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 June 30, 2020

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	**45-2748244**
(State or other jurisdiction of incorporation or organization)	**(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

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 Select Market

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 ☒

As of July 24, 2020, the registrant had 65,450,142 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)

	June 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 266,559	$ 79,880
Short-term investments	47,394	63,633
Trade receivables, net	25	—
Inventories	5,646	—
Prepaid expenses and other current assets	4,017	5,564
Total current assets	323,641	149,077
Long-term investments	4,127	14,661
Property and equipment, net	26,540	28,604
Operating lease right-of-use assets	10,397	11,512
Prepaid expenses and other assets	581	515
Total assets	$ 365,286	$ 204,369
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 15,107	$ 13,882
Accrued liabilities	25,468	31,286
Operating lease liabilities, current	2,399	2,257
Other current liabilities	27	23
Total current liabilities	43,001	47,448
Long term debt, net of discount	131,462	41,028
Operating lease liabilities	9,323	10,524
Other liabilities	1,642	1,345
Total liabilities	185,428	100,345
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, par value $0.0001 per share— 10,000 shares authorized at June 30, 2020 and December 31, 2019; 526 and 0 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	—	—
Common stock, par value $0.0001 per share—290,000 shares authorized as of June 30, 2020 and December 31, 2019; 65,440 and 63,779 shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively	7	6
Additional paid-in capital	1,059,968	828,618
Accumulated other comprehensive income	239	80
Accumulated deficit	(880,356)	(724,680)
Total stockholders' equity	179,858	104,024
Total liabilities and stockholders' equity	$ 365,286	$ 204,369

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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Product revenue, net	$ —	$ —	$ 575	$ —
Costs and operating expenses				
Cost of revenue	4,850	—	$ 5,107	—
Research and development	23,047	31,988	59,510	63,304
Selling, general and administrative	38,094	31,200	87,232	54,912
Total costs and operating expenses	65,991	63,188	151,849	118,216
Loss from operations	(65,991)	(63,188)	(151,274)	(118,216)
Interest income	428	1,710	1,406	3,611
Interest expense	(3,212)	(1,262)	(5,441)	(2,406)
Other income, net	(148)	(90)	73	(56)
Loss before provision for income taxes	(68,923)	(62,830)	(155,236)	(117,067)
Provision for income taxes	321	48	440	77
Net loss	$ (69,244)	$ (62,878)	$ (155,676)	$ (117,144)
Other comprehensive loss, net of tax:				
Foreign currency translation adjustment	$ 8	$ —	$ 18	$ —
Unrealized gain on available-for-sale investments	68	174	141	345
Comprehensive loss	$ (69,168)	$ (62,704)	$ (155,517)	$ (116,799)
Net loss per share, basic and diluted	$ (1.06)	$ (1.01)	$ (2.40)	$ (1.88)
Weighted average shares used in computing net loss per common share, basic and diluted	65,182	62,332	64,848	62,178

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)

	Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance as of December 31, 2019	—	$ —	63,779	$ 6	$ 828,618	$ 80	$ (724,680)	$ 104,024
Issuance of common stock pursuant to development arrangement	—	—	156	—	5,000	—	—	5,000
Issuance of preferred and common stock pursuant to financing arrangement	526	—	1,000	1	199,906	—	—	199,907
Issuance of common stock upon exercise of vested options and vesting of restricted stock units	—	—	288	—	2,098	—	—	2,098
Stock-based compensation expense	—	—	—	—	10,367	—	—	10,367
Foreign currency translation adjustment	—	—	—	—	—	10	—	10
Unrealized gain on available-for-sale investments	—	—	—	—	—	73	—	73
Net loss	—	—	—	—	—	—	(86,432)	(86,432)
Balance as of March 31, 2020	526	-	65,223	7	1,045,989	163	(811,112)	235,047
Issuance of common stock upon exercise of vested options and vesting of restricted stock units	—	—	217	—	2,131	—	—	2,131
Stock-based compensation expense	—	—	—	—	11,848	—	—	11,848
Foreign currency translation adjustment	—	—	—	—	—	8	—	8
Unrealized gain on available-for-sale investments	—	—	—	—	—	68	—	68
Net loss	—	—	—	—	—	—	(69,244)	(69,244)
Balance as of June 30, 2020	526	$ —	65,440	$ 7	$ 1,059,968	$ 239	$ (880,356)	$ 179,858

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 Income (Loss)	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 and vesting of restricted stock units	328	—	3,633	—	—	3,633
Stock-based compensation expense	—	—	7,765	—	—	7,765
Unrealized gain on available-for-sale investments	—	—	—	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
Issuance of common stock upon exercise of vested options and vesting of restricted stock units	189	—	2,637	—	—	2,637
Stock-based compensation expense	—	—	8,740	—	—	8,740
Unrealized gain on available-for-sale investments	—	—	—	173	1	174
Net loss	—	—	—	—	(62,878)	(62,878)
Balance as of June 30, 2019	62,659	$ 6	$ 798,058	$ 236	$ (593,326)	$ 204,974

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)

	Six Months Ended June 30,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (155,676)	$ (117,144)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization expense	2,738	1,751
Stock-based compensation expense	22,117	16,505
Non-cash interest expense	5,434	2,259
Amortization of premium on investment securities	1	(1,094)
Research and development expenses recognized from issuance of common stock	5,000	—
Non-cash inventory write-offs	3,458	—
Changes in operating assets and liabilities:		
Trade receivables, net	(25)	—
Inventories	(9,007)	—
Prepaid expenses and other assets	3,141	2,596
Accounts payable	1,359	5,466
Accrued liabilities	(5,818)	(2,887)
Other liabilities	358	553
Net cash used in operating activities	(126,920)	(91,995)
Cash flows from investing activities:		
Purchase of property and equipment	(807)	(4,860)
Purchase of investments	(32,457)	(106,980)
Maturities of investments	59,369	127,146
Net cash provided by investing activities	26,105	15,306
Cash flows from financing activities:		
Borrowings under debt agreement	85,000	40,000
Debt issuance costs	—	(3,856)
Net proceeds from issuance of preferred and common stock	199,907	—
Net cash proceeds from exercise of stock options	4,128	6,270
Tax withholdings related to net share settlements of restricted stock units	(1,559)	(672)
Net cash provided by financing activities	287,476	41,742
Effects of changes in foreign exchange rates	18	—
Net increase (decrease) in cash and cash equivalents	186,679	(34,947)
Cash and cash equivalents at the beginning of the period	79,880	107,511
Cash and cash equivalents at the end of the period	$ 266,559	$ 72,564
Supplemental disclosure of non-cash investing and financing activities:		
Property and equipment purchases included in accounts payable and accrued liabilities	$ 133	$ 1,916

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

1. Formation and Business of the Company

Aimmune Therapeutics, Inc., or the Company, is a biopharmaceutical company focused on developing and commercializing new therapeutic approaches, including the development of proprietary product candidates, for the treatment of peanut and other food allergies. We are headquartered in Brisbane, California, and were incorporated in the state of Delaware on June 24, 2011.

Our main 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 accidental exposure or reduce symptom severity should an allergic reaction occur.

PALFORZIA ™ (Peanut (Arachis hypogaea) Allergen Powder-dnfp) (formerly AR101) is our lead internally developed product utilizing CODIT and was approved by the FDA for marketing and sale in the United States in January 2020. PALFORZIA is an oral immunotherapy indicated for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut. Initiation of PALFORZIA is approved in patients aged 4 through 17 years with a confirmed diagnosis of peanut allergy. PALFORZIA may be continued in patients 18 years of age and older. PALFORZIA is to be used in conjunction with a peanut-avoidant diet. We are currently commercializing PALFORZIA in the United States through a specialty sales force of approximately 80 Practice Account Managers targeting practicing allergists.

Since inception, we have incurred net losses and negative cash flows from operations. During the quarter and six months ended June 30, 2020, we incurred a net loss of $69.2 million and $155.7 million, respectively, and we used $126.9 million of cash in operations. As of June 30, 2020, we had an accumulated deficit of $880.4 million, and we do not expect to experience positive cash flows in the near future. As of June 30, 2020, we had cash, cash equivalents and investments of $318.1 million. In February 2020, we received gross proceeds from Nestlé Health Science's $200.0 million equity investment and the draw of the second loan tranche from KKR of $85.0 million. In light of the launch delay caused by COVID-19, we are taking numerous active steps to conserve financial resources. We anticipate that based on our current business plan, our financial resources will fully fund us. 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 commercializing PALFORZIA, obtaining European Medicines Agency, or EMA, approval of our Marketing Authorization Application for PALFORZIA, 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 generate sufficient revenue in the United States, 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, 2019, 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 and six months ended June 30, 2020, are not necessarily indicative of the results to be expected for the year ending December 31, 2020, 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, 2019, 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, as well as the reported revenue, costs and expenses recognized during the reporting periods. 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 six months ended June 30, 2020, 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, 2019, except as noted below.

Foreign Currency Translation

The functional currency of our foreign subsidiaries is either the U.S. dollar or the Euro. For foreign subsidiaries with the functional currency of the Euro, assets and liabilities are translated to U.S. dollars using the exchange rates at the balance sheet date and expenses are translated using the monthly average exchange rates in effect during the period in which the transactions occur. Foreign currency translation adjustments are recorded as a component of accumulated other comprehensive income within stockholders' equity.

Monetary assets and liabilities in the non-functional currency of our subsidiaries are remeasured using exchange rates in effect at the end of the period. Costs in the non-functional currency are remeasured using average exchange rates for the period, except for costs related to those balance sheet items that are remeasured using historical exchange rates. The resulting transaction gains and losses are included in the consolidated statements of comprehensive loss as incurred and have not been material for all periods presented.

Concentration of Risk

Financial instruments that potentially subject us to concentrations of credit risk consist of cash, cash equivalents, trade receivables, and investments. Our investment policy limits investments to certain types of debt securities issued by the U.S. government, its agencies and institutions with investment-grade credit ratings and places restrictions on maturities and concentration by type and issuer. We are exposed to credit risk in the event of a default by the financial institutions holding our cash, cash equivalents and investments and issuers of investments to the extent recorded on the consolidated balance sheets.

We are dependent on a small number of third-party manufacturers to manufacture our drugs and drug candidates. We could be adversely affected by a significant interruption in the supply of bulk drug substances and the manufacturing activities to produce, package and distribute PALFORZIA.

During the quarter and six months ended June 30, 2020, we had four customers, of whom three accounted for approximately 75%, 13% and 12% of total net revenues. We had no such concentration during the quarter and six months ended June 30, 2019.

In March 2020, the World Health Organization declared the global novel coronavirus, or COVID-19, outbreak a pandemic. To date, our operations have been significantly impacted by the COVID-19 pandemic, including with respect to the commercial launch of PALFORZIA and enrollment in our Phase 2 clinical trial for AR201. However, we cannot at this time predict the specific extent, duration or full impact that the COVID-19 pandemic will have on our financial condition and results of operations. The impact of the COVID-19 pandemic on our financial performance will depend on future developments, including the duration and spread of the COVID-19 pandemic and related governmental advisories and restrictions. These developments and the impact of COVID-19 on the financial markets and the overall economy are also highly uncertain. If the financial markets and/or the overall economy are impacted for an extended period, our business, financial condition, results of operations and prospects may be adversely affected.

