

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2019

OR

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

For the transition period from _____ to _____

Commission File Number: 001-37519

AIMMUNE THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

45-2748244
(I.R.S. Employer
Identification No.)

8000 Marina Blvd., Suite 300
Brisbane, California 94005
(Address of principal executive offices including zip code)

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

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

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

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

Large accelerated filer Accelerated filer
Non-accelerated filer Smaller reporting company
Emerging growth company

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

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	AIMT	NASDAQ Global Market

As of April 30, 2019, the registrant had 62,492,435 shares of common stock, \$0.0001 par value per share, outstanding.

AIMMUNE THERAPEUTICS, INC.

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PART I. – FINANCIAL INFORMATION

Item 1. Financial Statements

AIMMUNE THERAPEUTICS, INC.
 CONDENSED CONSOLIDATED BALANCE SHEETS
 (In thousands, except per share amounts)
 (Unaudited)

	March 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 81,058	\$ 107,511
Short-term investments	202,113	196,421
Prepaid expenses and other current assets	8,220	8,687
Total current assets	291,391	312,619
Long-term investments	13,177	—
Property and equipment, net	26,824	26,328
Operating lease right of use assets	12,247	—
Prepaid expenses and other assets	514	608
Total assets	<u>\$ 344,153</u>	<u>\$ 339,555</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 10,517	\$ 8,833
Accrued liabilities	25,588	29,144
Operating lease liabilities, current	1,967	—
Other current liabilities	19	35
Total current liabilities	38,091	38,012
Long term debt, net of discount	37,268	—
Operating lease liabilities, non-current	11,633	—
Other liabilities	860	2,596
Total liabilities	<u>87,852</u>	<u>40,608</u>
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, par value \$0.0001 per share - 10,000 shares authorized at March 31, 2019 and December 31, 2018; 0 shares issued and outstanding at March 31, 2019 and December 31, 2018	—	—
Common stock, par value \$0.0001 per share—290,000 shares authorized as of March 31, 2019, and December 31, 2018; 62,470 and 62,142 shares issued and outstanding as of March 31, 2019, and December 31, 2018, respectively	6	6
Additional paid-in capital	786,681	775,283
Accumulated other comprehensive gain/(loss)	63	(108)
Accumulated deficit	(530,449)	(476,234)
Total stockholders' equity	<u>256,301</u>	<u>298,947</u>
Total liabilities and stockholders' equity	<u>\$ 344,153</u>	<u>\$ 339,555</u>

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

AIMMUNE THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands, except per share amounts)
(Unaudited)

	Quarter Ended March 31,	
	2019	2018
Operating expenses		
Research and development	\$ 31,316	\$ 33,446
General and administrative	23,712	16,673
Total operating expenses	<u>55,028</u>	<u>50,119</u>
Loss from operations	(55,028)	(50,119)
Interest income, net	791	636
Loss before provision for income taxes	(54,237)	(49,483)
Provision for income taxes	29	17
Net loss	<u>\$ (54,266)</u>	<u>\$ (49,500)</u>
Other comprehensive gain (loss), net of tax:		
Unrealized gains (losses) on investments	171	(17)
Comprehensive loss	<u>\$ (54,095)</u>	<u>\$ (49,517)</u>
Net loss per common share, basic and diluted	<u>\$ (0.87)</u>	<u>\$ (0.92)</u>
Weighted average shares used in computing net loss per common share, basic and diluted	62,022	53,578

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

AIMMUNE THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands)
(Unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive (Loss)/Gain	Accumulated deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2018	62,142	\$ 6	\$ 775,283	\$ (108)	\$ (476,234)	\$ 298,947
Issuance of common stock upon exercise of vested options	328	—	3,633	—	—	3,633
Stock-based compensation	—	—	7,765	—	—	7,765
Other comprehensive gain	—	—	—	171	—	171
Accumulated depreciation upon adoption of ASU Topic 842	—	—	—	—	51	51
Net loss	—	—	—	—	(54,266)	(54,266)
Balance as of March 31, 2019	62,470	\$ 6	\$ 786,681	\$ 63	\$ (530,449)	\$ 256,301

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

AIMMUNE THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands)
(Unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2017	51,091	\$ 5	\$ 443,390	\$ (108)	\$ (265,482)	\$ 177,805
Issuance of common stock upon exercise of vested options	308	—	2,743	—	—	2,744
Issuance of common stock upon securities agreement	300	—	—	—	—	—
Issuance of common stock upon public offering	6,325	1	190,453	—	—	190,453
Stock-based compensation	—	—	7,607	—	—	7,607
Other comprehensive loss	—	—	—	(17)	—	(17)
Net loss	—	—	—	—	(49,500)	(49,500)
Balance as of March 31, 2018	58,024	\$ 6	\$ 644,193	\$ (125)	\$ (314,982)	\$ 329,092

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

AIMMUNE THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Quarter Ended March 31,	
	2019	2018
Cash flows from operating activities:		
Net loss	\$ (54,266)	\$ (49,500)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation expense	666	356
Stock-based compensation expense	7,765	7,607
Non-cash interest expense	1,065	—
Amortization of premium on investment securities	(542)	(25)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	1,433	(36)
Accounts payable	1,945	(431)
Accrued liabilities	(3,555)	2,448
Other liabilities	(340)	(183)
Net cash used in operating activities	<u>(45,829)</u>	<u>(39,764)</u>
Cash flows from investing activities:		
Purchase of property and equipment	(1,372)	(2,383)
Purchase of investments	(85,564)	(64,274)
Maturities of investments	67,408	50,802
Net cash used in investing activities	<u>(19,528)</u>	<u>(15,855)</u>
Cash flows from financing activities:		
Borrowings under debt agreement	40,000	—
Debt issuance costs, net	(3,856)	—
Proceeds from underwritten public offering, net of offering costs	—	189,463
Net cash proceeds from exercise of stock options, including early exercise	3,250	1,993
Tax withholdings related to net share settlements of restricted stock units	(490)	—
Net cash provided by financing activities	<u>38,904</u>	<u>191,456</u>
Net increase (decrease) in cash and cash equivalents	(26,453)	135,837
Cash and cash equivalents at the beginning of the period	107,511	73,487
Cash and cash equivalents at the end of the period	<u>\$ 81,058</u>	<u>\$ 209,324</u>
Supplemental disclosure of non-cash investing and financing activities:		
Property and equipment purchases included in accounts payable and accrued liabilities	\$ 1,051	\$ 1,788
Receivable for underwritten public offering	—	\$ 990
Debt issuance costs, discount and interest payable	\$ 981	—
Receivable for stock option exercises	\$ 383	\$ 752

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

AIMMUNE THERAPEUTICS, INC.
NOTES TO UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
March 31, 2019
(Unaudited)

1. Formation and Business of the Company

Aimmune Therapeutics, Inc., or the Company, is 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. Our therapeutic approach, which we refer to as Characterized Oral Desensitization Immunotherapy, or CODITM, is a therapeutic approach designed to desensitize patients to food allergens using rigorously characterized biologic products, defined treatment protocols and tailored support services. We are headquartered in Brisbane, California, and were incorporated in the state of Delaware on June 24, 2011.

Since inception, we have incurred net losses and negative cash flows from operations. During the quarter ended March 31, 2019, we incurred a net loss of \$54.3 million, and we used \$45.8 million of cash in operations. As of March 31, 2019, we had an accumulated deficit of \$530.4 million, and we do not expect to experience positive cash flows in the near future. As of March 31, 2019, we had cash, cash equivalents and investments of \$296.3 million. We believe that our existing capital resources will be sufficient to fund our planned operations for at least the next 12 months and through expected regulatory approval in the United States for AR101, our lead CODITM product candidate. We have financed our operations to date primarily through private placements of our equity securities, our initial public offering, or IPO, of common stock in August 2015, an underwritten public offering of common stock in February and March 2018 and our loan agreement entered into in January 2019. Our ability to continue to meet our obligations and to achieve our business objectives is dependent upon a number of factors, which include obtaining U.S. Food and Drug Administration, or FDA, and European Medicines Agency, or EMA, approval, raising additional capital, the successful and timely completion of our clinical trials, our ability to control expenses and generating sufficient revenue in the United States and Europe. Failure to obtain FDA and EMA approval, commercialize our lead product candidate, manage discretionary expenditures, or raise additional financing, as required, may adversely impact our ability to achieve our intended business objectives.

2. Summary of Significant Accounting Policies

Basis of Preparation

The accompanying condensed consolidated financial statements have been prepared in accordance with Generally Accepted Accounting Principles, or GAAP, in the United States and applicable rules and regulations of the Securities and Exchange Commission, or SEC, regarding interim financial reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. GAAP have been condensed or omitted, and accordingly the balance sheet as of December 31, 2018, has been derived from audited consolidated financial statements at that date but does not include all of the information required by U.S. GAAP for complete financial statements. These condensed consolidated financial statements have been prepared on the same basis as our annual financial statements and, in the opinion of management, reflect all adjustments (consisting only of normal recurring adjustments) that are necessary for a fair presentation of our financial information. The results of operations for the quarter ended March 31, 2019, are not necessarily indicative of the results to be expected for the year ending December 31, 2019, or for any other interim period or for any other future year. We operate in one reportable segment.

The accompanying condensed consolidated financial statements and related financial information should be read in conjunction with the audited consolidated financial statements and the related notes thereto for the year ended December 31, 2018, included in our Annual Report on Form 10-K filed with the SEC.

Basis of Consolidation

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

Use of Estimates

The preparation of the accompanying condensed consolidated financial statements in accordance with U.S. GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements, and the reported amounts of costs and expenses during the reporting period. We base our estimates and assumptions on historical experience when available and on various factors that we believe to be reasonable under the circumstances. We evaluate our estimates and assumptions on an ongoing basis. Our actual results could differ from these estimates under different assumptions or conditions.

Significant Accounting Policies

There have been no significant changes to the accounting policies during the quarter ended March 31, 2019, as compared to the significant accounting policies described in Note 2 of the “Notes to Consolidated Financial Statements” in our audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2018, except as noted below.

Recently Adopted Accounting Pronouncements

We adopted Accounting Standards Update, or ASU No. 2016-02, *Leases (Topic 842)*, as of January 1, 2019 using the alternative modified retrospective approach provided in ASU No. 2018-11, *Lease (Topic 841): Targeted Improvements*. In doing so, we have continued to apply ASC 840 in the comparative periods and recognized the cumulative-effect of applying Topic 842 to retained earnings on January 1, 2019. We elected a package of practical expedients for leases that commenced prior to January 1, 2019, which among other things, allowed us to carry forward the historical lease assessment for: (i) whether any expired or existing contracts are or contain leases; (ii) lease classification for any expired or existing leases; and (iii) initial direct costs capitalization for any existing leases. We have also elected a practical expedient, by class of underlying asset, not to separate non-lease components from lease components and instead to account for each separate lease component and the non-lease components associated with that lease component as a single lease component. We have made an accounting policy election to not apply the recognition requirements to leases with a lease term of 12 months or less. We have recognized those lease payments in the consolidated statements of operations on a straight-line basis over the lease term and variable lease payments in the period in which the obligation for those payments is incurred.

Adoption of this standard has resulted in the recognition of operating lease right of use assets \$12.2 million and lease liabilities of \$13.6 million as of March 31, 2019. The standard did not materially impact our consolidated statement of operations or our consolidated statements of cash flows.

We adopted ASU No. 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting (Topic 718)*, as of January 1, 2019, which amends ASC Topic 718, “Compensation—Stock Compensation”. The ASU simplifies the accounting for share-based payments granted to nonemployees for goods and services. Under the ASU, most of the guidance on such payments to nonemployees would be aligned with the requirements for share-based payments granted to employees. Upon adoption of this standard, share-based awards issued to nonemployees are measured at the grant date and are not subject to remeasurement. We have elected to continue to use the contractual term as the estimated expected term. The adoption of ASU No. 2018-07 did not have a material impact on our financial statements and is expected to reduce the volatility in stock-based compensation expense for nonemployees recognized from period to period.

Recently Issued Accounting Pronouncements Not Yet Adopted

In August 2018, the Financial Accounting Standards Board, or the FASB issued ASU 2018-13, *Fair Value Measurement: Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement*, which adds and modifies certain disclosure requirements for fair value measurements. Under the new guidance, entities will no longer be required to disclose the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, or valuation processes for Level 3 fair value measurements. However, public companies will be required to disclose the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and related changes in unrealized gains and losses included in other comprehensive income. ASU 2018-13 is effective for fiscal periods beginning after December 15, 2019, with early adoption permitted. We are currently evaluating the impact that the adoption of ASU 2018-13 will have on our consolidated financial statements and related disclosures.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which requires measurement and recognition of expected credit losses for financial assets held. ASU 2016-13 modifies the other-than-temporary impairment model for available-for-sale debt securities and requires an estimate of expected credit losses when the fair value is below the amortized cost of the asset. ASU 2016-13 is effective for fiscal years beginning after December 15, 2019 and interim periods within those fiscal years. Early adoption is permitted. We are currently evaluating the impact that the adoption of ASU 2016-13 will have on our consolidated financial statements and related disclosures.

3. Available-for-Sale Securities and Fair Value Measurements

We define fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

Our valuation techniques are based on observable and unobservable inputs. Observable inputs reflect readily obtainable data from independent sources, while unobservable inputs reflect our market assumptions. We classify these inputs into the following hierarchy:

- Level 1—Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;
- Level 2—Inputs are observable, unadjusted quoted prices in active markets for similar assets or liabilities, unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and
- Level 3—Unobservable inputs that are significant to the measurement of the fair value of the assets or liabilities that are supported by little or no market data.

