc. of a convertible promissory note issued by us, $1.10 in cancellation of indebtedness, for a total amount raised (including the cancellation of indebtedness) of $16.9 million, net of offering costs. The table below sets forth the number of shares of Series A preferred stock sold to our directors, executive officers or owners of more than 5% of a class of our capital stock, or an affiliate or immediate family member thereof:

Name	Number of Shares of Series A Preferred Stock	Purchase Price ($)
Longitude Venture Partners II, L.P.[1]	3,873,530	5,000,001
Sunshine Charitable Foundation	2,711,471	3,500,001
Food Allergy Research & Education, Inc.[2]	2,708,600	3,364,487
Explore Holdings LLC.	2,324,117	3,000,000
Winchester Partners, L.P.[3]	774,705	1,000,000

(1) Mr. Enright, who is a member of our board of directors, is a managing member of Longitude Capital Partners II, LLC, which is the general partner of Longitude Venture Partners II, L.P.

(2)

Food Allergy Research & Education, Inc. was a holder of more than 5% of a class of our capital stock at the time of the Series A convertible preferred stock financing.

(3) Winchester Partners, L.P. was a holder of more than 5% of a class of our capital stock at the time of the Series A convertible preferred stock financing.

Series B Preferred Stock Financing

In January and February 2015, we issued an aggregate of 14,047,996 shares of our Series B convertible preferred stock at a price per share of $5.69, for a total amount raised of $79.8 million, net of offering costs. The

Table of Contents

table below sets forth the number of shares of Series B convertible preferred stock sold to our directors, executive officers or owners of more than 5% of a class of our capital stock, or an affiliate or immediate family member thereof:

Name	Number of Shares of Series B Preferred Stock	Purchase Price ($)
Foresite Capital Fund II, L.P.	3,775,400	21,500,003
Longitude Venture Partners II, L.P.[1]	3,248,600	18,500,003
Aisling Capital III, L.P.	2,195,000	12,500,003
Fidelity Select Portfolios: Biotechnology Portfolio, and its affiliated funds	2,633,999	15,000,000

(1) Longitude Venture Partners II, L.P. was a holder of more than 5% of a class of our capital stock at the time of the Series B convertible preferred stock financing.

Series A Preferred Stock Repurchase

In January 2015, we repurchased an aggregate of 2,260,706 shares of our Series A convertible preferred stock at $5.69 per share for a total amount of $12,874,185, using proceeds from our Series B convertible preferred stock financing. The table below sets forth the number of shares of Series A convertible preferred stock purchased from our directors, executive officers or owners of more than 5% of a class of our capital stock, or an affiliate or immediate family member thereof:

Name	Number of Shares of Series A Preferred Stock	Purchase Price ($)
Food Allergy Research & Education, Inc[1].	1,354,300	7,712,415

(1) Food Allergy Research & Education, Inc. was a holder of more than 5% of a class of our capital stock at the time of the Series A convertible preferred stock repurchase.

Participation in this Offering

Certain of our existing institutional investors, including investors affiliated with certain of our directors, have agreed to purchase an aggregate of 1,562,500 shares of our common stock in this offering at the initial public offering price. Additionally, at our request, the underwriters have reserved approximately 1% of the shares offered by this prospectus for sale, at the initial public offering price, to some of our directors, officers, employees, business associates and related persons in this offering. These purchases will be made on the same terms as the shares that are sold to the public generally and not pursuant to any pre-existing contractual rights or obligations. See the footnotes to the beneficial ownership table in Principal Stockholders for more details.

Consulting Agreements

In February 2015, we entered into a Consulting and Independent Contractor Agreement with Bryan L. Walser, M.D., J.D., a former member of our board of directors, or the 2015 Walser Consulting Agreement, under which Dr. Walser provides certain consulting services to us in connection with the development of additional oral immunotherapy product candidates. Pursuant to the 2015 Walser Consulting Agreement, Dr. Walser is entitled to a consulting fee equal to $300 per hour he provides consulting services to us, which is not to exceed 20 hours per week, as well as reimbursement for ordinary and necessary business expenses incurred in connection with his performance of the consulting services. The 2015 Walser Consulting Agreement includes confidentiality restrictions as well as non-solicit restrictions effective during the term of Dr. Walser s consulting relationship with the Company and for a period of two years thereafter. This agreement terminates on December 31, 2015.

Table of Contents

Indemnification Agreements and Directors and Officers Liability Insurance

We have entered into or intend to enter into indemnification agreements with each of our directors and executive officers. These agreements will require us to, among other things, indemnify each director and executive officer to the fullest extent permitted by Delaware law, including indemnification of expenses such as attorneys fees, judgments, penalties fines and settlement amounts incurred by the director or executive officer in any action or proceeding, including any action or proceeding by or in right of us, arising out of the person s services as a director or executive officer. We have obtained an insurance policy that insures our directors and officers against certain liabilities, including liabilities arising under applicable securities laws. For additional information see Management Limitation of Liability and Indemnification Matters.

Investor Rights Agreements

We entered into an amended and restated investor rights agreement with the purchasers of our outstanding convertible preferred stock, including entities with which certain of our directors are affiliated. As of March 31, 2015, the holders of approximately 25.1 million shares of our common stock, including the shares of common stock issuable upon the conversion of our convertible preferred stock, are entitled to rights with respect to the registration of their shares under the Securities Act. For a more detailed description of these registration rights, see Description of Capital Stock Registration Rights. The investor rights agreement also provides for a right of first refusal in favor of certain holders of convertible preferred stock with regard to certain issuances of our capital stock. The rights of first refusal will not apply to, and will terminate upon the consummation of, this offering.

Voting Agreement

We entered into an amended and restated voting agreement with certain holders of our common stock and convertible preferred stock. Upon the consummation of this offering, the amended and restated voting agreement will terminate. For a description of the amended and restated voting agreement, see Management Board Composition Voting Arrangements.

Right of First Refusal and Co-Sale Agreement

We entered into an amended and restated right of first refusal and co-sale agreement with certain holders of our common stock and convertible preferred stock. This agreement provides for rights of first refusal and co-sale relating to the shares of our common stock held by the parties to the agreement. Upon the consummation of this offering, the amended and restated right of first refusal and co-sale agreement will terminate.

Policies and Procedures for Related Party Transactions

Prior to the consummation of this offering, our board of directors will adopt a written related person transaction policy, to be effective upon the consummation of this offering, setting forth the policies and procedures for the review and approval or ratification of related person transactions. This policy will cover, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships in which we were or are to be a participant, where the amount involved exceeds $120,000 and a related person had or will have a direct or indirect material interest, including without limitation purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our audit committee is tasked to consider all relevant facts and circumstances, including but not limited to whether the transaction is on terms comparable to those that could be

obtained in an arm s length transaction with an unrelated third party and the extent of the related person s interest in the transaction. All of the transactions described in this section occurred prior to the adoption of this policy.

Table of Contents

PRINCIPAL STOCKHOLDERS

The following table sets forth information relating to the beneficial ownership of our common stock as of July 24, 2015, by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our outstanding shares of common stock;
- each of our directors;
- each of our named executive officers; and
- all directors and executive officers as a group.

The number of shares beneficially owned by each entity, person, director or executive officer is determined in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any shares over which the individual has sole or shared voting power or investment power as well as any shares that the individual has the right to acquire within 60 days after July 24, 2015 through the exercise of any stock option, warrants or other rights. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of common stock held by that person.

Certain of our existing institutional investors, including investors affiliated with certain of our directors, have agreed to purchase an aggregate of 1,562,500 shares of our common stock in this offering at the initial public offering price and on the same terms as the other purchasers in this offering. The figures in the table below reflect the purchase of the shares in this offering (based on the initial public offering price of $16.00 per share) by these potential investors in the amounts they have agreed to purchase.

Table of Contents

The percentage of shares beneficially owned is computed on the basis of 30,749,432 shares of our common stock outstanding as of July 24, 2015, which reflects the assumed conversion of all of our outstanding shares of convertible preferred stock into an aggregate of 25,051,257 shares of common stock. Shares of our common stock that a person has the right to acquire within 60 days after July 24, 2015 are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person, except with respect to the percentage ownership of all directors and executive officers as a group. Unless otherwise indicated below, the address for each beneficial owner listed is c/o Aimmune Therapeutics, Inc., 8000 Marina Blvd, Suite 300, Brisbane, CA 94005.

	Beneficial Ownership Prior to this Offering				Beneficial Ownership After this Offering	
Name of Beneficial Owner	**Number of Outstanding Shares Beneficially Owned**	**Number of Shares Exercisable Within 60 Days**	**Number of Shares Beneficially Owned**	**Percentage of Beneficial Ownership**	**Number of Shares Beneficially Owned**	**Percentage of Beneficial Ownership**
5% and Greater Stockholders:						
Longitude Venture Partners II, L.P.[1]	7,122,130	0	7,122,130	23.16%	7,434,630	18.24%
Aisling Capital III, L.P.[2]	2,195,000	0	2,195,000	7.14%	2,820,000	6.92%
Foresite Capital Fund II, L.P.[3]	3,775,400	0	3,775,400	12.28%	4,400,400	10.80%
Entities affiliated with Fidelity Management & Research[4]	2,633,999	0	2,633,999	8.57%	2,633,999	6.46%
Food Allergy Research & Education, Inc.[5]	2,573,744	0	2,573,744	8.37%	2,573,744	6.32%
Explore Holdings LLC[6]	2,324,117	0	2,324,117	7.56%	2,324,117	5.70%
Bryan L. Walser, M.D.[7]	2,206,197	0	2,206,197	7.17%	2,206,197	5.41%
Sunshine Charitable Foundation[8]	2,711,471	0	2,711,471	8.82%	2,711,471	6.65%
Executive Officers and Directors:						
Stephen G. Dilly, M.B.B.S, Ph.D[9]	897,008	595,942	1,492,950	4.76%	1,492,950	3.61%
Patrick G. Enright[10]	7,122,130	118,270	7,240,400	23.46%	7,552,900	18.48%
Kathryn E. Falberg[11]	69,894	0	69,894	*	94,894	*
Mark T. Iwicki[12]	0	139,789	139,789	*	159,789	*
Mark D. McDade[13]	0	104,842	104,842	*	121,502	*
Stacey D. Seltzer[14]	0	52,421	52,421	*	52,421	*
Howard V. Raff, Ph.D.[15]	428,575	98,775	527,350	1.71%	527,350	1.29%
Robert M. Elfont, M.D., Ph.D.[16]	299,002	26,340	325,342	1.06%	325,342	*
All executive officers and directors as a group (10 persons)[17]	8,816,609	1,835,329	10,651,938	32.69%	11,026,098	25.89%

* Indicates beneficial ownership of less than 1% of the total outstanding common stock.

(1) Consists of (a) 3,873,530 shares of common stock issuable upon conversion of Series A convertible preferred stock and (b) 3,248,600 shares of common stock issuable upon conversion of Series B convertible preferred stock. The number of shares beneficially owned after this offering also includes 312,500 shares that the holder has agreed to purchase in this offering. Longitude Capital Partners II, LLC (Longitude Capital II) is the general partner of Longitude Venture Partners II, L.P. (Longitude Venture II). Longitude Capital II and Longitude Venture II may be deemed to have sole voting, investment and dispositive power over the shares held by Longitude Venture II. Patrick G. Enright and Juliett Tammenoms Bakker are the managing members of Longitude Capital II and in their capacity as such, may be deemed to exercise shared voting and investment power with respect to such shares. Each of Ms. Bakker and Mr. Enright disclaim beneficial ownership of such shares except to the extent of his or her pecuniary interest therein. The address of Longitude Venture Partners II, L.P. is 800 El Camino Real, Suite 220, Menlo Park, CA 94025.