Trade Receivables, net

Trade receivables are recorded net of estimates for which reserves are established for distributor fees, prompt pay discounts and other distributor costs that are offered within contracts between us and a limited number of specialty distributors and pharmacies in the United States, which we refer to herein as Customers. These reserves are classified as reductions of trade receivables. Refer to our Revenue Recognition policy for additional information.

Accounts outstanding longer than the contractual payment terms are considered past due. We write off accounts receivable when they are deemed uncollectible and such write-offs, net of payments received, are recorded as a reduction to the allowance. As of June 30, 2020, and December 31, 2019, we did not have any allowances for doubtful accounts.

Inventories

Inventories are stated at the lower of cost or estimated net realizable value, on a first-in, first-out, or FIFO, basis. We use actual costs to determine our cost basis for inventories. Inventories consist of raw materials, work-in-process and finished goods.

Prior to regulatory approval of our product candidates, expenses incurred to manufacture drug products are recorded as research and development expense. We begin capitalizing these expenses as inventory upon regulatory approval.

We assess our inventory levels each reporting period and write-down inventory that is expected to be at risk of expiration, that has a cost basis in excess of its expected net realizable value and inventory quantities in excess of expected requirements. In evaluating the sufficiency of our inventory reserves or liabilities for firm purchase commitments, we also take into consideration our firm purchase commitments for future inventory production. When we recognize a loss on such inventory or firm purchase commitments, such amounts are recognized as cost of revenues.

Revenue Recognition

Pursuant to ASC Topic 606, *Revenue from Contracts with Customers*, or ASC 606, we recognize revenue upon transfer of control of promised goods or services, in an amount that reflects the consideration that we expect to receive in exchange for those goods or services.

To determine revenue recognition for arrangements that we determine are within the scope of ASC 606, we perform the following five steps:

(i) identify the contract(s) with a customer;
(ii) identify the performance obligations in the contract(s);
(iii) determine the transaction price;
(iv) allocate the transaction price to the performance obligations in the contract(s); and
(v) recognize revenue when (or as) we satisfy a performance obligation.

We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer.

Product Revenue, Net

Our product revenue consists of U.S. sales of PALFORZIA, which we began shipping to Customers in March 2020. Prior to March 2020 we had no product revenue. We sell PALFORZIA to a limited number of Customers under a Risk Evaluation and Mitigation Strategy, a drug safety program that the FDA requires for certain medications with safety concerns to help ensure the benefits of the medication outweigh its risks. Revenue from product sales are recognized when the performance obligation under the agreements with our Customers are fulfilled, which is when the product has been delivered to our Customers. These Customers subsequently resell our products to patients and sometimes to hospitals, pharmacies and allergists.

Shipping and handling activities are considered to be fulfillment activities rather than a separate performance obligation and are recorded as cost of revenue.

Reserves for Variable Consideration

Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established and which result from distribution fees, prompt pay discounts, expected product returns, chargebacks, rebates, co-pay assistance and other allowances that are offered relating to our product sales. These reserves as detailed below are based on the amounts earned or to be claimed on the related sales and are classified as reductions of trade receivables or accrued liabilities. Where appropriate, these estimates take into consideration a range of possible outcomes that are probability-weighted in accordance with the expected value method under ASC 606 for relevant factors. These factors include current contractual and statutory requirements, specific known market events and trends, industry data, and/or forecasted customer buying and payment patterns. Overall, these reserves are factored into our net estimate of transaction price and reflect our best estimates of the amount of consideration to which we are entitled based on the terms of the respective underlying contracts.

The amount of variable consideration that is included in the transaction price may be constrained and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur

in a future period. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our estimates, we will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

Distribution Fees: Under our inventory management agreements with our Customers, we pay them a fee primarily for compliance with certain contractually determined covenants such as the maintenance of agreed upon inventory levels. These distribution fees are based on a contractually determined fixed percentage of sales. We record these distribution fees as a reduction of trade receivables.

Prompt Pay Discounts: Our Customers receive a contractually agreed discount for prompt payment. We expect our Customers will earn 100% of their prompt pay discounts and we record these discounts as a reduction of trade receivables.

Product Returns: We generally offer our Customers a right of return based on the product's expiration date or other market-based factors for product that has been purchased from us. We estimate the amount of our product sales that may be returned by our Customers and record the estimates as an accrued liability. We currently estimate product returns using available industry data, our own sales information and our visibility into the inventory remaining in the distribution channel.

Rebates: We are subject to government mandated rebates under the Medicaid Drug Rebate Program and other government health care programs in the United States. Rebate amounts are based upon contractual agreements or legal requirements with public sector benefit providers. We use the expected-value method for estimating these rebates based on statutory discount rates and expected utilization. The expected utilization of such rebates is estimated based on third party market research data and data received from our Customers. Estimates for these rebates are adjusted quarterly to reflect the most recent information. We record the estimated rebates as an accrued liability.

Co-Pay Assistance: Patients who have commercial insurance and meet certain eligibility requirements may receive co-pay assistance. We record the estimated amounts as an accrued liability. Co-pay assistance is based on actual program participation on a patient-by-patient basis and estimates of program redemption using our patient data provided by the third-party administrator of our co-pay program. Estimates for these rebates are adjusted quarterly to reflect the most recent information.

Other Customer Credits: We pay fees to the specialty distributors and pharmacies for account management, data management and other administrative services. We have determined such services received to date are not distinct from our sale of products to the specialty distributors and pharmacies and, therefore, a fair market value for these services may not be reasonably determined for accounting purposes. We record these fees as an accrued liability.

Cost of Revenue

Cost of revenue consists primarily of direct and indirect costs related to the manufacturing of PALFORZIA units sold, including raw materials, third-party contract manufacturing and packaging costs, freight costs, storage costs, allocation of overhead costs of employees involved with production of PALFORZIA, write-downs of inventory to expected net realizable value and costs paid to our contract manufacturers, if any, for anticipated shortfall in product demand relative to committed volumes. Such product costs incurred prior to FDA approval of PALFORZIA in January 2020 have been recorded as research and development expense in our condensed consolidated statement of operations.

Income Taxes

On March 18, 2020, the Families First Coronavirus Response Act, or the FFCR Act, and on March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, were each enacted in response to the COVID-19 pandemic. The FFCR Act and the CARES Act contain numerous income tax provisions relating to refundable payroll tax credits, deferment of employer side social security payments, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction limitations and technical corrections to tax depreciation methods for qualified improvement property. The FFCR Act and CARES Act did not have a material impact on our condensed consolidated financial statements as of June 30, 2020; however, we continue to examine the impacts the FFCR Act and CARES Act may have on our business, results of operations, financial condition and liquidity.

Recently Adopted Accounting Pronouncements

We adopted Accounting Standards Update, or ASU, No. 2018-15, *Intangibles-Goodwill and Other – Internal Use Software: Subtopic 340-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That is a Service Contract*, as of January 1, 2020. This guidance required companies to apply the internal-use software guidance in Accounting Standards Codification, or ASC, 340-40 to implementation costs incurred in a hosting arrangement that is a service contract to determine whether to capitalize certain implantation costs or expense them as incurred. The adoption of ASU No. 2018-15 did not have a material impact on our consolidated financial statements.

We adopted ASU No. 2018-13, *Fair Value Measurement: Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement*, as of January 1, 2020. The ASU 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. The adoption of ASU No. 2018-13 did not have a material impact on our consolidated financial statements.

We adopted ASU No. 2016-13, *Financial Instruments — Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, as of January 1, 2020. The ASU 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. The adoption of ASU No. 2016-13 did not have a material impact on our consolidated financial statements.

We adopted ASU No. 2019-12, *Simplifying the Accounting for Income Taxes*, in the fourth quarter of 2019. The ASU, as part of the Financial Accounting Standards Board's Simplification Initiative to reduce the cost and complexity in accounting for income taxes, removes certain exceptions related to the approach for intraperiod tax allocation, which is the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. ASU 2019-12 also amends other aspects of the guidance to help simplify and promote consistent application of GAAP. The guidance is effective for interim and annual periods beginning after December 15, 2020, with early adoption permitted. The adoption of ASU No. 2019-12 did not have a material impact on our consolidated financial statements.

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):

	June 30, 2020			
	Level 1	Level 2	Level 3	Total
Cash and cash equivalents:				
Cash and money market funds	$ 266,559	$ —	$ —	$ 266,559
Total cash and cash equivalents	$ 266,559	$ —	$ —	$ 266,559
Investments:				
Agency securities	$ —	$ 2,500	$ —	$ 2,500
Corporate securities	—	20,839	—	20,839
Commercial paper	—	9,974	—	9,974
U.S. government securities	—	18,208	—	18,208
Total investments	$ —	$ 51,521	$ —	$ 51,521

	December 31, 2019			
	Level 1	Level 2	Level 3	Total
Cash and cash equivalents:				
Cash and money market funds	$ 79,880	$ —	$ —	$ 79,880
Total cash and cash equivalents	$ 79,880	$ —	$ —	$ 79,880
Investments:				
Agency securities	—	8,862	—	8,862
Corporate securities	—	30,338	—	30,338
Commercial paper	—	7,949	—	7,949
U.S. government securities	—	31,145	—	31,145
Total investments	$ —	$ 78,294	$ —	$ 78,294

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 at June 30, 2020.

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 June 30, 2020 and December 31, 2019, are as follows (in thousands):

	June 30, 2020			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Total Fair Value
Agency securities	$ 2,500	$ —	$ —	$ 2,500
Corporate securities	20,749	90	—	20,839
Commercial paper	9,974	—	—	9,974
U.S. government securities	18,077	131	—	18,208
Total available-for-sale investments	$ 51,300	$ 221	$ —	$ 51,521

	December 31, 2019			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Total Fair Value
Agency securities	$ 8,856	$ 6	—	$ 8,862
Corporate securities	30,286	55	(3)	30,338
Commercial paper	7,949	—	—	7,949
U.S. government securities	31,123	22	—	31,145
Total available-for-sale investments	$ 78,214	$ 83	$ (3)	$ 78,294

At June 30, 2020, all of the available-for-sale securities have contractual maturities within two years. During the quarters and six months ended June 30, 2020 and 2019, we did not have any allowance for credit losses. All marketable securities with unrealized losses have been in a loss position for less than twelve months.

The carrying value of our 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

Inventories

Inventories consists of the following (in thousands):

	June 30, 2020	December 31, 2019
Raw materials	$ —	$ —
Work in process	4,076	—
Finished goods	1,570	—
Total inventories	$ 5,646	$ —

Write-offs related to excess and expiring inventories during the quarter and six months ended June 30, 2020 were $4.5 million and $4.5 million, which includes $1.0 million of contractual minimum guarantee payment obligations owed to suppliers and recorded as an accrued liability as of June 30, 2020.