The following tables set forth our financial instruments that were measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

	March 31, 2019			
	Level 1	Level 2	Level 3	Total
Cash and cash equivalents:				
Cash and money market funds	\$ 74,044	\$ —	\$ —	\$ 74,044
Agency securities	—	\$ 2,191	—	\$ 2,191
Corporate securities	—	4,823	—	\$ 4,823
Total cash and cash equivalents	\$ 74,044	\$ 7,014	\$ —	\$ 81,058
Investments:				
Agency securities	\$ —	\$ 22,771	\$ —	\$ 22,771
Corporate securities	—	63,653	—	63,653
U.S. government securities	—	128,866	—	128,866
Total investments	\$ —	\$ 215,290	\$ —	\$ 215,290

	December 31, 2018			
	Level 1	Level 2	Level 3	Total
Cash and cash equivalents:				
Cash and money market funds	\$ 107,511	\$ —	\$ —	\$ 107,511
Total cash and cash equivalents	\$ 107,511	\$ —	\$ —	\$ 107,511
Investments:				
Agency securities	—	17,352	—	17,352
Corporate securities	—	54,474	—	54,474
Commercial paper	—	5,965	—	5,965
U.S. government securities	—	118,630	—	118,630
Total investments	\$ —	\$ 196,421	\$ —	\$ 196,421

Our valuation techniques used to measure the fair value of money market funds were derived from quoted prices in active markets for identical assets. The valuation techniques used to measure the fair value of investments, all of which have counterparties with high credit ratings, were valued based on quoted market prices or model-driven valuations using significant inputs derived from or corroborated by observable market data. Investments are carried at fair value. During the quarters ended March 31, 2019 and 2018, there were no transfers between Level 1 and Level 2 of the fair value hierarchy.

Available-for-sale investments are carried at fair value and are included in the tables above. The aggregate market value, cost basis, and gross unrealized gains and losses of available-for-sale investments by security type, classified in cash equivalents and investments, as of March 31, 2019 and December 31, 2018, are as follows (in thousands):

	March 31, 2019			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Total Fair Value
Agency securities	\$ 24,961	\$ 4	\$ (2)	\$ 24,963
Corporate securities	68,472	23	(20)	68,475
U.S. government securities	128,809	72	(15)	128,866
Total available-for-sale investments	<u>\$ 222,242</u>	<u>\$ 99</u>	<u>\$ (37)</u>	<u>\$ 222,304</u>

	December 31, 2018			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Total Fair Value
Agency securities	\$ 17,361	\$ —	\$ (9)	\$ 17,352
Corporate securities	54,536	—	(62)	54,474
Commercial paper	5,965	—	—	5,965
U.S. government securities	118,667	14	(51)	118,630
Total available-for-sale investments	<u>\$ 196,529</u>	<u>\$ 14</u>	<u>\$ (122)</u>	<u>\$ 196,421</u>

At March 31, 2019, all of the available-for-sale securities have contractual maturities within twenty-one months. We periodically review our available-for-sale investments for other-than-temporary impairment loss. We consider factors such as the duration, severity and the reason for the decline in value, the potential recovery period and our intent to sell. For debt securities, we also consider whether (i) it is more likely than not that we will be required to sell the debt securities before recovery of their amortized cost basis, and (ii) the amortized cost basis cannot be recovered as a result of credit losses. During the quarters ended March 31, 2019 and 2018, we did not recognize any other-than-temporary impairment losses. All marketable securities with unrealized losses have been in a loss position for less than twelve months.

The carrying value of the Company's long-term debt approximates its fair value at each balance sheet date due to its variable interest rate, which approximates a market interest rate.

4. Balance Sheet Components

Property and Equipment, Net

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

	March 31, 2019	December 31, 2018
Furniture and equipment	\$ 2,624	\$ 2,221
Computer equipment	2,380	2,073
Manufacturing equipment	5,446	1,733
Leased equipment	100	100
Leasehold improvements	15,458	4,469
Buildings	—	688
Construction in progress	4,627	18,295
Property and equipment, gross	30,635	29,579
Less: accumulated depreciation	(3,811)	(3,251)
Property and equipment, net	<u>\$ 26,824</u>	<u>\$ 26,328</u>

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	March 31, 2019	December 31, 2018
Compensation and benefits	\$ 5,938	\$ 8,912
Research and development	13,913	15,504
Professional and consulting	5,374	4,691
Other	363	37
Total accrued liabilities	\$ 25,588	\$ 29,144

5. Long-term debt, net of discounts

In January 2019, we entered into a loan agreement with an affiliate of KKR for up to \$170.0 million in three tranches, or KKR Loans. Of the total loan amount, \$40.0 million was funded upon closing of the transaction, with \$85.0 million to be funded upon FDA approval of AR101, or Regulatory Approval and satisfaction of other customary borrowing conditions, and \$45.0 million to be made available at our option in 2020 upon the satisfaction of certain borrowing conditions. The KKR Loans have a maturity date being the earliest of (a) January 3, 2025, or if Regulatory Approval has not occurred on or before December 31, 2020, January 15, 2021 and (b) the date that is 91 days prior to the earliest current maturity date of any other loans we might have in excess of \$15.0 million prior to the funding of the third tranche of the KKR Loans or \$25.0 million following the funding of the third tranche of the KKR Loans. The KKR Loans bear interest through maturity, at our election with respect to (a) Alternate Base Rate, or ABR Loans, 6.50% per annum and (b) London Interbank Offered Rate, or LIBOR Loans, 7.50% per annum. We have the option to elect to make interest payments from available funds or make interest payments in kind by capitalizing such interest amounts on the applicable interest payment date by adding the amounts to the outstanding principal amount of the loan. Any capitalized amounts also bear interest. We selected to pay in kind and have the interest capitalized for the fiscal quarter ending March 31, 2019. We will begin paying accrued interest on outstanding KKR Loans on the last business day of each March, June, September and December thereafter while any KKR Loans are outstanding, as well as on the final maturity date of the KKR Loans (each such date, an "Interest Payment Date").

Principal payments on the KKR Loans are paid according to the following schedule: (i) on December 31, 2023, 50.0% of the outstanding principal amount of the loans as of such date, including any capitalized interest, (ii) on each Interest Payment Date thereafter, 12.5% of the outstanding principal amount of the KKR Loans as of December 31, 2023 and (iii) on January 3, 2025, or the Maturity Date, any remaining outstanding balance of the KKR Loans. We are also required to make mandatory prepayments of the KKR Loans under the Agreement, subject to specified exceptions, with the proceeds of asset sales, debt issuances, royalty transactions, collaboration transactions, and specified other events. In addition, upon the occurrence of a change of control, we must prepay, the outstanding amount of the KKR Loans.

The KKR Loans can be prepaid at our discretion, at any time, subject to prepayment fees. If all or any of the KKR Loans are prepaid or required to be prepaid, then we must pay, in addition to such prepayment, a prepayment premium (the "Prepayment Premium") equal to (i) with respect to any such prepayment paid on or prior to January 3, 2021, the amount, if any, by which (a) the present value as of such date of determination of (x) 105.00% of the principal amount of the KKR Loans prepaid plus (y) all required interest payments that would have been due on the principal amount of the KKR Loans prepaid through and including January 3, 2021, computed using a discount rate equal to the treasury rate most nearly equal to the period from such date of prepayment to January 3, 2021 plus 50 basis points exceeds (b) the principal amount of the KKR Loans prepaid, (ii) with respect to any prepayment paid or required to be paid after January 3, 2021 but on or prior to January 3, 2022, 5.00% of the principal amount of the KKR Loans prepaid, (iii) with respect to any prepayment paid or required to be paid after January 3, 2022 but on or prior to January 3, 2023, 2.00% of the principal amount of the KKR Loans prepaid and (iv) with respect to any prepayment paid or required to be prepaid thereafter, 0.00% of the principal amount of the KKR Loans prepaid. If we receive Regulatory Approval and do not draw the \$85 million, then we would have to pay on the earlier of (i) the date on which commitments have been terminated and no KKR Loans are outstanding and (ii) the Interest Payment Date falling in the first full fiscal quarter after receipt of Regulatory Approval, a premium in an amount equal to \$3.4 million and the Prepayment Premium for such date on a principal amount equal to \$85.0 million. The premium with respect to the Regulatory Approval described in the immediately preceding sentence is not due if we draw the additional (after the first \$40.00 million on the closing date) \$85.0 million of the KKR Loans. In addition, upon the occurrence of a change of control, we must prepay, the outstanding amount of the KKR Loans. Upon the prepayment or repayment of all or any of the KKR Loans, we must pay an additional (in addition to the Prepayment Premium) exit fee in an amount equal to 4.00% of the principal amount of the KKR Loans prepaid or repaid.

In connection with the KKR Loans, we paid direct fees of \$3.9 million, including debt issuance costs. The fees are being amortized as interest expense over the term of the debt. As of March 31, 2019, and December 31, 2018, \$40.9 million and \$0, respectively, was outstanding under the KKR Loans. As of March 31, 2019, the interest rate on the KKR Loans was 9.99%.

The following table represents our short-term and long-term debt obligations (in thousands):

	March 31, 2019	
Principal amount of long-term debt	\$	40,920
Less: Current portion of long-term debt		-
Long-term debt, net of current portion		40,920
Unamortized discount relating to deferred financing costs, net		(3,712)
Accrued exit fee payment		60
Long-term debt, net of discount and current portion	\$	<u>37,268</u>

Future principal payments of our long-term debt as of March 31, 2019 are as follows:

Fiscal year ending December 31:	
2019	\$ -
2020	-
2021	-
2022	-
2023	20,460
Thereafter	20,460
Total	<u>\$ 40,920</u>

6. Commitments and Contingencies

Leases

We lease facilities for office and manufacturing space under various operating leases and a security system under a financing lease. Our leases have remaining lease terms of approximately 1 year to 6 years, which represent the non-cancellable periods of the leases and include extension options that we determined are reasonably certain to be exercised. We exclude extension options that are not reasonably certain to be exercised from our lease terms. Our lease payments consist primarily of fixed rental payments for the right to use the underlying leased assets over the lease terms. We often receive customary incentives from our landlords, such as reimbursements for tenant improvements and rent abatement periods, which effectively reduce the total lease payments owed for these leases.

Operating lease right-of-use assets and liabilities on our condensed consolidated balance sheets represent the present value of our remaining lease payments over the remaining lease terms. We do not allocate lease payments to non-lease components. We use our incremental borrowing rate to calculate the present value of our lease payments, as the implicit rates in our leases are not readily determinable.

As of March 31, 2019, the maturities of our operating lease liabilities were as follows (in thousands):

	Remaining Lease Payments			
	March 31, 2019			
	Operating	Financing	Total	
2019	\$ 2,350	\$ 25	\$ 2,375	
2020	3,330	34	3,364	
2021	3,413	35	3,448	
2022	3,497	9	3,506	
2023	3,378	-	3,378	
Thereafter	1,744	-	1,744	
Total lease payments	\$ 17,712	\$ 103	\$ 17,815	
Less: Effects of discounting	(4,112)	(29)	(4,141)	
Present value of lease liabilities	\$ 13,600	\$ 74	\$ 13,674	
Less: current portion	(1,967)	(19)	(1,986)	
Long-term lease liabilities	\$ 11,633	\$ 55	\$ 11,688	
Weighted-average remaining lease term	5.2 years	3 years		
Weighted-average incremental borrowing rate	11%	23%		

The component of our lease costs included in our condensed consolidated statements of income were as follows (in thousands):

Lease Cost	Three Months Ended March 31, 2019	
Operating lease cost	\$	965
Finance lease cost		
Amortization of leased assets		8
Interest on lease liabilities		4
Net lease cost	\$	977

Other information related to our operating lease was as follows (in thousands):

Other Information	Three Months Ended March 31, 2019	
Cash paid for amounts included in the measurement of lease liabilities		
Operating cash flows from operating leases	\$	965
Operating cash flows from finance leases	\$	12

Total future aggregate minimum lease payments calculated under ASC 840 at December 31, 2018 were as follows (in thousands):

	Remaining Lease Payments December 31, 2018		
	Operating	Financing	Total
2019	\$ 3,133	\$ 33	\$ 3,166
2020	3,330	34	3,364
2021	3,413	35	3,448
2022	3,497	9	3,506
2023	3,378	-	3,378
Thereafter	1,744	-	1,744
Total lease payments	\$ 18,495	\$ 111	\$ 18,606
Less: amount representing interest	-	(33)	(33)
Value of lease liabilities under ASC 840	\$ 18,495	\$ 78	\$ 18,573
Less: current portion	(3,133)	(17)	(3,150)
Long-term lease liabilities	\$ 15,362	\$ 61	\$ 15,423

Purchase Commitments

We purchase food-grade peanut flour from Golden Peanut Company, or GPC, pursuant to a long-term exclusive commercial supply agreement, which was expanded and extended in January 2018. GPC is precluded from selling several peanut flour products to any third party worldwide for use in oral immunotherapy, or OIT for the treatment or cure of peanut allergy, provided that we are in compliance with our exclusive purchase obligation and meet specified annual purchase commitments. The restated agreement remains in effect until ten 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.

In connection with the expansion and extension of the agreement, we issued Archer Daniels Midland Company 300,000 shares of restricted common stock, vesting in four tranches over a 3.5 year period. Expense related to these shares will be measured as each tranche vests and recognized over the vesting period. At issuance, these shares had a fair value of \$11.7 million, which will be remeasured as each tranche vests and recognized as general and administrative expense over the vesting period. Subject to certain exceptions, in the event that the price per share of our common stock were to fall below a specified level, the restated agreement provides that GPC would only be prohibited from selling one peanut flour product to any third party in the United States, Mexico, Canada, the European Union or Japan for use in OIT for the treatment or cure of peanut allergy.

Pursuant with the restated agreement, our purchase obligation commences with the first delivery of peanut flour for commercial use, which we currently anticipate will occur in 2019, and the aggregate purchase commitment under this agreement would be \$3.3 million over a term of ten years.

In December 2018, we entered into an exclusive supply agreement for egg protein with Michael Foods, Inc. Pursuant to the agreement, we have exclusive access to the clinical and commercial use of Michael Foods' egg products for any egg allergy treatment, prevention or cure for a period of up to 15 years beyond the potential approval of AR201.

Indemnifications

We indemnify each of our 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, we currently hold director and officer liability insurance. This insurance allows the transfer of risk associated with our exposure and may enable us to recover a portion of any future amounts paid. We believe that the fair value of these indemnification obligations is minimal. Accordingly, we have not recognized any liabilities relating to these obligations for any period.

Legal

We are currently not a party to any material legal proceedings. During the normal course of business, we may be a party to legal claims that may not be covered by insurance. We do not believe that any such claims would have a material impact on our consolidated financial statements.