(2) Consists of 2,195,000 shares of common stock issuable upon conversion of Series B convertible preferred stock. The number of shares beneficially owned after this offering also includes 625,000 shares that the holder has agreed to

purchase in this offering. Aisling Capital Partners III LLC (Aisling Capital III) is the general partner of Aisling Capital III, L.P. Steve Elms, Dennis J. Purcell and Andrew N. Schiff are the managing members of Aisling Capital III and in their capacity as such, may be deemed to have shared voting and investment power with respect to such shares. Each Mssrs. Elms, Pucell and Schiff disclaim beneficial ownership of such shares except to the extent of his pecuniary interest therein. The address of Aisling Capital III, L.P. is 888 Seventh Avenue, 30th Floor, New York, NY 10106.

(3) Consists of 3,775,400 shares of common stock issuable upon conversion of Series B convertible preferred stock. The number of shares beneficially owned after this offering also includes 625,000 shares that the holder has agreed to purchase in this offering, it will beneficially own 3,775,400 shares, or approximately 9.66% of the total outstanding common stock, after this offering. Foresite Capital Management II, LLC (Foresite Management II) is the general partner of Foresite Capital Fund II, L.P. (Foresite Capital II). Foresite Management II may be deemed to have sole voting, investment and dispositive power over the shares held by Foresite Capital II. James Tananbaum is the managing member of Foresite Management II and in his capacity as such, may be deemed to exercise sole voting and investment power with respect to such shares. The address of Foresite Capital Fund II, L.P. is 101 California Street, Suite 4100, San Francisco, CA 94111.

(4) Consists of (a) 2,173,892 shares of common stock issuable upon conversion of Series B convertible preferred stock held by Fidelity Select Portfolios: Biotechnology Portfolio (Fidelity Select Portfolios) and (b) 460,107 shares of common stock issuable upon conversion of Series B convertible preferred stock held by Fidelity Advisor Series VII: Fidelity Advisory Biotechnology Fund (Fidelity Advisors, and, together with Fidelity Select Portfolios, the Fidelity Investments). The Fidelity Investments are managed by direct or indirect subsidiaries of Fidelity Management and Research LLC (FMR LLC). Edward C. Johnson 3d is a Director and the Chairman of FMR LLC and Abigail P. Johnson is a Director, the Vice Chairman and the President of FMR LLC. Members of the family of Edward C. Johnson 3d, including Abigail P. Johnson, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other Series B shareholders have entered into a shareholders voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR LLC. Neither FMR LLC nor Edward C. Johnson 3d nor Abigail P. Johnson has the sole power to vote or direct the voting of the shares owned directly by the various investment companies registered under the Investment Company Act (Fidelity Funds) advised by Fidelity Management & Research Company (FMR Co), a wholly owned subsidiary of FMR LLC, which power resides with the Fidelity Funds Boards of Trustees. Fidelity Management & Research Company carries out the voting of the shares under written guidelines established by the Fidelity Funds Boards of Trustees. The address of entities affiliated with Fidelity Investments is 245 Summer Street, Boston, MA 02110.

(5) Consists of (a) 1,219,444 shares of common stock and (b) 1,354,300 shares of common stock issuable on conversion of Series A Preferred Stock. The Board of Directors of Food Allergy Research & Education, Inc. (FARE) has sole voting, investment and dispositive power over such shares. The address of FARE is 7925 Jones Branch Dr. Suite 1100 McLean, VA 22102.

(6)

Consists of 2,324,117 shares of common stock issuable upon conversion of Series A convertible preferred stock. Paul Dauber is the manager of Explore Holdings LLC and, in his capacity as such, may be deemed to have sole voting and investment power over such shares. The address of Explore Holdings LLC is Post Office Box 94314, Seattle, WA 98124.

(7) Consists of (a) 1,679,397 shares of common stock held by Dr. Walser individually, (b) 263,400 shares of common stock held by Bryan L. Walser, as Trustee of The Bryan L. Walser 2015 Grantor Retained Annuity Trust dated June 29, 2015 (The Bryan Walser Trust) and (c) 263,400 shares of common stock held by Bianca M. Walser, as Trustee of The Bianca M. Walser 2015 Grantor Retained Annuity Trust dated June 29, 2015 (The Bianca Walser Trust). Dr. Walser has sole voting, investment and dispositive power over the shares held by The Bryan Walser Trust. Ms. Walser has sole voting, investment and dispositive power over the shares held by The Bianca Walser Trust.

(8) Consists of 2,711,471 shares of common stock issuable upon conversion of Series A convertible preferred stock. The Board of Directors of Sunshine Charitable Foundation has sole voting, investment and dispositive power over such shares. The address of Sunshine Charitable Foundation is 225 East Deepath Road, Suite 210, Lake Forest, IL 60045.

(9) Consists of (a) 897,008 shares of common stock, of which 387,524 are subject to repurchase as of July 24, 2015, and (b) 595,942 shares of common stock that may be acquired pursuant to the exercise of stock options within 60 days of July 24, 2015. Of such 897,008 shares of common stock, (x) 765,308 shares are held by Dr. Dilly individually, (y) 65,850 shares are held by Stephen G. Dilly, as Trustee of The Stephen G. Dilly 2015 Grantor Retained Annuity Trust dated June 23, 2015 (The Dilly Trust) and (z) 65,850 shares are held by Edwina Lynette Mullens, as Trustee of The

Edwina Lynette Mullens 2015 Grantor Retained Annuity Trust dated June 23, 2015 (The Mullens Trust). Dr. Dilly has sole voting, investment and dispositive power over the shares held by The Dilly Trust. Ms. Mullens has sole voting, investment and dispositive power over the shares held by The Mullens Trust.

(10) Consists of (a) 118,270 shares of common stock that may be acquired pursuant to the exercise of stock options within 60 days of July 24, 2015, and (b) the securities beneficially owned by Longitude Venture Partners II, L.P. as set forth in footnote (1). The number of shares beneficially owned after this offering also includes 312,500 shares that Longitude Venture Partners II, L.P. has agreed to purchase in this offering. Mr. Enright disclaims beneficial ownership of the shares listed in footnote (1), except to the extent of his pecuniary interest therein.

(11) Consists of 94,894 shares of common stock, of which 61,158 shares were subject to repurchase as of July 24, 2015. The number of shares beneficially owned after this offering also includes 25,000 shares that the holder has agreed to purchase in this offering.

(12) Consists of 159,789 shares of common stock that may be acquired pursuant to the exercise of stock options within 60 days of July 24, 2015. The number of shares beneficially owned after this offering also includes 20,000 shares that the holder has agreed to purchase in this offering.

(13) Consists of 121,502 shares of common stock that may be acquired pursuant to the exercise of stock options within 60 days of July 24, 2015. The number of shares beneficially owned after this offering also includes 16,660 shares that the holder has agreed to purchase in this offering.

(14) Consists of 52,421 shares of common stock that may be acquired pursuant to the exercise of stock options within 60 days of July 24, 2015.

(15) Consists of (a) 428,575 shares of common stock held by Howard V. Raff, Trustee, and any successor trustee, of the Howard V. Raff Revocable Trust dated March 28, 2014 (The Raff Trust), of which 107,144 shares were subject to repurchase as of July 24, 2015 and (b) 98,775 shares of common stock that may be acquired pursuant to the exercise of stock options within 60 days of July 24, 2015. Dr. Raff has sole voting, investment and dispositive power over the shares held by The Raff Trust.

(16) Consists of (a) 299,002 shares of common stock, of which 199,335 shares were subject to repurchase as of July 24, 2015 and (b) 26,340 shares of common stock that may be acquired pursuant to the exercise of stock options within 60 days of July 24, 2015.

(17) Includes 1,756,139 shares of common stock and 7,434,630 shares of common stock issuable upon the conversion of shares of preferred stock, of which 755,161 shares were subject to repurchase as of July 24, 2015, and 1,835,329 shares of common stock issuable upon the exercise of stock options within 60 days of July 24, 2015. The number of shares beneficially owned after this offering also includes 61,660 shares that certain directors of the Company have agreed to purchase in this offering and 312,500 shares Longitude Venture Partners II, L.P. has

agreed to purchase in this offering.

Table of Contents

DESCRIPTION OF CAPITAL STOCK

The following summary describes our capital stock and the material provisions of our amended and restated certificate of incorporation and our amended and restated bylaws, which will become effective immediately prior to the consummation of this offering, the investor rights agreement to which we and certain of our stockholders are parties and of the Delaware General Corporation Law. Because the following is only a summary, it does not contain all of the information that may be important to you. For a complete description, you should refer to our amended and restated certificate of incorporation, amended and restated bylaws and amended and restated investor rights agreement, copies of which have been filed as exhibits to the registration statement of which this prospectus is a part.

General

Immediately prior to the consummation of this offering, we will file our amended and restated certificate of incorporation that authorizes 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. As of March 31, 2015, there were outstanding:

- 30,679,538 shares of our common stock, on an as-converted basis, held by approximately 25 stockholders of record; and
- 189,853 shares of our common stock issuable upon exercise of outstanding stock options.

In connection with this offering, we will consummate a 1-for-1.317 stock split of our outstanding common stock and preferred stock which we have effected.

Common Stock

Voting Rights

Each holder of our common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Our stockholders do not have cumulative voting rights in the election of directors. Accordingly, holders of a majority of the voting shares are able to elect all of the directors. In addition, the affirmative vote of holders of 66 ⅔% of the voting power of all of the then outstanding voting stock will be required to take certain actions, including amending certain provisions of our amended and restated certificate of incorporation, such as the provisions relating to amending our amended and restated bylaws, the classified board and director liability.

Dividends

Subject to preferences that may be applicable to any then outstanding preferred stock, holders of our common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other

liabilities and the satisfaction of any liquidation preference granted to the holders of any then outstanding shares of preferred stock.

Table of Contents

Rights and Preferences

Holders of our common stock have no preemptive, conversion, subscription or other rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of our preferred stock that we may designate in the future.

Fully Paid and Nonassessable

All of our outstanding shares of common stock are, and the shares of common stock to be issued in this offering will be, fully paid and nonassessable.

Preferred Stock

Immediately prior to the consummation of this offering, all outstanding shares of our convertible preferred stock will be converted into shares of our common stock. See Note 6 to our unaudited interim condensed financial statements included elsewhere in this prospectus for a description of our currently outstanding convertible preferred stock. Immediately prior to the consummation of this offering, our amended and restated certificate of incorporation will be amended and restated to delete all references to such shares of convertible preferred stock. From and after the consummation of this offering, our board of directors will have the authority, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of common stock. The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of our company or other corporate action. Immediately after consummation of this offering, no shares of preferred stock will be outstanding, and we have no present plan to issue any shares of preferred stock.

Registration Rights

Under our amended and restated investor rights agreement, following the consummation of this offering, the holders of approximately 25.1 million shares of common stock, or their transferees, have the right to require us to register their shares under the Securities Act so that those shares may be publicly resold, or to include their shares in any registration statement we file, in each case as described below.

Demand Registration Rights

Based on the number of shares outstanding as of March 31, 2015, after the consummation of this offering, the holders of approximately 25.1 million shares of our common stock (on an as-converted basis), or their transferees, will be entitled to certain demand registration rights. Beginning one hundred eighty (180) days following the effectiveness of the registration statement of which this prospectus is a part, the holders of at least fifty percent (50%) of these shares can, on not more than two occasions, request that we register all or a portion of their shares if the aggregate price to the public of the shares offered is at least $3,000,000. Additionally, we will not be required to effect a demand registration during the period beginning 90 days prior to the filing and ending 180 days following the effectiveness of a company-initiated registration statement relating to an initial public offering of our securities.