Property and Equipment, Net

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

	June 30, 2020	December 31, 2019
Furniture and equipment	$ 2,679	$ 2,660
Computer equipment	3,065	2,820
Manufacturing equipment	15,429	9,012
Leased equipment	102	100
Leasehold improvements	14,586	14,525
Construction in progress	579	6,649
Property and equipment, gross	36,440	35,766
Less: accumulated depreciation	(9,900)	(7,162)
Property and equipment, net	$ 26,540	$ 28,604

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	June 30, 2020	December 31, 2019
Compensation and benefits	$ 8,713	$ 13,286
Research and development	7,217	11,336
Professional and consulting	8,628	6,627
Other	910	37
Total accrued liabilities	$ 25,468	$ 31,286

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 the KKR Loans. Of the total loan amount, $40.0 million was funded upon closing of the transaction in January 2019 and $85.0 million was funded in February 2020 following FDA approval of PALFORZIA and satisfaction of other customary borrowing conditions. The remaining $45.0 million is to be made available at our option in 2020 upon the satisfaction of certain borrowing conditions, including our achievement of aggregate net sales (as defined in the agreement) for PALFORZIA by July 31, 2020 in an amount of at least $30.0 million. 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, ABR plus 6.50% per annum and (b) London Interbank Offered Rate, or LIBOR Loans, 30-day LIBOR plus 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. To date, we have selected to pay in kind and capitalized the interest through the six months ending June 30, 2020. For periods ending after June 30, 2020, interest accrued under this loan agreement will be paid in cash on a quarterly basis. We began accruing interest on outstanding KKR Loans on March 31, 2019, and continue to accrue interest on the outstanding KKR loans on the last business day of each March, June, September and December thereafter while any KKR Loan is outstanding, as well as on the final maturity date of the KKR Loans, with each such date being referred to herein as an Interest Payment Date.

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 June 30, 2020, $133.6 million was outstanding under the KKR Loans. As of June 30, 2020, the interest rate on the KKR Loans was 8.9% per annum.

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

	June 30, 2020	December 31, 2019
Principal amount of long-term debt	$ 133,641	$ 44,004
Less: Current portion of long-term debt	—	—
Long-term debt, net of current portion	133,641	44,004
Unamortized discount relating to deferred financing costs, net	(2,888)	(3,234)
Accrued exit fee payment	709	258
Long-term debt, net of discount and current portion	$ 131,462	$ 44,028

Future principal payments of our long-term debt as of June 30, 2020 are as follows (in thousands):

Fiscal year ending December 31:	
2020	$ —
2021	—
2022	—
2023	66,821
2024	66,820
Thereafter	—
Total	$ 133,641

6. 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.

The maturities of our operating lease liabilities were as follows (in thousands):

Remaining Lease Payments at June 30, 2020			
	Operating	Financing	Total
2020	$ 1,894	$ 17	$ 1,911
2021	3,875	35	3,910
2022	3,929	9	3,938
2023	3,762	—	3,762
2024	1,857	—	1,857
Thereafter	227	—	227
Total lease payments	$ 15,544	$ 61	$ 15,605
Less: Effects of discounting	(3,822)	(11)	(3,833)
Present value of lease liabilities	$ 11,722	$ 50	$ 11,772
Less: current portion	(2,399)	(26)	(2,425)
Long-term lease liabilities	$ 9,323	$ 24	$ 9,347
Weighted-average remaining lease term	4.0 years	1.8 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):

	Quarter Ended June 30,		Six Months Ended June 30,	
Lease Cost	**2020**	**2019**	**2020**	**2019**
Operating lease cost	$ 995	$ 914	$ 1,992	$ 1,879
Finance lease cost				
Amortization of leased assets	9	8	20	16
Interest on lease liabilities	3	4	6	8
Net lease cost	$ 1,007	$ 926	$ 2,018	$ 1,903

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

	Six Months Ended June 30,	
Other Information	**2020**	**2019**
Cash paid for amounts included in the measurement of lease liabilities		
Operating cash flows from operating leases	$ 1,992	$ 1,879
Operating cash flows from finance leases	$ 26	$ 24

7. Commitments and Contingencies

In-Licensing Agreement

In February 2020, we entered into a license agreement, or the License Agreement, with Xencor, Inc., or Xencor, for the exclusive, worldwide, royalty-bearing license for the development, manufacture and commercialization of biopharmaceutical products containing or comprising the humanized monoclonal antibody AIMab7195 (formerly XmAb7195) or certain variants of AIMab7195, each of which is referred to as an AIMab7195 Product. Initially, AIMab7195 will be developed as an adjunctive treatment with our existing CODIT pipeline assets, including PALFORZIA, to explore treatment outcomes, including the potential path to remission, in patients with food allergies. AIMab7195 is designed to mediate the suppression of IgE and IgE-producing cells and originally was developed for the treatment of allergic asthma and other IgE-mediated diseases.

In connection with the entry into the License Agreement, we paid Xencor an upfront payment of $5.0 million in cash, and we also issued to Xencor 156,238 shares of Common Stock.

Additionally, we are obligated to pay Xencor an aggregate of up to $380.0 million in milestone payments, which includes $17.0 million in development milestones, $53.0 million in regulatory milestones and $310.0 million in sales milestones, and to issue an additional number of shares of our Common Stock having an aggregate value of $5.0 million in connection with the achievement of the first development milestone with respect to a product containing an AIMab7195 Product. We will also pay a royalty to Xencor equal to a percentage of net sales of AIMab7195 Products in the high single-digit to mid-teen range.

The term of the License Agreement continues on a country-by-country and Product-by-Product basis until the expiration of our obligation to pay royalties with respect such Product and country. We may terminate the License Agreement in its entirety without cause on sixty days' prior written notice. Xencor may terminate the License Agreement in its entirety if we or our affiliates or sublicensees challenge the licensed patents. Either party may terminate the License Agreement for the other party's material breach that is not cured within a specified time period or for the other party's bankruptcy or insolvency-related events. We will be solely responsible for costs related to the development of AIMab7195.

In connection with our entry into the License Agreement, we also agreed to assume Xencor's rights and obligations under its license of the AIMab7195 cell line from Catalent Pharma Solutions LLC, which manufactures AIMab7195 using their proprietary GPEx® technology.

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 our 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.

8. Stockholders' Equity

As of June 30, 2020 and December 31, 2019 we had authorized 10,000,000 shares of convertible preferred stock, and we had issued and outstanding 525,634 shares and no shares, respectively of convertible preferred stock.

In February 2020, we sold Nestlé Health Science an additional 525,634 shares of our Series A Convertible Preferred Stock at a price of $319.675 per share and 1,000,000 shares of our common stock at a price of $31.97 per share for aggregate gross proceeds of $200.0 million.

The significant provisions of the Series A convertible preferred stock are as follows:

Dividends: Shares of Series A preferred stock will be entitled to receive any dividends payable to holders of common stock, and will rank:

- senior to all of the common stock;
- senior to any class or series of capital stock of the Company created after the designation of the Series A preferred stock specifically ranking by its terms junior to the Series A preferred stock;
- on parity with all shares of Series A preferred stock and any class or series of capital stock of the Company created after the designation of the Series A preferred stock specifically ranking by its terms on parity with the Series A preferred stock; and
- junior to any class or series of capital stock of the Company created after the designation of the Series A preferred stock specifically ranking by its terms senior to the Series A preferred stock;

in each case, as to distributions of assets upon the Company's liquidation, dissolution or winding up whether voluntarily or involuntarily and/or the right to receive dividends.

Liquidation: In the event of the Company's liquidation, dissolution, or winding up, holders of Series A preferred stock will be entitled to receive, before any proceeds are distributed to the holders of common stock or junior securities and pari passu with any distributions to the holders of the Series A preferred stock, (i) an amount equal to $0.0001 per share of Series A preferred stock, plus any dividends declared but unpaid on such shares, plus (ii) such amount per share as would have been payable to such holder if all shares of Series A preferred stock held by such holder had been converted to common stock immediately prior to such liquidation, dissolution or winding up of the Company; provided, however, that, in the event that the assets to be distributed pursuant to this clause (ii) constitute equity securities or convertible securities of the Company (or any successor thereof) and, following any such distribution, any holder would hold or have a right to acquire greater than 19.99% of the number of shares of common stock or voting power of the Company (or any successor thereof) outstanding immediately after giving effect to all such distributions (such amount of securities being referred to as the "Surplus Amount"), then (x) the Company shall use commercially reasonable efforts to promptly obtain the approval of stockholders of the Company for such distribution of such Surplus Amount and (y) unless such approval of the stockholders of the Company is obtained, such holder shall not be entitled to receive such Surplus Amount.

Conversion: Each share of Series A preferred stock is convertible into ten shares of common stock (subject to adjustment as provided in the Certificate of Designation) at any time at the option of the holder, provided that the holder will be prohibited from converting the Series A preferred stock into shares of common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 19.99% of the total number of shares of common stock then issued and outstanding, subject to certain exceptions.

Voting: Shares of Series A preferred stock will generally have no voting rights, except as required by law and except that the consent of holders of a majority of the then outstanding Series A preferred stock will be required to amend the terms of the Series A preferred stock.

Redemption: The Series A preferred stock is not redeemable.

In connection with the entry into the License Agreement, we issued to Xencor 156,238 shares of common stock, pursuant to a Securities Issuance Agreement dated February 4, 2020.

9. 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 June 30, 2020 and December 31, 2019, there were 4,121,726 and 4,599,005 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. As of June 30, 2020, 2,845,844 shares under the ESPP remain available for purchase. We issued 101,989 shares at a weighted average price of $17.67 per share during the year ended December 31, 2019.

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	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Balance, December 31, 2019	7,629,823	$ 21.52	8.0	$ 91,745
Options granted	2,709,741	$ 24.63		
Options exercised and shares vested	(200,089)	$ 14.49		
Options cancelled	(530,278)	$ 25.06		
Balance, June 30, 2020	9,609,197	$ 22.35	7.7	$ 10,726
Options vested and expected to vest as of June 30, 2020	8,768,426	$ 22.13	7.6	$ 10,634
Options exercisable as of June 30, 2020	4,159,659	$ 19.26	6.2	$ 10,242

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 June 30, 2020. The 2013 Plan provided for early exercise, therefore, all our outstanding stock options issued under that plan are exercisable. The total intrinsic value of options exercised during the quarter and six months ended June 30, 2020 was $0.1 million and $1.7 million, respectively.

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, 2019	530,795	$ 25.79
Awarded	887,429	$ 21.69
Released	(208,976)	$ 26.41
Forfeited	(98,826)	$ 24.22
Unvested Balance, June 30, 2020	1,110,422	$ 22.60

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 our common stock on December 31, 2018. As of June 30, 2020, 150,000 shares had vested, and the remaining shares were restricted. As of June 30, 2020, total estimated unrecognized expense related to these restricted shares was $1.8 million based upon the fair market value of our common stock on December 31, 2018, which is expected to be recognized over the remaining vesting period of one year as general and administrative expense. Stock-based compensation expense recognized during the quarters and six months ended June 30, 2020 and 2019 related to these shares was as follows (in thousands):

	2020	2019
Quarter ended June 30	$ 446	$ 532
Six months ended June 30	892	890

As of June 30, 2020, we had issued 58,000 RSUs with a grant date fair value of approximately $1.4 million, to certain key employees that include service and performance vesting conditions related to the achievement of certain regulatory approvals for PALFORZIA. During the quarter and six months ended June 30, 2020, we recognized $1.1 million of stock-based compensation expense for 36,000 of such shares that vested upon the satisfaction of a performance condition.