7. Stock-Based Compensation

Equity Incentive Plan

In July 2015, we adopted the 2015 Stock Plan, or the 2015 Plan. Under the 2015 Plan, 4,681,544 shares of our common stock were initially 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, or the Board, and approved by our stockholders. As of March 31, 2019 and December 31, 2018 there were 4,986,595 and 4,364,963 shares available for future grant, respectively.

Under the terms of the 2015 Plan, options may be granted at an exercise price not less than fair market value. For employees holding more than 10% of the voting rights of all classes of stock, the exercise prices for incentive stock options may not be less than 110% of fair market value, as determined by the Board. The terms of options granted under the 2015 Plan may not exceed ten years. All options issued to date have had a ten-year life. To date, options granted generally vest in three ways: 1) over four years at a rate of 25% upon the first anniversary of the issuance date and 1/48th per month thereafter, 2) over two years at a rate of 1/24th per month, or 3) over four years at a rate of 1/48th per month. The 2015 Plan contains certain change of control provisions and the employment offer letters of certain employees provide for varied acceleration of vesting in the event of a change of control and/or termination without cause. It also contains a net exercise provision and allows for cashless exercise upon the class of shares subject to the option becoming publicly traded in an established securities market.

In August 2015, we adopted the 2015 ESPP, which commenced on January 1, 2018. Under the 2015 ESPP our employees may purchase common stock through payroll deductions at a price equal to 85% of the lower of the fair market value of the stock at the beginning of the offering period or at the end of each applicable purchase period. The 2015 ESPP generally provides for offering periods of six months in duration with purchase periods ending on either May 15 or November 15. Contributions under the 2015 ESPP are limited to a maximum of 15% of an employee's eligible compensation. ESPP purchases are settled with common stock from the ESPP's previously authorized and available pool of shares. We issued 41,030 shares at a weighted average price of \$25.28 per share during the year ended December 31, 2018. As of March 31, 2019, 2,405,786 shares under the ESPP remain available for purchase.

Our 2013 Stock Plan, or the 2013 Plan, which was originally adopted during January 2013, was terminated upon consummation of our IPO in August 2015. As a terminated plan, no further options can be granted from the 2013 Plan, and no further shares are reserved for issuance under the 2013 Plan.

Option activity under the 2015 Plan and 2013 Plan is set forth below:

	Options Outstanding			
	Number of Options and Unvested Shares	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Balance, December 31, 2018	7,133,113	\$ 20.08	7.6	\$ 27,413
Options granted	1,716,250	23.27		
Options exercised and shares vested	(273,552)	13.28		
Options cancelled	(266,198)	27.50		
Balance, March 31, 2019	8,309,613	20.72	8.1	\$ 35,447
Options vested and expected to vest as of March 31, 2019	7,785,350	20.40	8.0	\$ 35,152
Options exercisable as of March 31, 2019	3,466,655	\$ 14.62	8.1	\$ 26,781

The aggregate intrinsic values of options outstanding, exercisable, and vested and expected to vest were calculated as the difference between the exercise price of the options and the market price for shares of our common stock as of March 31, 2019. The 2013 Plan provided for early exercise, therefore, all our outstanding stock options issued under that plan are exercisable.

Restricted stock unit, or RSU, activity under the 2015 Plan is set forth below:

	Shares	Weighted Average Grant Date Fair Value
Unvested Balance, December 31, 2018	309,847	\$ 33.37
Awarded	437,475	23.34
Released	(53,854)	34.21
Forfeited	(23,468)	32.36
Unvested Balance, March 31, 2019	670,000	\$ 26.79

RSUs are measured based on the fair market value of the underlying stock on the date of grant and recognized as expense on a straight-line basis over the employee's requisite service period (generally the vesting period).

In connection with the expansion and extension of our long-term exclusive commercial supply agreement with GPC, we issued 300,000 shares of restricted common stock in January 2018. The restricted common stock vests in four tranches over a 3.5 year period and is measured based on the fair market value of the underlying stock as the shares vest. As of March 31, 2019, 75,000 shares had vested, and the remaining shares were restricted. As of March 31, 2019, total estimated unrecognized expense related to these restricted shares was \$4.2 million based upon the fair market value of our common stock on March 31, 2019, which is expected to be recognized over the remaining vesting period of 2.3 years as general and administrative expense. Stock-based compensation expense recognized during the quarters ended March 31, 2019 and 2018 related to these shares was \$0.4 million and \$1.1 million, respectively.

In February 2019, the Company issued 52,000 restricted stock units with a grant date fair value of approximately \$1.3 million, to certain key employees that include service and performance vesting conditions related to the achievement of certain regulatory approvals for AR101. Stock-based compensation expense will be recognized when we conclude that it is probable that the performance conditions will be achieved. We will reassess the probability of vesting at each reporting period and adjust stock-based compensation expense based on this probability assessment. As the vesting is contingent upon specific performance conditions, stock-based compensation expense related to the grant will not be recognized until the specified conditions are determined to have occurred. As none of the performance criteria were met as of the quarter ended March 31, 2019, we have not recognized any stock-based compensation related to these restricted stock units.

Valuation Assumptions

The weighted-average assumptions used to estimate the fair value of stock options using the Black-Scholes option valuation model and the resulting weighted average fair value of stock options granted were as follows:

	Quarter Ended March 31,	
	2019	2018
Expected term (in years)	6.0	6.0
Expected volatility	63.5%	68.5%
Risk free interest rate	2.5%	2.3%
Dividend yield	—%	—%
Weighted average estimated fair value	\$ 13.89	\$ 21.43

The weighted-average assumptions used to estimate the fair value of ESPP using the Black-Scholes option valuation model were as follows:

	Quarter Ended March 31,	
	2019	2018
Expected term (in years)	0.8	0.9
Expected volatility	50.2%	50.4%
Risk free interest rate	2.0%	1.8%
Dividend yield	—%	—%
Weighted average estimated fair value	\$ 11.06	\$ 12.42

Stock-Based Compensation Expense

Stock-based compensation expense, net of estimated forfeitures, reflected in the condensed consolidated statements of comprehensive loss is as follows (in thousands):

	Quarter Ended March 31,	
	2019	2018
Research and development	\$ 2,743	\$ 2,047
General and administrative	5,022	5,560
Total stock-based compensation expense	\$ 7,765	\$ 7,607

During the quarters ended March 31, 2019 and 2018, we recorded approximately \$0.4 million and \$1.2 million, respectively, of stock-based compensation expense related to the acceleration of certain former executives' stock options.

As of March 31, 2019, total unrecognized stock-based compensation expense and expected period over which such compensation will be recognized are as follows (\$ in thousands):

	Quarter Ended March 31, 2019	
Stock-option		
Unrecognized stock compensation expense	\$	63,862
Weighted-average remaining vesting period (years)		2.9
RSU		
Unrecognized stock compensation expense	\$	12,981
Weighted-average remaining vesting period (years)		3.2
ESPP		
Unrecognized stock compensation expense	\$	107
Weighted-average remaining vesting period (years)		0.1

8. Net Loss per Share

Basic net loss per share is calculated based on the weighted-average number of common shares outstanding during the periods presented. For periods in which we have generated a net loss, basic and diluted net loss per share are the same due to the requirement

to exclude potentially dilutive securities, consisting of common shares underlying outstanding stock options and restricted stock units, which would have an anti-dilutive effect on net loss per share.

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

	Quarter Ended March 31,	
	2019	2018
Stock options	8,309,613	7,272,857
Restricted stock units	670,000	278,937

9. Related Party Transaction

In June 2017, Mark McDade, a member of our Board of Directors, joined the Board of Directors of MyHealthTeams, a private company that creates social networks for people living with chronic conditions by partnering with pharmaceutical and healthcare companies. We entered into an agreement with MyHealthTeams in 2015 under which they provide services to us. During the quarters ended March 31, 2019 and 2018, there were payments of \$0.1 million in each period to MyHealthTeams pursuant to such agreement. At March 31, 2019 and December 31, 2018, there were no accrued liabilities due under the MyHealthTeams agreement.

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

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our unaudited condensed consolidated financial statements and related notes included in Part 1, Item 1 of this Quarterly Report on Form 10-Q and with our audited financial statements and related notes thereto for the year ended December 31, 2018, included in our Annual Report on Form 10-K for the year ended December 31, 2018, filed with the Securities and Exchange Commission on February 28, 2019. This discussion and other parts of this report contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section of this report titled "Risk Factors." Except as may be required by law, we assume no obligation to update these forward-looking statements or the reasons that results could differ from these forward-looking statements.

Overview

We are a clinical-stage biopharmaceutical company advancing a new therapeutic approach, including the development of proprietary product candidates, to reduce the frequency and severity of allergic reactions, including anaphylaxis, upon exposure to peanut and other food allergens. 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. There are currently no approved medical therapies to cure food allergies or prevent their symptoms. Patients with food allergies are typically counseled to practice strict dietary avoidance. When accidental exposure to food allergens invokes a serious allergic reaction, rescue therapies, such as antihistamines or injectable epinephrine, are the only recourse available. Our therapeutic approach, which we refer to as Characterized Oral Desensitization ImmunoTherapy, or CODIT™, is designed to desensitize patients to food allergens and thereby reduce the risk of having an allergic reaction upon allergen exposure or reduce symptom severity should an allergic reaction occur. CODIT is intended to reduce meaningfully the burden and anxiety experienced by food-allergic patients and their families.

Our lead CODIT product candidate, AR101, is an investigational biologic for the treatment of patients with peanut allergy, which affects approximately three million patients in the United States and three million patients in Europe. AR101 has received Fast Track and Breakthrough Therapy Designations for the treatment of patients 4-17 years of age from the United States Food and Drug Administration, or FDA. In February 2018, we announced positive data from our Phase 3 efficacy trial of AR101 in the United States, Canada and Europe, which we refer to as the PALISADE (Peanut Allergy Oral Immunotherapy Study of AR101 for Desensitization in Children and Adults) trial. In November 2018, we announced positive topline results real-world experience safety trial of AR101 in the United States and Canada in patients ages 4-17, which we refer to as the RAMSES (Real-World AR101 Market-Supporting Experience Study in Peanut Allergic Children Ages 4-17 Years) trial. In addition, we have two ongoing roll-over studies relating to the PALISADE and RAMSES trials.

We filed a Biologics License Application, or BLA, for AR101 to the FDA in December 2018. The FDA initiated review of the BLA for AR101 in January 2019 and accepted the BLA filing on March 18, 2019. The FDA has determined that AR101, as an allergenic product candidate, is exempt from the Prescription Drug User Fee Act, as amended, or PDUFA, and has informed us that the BLA will be reviewed under a twelve-month target review period as measured from the January 2019 start date.

Our initial target patient population for AR101 is children and adolescents in the 4-17 age group with a diagnosed peanut allergy, which we estimate applied to approximately 1.6 million patients in the United States alone during 2018.

In February 2018, we completed enrollment of 175 patients in our European Phase 3 efficacy trial designed with a higher efficacy bar of tolerating 1,000 mg of peanut protein in an exit food-challenge without anything more than mild, transient symptoms, which we refer to as the ARTEMIS (AR101 Trial in Europe Measuring Oral Immunotherapy Success) trial. On March 25, 2019, we announced that the ARTEMIS trial met its primary efficacy endpoint, the ability of patients to tolerate a 1,000 mg single dose of peanut protein.

We expect to submit a Marketing Authorization Application, or MAA, with the European Medicines Agency, or EMA, in mid-2019.

We maintain worldwide commercial rights to all of our product candidates, including AR101 and, if approved, currently intend to commercialize in the United States and Europe by developing a specialty sales force targeting practicing allergists targeting a subset of the approximately 5,000 practicing allergists in the United States and allergy-focused clinicians in major European markets.

We are in the process of developing formulations for additional CODIT product candidates beyond peanut allergy and have formulation and manufacturing activities ongoing for a product candidate designed to treat egg allergy, AR201. We are also exploring a product candidate designed to treat multi-nut allergy, including walnut allergy. Review of our investigational new drug application, or IND, for AR201 was completed by the FDA in February 2019. As such, we have been cleared to advance AR201 into a Phase 2 clinical trial, which we expect to commence in mid-2019. In addition, we are also conducting research and development activities for potential CODIT product candidates targeting other food allergies, including cow's milk allergy.

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 \$54.3 million for the quarter ended March 31, 2019 and used \$45.8 million of cash in operations. As of March 31, 2019, our accumulated deficit was \$530.4 million. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase as we continue our development of, seek regulatory approval for, and begin to commercialize AR101, and as we develop other product candidates

In January 2019, we entered into a loan agreement with an affiliate of KKR for up to \$170.0 million in three tranches. Of the total loan amount, \$40.0 million was funded upon the closing of the transaction, with \$85.0 million to be funded upon FDA approval of AR101 and satisfaction of other customary borrowing conditions, and \$45.0 million to be made available at our option in 2020, upon the satisfaction of certain borrowing conditions.

We currently utilize contract manufacturers for all our manufacturing activities. In June 2015, we entered into a lease for a manufacturing facility in Clearwater, Florida. In June 2017, we completed the construction of the manufacturing facility within the leased building, which we intend to handle full-scale cGMP (current Good Manufacturing Practices) commercial production of AR101, if approved, and supply future clinical trials of AR101. This manufacturing facility became operational in November 2018. We plan to continue to rely on the contract manufacturer that is located at the same site to manage the operations of this new manufacturing facility. Additionally, we currently utilize specialized clinical vendors, clinical trial sites, consultants, and clinical research organizations, or CROs, to ensure the proper and timely conduct of our clinical trials, and we do not yet have a sales organization. We expect to continue to significantly increase our investment in our manufacturing process and commercial organization as we prepare for the filing of a MAA with the EMA and prepare for the potential approval of our BLA for AR101 in the United States and 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 condensed consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles, or GAAP, in the United States. The preparation of these condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated 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.

There have been no new policies or significant changes to our critical accounting policies as disclosed in the critical accounting policies described in our Annual Report on Form 10-K for the year ended December 31, 2018, except as noted below.

Recent Accounting Pronouncements

See Note 2, Summary of Significant Accounting Policies of the Notes to Condensed Consolidated Financial Statements included in Item 1 of this Quarterly Report on Form 10-Q for additional information.