143

Table of Contents

Piggyback Registration Rights

Based on the number of shares outstanding as of March 31, 2015, after the consummation of this offering, in the event that we determine to register any of our securities under the Securities Act (subject to certain exceptions), either for our own account or for the account of other security holders, the holders of approximately 25.1 million shares of our common stock (on an as-converted basis), or their transferees, will be entitled to certain piggyback registration rights allowing the holders to include their shares in such registration, subject to certain marketing and other limitations. As a result, whenever we propose to file a registration statement under the Securities Act, other than with respect to a registration related to employee benefit plans, the offer and sale of debt securities, or corporate reorganizations or certain other transactions, the holders of these shares are entitled to notice of the registration and have the right, subject to limitations that the underwriters may impose on the number of shares included in the registration, to include their shares in the registration. In an underwritten offering, the managing underwriter, if any, has the right, subject to specified conditions, to limit the number of shares such holders may include.

Form S-3 Registration Rights

Based on the number of shares outstanding as of March 31, 2015, after the consummation of this offering, the holders of approximately 25.1 million shares of our common stock (on an as-converted basis), or their transferees, will be entitled to certain Form S-3 registration rights. The holders of any of at least twenty five percent (25%) of these shares can make a written request that we register their shares on Form S-3 if we are eligible to file a registration statement on Form S-3 and if the aggregate price to the public of the shares offered is at least $1,000,000 net of certain expenses related to the sale of the shares. These stockholders may make an unlimited number of requests for registration on Form S-3, but in no event shall we be required to file more than two registrations on Form S-3 in any given calendar year.

Expenses of Registration

We will pay the registration expenses of the holders of the shares registered pursuant to the demand, piggyback and Form S-3 registration rights described above, including the expenses in an amount not to exceed $25,000 of one counsel for the selling holders.

Expiration of Registration Rights

The demand, piggyback and Form S-3 registration rights described above will expire, with respect to any particular stockholder, upon the earlier of five years after the consummation of this offering or when that stockholder can sell all of its shares under Rule 144 of the Securities Act during any three-month period.

Anti-Takeover Effects of Provisions of our Amended and Restated Certificate of Incorporation, our Amended and Restated Bylaws and Delaware Law

Some provisions of Delaware law and our amended and restated certificate of incorporation and our amended and restated bylaws that will become effective immediately prior to the consummation of this offering contain provisions that could make the following transactions more difficult: acquisition of us by means of a tender offer; acquisition of us by means of a proxy contest or otherwise; or removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions that might result in a premium over the market price for our shares.

These provisions, summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of increased protection of our

potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Delaware Anti-Takeover Statute

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits persons deemed interested stockholders from engaging in a business combination with a publicly-held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an interested stockholder is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation s voting stock. Generally, a business combination includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors, such as discouraging takeover attempts that might result in a premium over the market price of our common stock.

Undesignated Preferred Stock

The ability to authorize undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of us. These and other provisions may have the effect of deterring hostile takeovers or delaying changes in control or management of our company.

Special Stockholder Meetings

Our amended and restated bylaws provide that a special meeting of stockholders may be called at any time by the board of directors, but such special meetings may not be called by the stockholders or any other person or persons.

Requirements for Advance Notification of Stockholder Nominations and Proposals

Our amended and restated bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

Elimination of Stockholder Action by Written Consent

Our amended and restated certificate of incorporation eliminates the right of stockholders to act by written consent without a meeting.

Classified Board; Election and Removal of Directors; Filling Vacancies

Effective upon consummation of this offering, our board of directors will be divided into three classes. The directors in each class will serve for a three-year term, one class being elected each year by our stockholders, with staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Because our stockholders do not have cumulative voting rights, our stockholders holding a majority of the shares of common stock outstanding will be able to elect all of our directors. Our amended and restated certificate of incorporation provides for the removal of any of

our directors only for cause and requires a stockholder vote by the holders of at least a 66 2/3% of the voting power of the then outstanding voting stock. For more information on the classified board, see Management Board Composition. Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of the board, may only be

Table of Contents

filled by a resolution of the board of directors unless the board of directors determines that such vacancies shall be filled by the stockholders. This system of electing and removing directors and filling vacancies may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

Choice of Forum

Our amended and restated certificate of incorporation will provide that the Court of Chancery of the State of Delaware will be 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. Although our amended and restated certificate of incorporation contains the choice of forum provision described above, it is possible that a court could find that such a provision is inapplicable for a particular claim or action or that such provision is unenforceable.

Amendment of Charter Provisions

The amendment of any of the above provisions, except for the provision making it possible for our board of directors to issue undesignated preferred stock, would require approval by a stockholder vote by the holders of at least a 66 ⅔% of the voting power of the then outstanding voting stock.

The provisions of the Delaware General Corporation Law, our amended and restated certificate of incorporation and our amended and restated bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Limitations of Liability and Indemnification Matters

For a discussion of liability and indemnification, see Management Limitation on Liability and Indemnification Matters.

Listing

Our common stock has been approved for listing on The NASDAQ Global Select Market under the symbol AIMT.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Wells Fargo Shareowner Services. The transfer agent and registrar s address is 1110 Centre Pointe Curve, Mendota Heights, Minnesota 55120.

Table of Contents

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock. Future sales of our common stock, including shares issued upon the exercise of outstanding options or warrants, in the public market after this offering, or the perception that those sales may occur, could cause the prevailing market price for our common stock to fall or impair our ability to raise equity capital in the future. As described below, only a limited number of shares of our common stock will be available for sale in the public market for a period of several months after consummation of this offering due to contractual and legal restrictions on resale described below. Future sales of our common stock in the public market either before (to the extent permitted) or after restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price of our common stock at such time and our ability to raise equity capital at a time and price we deem appropriate.

Sale of Restricted Shares

Based on the number of shares of our common stock outstanding as of March 31, 2015 and an initial public offering price of $16.00 per share, upon the consummation of this offering and assuming (1) the conversion of our outstanding convertible preferred stock into 25,051,257 shares of common stock, (2) no exercise of the underwriters option to purchase additional shares of common stock and (3) no exercise of any of our other outstanding options, we will have outstanding an aggregate of approximately 40,679,538 shares of common stock. Of these shares, all of the shares of common stock to be sold in this offering, and any shares sold upon exercise of the underwriters option to purchase additional shares, will be freely tradable in the public market without restriction or further registration under the Securities Act, unless the shares are held by any of our affiliates as such term is defined in Rule 144 of the Securities Act. All remaining shares of common stock held by existing stockholders immediately prior to the consummation of this offering will be restricted securities as such term is defined in Rule 144. These restricted securities were issued and sold by us, or will be issued and sold by us, in private transactions and are eligible for public sale only if registered under the Securities Act or if they qualify for an exemption from registration under the Securities Act, including the exemptions provided by Rule 144 or Rule 701, which rules are summarized below.

As a result of the lock-up agreements referred to below and the provisions of Rule 144 and Rule 701 under the Securities Act, based on the number of shares of our common stock outstanding as of March 31, 2015 and assumptions (1) (3) described above, the shares of our common stock (excluding the shares sold in this offering) that will be available for sale in the public market are as follows:

Approximate Number of Shares	First Date Available for Sale into Public Market
31,106,458 shares	180 days after the date of this prospectus upon expiration of the lock-up agreements referred to below, subject in some cases to applicable volume limitations under Rule 144

Lock-Up Agreements

In connection with this offering, we, our directors, our executive officers and substantially all of our other stockholders and option holders have agreed, subject to certain exceptions, with the underwriters not to dispose of or hedge any shares of our common stock or securities convertible into or exchangeable for shares of common stock during the period from the date of the lock-up agreement continuing through the date 180 days after the date of this prospectus, except with the prior written consent of Merrill, Lynch, Pierce, Fenner & Smith Incorporated and Credit Suisse Securities (USA) LLC.

Prior to the consummation of the offering, certain of our employees, including our executive officers, and/or directors may enter into written trading plans that are intended to comply with Rule 10b5-1 under the Exchange Act. Sales under these trading plans would not be permitted until the expiration of the lock-up agreements relating to the offering described above.

Table of Contents

Following the lock-up periods set forth in the agreements described above, and assuming that the representatives of the underwriters do not release any parties from these agreements, all of the shares of our common stock that are restricted securities or are held by our affiliates as of the date of this prospectus will be eligible for sale in the public market in compliance with Rule 144 under the Securities Act.

Rule 144

In general, under Rule 144, as currently in effect, once we have been subject to the public company reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, for at least 90 days, a person (or persons whose shares are required to be aggregated) who is not deemed to have been one of our affiliates for purposes of Rule 144 at any time during the three months preceding a sale, and who has beneficially owned restricted securities within the meaning of Rule 144 for at least six months, including the holding period of any prior owner other than one of our affiliates, is entitled to sell those shares in the public market (subject to the lock-up agreement referred to above, if applicable) without complying with the manner of sale, volume limitations or notice provisions of Rule 144, but subject to compliance with the public information requirements of Rule 144. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than affiliates, then such person is entitled to sell such shares in the public market without complying with any of the requirements of Rule 144 (subject to the lock-up agreement referred to above, if applicable). In general, under Rule 144, as currently in effect, once we have been subject to the public company reporting requirements of the Exchange Act for at least 90 days, our affiliates, as defined in Rule 144, who have beneficially owned the shares proposed to be sold for at least six months are entitled to sell in the public market, upon expiration of any applicable lock-up agreements and within any three-month period, a number of those shares of our common stock that does not exceed the greater of:

- 1% of the number of common shares then outstanding, which will equal approximately 406,795 shares of common stock immediately after this offering (calculated as of March 31, 2015 on the basis of the assumptions (1) (3) described above); or
- the average weekly trading volume of our common stock on The NASDAQ Global Select Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Such sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to certain manner of sale provisions, notice requirements and to the availability of current public information about us. Notwithstanding the availability of Rule 144, the holders of substantially all of our restricted securities have entered into lock-up agreements as referenced above and their restricted securities will become eligible for sale (subject to the above limitations under Rule 144) upon the expiration of the restrictions set forth in those agreements.

Rule 701

In general, under Rule 701 as currently in effect, any of our employees, directors, officers, consultants or advisors who acquired common stock from us in connection with a written compensatory stock or option plan or other written agreement in compliance with Rule 701 under the Securities Act before the effective date of the registration statement of which this prospectus is a part (to the extent such common stock is not subject to a lock-up agreement) is entitled to rely on Rule 701 to resell such shares beginning 90 days after we become subject to the public company reporting requirements of the Exchange Act in reliance on Rule 144, but without compliance with the holding period requirements contained in Rule 144. Accordingly, subject to any applicable lock-up agreements, beginning 90 days

after we become subject to the public company reporting requirements of the Exchange Act, under Rule 701 persons who are not our affiliates, as defined in Rule 144, may resell those shares without complying with the minimum holding period or public information requirements of Rule 144, and persons who are our affiliates may resell those shares without compliance with Rule 144 s minimum holding period requirements (subject to the terms of the lock-up agreement referred to below, if applicable).

Table of Contents

Registration Rights

Based on the number of shares outstanding as of March 31, 2015, after the consummation of this offering, the holders of approximately 25.1 million shares of our common stock, or their transferees, will, subject to any lock-up agreements they have entered into, be entitled to certain rights with respect to the registration of the offer and sale of those shares under the Securities Act. For a description of these registration rights, see Description of Capital Stock Registration Rights. If the offer and sale of these shares are registered, they will be freely tradable without restriction under the Securities Act.

Stock Plans

We intend to file with the SEC a registration statement under the Securities Act covering the shares of common stock that we may issue upon exercise of outstanding options reserved for issuance under our 2013 Stock Plan and our 2015 Equity Incentive Annual Plan, as well as shares reserved for issuance under our Employee Stock Purchase Plan. Such registration statement is expected to be filed and become effective as soon as practicable after the consummation of this offering. Accordingly, shares registered under such registration statement will be available for sale in the open market following its effective date, subject to Rule 144 volume limitations and the lock-up agreements described above, if applicable.