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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Expected term (in years)	5.9	6.0	6.0	6.0
Expected volatility	59.1%	62.2%	57.4%	63.2%
Risk free interest rate	0.4%	2.3%	1.6%	2.5%
Dividend yield	—%	—%	—%	—%
Weighted average estimated fair value	$ 9.19	$ 11.93	$ 13.35	$ 13.38

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

	Quarter Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Expected term (in years)	0.5	0.5	0.5	0.5
Expected volatility	78.4%	50.7%	78.4%	50.7%
Risk free interest rate	0.2%	2.4%	0.2%	2.4%
Dividend yield	—%	—%	—%	—%
Weighted average estimated fair value	$ 6.01	$ 6.00	$ 6.01	$ 6.00

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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Cost of revenue	$ 81	$ —	$ 85	$ —
Research and development	3,483	2,957	7,544	5,700
Selling, general and administrative	8,250	5,783	14,488	10,805
Total stock-based compensation expense	$ 11,814	$ 8,740	$ 22,117	$ 16,505

During the quarter and six months ended June 30, 2020, stock-based compensation expense of $0.1 million and $0.1 million, respectively, was capitalized into inventory. During the quarter and six months ended June 30, 2020, we recorded approximately $0.2 million and $0.4 million, respectively, of stock-based compensation expense related to the acceleration of certain former executives' stock options. Such expense was approximately $0.5 million and $1.0 million for the quarter and six months ended June 30, 2019, respectively.

Total unrecognized stock-based compensation expense and expected period over which such compensation will be recognized were as follows ($ in thousands):

	As of June 30, 2020
Option	
Unrecognized stock compensation expense	$ 60,268
Weighted-average remaining vesting period (years)	2.9
RSU	
Unrecognized stock compensation expense	$ 17,828
Weighted-average remaining vesting period (years)	1.8
ESPP	
Unrecognized stock compensation expense	$ 377
Weighted-average remaining vesting period (years)	0.4

10. 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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Stock options	9,609,197	8,570,332	9,609,197	8,570,332
RSUs	1,110,422	639,829	1,110,422	639,829
Preferred stock	5,256,340	—	5,256,340	—

11. 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 quarter and six months ended June 30, 2020 and 2019, there were payments of $0 and $0.1 million, respectively, to MyHealthTeams pursuant to such agreement. At June 30, 2020 and December 31, 2019, 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, 2019, included in our Annual Report on Form 10-K for the year ended December 31, 2019, filed with the Securities and Exchange Commission on February 27, 2020. 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 biopharmaceutical company developing and commercializing treatments for potentially life-threatening food allergies. It is estimated that over 30 million people in the United States and Europe have a food allergy, with peanut allergy being the most prevalent and most commonly associated with severe outcomes and life-threatening events.

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 main therapeutic approach, which we refer to as Characterized Oral Desensitization Immunology Therapy, 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. As a result, we believe CODIT could contribute to reducing the burden and anxiety experienced by food-allergic patients and their families.

PALFORZIA™ (Peanut (Arachis hypogaea) Allergen Powder-dnfp) (formerly AR101) is our lead internally developed product utilizing CODIT and was approved by the FDA for marketing and sale in the United States in January 2020. PALFORZIA is indicated for the mitigation of allergic reactions, including anaphylaxis, after accidental exposure to peanut. PALFORZIA is approved for use in patients with a confirmed diagnosis of peanut allergy. Initial Dose Escalation may be administered to patients aged 4 through 17 years. Up-dosing and maintenance may be continued in patients 4 years of age and older. PALFORZIA is to be used in conjunction with a peanut-avoidant diet. We are currently commercializing PALFORZIA in the United States through a specialty sales force of approximately 80 Practice Account Managers targeting practicing allergists. We commenced commercial sales in the first quarter of 2020.

In addition to the approved indication, we are developing PALFORZIA for use in young children aged one to less than four years old in a randomized, double-blind, placebo controlled multinational Phase 3 trial called POSEIDON. We submitted a Marketing Authorization Application, or MAA, for PALFORZIA with the European Medicines Agency, or EMA, in June 2019 and the application is currently under review. If approved in the European Union, or EU, and the United Kingdom, we currently intend to commercialize PALFORZIA in Europe by developing a specialty sales force targeting allergy-focused clinicians in major European markets, beginning with Germany.

In June 2020, at the European Academy of Allergy and Clinical Immunology Digital Congress, we presented long-term safety, efficacy and immunological data from ARC004, an open-label, rollover study of the landmark pivotal PALISADE trial of PALFORZIA. After two years of daily treatment, more than 80% of patients were successfully desensitized to tolerate 2,000 mg of peanut protein, or 4,043 mg cumulatively, which is the equivalent of about 14 peanut kernels. Additionally, the safety profile of PALFORZIA, as measured by treatment-related exposure adjusted adverse events, improved over time.

We are developing additional CODIT product candidates beyond peanut allergy. In August 2019, we commenced a Phase 2 clinical trial in subjects with hen egg allergy for our product candidate, AR201. We recently completed a productive pre-investigational new drug meeting with the FDA regarding our multi-tree nut program that helped identify a clear path forward to the submission of an investigational new drug, or IND, application.

In February 2020, we in-licensed AIMab7195 (formerly XmAb7195) from Xencor, Inc. Initially, AIMab7195 will be developed as an adjunctive treatment with our existing CODIT pipeline assets, including PALFORZIA, to explore the potential path to remission in patients with food allergies. We expect to file an IND for AIMab7195 in the first quarter of 2021.

Since commencing our operations in 2011, substantially all of our efforts have been focused on research, development and commercialization of PALFORZIA. We started generating revenue from product sales in the first quarter of 2020, and, as a result, we have incurred significant losses in the past. We incurred net losses of $155.7 million and $117.1 million for the six months ended June 30, 2020 and 2019, respectively, and used $126.9 million of cash in operations for the six months ended June 30, 2020. As of June 30, 2020, our accumulated deficit was $880.4 million. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase as we continue to commercialize PALFORZIA and as we continue to 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 in January 2019 and $85.0 million was funded in February 2020 upon FDA approval of PALFORZIA and satisfaction of other customary borrowing conditions. The remaining $45.0 million is to be made available at our option in 2020, upon the satisfaction of certain borrowing conditions, including our achievement of aggregate net sales (as defined in the agreement) for PALFORZIA by July 31, 2020 in an amount of at least $30.0 million.

In February 2020, we sold Nestlé Health Science an additional 525,634 shares of our Series A Preferred Stock at a price of $319.675 per share and 1,000,000 shares of our common stock at a price of $31.97 per share for aggregate gross proceeds of $200.0 million.

We rely exclusively on the Golden Peanut Company, or GPC, to provide standard food-grade peanut flour pursuant to a long-term exclusive commercial supply agreement. 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 PALFORZIA, 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 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. We expect to continue to significantly increase our investment in our manufacturing process and commercial organization as we continue to commercialize PALFORZIA in the United States and as we prepare for the potential approval of our MAA for PALFORZIA by the EMA.

COVID-19 Update

To date, COVID-19 has had, and may continue to have, an adverse impact on our operations and the commercialization of PALFORZIA, our clinical trials, clinical trial material distribution system and our expenses, including as a result of preventive and precautionary measures that we, other businesses and governments are taking.

In particular, we have experienced significant business disruptions, including the continued delay of the commercialization of PALFORZIA in the United States as a result of a reduction in access to our customers due to the reduced business hours of medical facilities as local, state, federal, and foreign governments institute prolonged shelter-in-place and/or self-quarantine mandates. Under the Risk Evaluation and Mitigation Strategy, or REMS, for PALFORZIA, the first dose of each up-dosing level must be administered in a certified healthcare setting and, due to the strains placed on the providers of healthcare services by COVID-19, including shelter-in-place restrictions, many patients are not able to access physicians in a manner sufficient to commence treatment with PALFORZIA. Similarly, patients who have commenced treatment, but who have not yet advanced through the up-dosing phase, have been restricted from accessing the necessary healthcare settings and, as a result, are being maintained at their existing dose levels.

Formulary adoption conversations with payers regarding PALFORZIA are proceeding virtually. As of the end of July 2020, there were 39 plans in the United States that had either interim or permanent policies written to cover PALFORZIA. These plans cover approximately 102 million lives. We expect that these interactions will continue and lead to additional formulary coverage decisions by payers later this year. However, the impact of the COVID-19 pandemic on formulary coverage for PALFORZIA is hard to assess due the rapidly evolving nature of the situation and it is possible that formulary coverage may be delayed. Until PALFORZIA is formally covered on formularies, allergists can initiate patients on treatment via the use of the medical exception processes provided by payers.

In regards to clinical trials of PALFORZIA, our POSEIDON (ARC005) Phase 3 clinical trial to explore the efficacy and safety of PALFORZIA in young peanut-allergic children ages 1 to <4 years is ongoing. Assuming clinical sites are able to resume operations and enroll patients, we expect to complete enrollment in the second half of 2020 and report topline data in the second half of 2021. However, the impact of the COVID-19 pandemic on the timing of study enrollment and completions is hard to assess due the rapidly evolving nature of the situation and it is possible that the study enrollment completion and the availability of data may be delayed.

In regards to AR201, while we saw an increase in enrollment in our Phase 2 clinical trial in the first quarter of 2020, we experienced a significant decline in enrollment following the spread of COVID-19 in the United States. As a result, as a cost saving

measure and in light of the ongoing impacts of COVID-19, we have decided to end enrollment in the study. For those patients who had enrolled in the clinical trial and begun receiving treatment, we are continuing to deliver maintenance doses of AR201, and all patients presently enrolled in the study will be able to complete the trial once possible. We then intend to review the data from these subjects and determine the best path forward. We also plan to follow FDA guidance on clinical trial conduct during the COVID-19 pandemic, including with respect to the remote monitoring of clinical data.

In regards to our supply chain and distribution model, we have initiated direct-to-patient shipment of clinical trial materials in Europe and the United States, to permit uninterrupted supply of clinical trial materials to our clinical trial subjects. This measure became necessary as clinical trial subjects were unable to visit their physician offices to receive re-supply of clinical trial materials due to the COVID-19 pandemic. Other than this shift in our distribution model for clinical trial materials, there have been no disruptions in our supply chain of drug manufacturers necessary to conduct our clinical trials and we believe that we will be able to supply the clinical material needs of our ongoing clinical studies. In addition, our supply chain for PALFORZIA has not been significantly impacted to date by the COVID-19 pandemic. However, delays in the commercial launch of PALFORZIA have led to charges to write-off inventory of PALFORZIA due to product expirations.

We do not believe that the pandemic has to date caused, or will going forward cause, a significant delay in the review and potential approval of our MAA by the EMA or our MAA by Swissmedic. As a result, we expect a standard overall review period for our MAA for PALFORZIA with a target action date in the fourth quarter of 2020. We also believe the Swissmedic review of PALFORZIA is ongoing and remains on track. The target action date is mid-2021.