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 external clinical-related expenses, employee-related costs, stock-based compensation expense, and facilities and other costs, which include the following:

- External clinical-related expenses include costs incurred to conduct research, such as the discovery and development of our product candidates; costs related to the production of clinical supplies, including fees paid to contract manufacturers; fees paid to consultants 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; costs for scientific conferences and meetings; and costs related to compliance with drug development regulatory requirements.
- Employee-related costs include salaries, bonuses, severance and benefits for personnel in our research and development functions.

- Stock-based compensation expense is expense associated with our equity plans for awards to personnel in our research and development functions.
- Facilities and other costs include facilities-related rent, depreciation and other allocable expenses, which include general and administrative support functions and general supplies for our research and development activities.

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

General and Administrative Expenses

General and administrative expenses include employee-related costs, stock-based compensation expense, external professional services expenses, and facilities and other costs. Employee-related costs include salaries, bonuses, severance and benefits for personnel in our general and administrative functions, including medical affairs. Stock-based compensation expense is expense associated with our equity plans for awards to personnel in our general and administrative functions. External professional services expenses consist of legal, accounting, and audit services, certain medical affairs related-expenses and other consulting fees. Facilities and other costs consist of allocable expenses, including facilities-related rent and depreciation, from our facilities and information technology departments, which are allocated between research and development and general and administrative functions based on headcount.

Results of Operations

Comparison of the Quarters Ended March 31, 2019 and 2018

	Quarter Ended March 31,		\$ Change	% Change
	2019	2018		
	(In thousands)			
Operating expenses:				
Research and development	\$ 31,316	\$ 33,446	\$ (2,130)	(6)%
General and administrative	23,712	16,673	7,039	42%
Total operating expenses	55,028	50,119	4,909	10%
Loss from operations	(55,028)	(50,119)	(4,909)	10%
Interest income, net	791	636	155	24%
Loss before provision for income taxes	(54,237)	(49,483)	(4,754)	10%
Provision for income taxes	29	17	12	71%
Net loss	\$ (54,266)	\$ (49,500)	\$ (4,766)	10%

Research and Development Expenses

The following table summarizes our research and development expenses incurred during the quarters ended March 31, 2019 and 2018:

	Quarter Ended March 31,		\$ Change	% Change
	2019	2018		
	(In thousands)			
External clinical-related expenses	\$ 17,764	\$ 22,613	\$ (4,849)	(21)%
Employee-related costs	8,275	6,677	1,598	24%
Stock-based compensation expense	2,743	2,047	696	34%
Facilities and other costs	2,534	2,109	425	20%
Total research and development expenses	\$ 31,316	\$ 33,446	\$ (2,130)	(6)%

Research and development expenses decreased by \$2.1 million for the quarter ended March 31, 2019, compared to the quarter ended March 31, 2018, primarily due to decreased external clinical-related expenses, which were partially offset by increased employee-related costs, stock-based compensation expense, and facilities and other costs. External clinical-related costs decreased primarily due to the close-out of certain AR101 clinical trials, including RAMSES, ARCO09, ARTEMIS and ARCO11. Employee-related costs and stock-based compensation expense increased primarily due to increased headcount to support continued development of AR101. Facilities and other costs increased primarily due to the allocation of higher facilities and information technology costs, which are allocable from general and administrative to research and development expenses based on headcount.

We expect research and development expenses to continue to increase in the near-term as we develop additional CODIT product candidates, including for the treatment of egg allergy and walnut allergy.

General and Administrative Expenses

The following table summarizes our general and administrative expenses incurred during the quarters ended March 31, 2019 and 2018:

	Quarter Ended March 31,		\$ Change	% Change
	2019	2018		
	(In thousands)			
Employee-related costs	\$ 8,884	\$ 4,550	\$ 4,334	95%
Stock-based compensation expense	5,022	5,560	(538)	(10)%
External professional services	9,327	6,319	3,008	48%
Facilities and other costs	479	244	235	96%
Total general and administrative expenses	<u>\$ 23,712</u>	<u>\$ 16,673</u>	<u>\$ 7,039</u>	<u>42%</u>

General and administrative expenses increased by \$7.0 million for the quarter ended March 31, 2019, compared to the quarter ended March 31, 2018, primarily due to increased external professional services costs and employee-related costs, partially offset by lower stock-based compensation expense. External professional services increased primarily due to consulting services for commercial planning, medical education and grants, and support for AR101. The increased headcount was for additional administrative support for the continued buildout of our infrastructure to support the potential commercialization of AR101, including the establishment of key commercial functions such as marketing, market access and medical affairs. Stock-based compensation expense decreased primarily due to lower expense from GPC as a result of Tranche 1 vesting over a shorter period than Tranche 2 and lower stock option modification expense.

We expect our general and administrative expenses to continue to increase as we continue to build our infrastructure, including the hiring of additional personnel, incur expenses related to commercial planning for AR101.

Interest Income, net

Interest income, net, increased by \$0.2 million for the quarter ended March 31, 2019, compared to the quarter ended March 31, 2018, primarily due to higher average cash, cash equivalents, and investment balances, as well as higher average return on our investments during the period.

Liquidity and Capital Resources

As of March 31, 2019, we had cash, cash equivalents and investments of \$296.3 million. We believe that our existing capital resources will be sufficient to fund our planned operations for at least the next 12 months and through expected regulatory approval in the United States for AR101, our lead CODIT™ product candidate.

In January 2019, we entered into a loan agreement with an affiliate of KKR for up to \$170.0 million in three tranches. Of the total loan amount, \$40.0 million was funded upon the closing of the transaction, with \$85.0 million to be funded upon FDA approval of AR101 and satisfaction of other customary borrowing conditions, and \$45.0 million to be made available at our option in 2020 upon the satisfaction of certain borrowing conditions.

In February and March 2018, we issued and sold 6,325,000 shares of our common stock, par value \$0.0001 per share, during our public offering for total proceeds of \$190.4 million, net of offering costs.

In November 2016, we and Nestle Health Science entered into the Purchase Agreement, pursuant to which we issued and sold 7,552,084 shares of our common stock, par value \$0.0001 per share, to Nestle Health Science for an aggregate cash purchase price of \$145.0 million.

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 is subject to significant uncertainty. If we complete clinical testing and receive approval of a BLA for AR101 in-line with our current expected timing, we would expect to be able to commence commercial sales of AR101 in the first half of 2020. Even if we are able to commence commercial sales in 2020, we may need to raise additional capital to fund our future operations. Until such time that we can generate substantial revenue from product sales, if ever, we expect to finance our operating activities through a combination of equity offerings and debt financings, and we may seek to raise additional capital through strategic collaborations. However, we may be unable to raise additional funds or enter into such arrangements when needed on favorable terms, or at all, which would have a negative impact on our financial condition and could force us to delay, limit, reduce or terminate our development programs or commercialization efforts or grant to others rights to develop or market product candidates that we would otherwise prefer to develop and market ourselves. Failure to receive additional funding could cause us to cease operations, in part or in full. Furthermore, even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital due to favorable market conditions or strategic considerations.

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

- the number, size and type of additional clinical trials or studies that we choose to initiate or the FDA or a foreign regulatory authority requires us to complete for as well as the cost and time of such trials and studies;
- the time and cost necessary to complete our roll-over studies related to our PALISADE trial (ARC004), RAMSES trial (ARC011) and ARTEMIS trial (ARC008);
- the time and cost necessary to supply clinical trial materials for our clinical trials and develop a commercial-scale manufacturing process and establish commercial-scale manufacturing capacity for AR101;
- our ability to obtain regulatory approval for and subsequently commercialize AR101 or any other product candidates we develop;
- commercialization costs associated with AR101, or any other product candidate we develop, if approved, including the cost and timing of developing our sales and marketing capabilities;
- the amount of sales and other revenue from AR101 or any other product candidates we develop, 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 time and cost associated with designing and implementing quality systems for our product candidates in the United States and Europe;
- the time and cost associated with clinical trials and pre-clinical development of other product candidates;
- the availability of term loans under our credit agreement;
- 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 additional product candidate and the associated costs of such activities, including for filing, prosecuting, defending and enforcing any patents for AR101 or any additional 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 our product candidates;
- our research and development activities; or
- our establishment of commercial capabilities or other activities that may be necessary to commercialize AR101 or any future product candidate.

Summary Statement of Cash Flows

	Quarter Ended March 31,		\$ Change
	2019	2018	
	(In thousands)		
Net cash provided by (used in):			
Operating activities	\$ (45,829)	\$ (39,764)	\$ (6,065)
Investing activities	(19,528)	(15,855)	(3,673)
Financing activities	38,904	191,456	(152,552)
Net change in cash and cash equivalents	<u>\$ (26,453)</u>	<u>\$ 135,837</u>	<u>\$ (162,290)</u>

Net Cash Used In Operating Activities

Net cash used in operating activities was \$45.8 million for the three months ended March 31, 2019, an increase of \$6.1 million from \$39.8 million for the quarter ended March 31, 2018. This increase was primarily due to higher net loss from operations resulting from increased operating expenses.

Net Cash Used In Investing Activities

Net cash used in investing activities was \$19.5 million for the quarter ended March 31, 2019, an increase of \$3.7 million from net cash used in investing activities of \$15.9 million for the quarter ended March 31, 2018. The increase was primarily due to purchases of investments and property and equipment.

Net Cash Provided By Financing Activities

Net cash provided by financing activities was \$38.9 million for the quarter ended March 31, 2019, a decrease of \$152.6 million from \$191.5 million for the quarter ended March 31, 2018. The decrease was due to 6,325,000 shares issued and sold during our public offering in February 2018, which was partially offset by our net debt borrowing under the KKR agreement of \$36.1 million in January 2019.

As of March 31, 2019, we had cash, cash equivalents and investments of \$296.3 million.

Contractual Obligations and Other Commitments

There have been no material changes in our contractual obligations and commitments from those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2018, except as noted below.

In January 2019, we entered into a loan agreement with an affiliate of KKR for up to \$170.0 million in three tranches, or KKR Loans. Of the total loan amount, \$40.0 million was funded upon closing of the transaction, with \$85.0 million to be funded upon FDA approval of AR101, or Regulatory Approval and satisfaction of other customary borrowing conditions, and \$45.0 million to be made available at our option in 2020 upon the satisfaction of certain borrowing conditions. The KKR Loans have a maturity date being the earliest of (a) January 3, 2025, or if Regulatory Approval has not occurred on or before December 31, 2020, January 15, 2021 and (b) the date that is 91 days prior to the earliest current maturity date of any other loans we might have in excess of \$15.0 million prior to the funding of the third tranche of the KKR Loans or \$25.0 million following the funding of the third tranche of the KKR Loans.

Off-Balance Sheet Arrangements

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

Segment Information

We have one primary business activity and operate as one reportable segment.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Our market risks have not changed materially from those disclosed in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2018, except as follows. As of March 31, 2019, we had approximately \$40.9 million in long-term debt with variable interest rate components. A hypothetical increase or decrease in overall interest rates is not expected to have a material impact on our interest expense.

Item 4. Controls and Procedures*Evaluation of disclosure controls and procedures.*

As required by Rule 13a-15(b) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), our management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of March 31, 2019. Based on the evaluation of our disclosure controls and procedures, our Chief Executive Officer and Chief Financial Officer have concluded that, as of March 31, 2019, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in internal control over financial reporting.

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended March 31, 2019, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

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

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

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

Item 1A. Risk Factors.

Our business involves significant risks, some of which are described below. You should carefully consider these risks, as well as the other information in this Quarterly Report on Form 10-Q, including our unaudited condensed consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations." 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. 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 development 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 Characterized Oral Desensitization Immunotherapy, or CODITTTM, therapeutic approach 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 \$ 54.3 million for the quarter ended March 31, 2019 and a net loss of \$210.8 million, \$131.3 million, and \$80.8 million for the years ended December 31, 2018, 2017 and 2016, respectively. At March 31, 2019, our accumulated deficit was \$ 530.4 million. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase as we continue to seek regulatory approval for and begin to commercialize AR101, and as we develop other product candidates. Even if AR101 is approved and 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.

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 timing and cost of our clinical trials, including the ability to initiate sites, enroll patients in a timely manner and submit or obtain approval of regulatory filings;
- the cost of manufacturing our product candidates and establishing commercial manufacturing capacity for AR101, 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.

We could 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 our CODIT therapeutic approach and AR101. At March 31, 2019, we had capital resources consisting of cash, cash equivalents and investments of \$296.3 million. We believe that we will continue to expend substantial resources for the foreseeable future as we continue to 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 obtaining regulatory approvals, commercialization of our product candidates, manufacturing and supply, conducting clinical trials, pursuing research and development activities and conducting non-clinical studies and general operations. In addition, other unanticipated costs may arise. Because the outcome of any clinical trial and/or regulatory approval process is highly uncertain, we may not be able to accurately estimate the actual amounts necessary to successfully complete the development, regulatory approval process and commercialization of AR101 or any other product candidates.

We believe that our existing capital resources will be sufficient to fund our planned operations for at least the next 12 months and through expected regulatory approval in the United States for AR101, our lead CODITTM product candidate. 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 collaboration agreements, we may have to relinquish valuable rights to our product candidates including possible future revenue streams. In addition, any fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates.

Furthermore, even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital due to favorable market conditions or strategic considerations.

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

- the number, size and type of additional clinical trials or studies that we choose to initiate or the U.S. Food and Drug Administration, or FDA or a foreign regulatory authority requires us to complete for AR101 as well as the cost and time of such trials and studies;
- the time and cost necessary to complete our roll-over studies related to our PALISADE trial (ARC004), RAMSES trial (ARC011) and ARTEMIS trial (ARC008);
- the time and cost necessary to supply clinical trial materials for our clinical trials and develop a commercial-scale manufacturing process and establish commercial-scale manufacturing capacity for AR101;
- our ability to obtain regulatory approval for and subsequently commercialize AR101 or any other product candidates we develop;
- commercialization costs associated with AR101 or any other product candidates we develop, if approved, including the cost and timing of developing our sales and marketing capabilities;
- the amount of sales and other revenue from AR101 or any other product candidates we develop, 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 time and cost associated with designing and implementing quality systems for our product candidates in the United States and Europe;

- the time and cost associated with clinical trials and pre-clinical development of other product candidates;
- the availability of term loans under our credit agreement;
- 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 additional product candidate and the associated costs of such activities, including for filing, prosecuting, defending and enforcing any patents for AR101 or any additional 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 our product candidates;
- our research and development activities; or
- our establishment of commercial capabilities or other activities that may be necessary to commercialize AR101 or any additional product candidate.