Table of Contents

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following discussion is a summary of the material U.S. federal income tax consequences to Non-U.S. Holders (as defined below) of the purchase, ownership and disposition of our common stock issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax effects. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local or non-U.S. tax laws are not discussed. This discussion is based on the U.S. Internal Revenue Code of 1986, as amended (the Code), Treasury Regulations promulgated thereunder, judicial decisions and published rulings and administrative pronouncements of the U.S. Internal Revenue Service (the IRS), in each case in effect as of the date hereof. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a Non-U.S. Holder. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position to that discussed below regarding the tax consequences of the purchase, ownership and disposition of our common stock.

This discussion is limited to Non-U.S. Holders that hold our common stock as a capital asset within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a Non-U.S. Holder s particular circumstances, including the impact of the Medicare contribution tax on net investment income. In addition, it does not address consequences relevant to Non-U.S. Holders subject to special rules, including, without limitation:

- U.S. expatriates and former citizens or long-term residents of the United States;
- persons subject to the alternative minimum tax;
- persons holding our common stock as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies and other financial institutions;
- brokers, dealers or traders in securities;
- controlled foreign corporations, passive foreign investment companies, and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;

persons deemed to sell our common stock under the constructive sale provisions of the Code; and

tax-qualified retirement plans.

If an entity treated as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Accordingly, partnerships holding our common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR

Table of Contents

SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.

Definition of a Non-U.S. Holder

For purposes of this discussion, a Non-U.S. Holder is any beneficial owner of our common stock that is neither a U.S. person nor an entity treated as a partnership for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (1) is subject to the primary supervision of a U.S. court and all substantial decisions of which are controlled by one or more United States persons (within the meaning of Section 7701(a)(30) of the Code), or (2) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

Distributions

As described in the section entitled Dividend Policy, we do not anticipate paying any cash dividends in the foreseeable future. However, if we do make distributions of cash or property on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a Non-U.S. Holder s adjusted tax basis in its common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described below under Sale or Other Taxable Disposition.

Subject to the discussion below on effectively connected income, dividends paid to a Non-U.S. Holder will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty, provided the Non-U.S. Holder furnishes a valid IRS Form W-8BEN or W-8BEN-E (or other applicable documentation) certifying qualification for the lower treaty rate). A Non-U.S. Holder that does not timely furnish the required documentation, but that qualifies for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

If dividends paid to a Non-U.S. Holder are effectively connected with the Non-U.S. Holder s conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such dividends are attributable), the Non-U.S. Holder will be

exempt from the U.S. federal withholding tax described above. To claim the exemption, the Non-U.S. Holder must furnish to the applicable withholding agent a valid IRS Form W-8ECI, certifying that the dividends are effectively connected with the Non-U.S. Holder s conduct of a trade or business within the United States.

Any such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular graduated rates. A Non-U.S. Holder that is a corporation also may be subject to a branch

Table of Contents

profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected dividends, as adjusted for certain items. Non-U.S. Holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

Sale or Other Taxable Disposition

Subject to the discussion below regarding FATCA, a Non-U.S. Holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other taxable disposition of our common stock unless:

- the gain is effectively connected with the Non-U.S. Holder s conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such gain is attributable);
- the Non-U.S. Holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- our common stock constitutes a U.S. real property interest (USRPI) by reason of our status as a U.S. real property holding corporation (USRPHC) for U.S. federal income tax purposes.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular graduated rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items.

Gain described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty), which may be offset by certain U.S. source capital losses of the Non-U.S. Holder (even though the individual is not considered a resident of the United States), provided the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we currently are not, and do not anticipate becoming, a USRPHC. Because the determination of whether we are a USRPHC depends, however, on the fair market value of our USRPIs relative to the fair market value of our non-U.S. real property interests and our other business assets, there can be no assurance we currently are not a USRPHC or will not become one in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition by a Non-U.S. Holder of our common stock will not be subject to U.S. federal income tax if our common stock is regularly traded, as defined by applicable Treasury Regulations, on an established securities market, and such Non-U.S. Holder owned, actually and constructively, 5% or less of our common stock throughout the shorter of the five-year period ending on the date of the sale or other taxable disposition or the Non-U.S. Holder s holding period.

Non-U.S. Holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

Information Reporting and Backup Withholding

Payments of dividends on our common stock will not be subject to backup withholding, provided the applicable withholding agent does not have actual knowledge or reason to know the holder is a United States person and the holder either certifies its non-U.S. status, such as by furnishing a valid IRS Form W-8BEN, W-8BEN-E or W-8ECI, or otherwise establishes an exemption. However, information returns are required to be filed with the IRS in connection with any dividends on our common stock paid to the Non-U.S. Holder, regardless of whether any tax was actually withheld. In addition, proceeds of the sale or other taxable disposition

Table of Contents

of our common stock within the United States or conducted through certain U.S.-related brokers generally will not be subject to backup withholding or information reporting, if the applicable withholding agent receives the certification described above and does not have actual knowledge or reason to know that such holder is a United States person, or the holder otherwise establishes an exemption. Proceeds of a disposition of our common stock conducted through a non-U.S. office of a non-U.S. broker that does not have certain enumerated relationships with the United States generally will not be subject to backup withholding or information reporting.

Copies of information returns that are filed with the IRS may also be made available under the provisions of an applicable treaty or agreement to the tax authorities of the country in which the Non-U.S. Holder resides or is established.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a Non-U.S. Holder s U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

Additional Withholding Tax on Payments Made to Foreign Accounts

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code (such Sections commonly referred to as the Foreign Account Tax Compliance Act, or FATCA) on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax will be imposed on dividends on, or gross proceeds from the sale or other disposition on or after January 1, 2017 of, our common stock paid to a foreign financial institution or a non-financial foreign entity (each as defined in the Code), unless (1) the foreign financial institution undertakes certain diligence and reporting obligations, (2) the non-financial foreign entity either certifies it does not have any substantial United States owners (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (3) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in (1) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain specified United States persons or United States-owned foreign entities (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules.

Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our common stock.

Table of Contents

UNDERWRITING

Merrill Lynch, Pierce, Fenner & Smith Incorporated and Credit Suisse Securities (USA) LLC are acting as representatives of each of the underwriters named below. Subject to the terms and conditions set forth in an underwriting agreement among us and the underwriters, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of shares of common stock set forth opposite its name below.

Underwriter	Number of Shares
Merrill Lynch, Pierce, Fenner & Smith Incorporated	4,250,000
Credit Suisse Securities (USA) LLC	3,750,000
Piper Jaffray & Co.	2,000,000
Total	10,000,000

Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated.

Certain of our existing investors, including investors affiliated with certain of our directors, have agreed to purchase 1,562,500 shares of our common stock in this offering at the initial public offering price and on the same terms as the shares that are sold to the public generally and not pursuant to any pre-existing contractual rights or obligations. Whether or not these investors purchase any or all of the shares will not affect the underwriters commitment to purchase the common shares offered by us.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, including the validity of the shares, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officer s certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Commissions and Discounts

The representatives have advised us that the underwriters propose initially to offer the shares to the public at the public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of $0.672 per share. After the initial offering, the public offering price, concession or any other term of the offering may be changed.

The following table shows the public offering price, underwriting discount and proceeds before expenses to us. The information assumes either no exercise or full exercise by the underwriters of their option to purchase additional shares.

	Per Share	Without Option	With Option
Public offering price	$ 16.00	$ 160,000,000	$ 183,999,984
Underwriting discount	$ 1.12	$ 11,200,000	$ 12,879,999
Proceeds, before expenses, to the Company	$ 14.88	$ 148,800,000	$ 171,119,985

Table of Contents

The expenses of the offering, not including the underwriting discount, are estimated at $3.5 million and are payable by us. We have agreed to reimburse the underwriters for expenses of $35,000 relating to the clearance of this offering with the Financial Industry Regulatory Authority.

Option to Purchase Additional Shares

We have granted an option to the underwriters, exercisable for 30 days after the date of this prospectus, to purchase up to 1,499,999 additional shares at the public offering price, less the underwriting discount. If the underwriters exercise this option, each will be obligated, subject to conditions contained in the underwriting agreement, to purchase a number of additional shares proportionate to that underwriter s initial amount reflected in the above table.

Reserved Share Program

At our request, the underwriters have reserved approximately 1% of the shares offered by this prospectus for sale, at the initial public offering price, to some of our directors, officers, employees, business associates and related persons in this offering.

No Sales of Similar Securities

We, our executive officers and directors and our other existing security holders have agreed not to sell or transfer any common stock or securities convertible into, exchangeable for, exercisable for, or repayable with common stock, for 180 days after the date of this prospectus without first obtaining the written consent of Merrill, Lynch, Pierce, Fenner & Smith Incorporated and Credit Suisse Securities (USA) LLC. Specifically, we and these other persons have agreed, with certain limited exceptions, not to directly or indirectly:

offer, pledge, sell or contract to sell any common stock,

sell any option or contract to purchase any common stock,

purchase any option or contract to sell any common stock,

grant any option, right or warrant for the sale of any common stock,

lend or otherwise dispose of or transfer any common stock,

request or demand that we file a registration statement related to the common stock, or

enter into any swap or other agreement that transfers, in whole or in part, the economic consequence of ownership of any common stock whether any such swap or transaction is to be settled by delivery of shares or other securities, in cash or otherwise.

This lock-up provision applies to common stock and to securities convertible into or exchangeable or exercisable for or repayable with common stock. It also applies to common stock owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition.

The NASDAQ Global Select Market Listing

Our common stock has been approved for listing on The NASDAQ Global Select Market, subject to notice of issuance, under the symbol AIMT.

Table of Contents

Before this offering, there has been no public market for our common stock. The initial public offering price was determined through negotiations between us and the representatives. In addition to prevailing market conditions, the factors to be considered in determining the initial public offering price are

- the valuation multiples of publicly traded companies that the representatives believe to be comparable to us,
- our financial information,
- the history of, and the prospects for, our company and the industry in which we compete,
- an assessment of our management, its past and present operations and the prospects for, and timing of, our future revenues,
- the present state of our development, and
- the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

An active trading market for the shares may not develop. It is also possible that after the offering the shares will not trade in the public market at or above the initial public offering price.

The underwriters do not expect to sell more than 5% of the shares in the aggregate to accounts over which they exercise discretionary authority.

Price Stabilization, Short Positions and Penalty Bids

Until the distribution of the shares is completed, SEC rules may limit underwriters and selling group members from bidding for and purchasing our common stock. However, the representatives may engage in transactions that stabilize the price of the common stock, such as bids or purchases to peg, fix or maintain that price.

In connection with the offering, the underwriters may purchase and sell our common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering. Covered short sales are sales made in an amount not greater than the underwriters option to purchase additional shares described above. The underwriters may close out any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option granted to them. Naked short sales are sales in excess of such option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in

the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of shares of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Table of Contents

Similar to other purchase transactions, the underwriters purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. The underwriters may conduct these transactions on The NASDAQ Global Select Market, in the over-the-counter market or otherwise.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor any of the underwriters make any representation that the representatives will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

Electronic Distribution

In connection with the offering, certain of the underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail.

Other Relationships

Some of the underwriters and their affiliates have engaged in, and may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. They have received, or may in the future receive, customary fees and commissions for these transactions.