We cannot at this time predict the specific extent, duration or full impact that the COVID-19 pandemic will have on our financial condition and results of operations. The impact of the COVID-19 pandemic on our financial performance will depend on future developments, including the duration and spread of the COVID-19 pandemic and related governmental advisories and restrictions. These developments and the impact of COVID-19 on the financial markets and the overall economy are also highly uncertain. If the financial markets and/or the overall economy are impacted for an extended period, our business, financial condition, results of operations and prospects may be adversely affected.

In late February 2020, our executive leadership team began to closely monitor the evolving COVID-19 crisis and advise on our response. In alignment with public health guidance designed to slow the spread of COVID-19, as of mid-March 2020, we implemented a remote work plan for all employees. We are supporting all of our employees by leveraging virtual meeting technology and encouraging employees to follow local health authority guidance. We may need to undertake additional actions that could impact our operations as required by applicable laws or regulations, or which we determine to be in the best interests of our employees.

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 revenue, costs and expenses recognized 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, 2019, except as noted below. Our significant accounting policies are more fully described in Note 2 of the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Revenue Recognition

Pursuant to Accounting Standards Codification, or ASC, Topic 606, *Revenue from Contracts with Customers*, or ASC 606, we recognize revenue upon transfer of control of promised goods or services, in an amount that reflects the consideration to which we are entitled to in exchange for those goods or services. We calculate gross product revenues based on the price that we charge to the specialty pharmacies and distributors in the United States, which we refer to herein as Customers. We estimate our domestic net product revenues by deducting from our gross product revenues: (a) trade allowances, such as distribution fees and discounts for prompt payment; (b) estimated government rebates and chargebacks; (c) certain other fees paid to specialty pharmacies, distributors and commercial payors; and (d) product returns. Discounts and allowances are complex and require significant judgment by management. Management assesses estimates each period and updates them to reflect current information.

We initially record estimates for these deductions at the time we recognize the related gross product revenue, and revise these estimates in subsequent period as needed, resulting in net product revenue recognized. We base our estimates for the expected utilization on customer and payer data received from the specialty pharmacies and distributors and historical utilization rates as well as third-party market research data.

Inventories

Prior to regulatory approval of our product candidates, expenses incurred to manufacture drug products are recorded as research and development expense. Beginning in the first quarter of 2020, we began to capitalize inventory costs associated with PALFORZIA supply when it was determined that the inventory had a probable future economic benefit concurrent with FDA approval in January 2020.

Inventory costs are determined using the standard cost methodology, and this methodology approximates actual cost determined using a first-in, first-out, or FIFO, basis cost flow assumption for the purposes of matching such costs to the related product sale.

We periodically review our inventories for excess amounts or obsolescence and write down obsolete or otherwise unmarketable inventory to the estimated net realizable value. Our assessment of estimated excess, obsolete and non-sellable inventories are based on assumptions about future demand, past usage, changes to manufacturing processes and overall market conditions, and also consider future firm purchase commitments, which require management to utilize judgement in formulating estimates and assumptions that we believe to be reasonable under the circumstances.

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

Product Revenue, Net

Our product revenue, net consists of U.S. sales of PALFORZIA. Prior to March 2020, we had no product revenue.

Cost of Revenue

Cost of revenue relates to sales of PALFORZIA, which began in March 2020. Cost of revenue consists primarily of direct and indirect costs related to the manufacturing of PALFORZIA units sold, including raw materials, third-party contract manufacturing and packaging costs, freight costs, storage costs, allocation of overhead costs of employees involved with production of PALFORZIA, write-downs of inventory to expected net realizable value and fixed costs to our contract manufacturers, if any, for anticipated shortfall in product demand relative to committed volumes. Prior to regulatory approval of PALFORZIA, expenses incurred to manufacture PALFORZIA were recorded as research and development expense.

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

- External costs include costs incurred to conduct research, such as the discovery and development of our product candidates; costs related to the production of clinical supplies and pre-approval inventory, 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 prior to FDA approval and other development costs incurred by third parties are expensed as the contracted work is performed.

Selling, General and Administrative Expenses

Selling, 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 marketing expenses related to commercial launch preparation and execution. 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 selling, general and administrative functions based on headcount.

Results of Operations

Comparison of the Quarters Ended June 30, 2020 and 2019

	Quarter Ended June 30,			
	2020	2019	$ Change	% Change
	(In thousands)			
Product revenue, net	$ —	$ —	$ —	*
Costs and operating expenses:				
Cost of revenue	4,850	—	4,850	*
Research and development	23,047	31,988	(8,941)	(28)%
Selling, general and administrative	38,094	31,200	6,894	22%
Total costs and operating expenses	65,991	63,188	2,803	4%
Loss from operations	(65,991)	(63,188)	(2,803)	4%
Interest income	428	1,710	(1,282)	(75)%
Interest expense	(3,212)	(1,262)	(1,950)	155%
Other income, net	(148)	(90)	(58)	64%
Loss before provision for income taxes	(68,923)	(62,830)	(6,093)	10%
Provision for income taxes	321	48	273	569%
Net loss	$ (69,244)	$ (62,878)	$ (6,366)	10%

*Percentage not meaningful

Product Revenue, Net:

The following table summarizes our product revenue during the quarters ended June 30, 2020 and 2019:

	Quarter Ended June 30,			
	2020	2019	$ Change	% Change
	(In thousands)			
Product revenue, net	$ —	$ —	$ —	*

*Percentage not meaningful

Product revenue consists of sales of PALFORZIA, which was approved by FDA in January 2020. We first commenced commercial shipments of PALFORZIA in March 2020. Revenue to date comprises initial stocking by our customers and is not an indication of prescription pull-through to patients in the second quarter. Given stocking of inventory in the first quarter, and the closure of most allergists' offices through the end of May due to COVID-19, there was no revenue recognized during the second quarter of 2020.

Cost of Revenue:

The following table summarizes our cost of revenue expenses incurred during the quarters ended June 30, 2020 and 2019:

	Quarter Ended June 30,			
	2020	2019	$ Change	% Change
	(In thousands)			
Cost of revenue	$ 4,850	$ —	$ 4,850	*

*Percentage not meaningful

Cost of revenue during the quarter ended June 30, 2020 was also impacted by the pandemic due to the delay in the commercial launch of PALFORZIA and primarily consists of charges to write-off excess and expiring inventory totaling $4.5 million, which includes $1.0 million of contractual minimum guarantee payment obligations owed to suppliers. Due to the unusual circumstances caused by the pandemic in the second quarter, we do not expect these aggregate charges of $4.5 million to be a recurring event. Cost of revenue during the quarter ended June 30, 2020 also consists of costs associated with product shipments as well as the write-off of one manufacturing lot, which did not meet our stringent manufacturing specifications.

Prior to regulatory approval of PALFORZIA, we incurred expenses to manufacture PALFORZIA, which were recorded as research and development expense. We expect to sell inventory previously expensed to research and development over the next 12 months, and accordingly we expect our costs of product sales of PALFORZIA to increase as a percentage of net sales in future periods as we produce and sell inventory that reflects the full cost of manufacturing the product. Discrete period costs such as those incurred in the first quarter of 2020 are difficult to predict and will be recorded as incurred.

Research and Development Expenses

The following table summarizes our research and development expenses incurred during the quarters ended June 30, 2020 and 2019:

	Quarter Ended June 30,			
	2020	2019	$ Change	% Change
	(In thousands)			
External clinical-related expenses	$ 11,288	$ 17,750	$ (6,462)	(36)%
Employee-related costs	6,103	7,621	(1,518)	(20)%
Stock-based compensation expense	3,483	2,957	526	18%
Facilities and other costs	2,173	3,660	(1,487)	(41)%
Total research and development expenses	$ 23,047	$ 31,988	$ (8,941)	(28)%

Research and development expenses decreased by $8.9 million for the quarter ended June 30, 2020, compared to the quarter ended June 30, 2019, primarily due to cost containment measures and decreased external clinical-related and manufacturing expenses. External clinical-related expenses decreased primarily due to the close-out of certain PALFORZIA clinical trials and manufacturing expenses decreased as we began capitalizing costs for inventory upon FDA approval of PALFORZIA.

We expect research and development expenses to continue to decrease in the near-term as we continue to close-out PALFORZIA related clinical trials, which we expect to be partially offset by the development of additional CODIT product candidates, including for the treatment of egg allergy and multi-tree nut allergy.

Selling, General and Administrative Expenses

The following table summarizes our selling, general and administrative expenses incurred during the quarters ended June 30, 2020 and 2019:

	Quarter Ended June 30,			
	2020	2019	$ Change	% Change
	(In thousands)			
Employee-related costs	$ 15,729	$ 10,975	$ 4,754	43%
Stock-based compensation expense	8,250	5,783	2,467	43%
External professional services	12,283	14,090	(1,807)	(13)%
Facilities and other costs	1,832	352	1,480	420%
Total selling, general and administrative expenses	$ 38,094	$ 31,200	$ 6,894	22%

Selling, general and administrative expenses increased by $6.9 million for the quarter ended June 30, 2020, compared to the quarter ended June 30, 2019, primarily due to increased employee-related costs, stock-based compensation expense and facilities and other costs. Employee-related expenses and stock-based compensation expense increased as a result of increased headcount to support the commercialization of PALFORZIA, including the addition of a specialty field team of approximately 80 Practice Account Managers targeting practicing allergists. These increases were partially offset by decreased external professional services costs resulting from cost containment measures. Facilities and other costs increased due to increased general and administrative costs related to support functions and general supplies for our growing headcount.

We expect our quarterly selling, general and administrative expenses to continue at this level or increase for the remainder of 2020 as we focus on the commercialization of PALFORIZIA in both the United States and Europe. The commercialization of PALFORZIA in the United States remains our top priority.

Interest Income

Interest income decreased by $1.3 million for the quarter ended June 30, 2020, compared to the quarter ended June 30, 2019, primarily due to lower interest rates on our investments securities.

Interest Expense

Interest expense increased by $2.0 million for the quarter ended June 30, 2020, compared to the quarter ended June 30, 2019, primarily due to drawing the $85.0 million second tranche of the KKR loan in February 2020.

Other Income, net

Other income, net did not change materially for the quarter ended June 30, 2020, compared to the quarter ended June 30, 2019.

Provision for Income Taxes

The provision for income taxes for the quarters ended June 30, 2020 and 2019 resulted from our foreign operations.

Comparison of the Six Months Ended June 30, 2020 and 2019

	Six Months Ended June 30,			
	2020	2019	$ Change	% Change
	(In thousands)			
Product revenue, net	$ 575	$ —	$ 575	*
Costs and operating expenses:				
Cost of revenue	5,107	—	5,107	*
Research and development	59,510	63,304	(3,794)	(6)%
Selling, general and administrative	87,232	54,912	32,320	59%
Total costs and operating expenses	151,849	118,216	33,633	28%
Loss from operations	(151,274)	(118,216)	(33,058)	28%
Interest income	1,406	3,611	(2,205)	(61)%
Interest expense	(5,441)	(2,406)	(3,035)	126%
Other income, net	73	(56)	129	(230)%
Loss before provision for income taxes	(155,236)	(117,067)	(38,169)	33%
Provision for income taxes	440	77	363	471%
Net loss	$ (155,676)	$ (117,144)	$ (38,532)	33%

*Percentage not meaningful

Product Revenue, Net:

The following table summarizes our product revenue during the six months ended June 30, 2020 and 2019:

	Six Months Ended June 30,			
	2020	2019	$ Change	% Change
	(In thousands)			
Product revenue, net	$ 575	$ —	$ 575	*

*Percentage not meaningful

Product revenue consists of sales of PALFORZIA, which was approved by FDA in January 2020. We first commenced commercial shipments of PALFORZIA in March 2020. Revenue to date comprises initial stocking by our customers and is not an indication of prescription pull-through to patients in the second quarter. Given stocking of inventory in the first quarter, and the closure of most allergists' offices through the end of May due to COVID-19, there was no revenue recognized during the second quarter of 2020.