The terms of our credit agreement require us to meet certain operating covenants and place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

In January 2019, we entered into a credit agreement with an affiliate of KKR LLC, that is secured by a lien covering all of our tangible and intangible property. As of March 31, 2019, there was \$40.9 million of principal balance outstanding under the loan, which was funded in January 2019. An additional \$85.0 million term loan must be drawn by us following the fulfillment of certain customary conditions precedent, including the issuance of an approval letter from the FDA with respect to our Biologics License Application or BLA on or prior December 31, 2020. While our BLA for AR101 was accepted for review in March 2019, if we do not receive approval prior to December 31, 2020, the \$40.0 million initial term loan will terminate, which could restrict our operating and financial flexibility. Further, any delay or rejection of our AR101 could affect our ability to make scheduled interest payments on outstanding term loans under the credit agreement, which began on March 31, 2019, and could accelerate the maturity date of the term loans to January 15, 2021, which could have a material adverse effect on our business, results of operations, financial condition, prospects and stock price. The credit agreement contains customary affirmative and negative covenants and events of default, including, covenants and restrictions that among other things, require the Company and its subsidiary guarantors to satisfy a minimum cash balance covenant and restricts the ability of the Company and its subsidiary's ability to, incur liens, incur additional indebtedness, make loans and investments, engage in mergers and acquisitions, engage in asset sales or sale and leaseback transactions, and declare dividends or redeem or repurchase capital stock. A failure to comply with these covenants could permit the lenders under the credit agreement to declare the term Loans, together with accrued interest and fees, to be immediately due and payable. In addition, if we default under the terms of the credit agreement, including failure to satisfy our operating covenants, the lenders may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Further, if we are liquidated, the lender's right to repayment would be senior to the rights of the holders of our common stock. Any declaration by the lenders of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

Risks Related to Our Business

We are substantially dependent on the success of AR101 which may not be successful in clinical trials, receive regulatory approval or be successfully commercialized, even if approved.

We currently have no products approved for sale. To date, we have invested substantially all of our efforts and financial resources in the research and development of our CODIT therapeutic approach and AR101, which is currently our only product candidate in clinical development. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities. In order to obtain regulatory approval for the sale of AR101 from the FDA, or comparable foreign regulatory authorities, we must demonstrate the safety and efficacy of the product in humans. While we submitted our BLA for AR101 in December 2018 based upon the safety and efficacy findings in our completed and ongoing and future clinical trials, there can be no assurances that we will receive regulatory approval from the FDA, or that AR101 will successfully demonstrate safety and efficacy in any ongoing or future clinical trials we may be required to initiate. In addition, we cannot be certain AR101 will successfully demonstrate safety and efficacy in any clinical trials utilized for purposes of obtaining regulatory approval from any foreign regulatory authorities. Furthermore, even if we obtain approval for AR101, it may only be for a limited patient population, or may be received after significant delays. If we do not receive regulatory approval for AR101, we may not be able to continue our operations.

As a result, 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. The clinical and commercial success of AR101 will depend on a number of factors, many of which are out of our control, including the following:

- the results from our ongoing clinical trials, including ARC004, ARC005 and ARC011, and planned clinical trials, including ARC008;
- the frequency and severity of adverse effects experienced by patients treated with AR101, including in any clinical trials we may pursue with collaborators such as our Phase 2 trial sponsored by Regeneron evaluating AR101 treatment with adjunctive dupilumab;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing treatments;
- the ability of our third-party manufacturers to manufacture supplies of AR101, including their ability to provide adequate and timely supplies of our clinical trial materials 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, or GPC;
- 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 or other foreign regulatory authorities, or choose, to conduct additional clinical trials prior to the approval to market AR101, as well as the cost and time of such trials;
- whether the FDA or other foreign regulatory authorities may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the receipt of necessary regulatory approvals from the FDA and foreign regulatory authorities;
- the extent and nature of any Risk Evaluation and Mitigation Strategy, or REMS, or foreign equivalent, that may be required in connection with regulatory approval or following regulatory 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 comparable 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 continued prevalence of peanut allergy;
- 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 to AR101;

- our ability to avoid third-party intellectual property claims; and
- a continued acceptable safety profile of AR101 following approval.

Accordingly, we cannot assure our stockholders that we will ever be able to generate revenue through the sale of AR101 or become profitable as a result of such sales. If we are not able to successfully demonstrate the safety and efficacy of AR101 in humans in our clinical trials, obtain regulatory approval for AR101 for the indications we seek and successfully commercialize AR101, or if we are significantly delayed in doing so, our business will be materially harmed. In addition, if we are delayed in receiving or do not receive approval of our BLA for AR101, the availability of term loans under our credit agreement could be reduced, and the maturity of such term loans could be accelerated to January 15, 2021, any of which could further restrict our operating and financial flexibility as well as 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, which would delay the commercialization of AR101, adversely impact our ability to generate revenue, and harm our business and our results of operations.

We currently have no products approved for sale, and we may never obtain regulatory approval to commercialize AR101. To gain approval to market a biologic product candidate, such as AR101, a BLA or comparable foreign regulatory filing must be submitted to the FDA or comparable foreign regulatory authority. Such applications must include extensive clinical, non-clinical and manufacturing data that adequately demonstrate to the satisfaction of the FDA or comparable foreign 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. A BLA or other comparable foreign regulatory filing must also include significant information regarding the chemistry, manufacturing and controls for the product. Our AR101 BLA which we submitted in December 2018 and was accepted for review in March 2019 and we intend to file a Marketing Authorization Application, or MAA, for AR101 in the European Union in mid-2019.

The FDA or any comparable 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 that AR101 is safe, pure, potent and effective for the proposed indication or meets similar standards set by foreign authorities;
- the FDA or the applicable foreign regulatory authority may disagree with the interpretation of data from clinical trials;
- our inability to demonstrate that the clinical and other benefits of AR101 outweigh any safety or other perceived risks;
- the FDA or the applicable foreign regulatory authority may require additional nonclinical studies or clinical trials, including trials with additional patients in one or more subgroups or populations who have been administered AR101;
- 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 may disagree with the formulation, packaging, labeling and/or the specifications of AR101;
- if our AR101 BLA 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 that is more extensive than proposed by us;
- our inability to demonstrate that the manufacturing process for AR101 is adequately controlled to ensure that all product produced meets required quality standards;
- disruptions at the FDA and other regulatory agencies that are unrelated to our products, such as government shutdowns, that cause delays in the regulatory approval process;
- the FDA or the applicable foreign regulatory authority may fail to approve the manufacturing facilities or testing laboratories that we use; 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 foreign regulatory approval processes and are commercialized. In addition, the FDA has never approved a drug for treating food allergy through desensitization and, in particular, has never approved a drug based on efficacy as measured by a DBPCFC, which is the testing mechanism for determining the desensitization efficacy of AR101.

In addition, even though AR101 was granted Breakthrough Therapy designation by the FDA for oral immunotherapy of peanut allergic children and adolescents (ages 4 through 17), we may not experience a faster development, review or approval process compared to standard FDA procedures. Generally, 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 Breakthrough Therapy designation for AR101 has enabled us to hold additional meetings with the FDA during the development process and to receive advice from the FDA regarding development and approval for AR101. However, while our AR101 BLA, which we submitted in December 2018, was accepted for review in March 2019, the FDA has determined that our application will be reviewed under a twelve-month target review period applicable to Prescription Drug User Fee Act, as amended, or PDUFA, exempt applications, as measured from the date the FDA commenced review of our AR101 BLA in January 2019. As a result, review of the BLA may take until late January 2020. We are currently engaged in discussions with the FDA regarding the review timeline for the AR101 BLA.

Based on the FDA's current review timeline, review of the BLA for AR101 may take until late January 2020. However, we may not receive approval on this timeline or at all, in which case our ability to commence commercial sales of AR101 in the United States would be delayed. A significant delay could materially harm our business 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.

Even if we receive approval of a BLA or, following the completion of clinical testing, receive a foreign regulatory approval for AR101, pursuant to an MAA, 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 achieve our projected development and commercialization goals in the timeframes we announce and expect, the commercialization of AR101 or any additional product candidates may be delayed, and our business will be harmed.

For planning purposes, we sometimes estimate 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 and clinical trials, the submission of regulatory filings, or commercialization objectives. From time to time, we may publicly announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial, the initiation of other clinical programs, receipt of regulatory 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;
- our ability to identify and enroll patients who meet clinical trial eligibility criteria;
- the classifications of our product candidates by the FDA or other regulatory authorities;
- 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;
- our ability to manufacture and supply clinical trial materials to our clinical sites on a timely basis;
- 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 additional product candidates may be delayed, and our business and results of operations may be harmed.

We currently have no commercial field organization or distribution network, and we only recently deployed medical science liaison personnel. If we are unable to establish a commercial field organization 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 additional product candidates or generate product revenue.

We currently do not have a commercial field organization. In order to commercialize AR101, we will need to build our marketing, commercial field, 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 commercial field organization with technical expertise and supporting distribution capabilities to commercialize AR101 and any of our other product candidates that receive regulatory approval, which will be expensive and time-consuming.

We have no prior experience in the commercialization of pharmaceutical products and there are significant risks involved in building and managing a commercial field organization, including our ability to hire, retain, and incentivize qualified individuals, generate sufficient customer leads, provide adequate training to commercial field and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal commercial field, marketing and distribution capabilities would adversely impact the commercialization of these products. Further, given our lack of prior experience in commercializing pharmaceutical products, our estimates of the number of commercial field employees needed to commercialize AR101 may be materially less than the actual number of commercial field employees required. As such, we may be required to hire substantially more commercial field employees 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 began deployment of our medical science liaison, or MSL, organization in the third quarter of 2018. The MSL team is a field-based part of our medical affairs group. The role of MSLs is to serve as a liaison to members of the medical, scientific and patient advocate communities and to provide scientific expertise and clinical insights from health care practitioners to internal colleagues. The activities of MSLs are subject to extensive statutory and regulatory requirements and enforcement, in the United States, by the federal government and the states and, outside the United States, by the governments of the countries where we deploy MSLs. 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 MSL activities could be subject to challenge under one or more of such laws or regulations. 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.

We may also choose to collaborate with third parties that have direct commercial field forces or established distribution systems, either to augment our own commercial field force and distribution systems or in lieu of our own commercial field 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 additional product candidates, either on our own or through collaborations with one or more third parties, our additional product revenue will suffer and we would incur significant additional losses.

Even if AR101 or any additional 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 additional 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, caregivers and payors 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 additional 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 formulation and packaging;
- the willingness of patients to comply with a treatment regimen that requires daily administration of our product candidates on a chronic basis;
- the potential and perceived advantages of our product candidates over current treatment options or alternative treatments, including future alternative treatments;
- the cost of treatment in relation to alternative treatments and willingness to pay for our products, if approved, on the part of clinicians and patients;
- the availability of products and their ability to meet market demand, including a reliable supply for long-term daily treatment;
- the strength of our marketing and distribution organizations;
- the quality of our relationships with patient advocacy groups; sufficient third-party coverage or reimbursement for our product candidates; and
- sufficient third-party payments to clinicians for the procedures necessary to administer product candidates.

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

In September 2017, the FDA announced that it would permit the labeling of conventional food products containing ground peanuts to bear a qualified health claim stating that for certain infants and under certain conditions, the consumption of such products may reduce the risk of developing peanut allergy. This qualified health claim speaks to risk reduction rather than treatment of peanut allergy. AR101 is an investigational biologic for the treatment of peanut allergy. Significant and successful use of such food products or dietary supplements to reduce the risk of peanut allergy may impact the prevalence of peanut allergy and the level of demand for AR101, which may adversely impact our business and results of operations.

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 GPC pursuant to a long-term exclusive commercial supply agreement, which was expanded and extended in January 2018. In order to develop AR101 as an FDA-approvable biological product we were required to 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 restated agreement with GPC does not require GPC to provide us with peanut flour that has a specific protein signature or that meets other potentially relevant pharmaceutical standards. We have tested multiple lots of GPC peanut flour produced in several different years and generally have not identified significant variations in the protein signature between lots. We can provide no assurance that natural variations in the peanuts sourced by GPC, changes in the agricultural practices used to produce the peanuts sourced by GPC, or variations in GPC's manufacturing process will not result in alterations in the protein signature or other characteristics of GPC's peanut flour that would make it unsuitable for use in AR101. If such alterations occurred, we would not be able to manufacture AR101 and our business and operating results would be materially adversely affected. In addition, as our purchases of peanut flour from GPC represent an insignificant portion of GPC's total peanut flour sales, we have only a limited ability to influence GPC's decisions regarding its sourcing of peanuts or methods of producing peanut flour.

Our restated agreement with GPC restricts it from selling peanut flour products to any third party worldwide for use in oral immunotherapy, or OIT, for peanut allergy. The restated agreement remains in effect until ten 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. GPC may terminate the restated 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 120 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.

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 approximately six months to reach a daily dose level of 300 mg of peanut protein. Patients would then continue on a daily Therapeutic Dose.

In order to maintain desensitization, patients would need to continue to take a daily Therapeutic 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 or maintain 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 currently rely on single-source third-party manufacturers for our clinical trial materials and intend to rely on single-source third-party manufacturers for our commercial drug supply of AR101 and to manufacture nonclinical, clinical and commercial supplies of any additional product candidate. If any of these manufacturers fails to provide us or our collaborators with adequate supplies of materials for clinical trials or commercial product or fail to comply with the requirements of regulatory authorities, we may be unable to develop or commercialize AR101 or other product candidates.