In addition, in the ordinary course of their business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Notice to Prospective Investors in the European Economic Area

In relation to each Member State of the European Economic Area (each, a Relevant Member State), no offer of shares may be made to the public in that Relevant Member State other than:

A. to any legal entity which is a qualified investor as defined in the Prospectus Directive;

B. to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives; or

C. in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of shares shall require the Company or the representatives to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

Each person in a Relevant Member State who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed that it is a qualified investor within the meaning of the law in that Relevant Member State implementing Article 2(1)(e) of the Prospectus Directive. In the case of any shares being offered to a financial intermediary as that term is used in Article 3(2) of the Prospectus

Table of Contents

Directive, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any shares to the public other than their offer or resale in a Relevant Member State to qualified investors as so defined or in circumstances in which the prior consent of the representatives has been obtained to each such proposed offer or resale.

The Company, the representatives and their affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgements and agreements.

This prospectus has been prepared on the basis that any offer of shares in any Relevant Member State will be made pursuant to an exemption under the Prospectus Directive from the requirement to publish a prospectus for offers of shares. Accordingly any person making or intending to make an offer in that Relevant Member State of shares which are the subject of the offering contemplated in this prospectus may only do so in circumstances in which no obligation arises for the Company or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Directive in relation to such offer. Neither the Company nor the underwriters have authorized, nor do they authorize, the making of any offer of shares in circumstances in which an obligation arises for the Company or the underwriters to publish a prospectus for such offer.

For the purpose of the above provisions, the expression an offer to the public in relation to any shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the shares to be offered so as to enable an investor to decide to purchase or subscribe the shares, as the same may be varied in the Relevant Member State by any measure implementing the Prospectus Directive in the Relevant Member State and the expression Prospectus Directive means Directive 2003/71/EC (including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member States) and includes any relevant implementing measure in the Relevant Member State and the expression 2010 PD Amending Directive means Directive 2010/73/EU.

Notice to Prospective Investors in the United Kingdom

In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are qualified investors (as defined in the Prospectus Directive) (i) who have professional experience in matters relating to investments falling within Article 19 (5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the Order) and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as relevant persons). This document must not be acted on or relied on in the United Kingdom by persons who are not relevant persons. In the United Kingdom, any investment or investment activity to which this document relates is only available to, and will be engaged in with, relevant persons.

Notice to Prospective Investors in Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (SIX) or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly

available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, the Company, the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular,

Table of Contents

this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA (FINMA), and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes (CISA). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

Notice to Prospective Investors in the Dubai International Financial Centre

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority (DFSA). This prospectus is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The shares to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

Notice to Prospective Investors in Australia

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission (ASIC), in relation to the offering. This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001 (the Corporations Act), and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the shares may only be made to persons (the Exempt Investors) who are sophisticated investors (within the meaning of section 708(8) of the Corporations Act), professional investors (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the shares without disclosure to investors under Chapter 6D of the Corporations Act.

The shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

Notice to Prospective Investors in Hong Kong

The shares have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to professional investors as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or (b) in other circumstances which do not result in the document being a prospectus as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the

public within the meaning of that Ordinance. No advertisement, invitation or document relating to the shares has been or may be issued or has been or may be in the possession of any person

Table of Contents

for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to professional investors as defined in the Securities and Futures Ordinance and any rules made under that Ordinance.

Notice to Prospective Investors in Japan

The shares have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) and, accordingly, will not be offered or sold, directly or indirectly, in Japan, or for the benefit of any Japanese Person or to others for re-offering or resale, directly or indirectly, in Japan or to any Japanese Person, except in compliance with all applicable laws, regulations and ministerial guidelines promulgated by relevant Japanese governmental or regulatory authorities in effect at the relevant time. For the purposes of this paragraph, Japanese Person shall mean any person resident in Japan, including any corporation or other entity organized under the laws of Japan.

Notice to Prospective Investors in Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the SFA), (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275, of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

(a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

(b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:

(a) to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;

(b) where no consideration is or will be given for the transfer;

(c) where the transfer is by operation of law;

(d) as specified in Section 276(7) of the SFA; or

as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

Table of Contents

LEGAL MATTERS

The validity of the issuance of our common stock offered in this prospectus will be passed upon for us by Latham & Watkins LLP, Menlo Park, California. Davis Polk & Wardwell LLP, Menlo Park, California, is acting as counsel for the underwriters in connection with this offering. In connection with the offering and pursuant to our reserved share program, Latham & Watkins LLP and certain attorneys and investment funds affiliated with the firm will purchase 17,000 shares at the initial public offering price.

EXPERTS

The financial statements of Aimmune Therapeutics, Inc. as of December 31, 2013 and 2014 and for each of the years in the two-year period ended December 31, 2014, have been included herein in reliance upon the report of KPMG, LLP, independent registered public accounting firm appearing elsewhere herein and upon the authority of said firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information with respect to Aimmune Therapeutics, Inc. and the common stock offered hereby, reference is made to the registration statement and the exhibits and schedules filed therewith. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement. A copy of the registration statement and the exhibits and schedules filed therewith may be inspected without charge at the public reference room maintained by the SEC, located at 100 F Street N.E., Room 1580, Washington, D.C. 20549, and copies of all or any part of the registration statement may be obtained from such offices upon the payment of the fees prescribed by the SEC. Please call the SEC at 1-800-SEC-0330 for further information about the public reference room. The SEC also maintains a website that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. The address is www.sec.gov.

Upon consummation of this offering, we will become subject to the information and periodic reporting requirements of the Exchange Act and, in accordance therewith, will file periodic reports, proxy statements and other information with the SEC. Such periodic reports, proxy statements and other information will be available for inspection and copying at the public reference room and website of the SEC referred to above. We maintain a website at www.aimmune.com. Upon consummation of this offering, you may access our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act with the SEC free of charge at our website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The reference to our website address does not constitute incorporation by reference of the information contained on our website, and you should not consider the contents of our website in making an investment decision with respect to our common stock.

Table of Contents

Aimmune Therapeutics, Inc.

INDEX TO FINANCIAL STATEMENTS

Table of Contents

Report of Independent Registered Accounting Firm

We have audited the accompanying balance sheets of Aimmune Therapeutics, Inc. (the Company) as of December 31, 2013 and 2014, and the related statements of operations and comprehensive loss, stockholders equity, and cash flows for each of the years in the two-year period ended December 31, 2014. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Aimmune Therapeutics, Inc. as of December 31, 2013 and 2014, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2014, in conformity with U.S. generally accepted accounting principles.

/s/ KPMG LLP

San Francisco, California

June 4, 2015, except for note 11, which is as of July 30, 2015

Table of Contents

AIMMUNE THERAPEUTICS, INC.

BALANCE SHEETS

(in thousands, except share and per share amounts)

	December 31, 2013	2014
Assets		
Current assets:		
Cash and cash equivalents	$ 11,951	$ 2,269
Prepaid expenses	120	106
Total current assets	12,071	2,375
Property and equipment, net	60	87
Restricted cash		40
Other assets	25	29
Total assets	$ 12,156	$ 2,531
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 272	$ 478
Accrued liabilities	238	1,259
Other current liabilities	9	67
Total current liabilities	519	1,804
Other liabilities		56
Total liabilities	519	1,860
Commitments and contingencies (Note 4)		
Stockholders equity:		
Series A convertible preferred stock, par value $0.0001 per share 13,263,967 shares authorized as of December 31, 2013 and 2014; 13,263,967 shares issued and outstanding as of December 31, 2013 and 2014; aggregate liquidation preference of $16,989 as of December 31, 2013 and 2014	16,928	16,928
Common stock, par value $0.0001 per share 32,925,000 shares authorized as of December 31, 2013 and 2014; 2,926,665 and 4,252,248 shares issued and outstanding as of December 31, 2013 and 2014 (including 788,873 shares subject to repurchase, legally issued and outstanding as of December 31, 2014), respectively		
Additional paid-in capital	1,106	1,260
Accumulated deficit	(6,397)	(17,517)
Total stockholders equity	11,637	671

Total liabilities and stockholders equity	$ 12,156	$ 2,531

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

Table of Contents

AIMMUNE THERAPEUTICS, INC.

STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands, except share and per share amounts)

	Year Ended December 31,	
	2013	**2014**
Operating expenses:		
Research and development	$ 3,495	$ 8,181
General and administrative	1,263	2,951
Total operating expenses	4,758	11,132
Loss from operations	(4,758)	(11,132)
Other income (expense), net		
Interest income	24	12
Interest expense	(91)	
Total other income (expense), net	(67)	12
Net loss and comprehensive loss	$ (4,825)	$ (11,120)
Net loss per share, basic and diluted	$ (1.65)	$ (3.80)
Weighted-average shares used in computing net loss per share, basic and diluted	2,926,665	2,928,896
Pro forma net loss per share, basic and diluted (unaudited)		$ (0.69)
Shares used in computing pro forma net loss per share, basic and diluted (unaudited)		16,192,863

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

Table of Contents

AIMMUNE THERAPEUTICS, INC.

STATEMENTS OF STOCKHOLDERS EQUITY

(in thousands, except share and per share amounts)

	Series A Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Total Stockholders
	Shares	Amount	Shares	Amount	Capital	deficit	Equity
Balance as of December 31, 2012		$	2,926,665	$	$ 1,025	$ (1,572)	$ (547)
Issuance of Series A convertible preferred stock for cash at $1.29 per share, net of $61 of issuance costs	12,569,603	16,164					16,164
Conversion of convertible promissory note at $1.10 per share of Series A convertible preferred stock	694,364	764					764
Stock-based compensation					81		81
Net loss						(4,825)	(4,825)
Balance as of December 31, 2013	13,263,967	$ 16,928	2,926,665		$ 1,106	(6,397)	$ 11,637
Issuance of common stock upon exercise of vested options			1,325,583		77		77
Stock-based compensation					77		77
Net loss						(11,120)	(11,120)
Balance as of December 31, 2014	13,263,967	$ 16,928	4,252,248	$	$ 1,260	$ (17,517)	$ 671

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

Table of Contents

AIMMUNE THERAPEUTICS, INC.

STATEMENTS OF CASH FLOWS

(in thousands)

	Year Ended December 31,	
	2013	**2014**
Cash flows from operating activities:		
Net loss	$ (4,825)	$ (11,120)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	9	29
Stock-based compensation	81	77
Non-cash interest expense on convertible note	90	
Changes in operating assets and liabilities		
Prepaid expenses	(117)	14
Accounts payable	208	206
Accrued liabilities	208	1,021
Other	(16)	(4)
Net cash used in operating activities	$ (4,362)	$ (9,777)
Cash flows from investing activities:		
Purchase of property and equipment	(69)	(56)
Increase in restricted cash		(40)
Net cash used in investing activities	(69)	(96)
Cash flows from financing activities:		
Net cash proceeds from issuance of Series A convertible preferred stock, net of issuance costs	16,164	
Net cash proceeds from exercise of stock options, including early exercise		191
Net cash provided by financing activities	16,164	191
Net increase (decrease) in cash and cash equivalents	11,733	(9,682)
Cash and cash equivalents at the beginning of the period	218	11,951
Cash and cash equivalents at the end of the period	$ 11,951	$ 2,269
Supplemental disclosures of non-cash financing information:		
Conversion of convertible promissory note and accrued interest into Series A convertible preferred stock	$ 764	$

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

Table of Contents

AIMMUNE THERAPEUTICS, INC.

NOTES TO THE FINANCIAL STATEMENTS

1. Organization and Description of Business

Aimmune Therapeutics, Inc. (Aimmune Therapeutics or the Company) (formerly known as Allergen Research Corporation) is a clinical-stage biopharmaceutical company focused on developing treatments to protect children with food allergies from the threatening consequences of accidental exposure. The Company is headquartered in the San Francisco Bay Area 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 years ended December 31, 2013 and 2014, the Company incurred a net loss of $4.8 million and $11.1 million, respectively, and used $4.4 million and $9.8 million of cash in operations, respectively. At December 31, 2013 and 2014, the Company had an accumulated deficit of $6.4 million and $17.5 million, respectively, and 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. The Company s ability to continue to meet its obligations and to achieve its business objectives is dependent upon, amongst other things, 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.

2. Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United State of America (U.S. GAAP). The preparation of the accompanying 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 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. The Company operates in one reportable segment in the United States of America.

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 amounts invested in a bank high yield savings account.

Concentration of Credit Risk Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents. The Company s cash and cash equivalents are held primarily in one large financial institution in the United States. Management believes that this financial institution is financially sound, and accordingly, minimal credit risk exists with respect to this financial institution. The Company is exposed to credit risk in the event of default by the financial institution holding its cash and cash equivalents to the extent recorded on the balance sheets.

Fair Value Measurement The carrying amounts of certain financial instruments, including cash and cash equivalents, restricted cash, accounts payable and accrued liabilities approximate fair value due to their relatively short maturities.

Table of Contents

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

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 has entered into lease agreements for its corporate headquarters and research facilities in San Mateo, California through July 2017. 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 March 2015, the Company entered into a new lease for its corporate headquarters and research facilities in Brisbane, California. In May 2015, the Company ceased use of its San Mateo facilities and moved into its new facilities. The new lease, which expires in 2019, will also be classified as an operating lease. See Note 11, Subsequent Events .

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 estimate at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from estimates.

Table of Contents

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 December 31, 2013 and 2014, the Company does not have any unrecognized tax benefits.

Recent Accounting Pronouncements The Company is an emerging growth company as defined in the JOBS Act of 2012. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has irrevocably elected not to avail itself of this exemption from new or revised accounting standards, and therefore, will be subject to the same new revised accounting standard as other public companies that are not emerging growth companies.

In May 2014, the FASB issued ASU 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. ASU 2014-09 is effective for annual periods beginning after December 15, 2016, for public business entities. On April 29, 2015, the FASB issued for comment a proposed ASU, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date.* The proposed ASU would permit both public and nonpublic organizations to adopt the new revenue standard early, but not before the original public organization effective date (that is, annual periods beginning after December 15, 2017).

In June 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2014-10, *Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation.* ASU 2014-10 simplifies the accounting guidance by removing all incremental financial reporting requirements for development stage entities. The amendments related to the elimination of the inception-to-date information and other disclosure requirement of Topic 915 should be applied retrospectively, and are effective for annual reporting periods beginning after December 15, 2014, and interim periods therein. The Company has elected to early adopt this guidance as of January 1, 2013.

In August 2014, the FASB issued ASU 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 first quarter of 2016 with early adoption permitted. We do not believe the impact of adopting ASU 2014-15 on our financial statements will be material.

Table of Contents

3. Balance Sheet Components

Property and Equipment, Net

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

	Year Ended December 31,	
	2013	**2014**
Furniture and equipment	$ 30	$ 58
Computer equipment	39	67
Property and equipment, gross	69	125
Less: accumulated depreciation	(9)	(38)
Property and equipment, net	$ 60	$ 87

Depreciation expense for the years ended December 31, 2013 and 2014 was $9,000 and $29,000, respectively.

Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	Year Ended December 31,	
	2013	**2014**
Compensation and benefits	$ 208	$ 645
Research and development		542
Professional and consulting	30	71
Other		1
Total	$ 238	$ 1,259

4. Commitments and Contingencies

Facility Leases

In July 2013, the Company entered into a 48-month lease for its corporate headquarters and research facilities. In July 2014, the Company entered into a second lease that expanded the current space and is for a term of 36 months beginning in July 2014 and coterminous with the first lease. Under both leases, the Company pays base rent plus the tenant s proportionate share of estimated basic operating cost as defined in the leases. The leases required a $25,000 security deposit for the duration of the leases.

Future aggregate minimum lease payments under the non-cancelable operating leases as of December 31, 2014 (in thousands):

Year Ended December 31,	
2015	$ 167
2016	170
2017	86
Total	$ 423

Table of Contents

Rent expense under operating leases was $42,000 and $131,000 for the years ended December 31, 2013 and 2014.

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.

5. Common Stock

As of December 31, 2013 and 2014, the Company had authorized 32,925,000 shares of common stock. The Company has reserved sufficient shares of common stock for issuance upon conversion of the Series A convertible preferred stock and the exercise of stock options. Common stockholders are entitled to dividends if and when declared by the Board of Directors subject to the prior rights of the Series A preferred stockholders. As of December 31, 2014, no common stock dividends had been declared by the Board of Directors.

6. Convertible Preferred Stock

As of December 31, 2013 and 2014, the Company had authorized 13,263,967 shares of Series A convertible preferred stock. In February 2013, the Company issued 7,046,953 shares of Series A preferred stock, $0.0001 par value, original issue price of $1.29 in the case of cash proceeds and $1.10 in the case of an outstanding note and accrued interest converted into the Series A convertible preferred stock (see Conversion of Convertible Note Payable below). In April 2013, the Company issued an additional 6,217,014 shares of Series A convertible preferred stock, $0.0001 par value, original issue price of $1.29. As of December 31, 2013 and 2014, Series A convertible preferred stock consisted of the following (in thousands, except share amounts):

	As of December 31, 2013 and 2014			
Convertible preferred stock	Shares Authorized	Shares Issued and Outstanding	Proceeds Net of Issuance Costs	Aggregate Liquidation Preference
Series A	13,263,967	13,263,967	$ 16,928	$ 16,989

Significant provisions of Series A convertible preferred stock are as follows:

Dividends Holders of Series A convertible preferred stock, in preference to common stockholders, shall be entitled to receive when, as and if declared by the Board of Directors non-cumulative cash dividends at

the rate of 8% of the original issue price per annum on each outstanding share of Series A convertible preferred stock. No Series A convertible preferred stock dividends have been declared or paid as of December 31, 2014.

Liquidation In the event of any liquidation, dissolution, or winding up of the Company, the holders of Series A convertible preferred stock shall be entitled to be paid out of the assets of the Company available for distribution to its stockholders, before any payment shall be made to holders of common stock, an amount equal to $1.29 per share of Series A convertible preferred stock plus any declared but unpaid dividends. If upon such liquidation, dissolution, or winding up of the Company, the assets available for distribution to stockholders are insufficient to pay in full holders of Series A convertible preferred stock amounts to which they are entitled, the holders of Series A convertible preferred stock shall share ratably in any assets available for distribution in proportion to the respective amounts which would otherwise be payable in respect to the shares held by them. Following payment in full to the holders of Series A convertible preferred stock, the remaining assets and funds of the Company, if any, shall be divided among and paid ratably to the holders of Common Stock in proportion to the number of shares held by them.

A consolidation or merger of the Company with or into any other corporation or corporations, acquisition by any other corporation or corporations, or a sale of all or substantially all of the assets or voting control of the Company in which the prior stockholders of the Company do not own a majority of the outstanding shares of the surviving corporation is deemed to be a liquidation.

Conversion Each share of Series A convertible preferred stock is convertible into shares of common stock at the option of the holder at any time. Conversion is automatic upon either the written consent of not less than 66.67% of the holders of the Series A convertible preferred stock outstanding or the effective date of a firm commitment underwritten public offering that yields net proceeds to the Company of not less than $40,000,000 at an equivalent price per share of common stock of not less than $6.45. Each share of Series A convertible preferred stock is convertible into the number of shares of which results from dividing the original issue price of the Series A convertible preferred stock by the conversion price for the Series A convertible preferred Stock that is in effect at the time of conversion. As of December 31, 2013 and 2014, the conversion price of the Series A convertible preferred stock was $1.29 and, as such, all outstanding shares of Series A convertible preferred stock had a conversion ratio of 1-to-1.

Voting Each holder of share of Series A convertible preferred stock shall be entitled to the number of votes equal to the number of shares of common stock into which such shares of preferred stock could be converted and shall have voting rights and powers equal to the voting rights and powers of the holders of common stock. The holders of Series A convertible preferred stock shall be entitled to elect two directors of the Company.

Redemption The Series A convertible preferred stock is not redeemable at the option of the holders and there is no event in which the Series A holders can require liquidation in which the common stockholders would not participate in the liquidation proceeds in accordance with their relative liquidation rights as described above.

Conversion of Convertible Note Payable

In June 2012, the Company entered into an unsecured convertible promissory note in the amount of $750,000 with an existing stockholder. The note provided for an annual interest rate of 3% and a due date of December 31, 2013, but could be extended by mutual agreement for an additional year. Under the terms of the note, under certain circumstances, the balance of the note, including any accrued interest, would convert into preferred stock upon the closing of a future preferred stock financing that met specified criteria. Such conversion would be at a 15% discount to the per share price of the preferred stock sold in the financing.

In February 2013, as part of the issuance of Series A convertible preferred stock, the note, plus $14,000 of accrued interest converted into 694,364 shares of Series A convertible preferred stock at a rate of $1.10 per

Table of Contents

share in full payment for the note and accrued interest. The discount of $112,000 was recorded at the time of issuance of the note as an offset to the note on the balance sheet and was amortized as additional interest expense over the original term of the note. At the conversion date, the remaining unamortized discount of $88,000 was recorded as interest expense.

7. Stock-based Awards

In January 2013, the Company adopted its Stock Plan (the Plan). Under the Plan, shares of the Company s common stock have been reserved 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. At December 31, 2013 and 2014, there were 609,958 and 639,625 shares available for future grant. Under the terms of the 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 two ways: 1) over four years at a rate of 25% upon the first anniversary of the issuance date and 1/48th per month thereafter, and 2) over two years at a rate of 1/24th per month. The 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 Plan allows employees to exercise a stock option in exchange for stock 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. At December 31, 2014, 788,873 unvested shares were legally issued and outstanding. In connection with these unvested shares, the Company has recorded an early exercise liability of $114,000, of which $58,000 is included in other current liabilities and $56,000 is included in other non-current liabilities in the Company s Balance Sheet. No options were early exercised in 2013. These shares are excluded from basic net loss per share until the Company repurchase right lapses and the shares are no longer subject to the repurchase feature.

Activity under the Plan is set forth below:

	Shares Available for Grant	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Initial shares authorized, January 29, 2013	1,334,219			
Additional shares authorized	1,522,951			
Options granted	(2,247,212)	2,247,212	$ 0.14	
Balances, December 31, 2013	609,958	2,247,212	$ 0.14	9.67
Additional shares authorized	885,724			

Options granted	(1,635,681)	1,635,681	$	0.14	
Options exercised		(536,710)	$	0.14	
Options cancelled	779,624	(779,624)	$	0.14	
Balances, December 31, 2014	639,625	2,566,559	$	0.14	9.19
Vested and expected to vest as of December 31, 2014		2,251,169	$	0.14	9.13
Exercisable as of December 31, 2014		1,777,683	$	0.14	9.05

Table of Contents

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 estimated value of the Company common stock as determined by the Company s Board of Directors as of December 31, 2014. The Plan provides for early exercise, therefore, all the Company s outstanding stock options are exercisable. At December 31, 2013 and 2014, the exercise price of all stock options was $0.14 per share and the estimated value of the Company common stock was also $0.14 per share. Consequently, the intrinsic value for the options outstanding, exercisable, and vested was nil.

Stock Options Granted to Employees

During the years ended December 31, 2013 and 2014, the Company granted stock options to employees to purchase shares of common stock with a weighted-average grant date fair value of $0.09 and $0.09 per share, 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.

As of December 31, 2014, total unrecognized employee stock-based compensation was $120,000, which is expected to be recognized over the weighted-average remaining vesting period of 2.43 years.