Cost of Revenue:

The following table summarizes our cost of revenue expenses incurred during the six months ended June 30, 2020 and 2019:

	Six Months Ended June 30,			
	2020	2019	$ Change	% Change
	(In thousands)			
Cost of revenue	$ 5,107	$ —	$ 5,107	*

*Percentage not meaningful

Cost of revenue during the six months ended June 30, 2020 was also impacted by the pandemic due to the delay in the commercial launch of PALFORZIA and primarily consists of charges to write-off excess and expiring inventory totaling $4.5 million, which includes $1.0 million of contractual minimum guarantee payment obligations owed to suppliers. Due to the unusual circumstances caused by the pandemic, we do not expect these aggregate charges of $4.5 million to be a recurring event. Cost of revenue during the six months ended June 30, 2020 also consists of costs associated with product shipments as well as the write-off of manufacturing lots, which did not meet our stringent manufacturing specifications.

Research and Development Expenses

The following table summarizes our research and development expenses incurred during the six months ended June 30, 2020 and 2019:

	Six Months Ended June 30,			
	2020	2019	$ Change	% Change
	(In thousands)			
External costs	$ 32,894	$ 35,514	$ (2,620)	(7)%
Employee-related costs	14,534	15,896	(1,362)	(9)%
Stock-based compensation expense	7,544	5,700	1,844	32%
Facilities and other costs	4,538	6,194	(1,656)	(27)%
Total research and development expenses	$ 59,510	$ 63,304	$ (3,794)	(6)%

Research and development expenses decreased by $3.8 million for the six months ended June 30, 2020, compared to the six months ended June 30, 2019, primarily due to cost containment measures and decreased external clinical-related and manufacturing costs as we began capitalizing costs for inventory upon FDA approval of PALFORZIA. These decreases were partially offset by $10.0 million of equity and cash upfront payments to Xencor in February 2020 under our development arrangement for AIMab7195 and stock-based compensation expense. Stock-based compensation expense increased as a result of the vesting of RSUs granted to certain key employees based on the achievement of certain regulatory approvals for PALFORZIA.

We expect research and development expenses to continue to decrease in the near-term as we continue to close-out PALFORZIA related clinical trials, which we expect to be partially offset by the development of additional CODIT product candidates, including for the treatment of egg allergy and multi-tree nut allergy.

Selling, General and Administrative Expenses

The following table summarizes our selling, general and administrative expenses incurred during the six months ended June 30, 2020 and 2019:

	Six Months Ended June 30,			
	2020	2019	$ Change	% Change
	(In thousands)			
Employee-related costs	$ 36,256	$ 19,859	$ 16,397	83%
Stock-based compensation expense	14,488	10,805	3,683	34%
External professional services	33,272	23,417	9,855	42%
Facilities and other costs	3,216	831	2,385	287%
Total selling, general and administrative expenses	$ 87,232	$ 54,912	$ 32,320	59%

Selling, general and administrative expenses increased by $32.3 million for the six months ended June 30, 2020, compared to the six months ended June 30, 2019, primarily due to increased employee-related costs, external professional services costs, stock-based compensation expense and facilities and other costs. Employee-related expenses and stock-based compensation expense increased as a result of increased headcount to support the commercialization of PALFORZIA, including the addition of a specialty field team of approximately 80 Practice Account Managers targeting practicing allergists. External professional services increased primarily due to consulting services for commercial launch, medical education and grants, and support for PALFORZIA. Facilities and other costs increased due to increased general and administrative costs related to support functions and general supplies for our growing headcount.

We expect our quarterly selling, general and administrative expenses to continue at this level or increase for the remainder of 2020 as we focus on the commercialization of PALFORIZIA in both the United States and Europe. The commercialization of PALFORZIA in the United States remains our top priority.

Interest Income

Interest income decreased by $2.2 million for the six months ended June 30, 2020, compared to the six months ended June 30, 2019, primarily due to lower rates on our investment securities.

Interest Expense

Interest expense increased by $3.0 million for the six months ended June 30, 2020, compared to the six months ended June 30, 2019, primarily due to drawing the $85.0 million second tranche of the KKR loan in February 2020.

Other Income, net

Other income, net did not change materially for the six months ended June 30, 2020, compared to the six months ended June 30, 2019.

Provision for Income Taxes

The provision for income taxes for the six months ended June 30, 2020 and 2019 resulted from our foreign operations.

Liquidity and Capital Resources

As of June 30, 2020, we had cash, cash equivalents and investments of $318.1 million. In light of the launch delay caused by COVID-19, we are taking numerous active steps to conserve financial resources. We anticipate that based on our current business plan, our financial resources fully fund us.

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 in January 2019 and $85.0 million was funded in February 2020 upon FDA approval of AR101 and satisfaction of other customary borrowing conditions. The remaining $45.0 million is to be made available at our option in 2020, upon the satisfaction of certain borrowing conditions, including our achievement of aggregate net sales (as defined in the agreement) for PALFORZIA by July 31, 2020 in an amount of at least $30.0 million. The loan can be prepaid at our discretion, at any time, subject to prepayment fees. The weighted-average interest rate will be calculated based on the daily cost of borrowing, reflecting the relevant adjusted London Interbank Offered Rate, or LIBOR, or Alternate Base Rate, or ABR plus the applicable margin. 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 shall thereafter bear interest. The Company has selected to pay in kind and have the interest capitalized for the quarters and six months ended June 30, 2020 and 2019. For periods ending after June 30, 2020, interest accrued under this loan agreement will be paid in cash on a quarterly basis.

In February 2020, we sold Nestlé Health Science an additional 525,634 shares of our Series A Preferred Stock at a price of $319.675 per share and 1,000,000 shares of our common stock at a price of $31.97 per share for gross aggregate proceeds of $200.0 million.

With FDA approval of PALFORZIA in January 2020, we commenced commercial sales in the first quarter of 2020. Until such time that we can generate substantial revenue from product sales, if ever, we expect to finance our operating activities with existing cash and investment and through a combination of equity offerings and debt financings and we may seek to raise additional capital through strategic collaborations. However, we may be unable to raise additional funds or enter into such arrangements when needed on favorable terms, or at all, which would have a negative impact on our financial condition and could force us to delay, limit, reduce or terminate our development programs or commercialization efforts or grant to others rights to develop or market product candidates that we would otherwise prefer to develop and market ourselves. Failure to receive additional funding could cause us to cease operations, in part or in full. Furthermore, even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital due to favorable market conditions or strategic considerations.

We expect to incur continued expenditures in the future in connection with the expansion of our U.S. commercial infrastructure and sales force in connection with commercializing PALFORZIA in the United States. While we have ended enrollment in our Phase 2 clinical trial of AR201, we intend to continue to make investments to develop our product candidates.

Summary Statement of Cash Flows

	Six Months Ended		
	2020	2019	$ Change
	(In thousands)		
Net cash provided by (used in):			
Operating activities	$ (126,920)	$ (91,995)	$ (34,925)
Investing activities	$ 26,105	$ 15,306	$ 10,799
Financing activities	$ 287,476	$ 41,742	$ 245,734

Net Cash Used In Operating Activities

Net cash used in operating activities was $126.9 million for the six months ended June 30, 2020, an increase of $34.9 million from $92.0 million for the six months ended June 30, 2019. This increase was primarily due to higher net loss from operations resulting from increased operating expenses, which included approximately $15.0 million of cash expenses unique to the first six months of 2020. As a result, we expect that quarterly cash spending from operations for the remainder of the year will be substantially lower than what we reported in the first six months of 2020.

Net Cash Provided By Investing Activities

Net cash provided by investing activities was $26.1 million for the six months ended June 30, 2020, an increase of $10.8 million from net cash used in investing activities of $15.3 million for the six months ended June 30, 2019. The increase was primarily due to the timing of net maturities of various investments as we monitor the balance of our portfolio's investments while managing our cash requirements.

Net Cash Provided By Financing Activities

Net cash provided by financing activities was $287.5 million for the six months ended June 30, 2020, an increase of $245.7 million from $41.7 million for the six months ended June 30, 2019. The increase was primarily due to Nestle Health Science's equity investment of $200.0 million as well as well as our net debt borrowing under the KKR agreement of $85.0 million in February 2020.

As of June 30, 2020, we had cash, cash equivalents and investments of $318.1 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, 2019.

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, 2019, except as follows. As of June 30, 2020, we had approximately $133.6 million of future principal payments associated with long-term debt with variable interest rate components. Assuming constant debt levels, a theoretical change of 100 basis points (1%) on our current interest rate of 8.9% on our long-term debt as of June 30, 2020, would result in a change in our annual interest expense impacting the financial statements by approximately $1.3 million. This hypothetical increase or decrease will likely be different from what actually occurs in the future, and the impact may differ from that quantified herein.

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 June 30, 2020. Based on the evaluation of our disclosure controls and procedures, our Chief Executive Officer and Chief Financial Officer have concluded that, as of June 30, 2020, 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 June 30, 2020, 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. Many of the following risks and uncertainties are, and will be, exacerbated by the COVID-19 pandemic and any worsening of the global business and economic environment as a result. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

Risks Related to the COVID-19 Pandemic

Public health crises, epidemics and pandemics, or the perception of their effects, have had and could continue to have an adverse effect on our business, financial condition and results of operations, or cash flows.

Our global operations expose us to risks associated with public health crises and outbreaks of epidemic, pandemic, or contagious diseases, such as the current outbreak of a novel strain of coronavirus (COVID-19). To date, COVID-19 has had, and may continue to have, an adverse impact on our operations and the commercialization of PALFORZIA, our clinical trials, as well as on our clinical trial material distribution system and our expenses, including as a result of preventive and precautionary measures that we, other businesses and governments are taking. Due to these impacts and measures, we have experienced and may continue to experience significant and unpredictable reductions in demand for PALFORZIA. Though the effect has been limited to date, COVID-19 may eventually also affect our supply chains.