We do not currently have the internal capability to produce our clinical or commercial supply of AR101, and we lack the internal resources and the capability to manufacture any other product candidates on a nonclinical, clinical or commercial scale. As a result, we currently rely and intend to continue to rely on a single manufacturer for the production of the drug product used in AR101, a single contract manufacturer for the commercial packaging of AR101 for the foreseeable future, and a single contract manufacturer for the nonclinical supply of our other product candidates. We have agreements in place with both contract manufacturers of AR101. However, while we expect to enter into a commercial supply agreement with our AR101 drug product manufacturer in 2019, we have not yet entered into an agreement with any third-party manufacturers to produce commercial quantities of drug product used in AR101 or the packaging 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. In addition, even if we are able to reach such agreements, 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 manufacturers are not able to develop successfully 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.

Our dependence on single source suppliers with respect to our supply chain for AR101 exposes us to certain risks, including the following:

- our suppliers may cease or reduce production or deliveries, raise prices or renegotiate terms;
- we may be unable to locate a suitable replacement on acceptable terms or on a timely basis, if at all;
- delays caused by supply issues may harm our reputation; and
- our ability to progress our business could be materially and adversely impacted if our single-source supplier upon which we rely were to experience a significant business challenge, disruption or failure due to issues such as financial difficulties or bankruptcy, issues relating regulatory or quality compliance issues, or other legal or reputational issues.

The FDA and other comparable foreign regulatory authorities must, pursuant to inspections that will be conducted prior to any approval of our AR101 BLA or relevant foreign regulatory submission, approve our contract manufacturers to manufacture AR101. While we completed construction of a manufacturing facility in a leased building in Clearwater, Florida, at the site of our primary contract manufacturer; however, we do not directly control the manufacturing operations of our contract manufacturers, and we are completely dependent on them for operating that facility and for compliance with cGMP for the manufacture of AR101. If the contract manufacturer operating that facility or our other 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 our or 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.

Further, we plan on using blister packs and sachets as the final packaging configuration for our potential commercial launch of AR101. Stability testing of AR101 in the blister pack and sachet configurations is ongoing. Any complications with the stability testing in the blister pack or sachet configurations could extend the timelines for our regulatory filings for AR101 and could limit the shelf life of the commercial product at the time of launch. In addition, regulatory authorities may not find our proposed packing configuration acceptable, which would also delay the timing of our foreign regulatory filings or potential approval of AR101.

Failures or difficulties faced at any level of our supply chain could materially adversely affect our business and delay or impede commercialization of AR101, if approved, and the development of any additional product candidates, and could have a material adverse effect on our business, results of operations, financial conditions and prospects.

Supplying our ongoing clinical trials and planned clinical trials is a complex operation, and delays in the supply chain could harm our clinical trials and our ability to commercialize AR101, if approved.

Supplying appropriate clinical trial materials for our ongoing and planned clinical trials on a timely basis is a complex operation. There are multiple doses in the dose escalation phase of our AR101 clinical trials. In addition, each subject can proceed through the dose escalation phase at a different rate depending on how the subject responds to each new dose. For example, a subject can move up to the next dose, remain on the current dose or move down to the prior lower dose during the dose escalation phase of our trials. We believe that this dosing flexibility improves outcomes for clinical trial subjects. But this dosing flexibility also increases the complexity of supplying the appropriate doses to each clinical site on a timely basis. The complexity of our logistics operations for our clinical trial materials increased significantly throughout 2017 and 2018, and we expect such complexity to increase further as we continue to operate multiple large trials concurrently, including trials in Europe, and in connection with the potential commercialization of AR101, if approved. EU regulations require that each lot of clinical trial material be certified and released by a designated qualified person. This certification and release process in the EU can cause delays in supplying clinical trial materials to clinical sites. Any delays or errors in our AR101 supply chain logistics could delay or adversely affect our clinical trials or our ability to commercialize AR101, if approved.

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 top-line results generated in our PALISADE, RAMSES and ARTEMIS trials for AR101, as well as our prior clinical trials, do not ensure that our roll-over studies for such trials or any future clinical trials 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 the indications that we are seeking or at all. For example, while the majority of adults who completed the PALISADE trial in the AR101 arm successfully tolerated the 600 mg dosage (85%), the percentage of dropouts in the 18-49 age range was substantially higher than in our 4-17 year old study population thereby reducing the number of our ITT population in the 18-49 year old age range who successfully completed the DBPCFC. As a result, in the exploratory subpopulation ages 18-49, the Intent to Treat, or ITT analysis did not show statistical significance at the 600 mg dose level.

In addition, we do not know whether our planned or future clinical trials will need to be redesigned, enroll an adequate number of patients on time or be conducted 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, clinical trial sites, and specialized clinical vendors, the terms of which can be subject to extensive negotiation and may vary significantly among CROs, clinical trial sites and vendors;
- obtain institutional review board, or IRB, or foreign equivalent approval at each site;
- recruit suitable patients to participate in a clinical trial, including, in particular, a sufficient number of adult patients to support approval in that patient population;
- 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 DBPCFCs;
- address any conflicts with new or existing laws or regulations;
- initiate or add a sufficient number of clinical trial sites;
- demonstrate that the manufacturing process for AR101 is adequately controlled to ensure that all product produced meets required quality and regulatory standards;
- manufacture sufficient quantities of product candidate for use in clinical trials; or
- provide clinical trial materials to our clinical sites on a timely basis.

We rely on CROs, specialized clinical vendors, clinical trial sites and consultants 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 are conducting our clinical trials at leading academic allergy research centers in the United States and Europe, as well as at community allergy practices. 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 have done for our ARTEMIS trial, and are doing or plan to do for our ARC004, ARC005 and ARC008 trials, presents additional risks that may delay completion of our clinical trials. These risks include a foreign regulatory authority imposing additional requirements prior to the commencement of clinical trials in a foreign country, 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, complying with data privacy regulations in the European Union and Canada, managing additional administrative burdens associated with foreign regulatory schemes, and political and economic risks relevant to such foreign countries. For example, clinical trial materials in the European Union must be certified and released by a designated qualified person, which can delay the release of clinical trial materials to clinical sites in the European Union.

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, to date, we have enrolled 57 patients above the age of 17, and we believe the adult patient population is more difficult to recruit than younger patients. The FDA has concluded that additional safety and efficacy data is required for the adult patient subgroup and any initial approval that we may obtain will not include an indication for patients of such subgroup. 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 or foreign equivalents 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, issues with the quality of or the manufacturing process used to produce our clinical trial materials or lack of adequate funding to continue the clinical trial. For example, the protocols for certain of 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 an event, we could be required to suspend or terminate our clinical trials.

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

In certain of 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, in certain clinical trials we utilize a DBPCFC procedure. This consists of giving the offending food protein to patients in order to assess the sensitivity of their food allergy, and thus to assess 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 or near intensive care units, there are inherent risks in conducting a clinical trial of this nature. Such risks may dissuade patients or parents of patients from electing to participate in our clinical trials. In addition, an uncontrolled allergic reaction could potentially lead to a serious or even fatal reaction 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.

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

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

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 additional product candidates.

We do not have the ability to conduct clinical trials independently. We rely and plan to continue to rely on medical institutions, clinical investigators, contract laboratories, collaborative partners and other third parties, such as CROs, specialized clinical vendors and consultants 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 or data privacy requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure our stockholders that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or regulatory authorities conclude that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection by the regulatory authority of any marketing application we submit. Any such delay or rejection could prevent us from commercializing AR101 or our other future product candidates.

Furthermore, 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. The collection and use of clinical data by us and our clinical sites, CROs, clinical vendors, clinical labs and collaborators is governed by strict data privacy laws in the United States, Canada and, especially, the EU. Failure to comply with these data privacy regulations could prevent us from using clinical data, and subject us to penalties and fines, which could delay or impair review and potential approval of marketing approval applications for our product candidates. 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, GCPs or data privacy requirements, 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.

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

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.

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 have and may in the future 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 PALISADE clinical trial, one patient had a severe allergic hypersensitivity reaction that was attributed to AR101 compared to none of the placebo-treated patients and 12.4% of patients ages 4-17 who received AR101 dropped out of the clinical trial due to gastrointestinal side effects, compared to 2.4% of placebo-treated patients. It is possible that the FDA may ask for additional data regarding such matters.

If safety problems relating to AR101 are identified in our clinical trials or in any clinical trials conducted by collaborators 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 regulatory 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.

AR101, if approved, or any additional 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. For example, in October 2017, DBV Technologies S.A. announced results from its completed Phase 3 clinical trial evaluating Viaskin Peanut, a patch technology that epicutaneously delivers food allergens to the patient with the goal of desensitizing the patient to the allergens, in peanut-allergic patients (4 to 11 years of age). DBV submitted, and then subsequently withdrew, a BLA for this product. However, DBV may choose to resubmit the BLA after additional discussions with the FDA. AnaptysBio, Inc. is developing an IL-33 antibody, ANB020, for the treatment of atopic diseases including atopic dermatitis, eosinophilic asthma and peanut allergy. ANB020 is under investigation in a Phase 2a trial of approximately 20 adults with peanut allergy.

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 additional products approved for the treatment of peanut allergy could harm our business and results of operations.

We may also face competition from clinicians who provide oral immunotherapy to patients using commercially available source material. In addition, peanut allergic patients may attempt to use food products as a substitute for AR101 in the maintenance portion of our AR101 treatment program. 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 additional 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.

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 adequate 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 are generally able to affect the utilization of drugs by a variety of mechanisms, including deciding which medications they will cover, determining the amount they will pay for a product, establishing which formulary tier to place the drug on that may result in, among other things, greater out-of-pocket costs to patients, and creating pre-authorization procedures. A primary trend in the U.S. healthcare industry is cost containment. Coverage, reimbursement, out-of-pocket costs to patients, and pre-authorization requirements may impact the demand for any product for which we obtain regulatory 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 adequate 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 dose escalation 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 the past, under the Medicare program, physician payments were updated on an annual basis according to a statutory formula. When the application of the statutory formula for the update factor would have resulted in a decrease in total physician payments, Congress would intervene 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 provided 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 provides for a 0.25% update through 2019, and a 0% annual update each year through 2025. In addition, MACRA required the establishment of the Merit-Based Incentive Payment System, or 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 required the 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 regulatory 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 additional 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 additional product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to clinical trial participants or patients;
- regulatory investigations, product recalls or withdrawals, or labeling, marketing or promotional restrictions;
- loss of revenue; and
- the inability to commercialize AR101 or any additional 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 additional products we develop. Although we maintain product liability insurance covering the use of our product candidates in clinical trials, 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 March 31, 2019, we had 228 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 additional 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, commercialization and clinical development organizations;
- identify, recruit, retain, incentivize and integrate additional employees;
- establish the infrastructure necessary to support international operations;
- manage our internal development efforts effectively while carrying out our contractual obligations to third parties; and
- continue to improve our operational, legal, financial and management controls, reporting systems and procedures.

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

If we fail to attract and retain senior management, we may be unable to successfully develop AR101 or any additional product candidates, conduct our clinical trials and commercialize AR101 or any additional 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 additional 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. In addition, certain members of our senior management team, including our President and Chief Executive Officer, who joined us in June 2018, have worked together for only a relatively short period of time and it may be difficult to evaluate their effectiveness, on an individual or collective basis, and ability to address future challenges to our business.

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 incur significant costs as a result of operating as a public company, and our management devotes substantial time to new compliance initiatives. We may fail to comply with the rules that apply to public companies, including Section 404 of the Sarbanes-Oxley Act of 2002, which could result in sanctions or other penalties that would harm our business.

We incur significant legal, accounting and other expenses as a public company, including costs resulting from public company reporting obligations under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and regulations regarding corporate governance practices. We are subject to Section 404 of The Sarbanes-Oxley Act of 2002, or Section 404, 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. In addition, 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, as a public company we are 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 affect our business.

We implemented an enterprise resource planning, or ERP, system for our company during the third quarter of 2018. Our 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, our ERP system will require us to complete many processes and procedures for the effective use of the system and to run our business using the system. As a result, we expect to incur substantial costs in order to utilize the system going forward. Additionally, in the future, 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 our 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.

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 therapeutic approach, including product candidates for the treatment of egg allergy and multi-nut allergy. A key component of our CODIT approach is utilizing defined dosages of well-characterized food proteins in order to allow for gradual up dosing. This requires manufacturing stable and standardized drug product, which, for naturally occurring food-based drug products, can be complex and difficult especially in low doses. Other than AR101, none of our product candidates have been tested in human clinical trials. In addition, we intend to evaluate third-party product candidates and technologies for the treatment of food allergies. 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;
- we may have difficulties finding contract manufacturers willing to manufacture our product candidates, which include food allergens;
- a product candidate may not be capable of being produced in clinical or 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.

Our existing and any future 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 additional product candidates.

In October 2017, we entered into a clinical collaboration agreement with Regeneron Ireland Unlimited Company and Sanofi Biotechnology SAS to study AR101 with adjunctive dupilumab in peanut-allergic patients in a Phase 2 trial sponsored by Regeneron, which was initiated in October 2018. In the future we may seek additional 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 face significant competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time-consuming to negotiate, document, implement and maintain. We may also not be successful in our efforts to establish and implement collaborations or other alternative arrangements that we have entered into or that we may choose to enter into in the future. The terms of any such collaborations or other arrangements may also not be favorable to us.

Our existing and any future collaborations that we may enter into may not be successful. The success of such collaboration arrangements will depend heavily on the efforts and activities of our collaborators and any such collaboration agreement may not result in the realization of the benefits we expected to achieve upon our entry into such arrangements. 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;
- any of our product candidates that are administered in combination with a collaborator's product or product candidate could result in previously unforeseen adverse events or adverse events that are primarily related to the adjunctive therapy but cause higher rates or more severe events of treatment related adverse events;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of our current or additional 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 additional 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.

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.

Recent U.S. tax legislation and future changes to applicable U.S. or foreign tax laws and regulations may have a material adverse effect on our business, financial condition and results of operations.

We are subject to income and other taxes in the U.S. and foreign jurisdictions. Changes in laws and policy relating to taxes or trade may have an adverse effect on our business, financial condition and results of operations. For example, the U.S. government recently enacted significant tax reform, and certain provisions of the new law may adversely affect us. Changes include, but are not limited to, a federal corporate tax rate decrease from 34% to 21% for tax years beginning after December 31, 2017, the transition of U.S. international taxation from a worldwide tax system to a more generally territorial system, and a one-time transition tax on the mandatory deemed repatriation of foreign earnings. The legislation is unclear in many respects and could be subject to potential amendments and technical corrections and will be subject to interpretations and implementing regulations by the Treasury and Internal Revenue Service, any of which could mitigate or increase certain adverse effects of the legislation. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation. Generally, future changes in applicable U.S. or foreign tax laws and regulations, or their interpretation and application could have an adverse effect on our business, financial conditions and results of operations.