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

	Year Ended December 31,	
	2013	**2014**
Expected volatility	85.52%	79.62%
Risk-free interest rate	1.56%	1.51%
Dividend yield	0.00%	0.00%
Expected term (in years)	4.76	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.

Table of Contents

Fair value of common stock The fair value of the shares of common stock underlying the stock options has historically been the responsibility of and determined by the Company s board of directors. Because there has been 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.

The fair value of the underlying common stock will be determined by the Company s board of directors until such time as the Company s common stock is listed on an established exchange or national market system.

Stock-based compensation expense, net of estimated forfeitures, is reflected in the statements of operations and comprehensive loss as follows (in thousands):

	Year Ended December 31,	
	2013	2014
Operating expenses:		
Research and development	$ 21	$ 23
General and administrative	60	54
Total	$ 81	$ 77

8. Income Taxes

The Company has not recorded any net tax provision in the periods presented due to net operating losses incurred and the need for a full valuation allowance on deferred tax assets.

Income tax expense in 2013 and 2014 differed from the amount expected by applying the statutory federal tax rate to the loss before taxes as summarized below (in thousands):

	Year Ended December 31,	
	2013	2014
Federal tax benefit at statutory rate	$ (1,640)	$ (3,751)
State tax benefit, net of federal benefit	(313)	(698)
Change in valuation allowance	1,975	4,549
Research and development credits	(53)	(119)
Other	31	19
	$	$

The significant components of the Company s deferred taxes are as follows (in thousands):

	December 31,	
	2013	2014
Deferred tax assets (liabilities):		
Net operating loss carryforwards	$ 1,663	$ 4,723
Start-up costs	596	1,736
Tax credit carryforwards	98	274
Accruals	78	227
Other	28	52
Total deferred tax assets	2,463	7012
Less: valuation allowance	(2,463)	(7,012)
Net deferred income taxes	$	$

Table of Contents

The Company has provided a valuation allowance for the full amount of the net deferred tax assets as the realization of the deferred tax assets is not determined to be more likely than not. The valuation allowance increased by $2.0 and $4.5 million in 2013 and 2014, respectively, primarily due to the increase in net operating loss carryforwards and start-up costs.

As of December 31, 2014, the Company had $11.9 million in both federal and state net operating losses, which will begin to expire beginning in 2031 if not utilized. Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, our ability to utilize net operating loss carryforwards or other tax attribute, such as research tax credits, in any taxable year may be limited if we have experienced an ownership change. Following the issuance of the Series B convertible preferred stock in January and February 2015 (see Note 11), we performed a Section 382 analysis and believe that we experienced multiple ownership changes under Section 382 of the Code and, as a result, our federal and state net operating loss carryforwards and tax credits are subject to limitation.

Realization of net operating loss carryforwards and research and development carryforwards may be impaired or limited in certain circumstances.

The Company has adopted Financial Accounting Standards Board Accounting Standards Codification (FASB ASC) 740, *Income Taxes*, regarding how uncertain tax positions should be recognized, measured, presented and disclosed in the financial statements. As of December 31, 2013 and 2014, the Company does not have any unrecognized tax benefits.

9. Defined Contribution Plan

The Company sponsors a 401(k) Plan which stipulates that eligible employees may contribute to the Plan subject to certain limitations. The Company may match employee contributions in amounts to be determined at the Company s sole discretion. To date, the Company has not made any matching contributions.

10. Net Loss and Pro Forma Net Loss Per Share

The following table sets forth the computation of the basic and diluted net loss per share during the years ended December 31, 2013 and 2014 (in thousands, except share and per share data):

	Year ended December 31,	
	2013	**2014**
Numerator:		
Net loss	$ (4,825)	$ (11,120)
Denominator:		
Weighted average common shares outstanding	2,926,665	2,928,896
Net loss per share, basic and diluted	$ (1.65)	$ (3.80)

The following common stock equivalents were excluded from the computation of diluted net loss per share for the periods present because including them would have been antidilutive:

	Year ended December 31,	
	2013	2014
Series A convertible preferred stock	10,769,030	13,263,967
Stock options	2,247,212	2,566,559

Table of Contents

Unaudited Pro Forma

The following table sets forth the computation of the Company s unaudited pro forma basic and diluted net loss per share during the year ended December 31, 2014 (in thousands, except for share and per share amounts).

Net loss	$ (11,120)
Shares used in computing net loss per share basic and diluted	2,928,896
Pro forma adjustments to reflect assumed conversion of convertible preferred stock	13,263,967
Shares used in computing pro forma net loss per share, basic and diluted	16,192,863
Pro forma net loss per share, basic and diluted	$ (0.69)

11. Subsequent Events

Series B Convertible Preferred Stock

In January and February 2015, the Company authorized 14,245,550 and issued 14,047,996 shares of Series B convertible preferred stock, $0.0001 par value, original issue price of $5.69 per share, for cash proceeds of $66.9 million net of $12.9 million in repurchases of the Company s Series A convertible preferred stock and $243,000 of offering costs. The Company plans to use the net proceeds to fund the upcoming Phase 3 registration trial of the Company s AR101 product. The rights and preferences of the Series B convertible preferred stock are similar to those of the Series A convertible preferred stock.

New Facilities Lease

In March 2015, the Company signed a new facilities lease for its corporate headquarters and research facilities in Brisbane, California. In May 2015, the Company ceased use of its San Mateo facilities and accrued a liability for costs that will continue to be incurred under the San Mateo leases for the remaining terms, net of estimated sublease payments.

The new lease commenced on May 1, 2015 with an initial term of 51 months. The Company has the right to extend the lease term for an additional 3 years at the greater of the then current base rent or the then prevailing market rent, as defined by the Renewal Option contained in the lease. The agreement calls for a security deposit of $85,000. The new lease calls for future aggregate minimum noncancelable lease payments as of May 1, 2015 (the inception of the lease) as follows (in thousands):

Year ended December 31,	
2015	$ 190
2016	464
2017	478
2018	492
and after	294

Total	$ 1,918

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

Table of Contents

In June 2015, the Company signed a new facilities lease for a manufacturing facility in Clearwater, Florida. The new lease is expected to commence in mid to late September. The initial terms of the lease are for 120 months. 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.

Income Taxes

In July 2015, the Company formed a wholly-owned foreign subsidiary to which the Company licensed certain intangible rights. The Company expects that 2015 recognized revenue in the U.S., if any, as a result of this transaction will be fully offset by prior year NOLs and current year expenses. The Company expects to recognize revenue from the license in future years, in the form of royalties, if any are received in such years.

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 also increased the number of shares of authorized 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 financial statements and notes to the financial statements have been retroactively adjusted to give effect to the stock split for all periods presented.

Table of Contents

AIMMUNE THERAPEUTICS, INC.

CONDENSED BALANCE SHEETS

(in thousands, except share and per share amounts)

	December 31, 2014	March 31, 2015 (Unaudited)	Pro forma Stockholders Equity as of March 31, 2015 (Unaudited)
Assets			
Current assets:			
Cash and cash equivalents	$ 2,269	$ 65,313	
Prepaid expenses	106	309	
Total current assets	2,375	65,622	
Property and equipment	87	120	
Restricted cash	40	40	
Other assets	29	113	
Total Assets	$ 2,531	$ 65,895	
Liabilities and Stockholders Equity			
Current liabilities:			
Accounts payable	$ 478	$ 977	
Accrued liabilities	1,259	458	
Other current liabilities	67	122	
Total current liabilities	1,804	1,557	
Other liabilities	56	99	
Total liabilities	1,860	1,656	
Commitments and contingencies (Note 4)			
Stockholders equity:			
Series A convertible preferred stock, par value $0.0001 per share 13,263,967 shares authorized, issued and outstanding as of December 31, 2014; 11,003,261 shares authorized, issued and outstanding as of March 31, 2015 (unaudited);	16,928	4,054	

aggregate liquidation preference of $16,989 and $14,071 as of December 31, 2014 and March 31, 2015 (unaudited), respectively; no shares authorized, issued and outstanding, pro forma (unaudited).			
Series B convertible preferred stock, par value $0.0001 per share no and 14,245,550 shares authorized as of December 31, 2014 and March 31, 2015 (unaudited), respectively; no and 14,047,996 shares issued and outstanding as of December 31, 2014 and March 31, 2015 (unaudited), respectively; aggregate liquation preference of nil and $80,000 as of December 31, 2014 and March 31, 2015 (unaudited); no shares authorized, issued and outstanding, pro forma (unaudited).		79,757	
Common stock, par value $0.0001 per share 32,925,000 and 50,046,000 shares authorized as of December 31, 2014 and March 31, 2015, respectively; 4,252,248 and 5,628,281 shares issued and outstanding as of December 31, 2014 and March 31, 2015, respectively (unaudited) (including 788,873 and 1,328,993 shares subject to repurchase, legally issued and outstanding as of December 31, 2014 and March 31, 2015) (unaudited)			
Additional paid-in capital	1,260	1,386	85,197
Accumulated deficit	(17,517)	(20,958)	(20,958)
Total stockholders equity	671	64,239	$ 64,239
Total liabilities and stockholders equity	$ 2,531	$ 65,895	

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

Table of Contents

AIMMUNE THERAPEUTICS, INC.

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands, except share and per share amounts)

	Unaudited	
	Three Months Ended March 31,	
	2014	2015
Operating expenses:		
Research and development	$ 1,199	$ 2,069
General and administrative	401	1,372
Total operating expenses	1,600	3,441
Loss from operations	(1,600)	(3,441)
Other income (expense), net		
Interest income	7	
Interest expense		
Total other income (expense), net	7	
Net loss and comprehensive loss	$ (1,593)	$ (3,441)
Net loss per share, basic and diluted	$ (0.54)	$ (0.81)
Weighted-average shares used in computing net loss per share, basic and diluted	2,926,665	4,258,877
Pro forma net loss per share, basic and diluted		$ (0.15)
Shares used in computing pro forma net loss per share, basic and diluted		22,467,561

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

Table of Contents

AIMMUNE THERAPEUTICS, INC.

CONDENSED STATEMENTS OF CASH FLOWS

(in thousands)

	Unaudited	
	Three Months Ended March 31,	
	2014	2015
Cash flows from operating activities:		
Net loss	$ (1,593)	$ (3,441)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	5	11
Stock-based compensation	16	26
Changes in operating assets and liabilities:		
Prepaid expenses	(113)	(203)
Other assets	(1)	(84)
Accounts payable	(236)	499
Accrued liabilities	(127)	(801)
Other	100	
Net cash used in operating activities	(1,949)	(3,993)
Cash flows from investing activities:		
Purchase of property and equipment	(5)	(44)
Net cash used in investing activities	(5)	(44)
Cash flows from financing activities:		
Net proceeds from issuance of Series B convertible preferred stock, net of issuance costs		79,757
Repurchase of Series A convertible preferred stock		(12,874)
Net cash proceeds from exercise of stock options, including early exercise		229
Repurchases of common stock subject to early exercise		(31)
Net cash provided by financing activities		67,081
Net increase (decrease) in cash and cash equivalents	(1,954)	63,044
Cash and cash equivalents at the beginning of the period	11,951	2,269
Cash and cash equivalents at the end of the period	$ 9,997	$ 65,313

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

Table of Contents

AIMMUNE THERAPEUTICS, INC.

NOTES TO UNAUDITED INTERIM CONDENSED FINANCIAL STATEMENTS

1. Formation and Business of the Company

Aimmune Therapeutics (the Company) is a clinical-stage biopharmaceutical company focused on developing treatments to protect children with food allergies from the threatening consequences of accidental exposure. The Company is headquartered in the San Francisco Bay Area 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 three months ended March 31, 2015, the Company incurred a net loss of $3.4 million and used $4.0 million of cash in operations. At March 31, 2015 the Company had an accumulated deficit of $21.0 million and 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. The Company s ability to continue to meet its obligations and to achieve its business objectives is dependent upon, amongst other things, 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.