Public health crises or outbreaks of epidemic, pandemic, or contagious diseases could also cause disruptions to our business. As a result of the COVID-19 outbreak, we have experienced significant business disruptions, including delaying the commercialization of PALFORZIA in the United States, restricting our ability to travel and the temporary closing of our facilities. While the complexity of our supply chain and logistics operations has been increased as a result of the COVID-19 outbreak, our manufacturing facilities remain fully operational and we believe we have sufficient product supply of PALFORZIA to meet demand in the near-term. However, the COVID-19 outbreak has resulted in a reduction in access to our customers due to the reduced business hours of medical facilities as local, state, federal, and foreign governments institute prolonged shelter-in-place and/or self-quarantine mandates. In addition, our corporate headquarters and many of our operations are in locations which have instituted shelter-in-place orders applicable to most of our employees in that region, requiring our employees to work from home. These unprecedented measures to slow the spread of the virus taken by local governments and health care authorities globally, have had, and we expect will continue to have, a significant negative impact on our operations and financial results. Moreover, although we have incurred costs in an effort to create a safe work environment for employees who may eventually return to work at our facilities, our efforts may not be sufficient to prevent employees from contracting COVID-19.

We have experienced significant business disruptions, including delaying the commercialization of PALFORZIA in the United States as a result of a reduction in access to our customers due to the reduced business hours of medical facilities as local, state, federal, and foreign governments institute prolonged shelter-in-place and/or self-quarantine mandates. Under the Risk Evaluation and Mitigation Strategy, or REMS, for PALFORZIA, the first dose of each up-dosing level must be administered in a certified healthcare setting and, due to the strains placed on the providers of healthcare services by COVID-19, including shelter-in-place restrictions, many patients are not able to access physicians in a manner sufficient to commence treatment with PALFORZIA. Similarly, patients who have commenced treatment, but who have not yet advanced through the up-dosing phase, have been restricted from accessing the necessary healthcare settings and, as a result, are being maintained at their existing dose levels.

We submitted a Marketing Authorization Application, or MAA, for PALFORZIA with the EMA in June 2019 and the application is currently under review. While we do not believe that the pandemic has to date caused, or will going forward cause, a significant delay in the review and potential approval of our MAA by the European Medicines Agency, or EMA, or our MAA by Swissmedic. However, the impact of the COVID-19 pandemic is hard to assess and it is possible that the review process for our applications may be delayed.

In addition, current and upcoming clinical trials run in the United States and Europe by us have been and may continue to be affected by the COVID-19 outbreak. Patient enrollment and randomization have been delayed as patients remain subject to shelter-in-place orders. For example, our POSEIDON (ARC005) Phase 3 clinical trial to explore the efficacy and safety of PALFORZIA in young peanut-allergic children ages 1 to <4 years is ongoing. The duration of these delays is unknown at this time. If the COVID-19

outbreak continues as a worldwide pandemic, it may delay enrollment in our clinical trials, including here in the United States and Europe, and some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services, which would delay our clinical results and ultimate commercialization of our product candidates affected and increase our clinical trial costs.

Finally, the widespread health crisis resulting from the outbreak of COVID-19 has adversely affected, and may continue to adversely affect, the economies and financial markets of many countries, which may result in an economic downturn that could curtail or delay demand for PALFORZIA. Due to the uncertain scope and duration of the pandemic, and uncertain timing of global recovery and economic normalization, we are unable to estimate the overall impacts on our operations and financial results.

The COVID-19 pandemic could adversely impact our clinical trials.

In response to the spread of COVID-19, we have closed our offices with our employees continuing their work outside of our offices. We have also had to adjust protocols for our clinical trials as patients remain subject to shelter-in-place restrictions. If COVID-19 continues to spread in the United States, Europe and elsewhere, we may experience additional disruptions that could severely impact our clinical trials, including:

- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials, including interruption in global shipping that may affect the transport of clinical trial materials;
- changes in local regulations as part of a response to the COVID-19 coronavirus pandemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue such clinical trials altogether;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;
- risk that participants enrolled in our clinical trials will contract COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- interruptions or delays in preclinical studies due to restricted or limited operations at research and development laboratory facilities;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; and
- refusal of the FDA to accept data from clinical trials in affected geographies.

The COVID-19 pandemic continues to rapidly evolve. The extent to which the pandemic impacts our business and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States, Europe and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States, Europe and other countries to contain and treat the disease.

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 recently received approval to market our first product, PALFORZIA™, and have just begun commercial sales, which, together with our limited operating history, make it difficult to assess our future viability.

We are a 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 CODIT™, therapeutic approach and our lead product, PALFORZIA (AR101), as well as researching and developing additional CODIT product candidates. On January 31, 2020, the United States Food and Drug Administration, or FDA, approved our Biologics License Application, or BLA, for PALFORZIA for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut in patients aged 4 to 17 years old with a confirmed diagnosis of peanut allergy. We had just begun commercial sales when the COVID-19 pandemic interrupted our commercial roll out. 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 incurred a net loss of $155.7 million for the six months ended June 30, 2020 and a net loss of $248.5 million, $210.8 million, and $131.3 million for the years ended December 31, 2019, 2018 and 2017, respectively. At June 30, 2020, our accumulated deficit was $ 880.4 million. We expect to continue to incur losses for the foreseeable future. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

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 level of demand for PALFORZIA and any of our product candidates that are approved, if any, may vary significantly;
- coverage and reimbursement policies with respect to PALFORZIA and our product candidates, if approved, and potential future drugs that compete with PALFORZIA and our product candidates;
- the timing and cost of, and level of investment in, the commercialization and further development of PALFORZIA, which may change from time to time;
- the negative impact of COVID-19 on the commercialization of PALFORZIA, which has affected and may continue to affect our revenues;
- the cost of manufacturing PALFORZIA and our product candidates and our ongoing establishment of commercial manufacturing capacity for PALFORZIA, which may vary depending on the quantity of production and the terms of our agreements with manufacturers;
- the timing and cost of, and level of investment in, research and development of our product candidates, which may change from time to time;
- 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;
- expenditures that we may incur to acquire, develop or commercialize additional product candidates and technologies;
- future accounting pronouncements or changes in our accounting policies; and
- the timing and success or failure of clinical trials for PALFORZIA and 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 may choose, or need, to obtain 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, PALFORZIA, and researching and developing additional CODIT product candidates. At June 30, 2020, we had capital resources consisting of cash, cash equivalents and investments of $318.1 million. We believe that we will continue to expend substantial resources for the foreseeable future on the commercialization of PALFORZIA, including sales and marketing efforts, physician and patient education and training and seeking foreign regulatory approval of PALFORZIA, and as we continue to develop and seek regulatory approval for our product candidates.

In addition, other unanticipated costs may arise. Because the outcome of any drug development and/or regulatory approval process is highly uncertain, we may not be able to accurately estimate the actual amounts necessary to successfully complete the commercialization of PALFORZIA or the development, regulatory approval process and commercialization of AR201 or any other product candidates.

With the proceeds from Nestlé Health Science's $200.0 million equity investment and the draw of the second tranche under our loan from KKR of $85.0 million in February 2020, we anticipate that based on our current business plan, our financial resources fully fund us. However, our operating plan may change as a result of many factors, including the effects of the COVID-19 pandemic and other 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 PALFORZIA and 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 amount of sales and other revenue from PALFORZIA or, if approved, AR201 or any other product candidates we develop;
- the extent to which the COVID-19 coronavirus and related governmental regulations and restrictions may continue to affect our business, including our research, clinical trials, manufacturing, PALFORZIA launch plans and financial condition;
- our ability to achieve sufficient market acceptance, coverage and reimbursement from third-party payors and adequate market share for PALFORZIA and our product candidates, if approved;
- the timing and scope of the investment we make in continuing the development of our commercial infrastructure and sales force in connection with the commercialization of PALFORZIA in the United States, including our patient and physician education and training program;
- commercialization costs associated with PALFORZIA, or if approved, AR201 or any other product candidates we develop, including the cost and timing of expanding our commercialization capabilities;
- the time and cost necessary to continue to develop a commercial-scale manufacturing process and establish commercial-scale manufacturing capacity for PALFORZIA and the time and cost necessary to supply clinical trial materials for our clinical trials for AR201 and any other product candidates we develop;

- 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 PALFORZIA, AR201 or any other product candidates we develop, as well as the cost and time of such trials and studies;
- our ability to obtain regulatory approval for and subsequently commercialize PALFORZIA outside the United States and our ability to obtain foreign regulatory approval for and subsequently commercialize AR201 or any other product candidates we develop;
- any unexpected results from further analysis of clinical data from our completed clinical trials;
- the time and cost necessary to complete our ongoing and roll-over clinical trials for PALFORZIA and our phase 2 clinical trial for AR201;
- the time and cost associated with designing and implementing quality systems for PALFORZIA and 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 PALFORZIA, AR201, AIMab7195 or any additional product candidate and the associated costs of such activities, including for filing, prosecuting, defending and enforcing any patents for PALFORZIA, AR201 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:

- our establishment of commercial capabilities or other activities that may be necessary to further commercialize PALFORZIA, or, if approved, AR201, or any additional product candidate;
- clinical trials or other development activities for our product candidates; or
- our research and development activities.

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 June 30, 2020, there was approximately $133.6 million of principal balance outstanding under the loan. We drew down an additional $85.0 million term loan available under the credit agreement following the fulfillment of certain customary conditions precedent in February 2020. The launch delay caused by COVID-19 or any failure to commercialize PALFORZIA could affect our ability to make scheduled interest payments on outstanding term loans under the credit agreement, which began on March 31, 2019, 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 us and our subsidiary guarantors to satisfy a minimum cash balance covenant and restricts our ability and our subsidiaries' 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 PALFORZIA, which was only recently approved by the FDA.

To date, we have invested substantially all of our efforts and financial resources in the research and development of our CODIT therapeutic approach, including PALFORZIA and our additional CODIT product candidates and the commercialization of PALFORZIA.

As a result, our prospects, including our ability to finance our operations and generate revenue, will depend largely on the successful development and commercialization of PALFORZIA. In January 2020, the FDA approved our BLA for PALFORZIA for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut in patients aged 4 to 17 years old with a confirmed diagnosis of peanut allergy. However, we are not permitted to market or promote PALFORZIA outside the United States before we receive regulatory approval from the EMA or other comparable foreign regulatory authorities. In order to obtain regulatory approval for the sale of PALFORZIA from the EMA or other comparable foreign regulatory authorities, we must demonstrate the safety and efficacy of PALFORZIA in humans in our proposed indication. While we submitted our MAA for PALFORZIA in June 2019 based upon the safety and efficacy findings in our completed and ongoing clinical trials, there can be no assurance that we will receive regulatory approval from the EMA, or that PALFORZIA will successfully demonstrate safety and efficacy in any ongoing or future clinical trials we may be required to initiate.