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;
- different data privacy regulations, especially in the European Union;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- potential liability resulting from activities conducted on our behalf by distributors or other vendors we engage; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters.

The results of the United Kingdom's referendum on withdrawal from the European Union may have a negative effect on global economic conditions, financial markets and our business.

In June 2016, a majority of voters in the United Kingdom elected to withdraw from the European Union in a national referendum, which is commonly referred to as Brexit. In March 2017, the U.K. government delivered to the European Council notice of its intention to leave the European Union. In the absence of an executed withdrawal agreement with the European Union, the effective date of the United Kingdom's withdrawal from the European Union will, unless extended by the European Council in agreement with the United Kingdom, be October 31, 2019. There are many ways in which our business could be affected by this event, only some of which we can identify at this time. The negotiation of the withdrawal agreement has been, to date, a lengthy and contentious process, and we do not, as at the date of this Annual Report, have certainty as to the terms of the United Kingdom's future relationship with the European Union. Indeed, the negotiations may, ultimately, be unsuccessful and the United Kingdom may not reach agreement with the European Union on the future terms of the United Kingdom's relationship with the European Union. If no agreement is reached, there will be a period of considerable uncertainty particularly in relation to United Kingdom financial and banking markets as well as on the regulatory process in Europe. These developments, or the perception that any of them could occur, have had and may continue to have a material adverse effect on global economic conditions and the stability of global financial

markets, and may significantly reduce global market liquidity and restrict the ability of key market participants to operate in certain financial markets.

We have ongoing business in the United Kingdom and the European Union, including employees in the United Kingdom. Further, our ARTEMIS study was conducted solely in Europe. Any application for Marketing Authorization, or MA, for AR101 or any other product candidate that we may file in the future must be filed by an entity located in a European Union member nation. While we are already in the process of establishing a network of subsidiary undertakings in continental Europe and anticipate that our MAA for AR101 will be filed by our subsidiary, Aimmune Therapeutics Netherlands B.V., we may face new regulatory costs and challenges that could have a material adverse effect on our operations. In addition, the lack of clarity about future United Kingdom laws and regulations, as the United Kingdom determines which European Union laws to replace or replicate in the event of a withdrawal, includes regulations related to clinical trials, marketing authorization for drug products, intellectual property rights and employment and labor matters. A lack of clarity in these areas, which are central to the development of our product candidates in the United Kingdom and the European Union and our ongoing business activities in the United Kingdom, may cause operational and strategic uncertainty for us as we consider the timing of and requirements for approval in the United Kingdom for AR101 and the effect of a potential withdrawal on our employees located in the United Kingdom, including those employees who are non-UK citizens and whose rights to live and work in the UK may change following Brexit.

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

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

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

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

Furthermore, our contract manufacturer and integral parties in our supply chain, are operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen and severe adverse events. In particular, our manufacturing facility for AR101 is located in Florida, which has historically and very recently experienced severe hurricanes. In addition, the source material for AR101 is a specific type of peanut flour that is grown and processed in Georgia, which has historically experienced tornadoes and 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.

A failure in our operational systems or infrastructure or those of third parties, including those caused by security breaches, cyber-attacks or data protection failures, could disrupt our business, damage our reputation and causes losses.

Our operations rely on the secure processing, storage, and transmission of confidential and other information and assets, including in our computer systems and networks. Our business, including our ability to report our financial results in a timely and accurate manner and our ability to collect and analyze clinical data to support regulatory filings for our product candidates, depends significantly on the integrity, availability and timeliness of the data we maintain, as well as the data and assets held through third party outsourcers, such as clinical vendors and clinical research organizations, service providers and systems.

Although we have implemented administrative and technical controls and take protective actions to reduce the risk of cyber incidents and to protect our information technology and assets, and we endeavor to modify such procedures as circumstances warrant and negotiate agreements with third party providers to protect our assets, such measures may be insufficient to prevent, among other things, unauthorized access, computer viruses, malware or other malicious code or cyber-attack, catastrophic events, system failures and disruptions (including in relation to new security measures and systems), employee errors or malfeasance, third party (including outsourced service providers) errors or malfeasance, loss of assets and other security events (each, a "Security Event"). We may be subject to Security Events, which could have a material adverse impact on our business, results of operations or financial condition. As the breadth and complexity of our security infrastructure continues to grow, the potential risk of a Security Event increases. If Security Events occur, these events may jeopardize our or our clinical vendors' or collaborators' or counterparties' confidential and other information processed and stored with us, and transmitted through our computer systems and networks, or otherwise cause interruptions, delays, or malfunctions in our, counterparties' or third parties' operations, or result in data loss or loss of assets which could result in significant losses and/or fines, reputational damage or a material adverse effect on our business, financial condition or operating results. We may be required to expend significant additional resources to modify our protective measures or to investigate and remediate vulnerabilities or other exposures and to pursue recovery of lost data or assets and we may be subject to litigation and financial losses. We currently maintain cyber liability insurance that provides third party or first party liability coverages to protect us, subject to policy limits and coverages, against certain events that could be a Security Event. However, a Security Event could nonetheless have a material adverse effect on our operating results or financial condition.

We outsource certain technology and business process functions to third parties and may increasingly do so in the future. For example, we outsource certain data management and analysis functions for our clinical trials and use cloud-based systems for financial and human resources data. If we do not effectively develop, implement and monitor our outsourcing strategy, third party providers do not perform as anticipated or we experience technological or other problems with a transition, we may not realize productivity improvements or cost efficiencies and may experience operational difficulties, increased costs and loss of business. Our outsourcing of certain technology and business processes functions to third parties may expose us to enhanced risks related to data security, which could result in monetary and reputational damages. In addition, our ability to receive services from third party providers may be impacted by cultural differences, political instability, unanticipated regulatory requirements or policies. As a result, our ability to conduct our business may be adversely affected.

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 additional product candidates. Our current development programs for such additional product candidates are in the pre-clinical formulation and process development 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, and we may never satisfy these requirements. We filed an IND application for a product candidate for the treatment of egg allergy in December 2018, and we are exploring and expect to continue to explore activities to support filing of an IND for a product candidate for the treatment of multi-nut allergy. 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, and we may never commence clinical trials of such development programs despite expending significant resources in pursuit of their development. Even if we do commence clinical trials of our other potential product candidates, such product candidates may never be approved by the FDA or the foreign regulatory authorities.

Risks Related to Government Regulation

The regulatory approval process is highly uncertain and we may not obtain regulatory approval for the commercialization of AR101 or any additional 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 additional 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 submitted our AR101 BLA but have not yet obtained regulatory approval for AR101 anywhere in the world and may 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, potent and effective 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, we may be required to expend additional time and resources to obtain an approval, if any, and any approval we may seek may be delayed or prevented. For example, the FDA or other regulatory authorities may require us to conduct additional clinical trials for AR101 either prior to or post-approval, such as additional trials in specific patient subpopulations or to establish a larger safety database of patients who have been administered AR101. The FDA or other regulatory authority may also 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 additional 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.

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 have received 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. Both the Fast-Track designation and the Breakthrough Therapy designation support expedited review of new drugs and biologics. However, the FDA has determined that AR101, as an allergenic product candidate, is exempt from PDUFA, and has informed us that the BLA will be reviewed under a twelve-month target review period, as measured from the January 2019 start date. Moreover, the review period for PDUFA-exempt applications is subject to uncertainty, and, as a result, the FDA may take longer than twelve months to review the BLA for AR101.

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

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

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

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

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

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

We are subject to governmental regulation and other legal obligations, particularly related to privacy, data protection and information security. Our actual or perceived failure to comply with such obligations could harm our business.

The regulatory environment surrounding information security, confidentiality and privacy is increasingly demanding. We are subject to numerous U.S. federal and state laws both generally and specifically in relation to protected health information, including the U.S. federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and related laws, and European laws and regulations, including the General Data Protection Regulation, or GDPR, and the e-Privacy Directive (2002/58/EC), soon to be replaced by an e-Privacy Regulation, and the EU national laws implementing or supplementing the GDPR or e-Privacy Directive, as well as upcoming US laws such as the California Consumer Privacy Act. Compliance with these data privacy and security requirements is rigorous and time-intensive and may increase our cost of doing business, and despite those efforts, there is a risk, particularly given uncertainty that sometimes exists surrounding how to comply, that we may be subject to fines and penalties, regulatory investigations, litigation and reputational harm, which could materially and adversely affect our clinical trials, business, financial condition and operations.

In addition, the legal and regulatory framework for the receipt, collection, processing, use, safeguarding, sharing and transfer of personal and confidential data is evolving as new global privacy laws are being enacted and existing ones are being updated and strengthened. For example, the GDPR repealed the Data Protection Directive (95/46/EC) and is directly applicable in all EU member states since its effective date of May 25, 2018. The GDPR applies to companies established (for data processing purposes) in the EU or EEA as well as companies that are not so established in the EU or EEA and which collect and use personal data in relation to offering goods or services to, or monitoring the behavior of, individuals located in the EU or EEA, including, for example, through the conduct of clinical trials (whether the trials are conducted directly by us or through a clinical vendor or collaborator). The GDPR sets out requirements that must be complied with when handling personal data including: providing detailed disclosures about how data subjects' personal data will be used; demonstrating that they have an appropriate legal basis in place to justify their data processing activities; appointing data protection officers in certain circumstances; enhancing existing rights and granting rights for data subjects in regard to their personal data (including the right to be "forgotten", to data access and to data portability); strengthening the obligation to notify data protection regulators or supervisory authorities (and in certain cases, affected individuals) of data security breaches; and complying with principal of accountability and complying with the obligation to demonstrate compliance through policies, procedures, training and audit.

In addition, the GDPR permits EU and EEA Member States the ability to introduce derogations for certain matters and, accordingly we are also subject to national legislation in the EU and EEA which implements or supplements the GDPR, including in relation to the processing of genetic, biometric and health data. We will need to monitor compliance with such EU and EEA Member State laws and regulations, including in relation to these permitted derogations from the GDPR, all of which will increase our compliance obligations and may necessitate the review and implementation of policies and processes relating to our collection and use of data, which may also lead to an increase in compliance costs, ultimately having an adverse impact on our business, financial condition or operations.

If any person, including any of our employees, contractors, clinical vendors, service providers, partners or collaborators or those with whom we share such information, fails to comply with applicable data privacy or security laws, or breaches our established controls with respect to personal or confidential data, or otherwise mismanages or misappropriates that data including where that results in the unauthorized access to or transfer of personal data, we may be subject to significant monetary damages, regulatory enforcement actions, assessment notices (for a compulsory audit), orders to cease/change our processing of our data, adverse publicity, fines and/or criminal prosecution in one or more jurisdictions. For example, certain breaches under the GDPR may result in a penalty of up to 4% of an organization's total global annual revenue or 20 million Euros (whichever is higher). In addition, a data breach could result in negative publicity which could damage our reputation and have an adverse effect on our clinical trials, business, financial condition or operations.

We are also subject to EU and EEA laws on data export, where we transfer personal data outside the E.E.A. to group companies or third parties. The GDPR only permits exports of personal data outside EEA where there is a suitable data transfer solution in place to safeguard the personal data (e.g., the EU Commission approved Standard Contractual Clauses or, in relation to exports of personal data to the US, the EU-US- Privacy Shield) or where the country receiving such data is approved by the EU Commission as providing adequate protection for personal data. Where we transfer personal data out of the EU or EEA, we rely on a number of data transfer solutions including in regard to transfers of personal data (HR data and non-HR data) to the US (and Switzerland), we are certified under the EU-US (and Switzerland-US) Privacy Shield. In addition, if it were to be determined that we were not complying with our obligations under the Privacy Shield framework and we were to lose our Privacy Shield certification from the Department of Commerce, we will need to find an alternative solution for transferring data out of the EEA to the U.S. Also, Brexit will mean that at some point the United Kingdom, or UK, will become a "third party" for the purposes of data transfers under the GDPR. Unless a withdrawal agreement and political declaration (the "Proposed Deal") is agreed and approved between the EU and the UK prior to 29 March 2019 (the "Exit Date"), the UK will become a third party on the Exit Date. If the Proposed Deal is agreed and approved prior to 29 March 2019, the GDPR will continue to apply during the transition period (which is currently due to end on December 31 2020, but may be extended) meaning that data transfers from the EU / EEA to the UK can continue in the same manner until the end of the transition period (upon which compliant data transfer solutions will need to be put in place in regard to transfers from the EU / EEA to the UK). These changes introduced by Brexit may require us to find alternative solutions for the compliant transfer of personal data into (and possibly from) the UK.

Where we are a data controller, we will be accountable for any service providers (including clinical research organizations) we engage to process personal data on our behalf. We attempt to mitigate the associated risks of using service providers by entering into contractual arrangements to ensure that they only process personal data according to our instructions, and that they have sufficient technical and organizational security measures in place. Where we transfer personal data from the EEA to such third parties, we do so in compliance with the relevant data export requirements as described above. There is no assurance that these contractual measures and our own privacy and security-related safeguards will protect us from the risks associated with the service provider's processing, storage and transmission of such data. Any violation of data or security laws by our processors could have a material adverse effect on our business and result in the fines and penalties outlined above.

We are also subject to evolving EU privacy laws on cookies and e-marketing. The EU is in the process of replacing the e-Privacy Directive (2002/58/EC) with a new set of rules taking the form of a regulation, which will be directly implemented in the laws of each EU Member State. The draft e-Privacy Regulation imposes strict opt-in marketing rules with limited exceptions for business-to-business communications, alters rules on third-party cookies, web beacons and similar technology and significantly increases fining powers to the same levels as the GDPR (i.e. the greater of 20 million Euros or 4% of total global annual revenue). While the e-Privacy Regulation was originally intended to be adopted on May 25, 2018 (alongside the GDPR), it is still going through the European legislative process and commentators now expect it to be adopted during the second half of 2020 or during 2021 following a transition period.