2. Summary of Significant Accounting Policies

Basis of Preparation and Use of Estimates The preparation of the accompanying 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 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.

Unaudited Interim Condensed Financial Statements The interim condensed balance sheet as of March 31, 2015 and the condensed statements of operations and comprehensive loss, and the condensed statements of cash flows for the three months ended March 31, 2014 and 2015 are unaudited. The unaudited interim financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to present fairly the Company s financial position as of March 31, 2015 and its results of operations and cash flows for the three months ended March 31, 2014 and 2015. The financial data and the other financial information disclosed in these notes to the financial statements related to the three-month periods are also unaudited. The results of operations for the three months ended March 31, 2015 are not necessarily indicative of the results to be expected for the year ending December 31, 2015 or for any other future annual or interim period. The condensed balance sheet as of December 31, 2014 included herein was derived from the audited financial statements as of that date. These financial statements should be read in conjunction with the Company s audited financial statements included elsewhere in this prospectus.

Unaudited Pro Forma Stockholders Equity The pro forma stockholders equity as of March 31, 2015 presents the Company s stockholders equity as though all of the Company s outstanding convertible preferred stock had

automatically converted into shares of common stock upon the completion of an initial public offering (IPO) of the Company s common stock.

Table of Contents

Fair Value Measurement The carrying amounts of certain financial instruments, including cash and cash equivalents, restricted cash, accounts payable and accrued liabilities approximate fair value due to their relatively short maturities.

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 preclinical 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 estimate at the time of grant and revised, if necessary, in subsequent period if actual forfeitures differ from estimates. There were no stock options granted during the three month periods ended March 31, 2014 and 2015.

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 December 31, 2014 and March 31, 2015, the Company does not have any unrecognized tax benefits.

Recent Accounting Pronouncements In May 2014, the FASB issued ASU 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. ASU 2014-09 is effective for annual periods beginning after December 15, 2016, for public business entities. On April 29, 2015, the FASB issued for comment a proposed ASU, Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date. The proposed ASU would permit both public and nonpublic organizations to adopt the new revenue standard early, but not before the original public organization effective date (that is, annual periods beginning after December 15, 2017).

The Company is an emerging growth company as defined in the JOBS Act of 2012. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to

Table of Contents

the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has irrevocably elected not to avail itself of this exemption from new or revised accounting standards, and therefore, will be subject to the same new revised accounting standard as other public companies that are not emerging growth companies.

3. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	December 31, 2014	March 31, 2015
Compensation and benefits	$ 645	$ 95
Research and development	542	363
Professional and consulting	71	
Other	1	
Total	$ 1,259	$ 458

4. Commitments and Contingencies

Facility Leases

In July 2013, the Company entered into a 48-month lease for its corporate headquarters and research facilities in San Mateo, California. In July 2014, the Company entered into a second lease that expanded the space and was for a term of 36 months beginning in July 2014 and coterminous with the first lease. Under both leases, the Company paid base rent plus the tenant s proportionate share of estimated basic operating cost as defined in the leases. The leases required a $25,000 security deposit for the duration of the leases.

Rent expense under operating leases was $25,000 and $41,000 for the three-month periods ended March 31, 2014 and 2015.

New Facilities Lease

In March 2015, the Company signed a new facilities lease for its corporate headquarters and research facilities in Brisbane, California. In May 2015, the Company ceased use of its San Mateo facilities and accrued a liability for costs that will continue to be incurred under the San Mateo leases for the remaining terms, net of estimated sublease payments.

The new lease commenced on May 1, 2015 with an initial term of 51 months. The Company has the right to extend the lease term for an additional 3 years at the greater of the then current base rent or the then prevailing market rent, as defined by the Renewal Option contained in the lease. The agreement calls for a security deposit of $85,000. The new lease calls for future aggregate minimum noncancelable lease payments as of May 1, 2015 (the inception of the lease) as follows (in thousands):

Year Ended December 31,	
2015	$ 190
2016	464
2017	478
2018	492
and after	294
Total	$ 1,918

Table of Contents

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 new facilities lease for a manufacturing facility in Clearwater, Florida. The new lease is expected to commence in mid to late September. The initial terms of the lease are for 120 months. 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.

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.

5. Common Stock

As of December 31, 2014 and March 31, 2015 (unaudited), the Company had authorized 32,925,000 and 50,046,000 shares of common stock. The Company has reserved sufficient shares of common stock for issuance upon the conversion of the Series A convertible preferred stock, the conversion of the series B convertible preferred stock and the exercise of stock options. Common stockholders are entitled to dividends if and when declared by the Board of Directors subject to the prior rights of the Series A and B convertible preferred stockholders. As of December 31, 2014, no common stock dividends had been declared by the Board of Directors.

6. Convertible Preferred Stock

As of December 31, 2014 and March 31, 2015 (unaudited), the Company had authorized no and 14,245,550 shares of Series B convertible preferred stock, respectively, and 13,263,967 and 11,003,261 shares of Series A convertible preferred stock, respectively. In February 2013, the Company issued 7,046,953 shares of Series A convertible

preferred stock, $0.0001 par value, original issue price of $1.29 in the case of cash proceeds and $1.10 in the case of an outstanding note and accrued interest converted into the Series A convertible preferred stock. In April 2013, the Company issued an additional 6,217,014 shares of Series A convertible

Table of Contents

preferred stock, $0.0001 par value, original issue price of $1.29. In January and February 2015, the Company issued 14,047,996 shares of Series B convertible preferred stock, $0.0001 par value, original issue price of $5.69 per share, for gross cash proceeds of $80.0 million and, in January 2015, the Company repurchased 2,260,706 shares of Series A convertible preferred stock from certain investors. The purchase price of the Series A convertible preferred stock was $5.69 per share, the same as the issue price of the Series B convertible stock, and was at an aggregate cost of $12.9 million. The offering costs for the issuance and sale of Series B convertible preferred stock was $243,000. As of December 31, 2014 and March 31, 2015, the convertible preferred stock consisted of the following (in thousands, except share amounts):

	As of December 31, 2014			
Convertible Preferred Stock	Shares Authorized	Shares Issued and Outstanding	Proceeds Net of Issuance Costs	Aggregate Liquidation Preference
Series A	13,263,967	13,263,967	$ 16,928	$ 16,989

	As of March 31, 2015			
Convertible Preferred stock	Shares Authorized	Shares Issued and Outstanding	Proceeds Net of Issuance Costs and Repurchases	Aggregate Liquidation Preference
Series A	11,003,261	11,003,261	$ 4,054	$ 14,071
Series B	14,245,550	14,047,996	$ 79,757	$ 80,000

Significant provisions of each series of convertible preferred stock are as follows:

Dividends Holders of convertible preferred stock, in preference to common stockholders, shall be entitled to receive when, as and if declared by the Board of Directors, non-cumulative cash dividends at the rate of 8% of the original issue price of such series of convertible preferred stock per annum on each outstanding share of convertible preferred stock. No convertible preferred stock dividends have been declared or paid as of March 31, 2015.

Liquidation In the event of any liquidation, dissolution, or winding up of the Company, the holders of Series B convertible preferred stock shall be entitled to be paid out of the assets of the Company available for distribution to its stockholders, before any payment shall be made to holders of common stock, an amount equal to $5.69 per share of Series B convertible preferred stock plus any declared but unpaid dividends. In the event of any liquidation, dissolution, or winding up of the Company, the holders of Series A convertible preferred stock shall be entitled to be paid out of the assets of the Company available for distribution to its stockholders, before any payment shall be made to holders of common stock, an amount equal to $1.29 per share of Series A convertible preferred stock plus any declared but unpaid dividends. If upon such liquidation, dissolution, or winding up of the Company, the assets available for distribution to stockholders are insufficient to pay in full holders of the convertible preferred stock amounts to which they are entitled, the holders of convertible preferred stock shall share ratably in any assets available for distribution in proportion to the respective amounts which would otherwise be payable in respect to the shares held by them. Following payment in full to the holders of convertible preferred stock, the remaining assets and funds of the Company, if any, shall be divided among and paid ratably to the holders of Common Stock in proportion to the number of shares held by them.

A consolidation or merger of the Company with or into any other corporation or corporations, acquisition by any other corporation or corporations, or a sale of all or substantially all of the assets or voting control of the Company in which the prior stockholders of the Company do not own a majority of the outstanding shares of the surviving corporation is deemed to be a liquidation.

Conversion Each share of convertible preferred stock is convertible into shares of common stock at the option of the holder at any time. Conversion is automatic upon either (a) the written consent of not less than (i) a majority of the holders of the Series A convertible preferred stock outstanding and (ii) a majority of the

Table of Contents

holders of the Series B convertible preferred stock outstanding or (b) the effective date of a firm commitment underwritten public offering that yields net proceeds to the Company of not less than $40,000,000 at an equivalent price per share of common stock of not less than $8.54. Each share of convertible preferred stock is convertible into the number of shares of which results from dividing the original issue price of the such series of convertible preferred stock by the conversion price for such series of convertible preferred stock that is in effect at the time of conversion. As of December 31, 2014 and March 31, 2015, the conversion price of the Series A convertible preferred stock and Series B convertible preferred stock was $1.29 and $5.69, respectively. As such, all outstanding shares of convertible preferred stock had a conversion ratio of 1-to-1.

Voting Each holder of share of convertible preferred stock shall be entitled to the number of votes equal to the number of shares of common stock into which such shares of convertible preferred stock could be converted and shall have voting rights and powers equal to the voting rights and powers of the holders of common stock. The holders of Series A convertible preferred stock shall be entitled to elect one director of the Company. The holders of Series B convertible preferred stock shall be entitled to elect two directors of the Company.

Redemption The convertible preferred stock is not redeemable at the option of the holders and there is no event in which the holders of convertible preferred stock can require liquidation in which the common shareholders would not participate in the liquidation proceeds in accordance with their relative liquidation rights as described above.

7. Net Loss Per Share and Pro Forma Net Loss Per Share

Net Loss Per Share

The following table sets forth the computation of the basic and diluted net loss per share during the three months ended March 31, 2014 and 2015 (in thousands, except share and per share data):

	Three Months Ended March 31,	
	2014	**2015**
Numerator:		
Net loss	$ (1,593)	$ (3,441)
Denominator		
Weighted average common shares outstanding	2,926,665	4,258,877
Net loss per share basic and diluted	$ (0.54)	$ (0.81)

The following common stock equivalents were excluded from the computation of diluted net loss per share for the periods presented because including them would have been antidilutive:

	Three Months Ended March 31,	
	2014	**2015**
Convertible preferred stock	13,263,967	18,208,684

Stock options	2,247,212	1,730,647

Table of Contents

Unaudited Pro Forma Net Loss Per Share

The following table sets forth the computation of the Company s unaudited pro forma basic and diluted net loss per share during the three months ended March 31, 2015 (in thousands, except for share and per share amounts):

Net loss	$ (3,441)
Shares used in computing net loss per share, basic and diluted	4,258,877
Pro forma adjustments to reflect assumed conversion of convertible preferred stock	18,208,684
Shares used in computing pro forma net loss per share, basic and diluted	22,467,561
Pro forma net loss per share, basic and diluted	$ (0.15)

8. Subsequent Events

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 also increased the number of shares of authorized common stock to 55,051,264 and the number of shares of authorized 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 financial statements and notes to the financial statements have been retroactively adjusted to give effect to the stock split for all periods presented.

Table of Contents

Through and including August 30, 2015, (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to a dealer s obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

10,000,000 Shares

Common Stock

PROSPECTUS

BofA Merrill Lynch **Credit Suisse** **Piper Jaffray**

August 5, 2015