We strive to comply with all applicable laws, including privacy laws, but they may conflict with each other. Despite our efforts, we may not have fully complied in the past and may not in the future. If we become liable under laws or regulations applicable to us, we could be required to pay significant fines and penalties as outlined above, our reputation may be harmed and we may be forced to change the way we operate. That could require us to incur significant expenses or to discontinue certain services (including clinical trials) and/or processing of personal data (including health data), which could negatively affect our business.

If approved, AR101 or any additional 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 PALISADE clinical trial, of patients ages 4-17, 12.4% of patients from the AR101 treatment arm and 2.4% of patients from the placebo-treatment arm discontinued due to investigator-reported adverse events. Additionally, eight AR101-treated patients in the PALISADE trial experienced a total of ten severe adverse events, and four of these patients discontinued treatment. 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 additional products.

Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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 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. A foreign regulatory authority may impose additional requirements prior to the commencement of clinical trials in one country that were not required in other countries, including the United States. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. For example, a foreign regulatory authority may determine that our clinical trial results obtained in U.S. subjects are not representative of foreign patient populations and are thus not supportive of an approval outside of the United States. 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 in 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;
- U.S. federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;
- U.S. federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information;
- the U.S. federal physician sunshine requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the Affordable Care Act, which requires certain manufacturers of drugs, devices, biologics, and medical supplies to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members;
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers;
- state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources;
- state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; and state laws governing the privacy and security of health information (or personal information generally) in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts;
- state laws that require drug manufacturers to obtain licenses prior to distribution or sale of pharmaceutical products in that state; 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, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and imprisonment, any of which could adversely affect our ability to market our products and adversely impact our financial results.

Further, regulations may change, and any additional regulation could prevent, limit or delay regulatory approval of our product candidates, which could harm our business. For example, in December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of biologics and spur innovation, but its ultimate implementation remains unclear. We could also be subject to new international, federal, state or local regulations that could affect our R&D programs and harm our business in unforeseen ways. If this happens, we may have to incur significant costs to comply with such laws and regulations, which will harm our results of operations.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including shutting down the government, and the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these Executive Orders will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

If we participate in and then fail to comply with our reporting and payment obligations under governmental pricing programs in the U.S., we could be subject to additional reimbursement requirements, penalties, sanctions and fines which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

With the approval of any product candidate, we anticipate that we will may participate in a number of federal and state government pricing programs in the U.S. in order to obtain coverage for the product by certain government healthcare programs. These programs would generally require us to pay rebates or provide discounts to certain private purchasers or government payers in connection with our products when dispensed to beneficiaries of these programs. In some cases, such as with the Medicaid Drug Rebate Program, the rebates are based on pricing and rebate calculations that we report on a monthly and quarterly basis to the government agencies that administer the programs. The terms, scope and complexity of these government pricing programs change frequently. We may also have reimbursement obligations or be subject to penalties if we fail to provide timely and accurate information to the government, pay the correct rebates or offer the correct discounted pricing. Changes to the price reporting or rebate requirements of these programs would affect our obligations to pay rebates or offer discounts. Responding to current and future changes may increase our costs and the complexity of compliance, will be time-consuming, and could have a material adverse effect on our results of operations.

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 additional products could have a material adverse effect on our business, results of operations, financial condition, prospects and stock price.

In addition, the full impact of recent healthcare reform and other changes in the healthcare industry and in healthcare spending is currently unknown and may adversely affect our business model. In the United States, the Affordable Care Act was enacted in 2010 with a goal of reducing the cost of healthcare and substantially changing the way healthcare is financed by both government and private insurers. The Affordable Care Act, among other things, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations and established annual fees and taxes on manufacturers of certain branded prescription drugs. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. The current Presidential Administration and U.S. Congress will likely continue to seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the Affordable Care Act. For example, the Tax Act was enacted, which, among other things, removes penalties for not complying with the Affordable Care Act's individual mandate to carry health insurance. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseparable feature of the Affordable Care Act, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the Affordable Care Act are invalid as well. While the Trump Administration and the Centers for Medicare & Medicaid Services have both stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, if any, will impact the law. Any changes will likely take time to unfold and it is uncertain the extent to which any such changes may impact our business or financial condition.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. These changes include the Budget Control Act of 2011, which resulted in 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 2027 unless additional Congressional action is taken, as well as the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Recently, there has also been heightened government scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed to, among other things, reform government program reimbursement methodologies. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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 adequate 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.

Risks Related to Intellectual Property

If we are unable to obtain and maintain adequate intellectual property protection for AR101 or any additional 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 additional 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. Though we currently own three issued patents in the United States covering certain of our manufacturing methods and the formulation for AR101, 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. We have filed additional patent applications that relate to the manufacture, formulation, use and other aspects of AR101 and certain of our other product candidates. We cannot assure our stockholders that these applications will result in any additional issued patents in the U.S. or foreign countries. Even if any such additional patents issue, we cannot assure our stockholders that they or any other patents we obtain will include any claims with a scope sufficient to protect AR101 or any other additional 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. Similarly, laws of the United States may not protect our rights to the same extent as the laws of foreign countries. Furthermore, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally twenty years after it is filed as a regular, non-provisional application. 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, even if we are able to obtain an extension of patent term due to regulatory delay. 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 AR101 or our other product candidates, including generic versions of such products.

The issuance of a patent is not conclusive as to its inventorship, ownership, scope, validity or enforceability, and therefore, to the extent that we acquire patent protection with respect to AR101 or other product candidates, third parties may still 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 the same or 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. Our competitors might commercialize products in countries where we do not have patent rights. Such challenges may also result in our inability to manufacture or commercialize our 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 additional product candidates is successfully challenged, then our ability to commercialize AR101 or any additional 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 products in a non-infringing manner. For example, a third party may develop a competitive product that provides benefits similar to AR101 or an additional product candidate but falls outside the scope of our patent protection. If the patent protection covering our product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our product candidates could be negatively affected, which would harm our business.

In addition, we may in the future be subject to claims by our former employees or consultants asserting an ownership right in our patents or patent applications, as a result of the work they performed on our behalf. Although we generally require all of our employees, consultants and advisors and any other third parties who have access to our proprietary know-how, information or technology to assign 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 additional 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 product 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 significant number of patents in our field of technology, we cannot assure our stockholders that AR101 or any additional 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, or even after 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 additional product candidates. If a patent holder believes AR101 or any of our product candidates 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 of our collaborators, we or they could be forced to stop or delay the research, development, manufacturing or sales of AR101 or the 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. Similarly, laws of the United States may not protect our rights to the same extent as the laws of foreign countries.

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 or other proceedings 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 litigation, 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 invention claimed within any patent we may obtain, such as in an *inter partes* review proceeding. 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 additional product candidates, we would lose at least part, and perhaps all, of any patent protection covering such product candidate, which would materially impair our competitive position.

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

Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time-consuming and is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

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

Changes in U.S. or foreign 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. For example, 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 became effective on March 16, 2013. Thus, it is possible that another party will have filed on the same technology for which we are seeking patent protection before we have or will have filed and thus be able to obtain competing patent coverage or even preclude our ability to obtain such coverage. Accordingly, it is not yet clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. 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.

Court decisions can also have an impact on our intellectual property rights, including patent rights. 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 obtain or effectively enforce our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on AR101 or any of 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 or may 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 additional 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 or other confidential or proprietary information. If any of the parties to these confidentiality agreements breaches or violates the terms of such agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Enforcing a claim that a third party illegally obtained and is using our trade secrets, like patent litigation, is expensive and time-consuming, and the outcome is unpredictable. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad.

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

Risks Related to Our Common Stock

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

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

- results of, or delays in, our clinical trials;
- delays in our product development timelines;
- the number, size and type of additional clinical trials or studies that we choose to conduct or the FDA requires us to complete for AR101 and the cost and time of such trials and studies;

- 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, in any clinical trials with AR101 sponsored by collaborators or in our competitors' trials as a result of exposure to the peanut allergen;
- announcements concerning our competitors or the pharmaceutical industry in general;
- 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;
- achievement of expected product sales and profitability;
- manufacturing, supply or distribution delays or shortages;
- acquisitions or significant partnerships by us or our competitors;
- actual or anticipated fluctuations in our operating results;
- changes in financial estimates or recommendations by securities analysts;
- failure to meet financial projections that we or the investment community may provide;
- trading volume of our common stock;
- an inability to obtain additional funding;
- sales of our common stock by us, our executive officers and directors or our stockholders in the future;
- general economic and market conditions and overall fluctuations in the United States equity markets; and
- additions or departures of any of our key scientific or management personnel.

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

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

If securities or industry analysts issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.

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

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 March 31, 2019, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned 58% of our outstanding common stock. Therefore, these stockholders have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that our stockholders may feel are in their best interest.

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

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

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- the required approval of at least 66 2/3% of the shares entitled to vote to remove a director for cause, and the prohibition on removal of directors without cause;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;
- the ability of our board of directors to alter our bylaws without obtaining stockholder approval;
- the required approval of at least 66 2/3% 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.

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

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

As a California-domiciled public company, if we fail to attract and retain women to serve on our board of directors, we could incur penalties.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified individuals to our board of directors. As a public company headquartered in California, we are required to have at least one woman on our board of directors by the end of 2019, and two or three women on our board by the end of 2021, depending on the size of our board at the time. While we currently have two women on our board and intend to continue to comply with this California law, recruiting and retaining board members carries uncertainty, and failure to comply with this requirement could result in financial penalties.

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

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

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

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

Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership over a rolling three-year period, the corporation's ability to use its pre-change net operating loss, or NOL, carryforwards to offset its post-change taxable income may be limited. Limitations may also apply to the utilization of other pre-change tax attributes as a result of an ownership change. As of December 31, 2019, we had generated NOL carryforwards for federal income tax purposes of \$321.6 million and for California income tax purposes of \$12.0 million. These federal and California NOL carryforwards will begin to expire in 2031, if not utilized. Following the equity investment by Nestle Health Science in November 2016, we performed a Section 382 analysis and determined that we experienced multiple ownership changes under Section 382 of the Code prior to December 31, 2017. Such annual limitations could affect the utilization of NOL and tax credit carryforwards in the future. We experienced no significant permanent losses of tax attributes due to these ownership changes.

In addition, we may experience more ownership changes under Section 382 of the Code as a result of future changes in our stock ownership, some of which may be outside our control. As a result, our ability to utilize NOL carryforwards or other tax attributes, such as research tax credits, in any taxable year may be further limited.

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

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

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

a) Sales of Unregistered Securities

None.

b) Use of Proceeds

None.

c) Repurchases of Shares or of Company Equity Securities

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits

a) Exhibits

Exhibit Number	Exhibit Description	Form	Incorporated by Reference		Filed Herewith
			Date	Number	
3.1	Amended and Restated Certificate of Incorporation of Aimmune Therapeutics, Inc.	8-K	8/11/2015	3.1	
3.2	Amended and Restated Bylaws of Aimmune Therapeutics, Inc.	8-K	8/11/2015	3.2	
4.1	Reference is made to exhibits 3.1 through 3.2 .				
4.2	Form of Common Stock Certificate.	S-1/A	7/27/2015	4.2	
4.3	Amended and Restated Investors' Rights Agreement, dated January 20, 2015, by and among Aimmune Therapeutics, Inc. and the investors listed therein.	S-1	7/6/2015	10.1	
4.4	Amended and Restated Registration Rights Agreement, dated November 11, 2018, by and between the Company and Nestle Health Science US Holdings, Inc.	10-K	2/28/2019	4.4	
4.5	Amended and Restated Standstill Agreement, dated November 11, 2018, by and between the Company and Nestle Health Science US Holdings, Inc.	10-K	2/28/2019	4.5	
10.1 (††)	Credit Agreement dated January 3, 2019, by and among the Company, KKR Peanut Aggregator L.P. and Cortland Capital Markets Services LLC. By and between the Company and Nestle Health Science US Holdings Inc.	10-K	2/28/2019	10.6	
10.2(a)#	2015 Equity Incentive Annual Plan.	S-8	8/11/2015	99.2(a)	
10.2(b)#	Form of Stock Option Grant Notice and Stock Option Agreement under the 2015 Equity Incentive Annual Plan.	S-1/A	7/27/2015	10.6(b)	
10.2(c)#	Form of Restricted Stock Award Agreement and Restricted Stock Unit Award Grant Notice under the 2015 Equity Incentive Annual Plan.	S-1/A	7/27/2015	10.6(c)	
10.3#	Aimmune Therapeutics, Inc. Employee Stock Purchase Plan.	S-8	8/11/2015	99.3	
10.4#	Non-Employee Director Compensation Program.	10-K	2/28/2019	10.18	
10.5#	Aimmune Therapeutics, Inc. Corporate Bonus Plan.	8-K	2/25/2016	10.1	
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
101.INS	XBRL Instance Document -the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document				
101.SCH	XBRL Taxonomy Extension Schema Document				X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				X

† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment filed separately with the Securities and Exchange Commission.

Indicates management contract or compensatory plan.

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

SIGNATURES

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

Date: May 8, 2019

Aimmune Therapeutics, Inc.

By: /s/ Jayson Dallas
Jayson Dallas, M.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 8, 2019

Aimmune Therapeutics, Inc.

By: /s/ Eric H. Bjerkholt
Eric H. Bjerkholt
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

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

I, Jayson Dallas, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Aimmune Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 8, 2019

By: _____
/s/ Jayson Dallas
Jayson Dallas, M.D.
President and Chief Executive Officer
(Principal Executive Officer)

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

I, Eric H. Bjerkholt, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Aimmune Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 8, 2019

By: _____
/s/ Eric H. Bjerkholt
Eric H. Bjerkholt
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

In connection with the Quarterly Report of Aimmune Therapeutics, Inc. (the "Company") on Form 10-Q for the period ending March 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jayson Dallas, President and Chief Executive Officer of the Company, and Eric H. Bjerkholt, Chief Financial Officer of the Company, do each hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: May 8, 2019

By: _____
/s/ Jayson Dallas
Jayson Dallas M.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 8, 2019

By: _____
/s/ Eric H. Bjerkholt
Eric H. Bjerkholt
Chief Financial Officer
(Principal Financial and Accounting Officer)

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Aimmune Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.