The commercial success of PALFORZIA will depend on a number of factors, many of which are out of our control, including the following:

- our ability to successfully commercialize PALFORZIA in the United States, including any direct-to-consumer marketing efforts for PALFORZIA, and, if approved for marketing and sale by the EMA or comparable foreign regulatory authorities, outside the United States, whether alone or in collaboration with others;
- acceptance of PALFORZIA as safe and effective by patients and the medical community;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing treatments;
- our success in educating physicians and patients about the benefits, administration and use of PALFORZIA;
- the Risk Evaluation and Mitigation Strategy, or REMS, to be utilized for PALFORZIA in the United States and the extent and nature of any foreign equivalent required in connection with regulatory approval or following regulatory approval;
- the effectiveness of our own or any future collaborators' marketing, pricing, coverage and reimbursement, sales and distribution strategies and operations;
- the size of the patient population for which PALFORZIA received approval for treatment (patients aged 4 to 17 years) and whether the FDA may restrict the use of our products to a more narrow population;
- maintaining compliance with all regulatory requirements applicable to PALFORZIA;
- the frequency and severity of adverse effects experienced by patients treated with PALFORZIA, including in any clinical trials we may pursue with collaborators, such as our Phase 2 trial sponsored by Regeneron evaluating PALFORZIA treatment with adjunctive dupilumab, or in which we may pair PALFORZIA with another therapeutic;
- the ability of our third-party manufacturers to manufacture supplies of PALFORZIA, including their ability to provide adequate and timely commercial and clinical supplies and to 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 PALFORZIA's safety and efficacy to the satisfaction of the EMA or other foreign regulatory authorities;
- whether we are required by the EMA or other foreign regulatory authorities, or choose, to conduct additional clinical trials prior to the approval to market PALFORZIA outside the United States, as well as the cost and time of such trials;
- whether the EMA 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 EMA or other foreign regulatory authorities;
- the continued prevalence of peanut allergy;
- our ability to obtain issued patents that cover PALFORZIA and to enforce such patents and other intellectual property rights to PALFORZIA;
- our ability to avoid third-party intellectual property claims; and
- a continued acceptable safety profile of PALFORZIA.

As part of our original PALFORZIA BLA submission, we proposed a number of risk management measures for PALFORZIA. The FDA has determined that PALFORZIA will only be available in the United States through a REMS. A REMS is a drug safety program that the FDA can require for certain medications with safety concerns to help ensure the benefits of the medication outweigh its risks. The requirements of the PALFORZIA REMS include: the prescribing physician and patient must be enrolled in the REMS prior to initiation of treatment; the initial dose escalation and the first dose of each up-dosing level must be administered in a certified healthcare setting; epinephrine must always be immediately available to patients; and pharmacies/distributors must be certified with the REMS and dispense PALFORZIA only to certified healthcare settings or to patients who are enrolled in the REMS. Consistent with immunotherapies indicated to treat allergic conditions, the approved labeling for PALFORZIA also includes a "black box"

warning for risk of anaphylaxis. The imposition of the REMS or the inclusion of the "black box" warning could make it more difficult for PALFORZIA it to achieve its full commercial potential.

Accordingly, we cannot assure our stockholders that we will ever become profitable as a result of such sales. If we are not able to successfully commercialize PALFORZIA, or if we are significantly delayed in doing so, our business will be materially harmed.

We have built a commercial field organization and distribution network, and deployed medical science liaison personnel. If we are unable to appropriately train and monitor our commercial field organization and a distribution network on our own or through third parties, we may not be able to market, sell and distribute PALFORZIA or any additional product candidates or generate product revenue.

In order to commercialize PALFORZIA, we will need to continue to train and monitor 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.

We have no prior experience in the commercialization of pharmaceutical products and there are significant risks involved in training 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 commercialization team. Any failure or delay 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 PALFORZIA 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 PALFORZIA, which could have a material adverse effect on our business, results of operations, financial condition, prospects and stock price.

We implemented a training program to educate physicians and patients on the safe use of PALFORZIA and its approved indication. While we have made web conference technology available to our practice account managers so that they can support physicians and patients remotely in light of the COVID-19 pandemic, there could be delays in the engagement and completion of such programs. In addition, as part of the PALFORZIA REMS mandated by the FDA, the healthcare provider who prescribes PALFORZIA (the prescriber) and the practice that administers PALFORZIA (healthcare setting) must be certified in the PALFORZIA REMS. Prescribers must also enroll their patients in the PALFORZIA REMS before treatment can begin. Pharmacies and wholesale distributors will also have to be certified in the PALFORZIA REMS by enrolling before they can dispense or distribute PALFORZIA. A commercial launch, training program and REMS program of this size is a significant undertaking that requires substantial financial and managerial resources.

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 PALFORZIA. If we are not successful in commercializing PALFORZIA 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.

PALFORZIA may never achieve market acceptance or commercial success, which will depend, in part, upon our ability to properly and effectively train physicians on the safe and effective use and administration of PALFORZIA and the degree of acceptance among physicians, patients, patient advocacy groups, healthcare payors and the general medical community.

PALFORZIA may not achieve market acceptance among physicians, patients, patient advocacy groups, healthcare payors and the general medical community. While we intend to market PALFORZIA as a means of obtaining protection from accidental exposure to peanut protein and not as a cure for peanut allergy, we anticipate that physicians will continue to recommend that their patients strictly avoid foods that may contain any amount of peanut protein, continue to carry epinephrine, and otherwise behave in accordance with the PALFORZIA REMS, even if the patients have been successfully desensitized with PALFORZIA. Requirements of the PALFORZIA REMS includes: the prescribing physician and patient must be enrolled in the REMS prior to initiation of treatment; the initial dose escalation and the first dose of each up-dosing level must be administered in a certified healthcare setting; epinephrine must always be immediately available to patients; and pharmacies/distributors must be certified with the REMS and dispense PALFORZIA only to certified healthcare settings or to patients who are enrolled in the REMS. If we are unable to persuade physicians, patients, caregivers and payors that PALFORZIA has therapeutic value when used in conjunction with the practice of avoidance, our sales will be adversely affected.

We may also 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 physicians believe that previous oral immunotherapy approaches to the treatment of peanut allergy are too unsafe or unreliable to use in clinical practice. Consistent with immunotherapies indicated to treat allergic conditions, the PALFORZIA BLA proposed a "black box" warning within the product labeling. The FDA approval of PALFORZIA requires the inclusion of a "black box" warning for risk of anaphylaxis, which could make it more difficult for it to achieve its full commercial potential. 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 physicians and their patients that PALFORZIA is safe and reliable, our sales will be adversely affected.

In addition, the commercial success of PALFORZIA will depend significantly on our ability to properly and effectively train physicians on the safe and effective use and administration of PALFORZIA. We believe that proper training and education will be critical to physicians' administering PALFORZIA in a manner that achieves the physician's and patient's desired outcomes. We have deployed medical science liaisons, or MSLs, 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.

If we obtain EMA or other foreign regulatory approvals for PALFORZIA, we expect to face similar challenges outside the United States for PALFORZIA. Furthermore, market acceptance of PALFORZIA depends on a number of factors, including:

- the safety and efficacy of PALFORZIA;
- our success in educating physicians and patients about the benefits, administration and use of PALFORZIA;
- acceptance by physicians and patients of PALFORZIA as a safe and effective treatment and their perceptions of the benefit of the product;
- the relative convenience and ease of administration of our products, including patients' acceptance of the need to take PALFORZIA 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 on a chronic basis;
- the potential and perceived advantages of our product 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 product on the part of physicians and patients;
- the availability of PALFORZIA and our 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 PALFORZIA; and
- sufficient third-party payments to physicians for the procedures necessary to administer PALFORZIA.

Any failure by PALFORZIA to achieve market acceptance or commercial success would adversely affect the results of our operations. In addition, if we obtain FDA, EMA or other foreign regulatory approvals for AR201 or our other product candidates, we would expect to face similar challenges both within and outside the United States.

In 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. PALFORZIA is designed to reduce the incidence and severity of allergic reactions, including anaphylaxis, after accidental exposure to peanut in patients aged 4 through 17 years with a confirmed diagnosis 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 PALFORZIA, which may adversely impact our business and results of operations.

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

The source material for PALFORZIA 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 PALFORZIA 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 PALFORZIA. 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 PALFORZIA. If such alterations occurred, we would not be able to manufacture PALFORZIA 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 efficacy of PALFORZIA 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 PALFORZIA treatment regimen requires that patients start with a very low dose of PALFORZIA 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. PALFORZIA is available only through a REMS. Requirements of the PALFORZIA REMS include; the prescribing physician and patient must be enrolled in the REMS prior to initiation of treatment; the initial dose escalation and the first dose of each up-dosing level must be administered in a certified healthcare setting; epinephrine must always be immediately available to patients; and pharmacies/distributors must be certified with the REMS and dispense PALFORZIA only to certified healthcare settings or to patients who are enrolled in the REMS.

In order to maintain desensitization, patients would need to continue to take a daily therapeutic dose. The efficacy of PALFORZIA 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 PALFORZIA.

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, and intend to continue, to rely on single-source third-party manufacturers for commercial drug supply and clinical trial supply of PALFORZIA and to manufacture nonclinical, clinical and commercial supplies of AR201 and other product candidates. If any of these manufacturers fails to provide us or our collaborators with adequate supplies of materials for commercial product or clinical trials or fail to comply with the requirements of regulatory authorities, we may be unable to develop PALFORZIA, AR201 or other product candidates.

We do not currently have the internal capability to produce our commercial supply or clinical supply of PALFORZIA, and we lack the internal resources and the capability to manufacture AR201 and 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 PALFORZIA, and a single contract manufacturer for the commercial packaging of PALFORZIA for the foreseeable future. We have agreements in place with both contract manufacturers of PALFORZIA. In May 2019, we entered into a commercial supply agreement with CoreRx, Inc., the contract manufacturer utilized for our clinical supply of PALFORZIA, for the commercial supply of PALFORZIA in bulk capsule and sachet dosage forms according to agreed-upon specifications in sufficient quantities to meet our projected supply requirements in the United States and Canada. In November 2019, we entered into an agreement with AndersonBrecon Inc., doing business as PCI of Illinois, and Millmount Healthcare Limited to produce commercial quantities of the packaging of PALFORZIA to meet our requirements in the United States, Canada, the EU (including the United Kingdom), Norway, Switzerland and Australia. Even though we have entered into such agreements, aspects of our manufacturing process for PALFORZIA are complex and the existing manufacturing process of our contract manufacturer 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 PALFORZIA within our estimated timeline, if at all. Similarly, we currently rely and may continue to rely on a single contract manufacturer for the clinical supply of each of our other product candidates and face similar risks with respect to the supply and manufacturing processes for such product candidates.

Our dependence on single source suppliers with respect to our supply chain for PALFORZIA, AR201 and our other product candidates 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, pursuant to inspections conducted prior to approval of our PALFORZIA BLA, was required to approve our contract manufacturers to manufacture PALFORZIA. In addition, other comparable foreign regulatory authorities must, pursuant to inspections conducted prior to approval of any foreign regulatory submission for PALFORZIA, approve our contract manufacturers to manufacture PALFORZIA. While we completed construction of a manufacturing facility in a leased building in Clearwater, Florida, at the site of our primary contract manufacturer and have a commercial supply agreement with such contract manufacturer, we do not directly control the manufacturing operations and we are completely dependent on them for operating that facility and for compliance with cGMP for the manufacture of PALFORZIA. 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 withdraws its approval of the facilities that manufacture PALFORZIA in the future or if the FDA or a comparable foreign regulatory authority does not approve the facilities that manufacture our product candidates, we may need to find alternative manufacturing facilities, which would negatively impact our ability to market PALFORZIA and to develop, obtain regulatory approval for or market our product candidates, if approved.

Further, we used blister packs and sachets as the final packaging configuration for our commercial launch of PALFORZIA. Foreign 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 PALFORZIA outside the United States.

Failures or difficulties faced at any level of our supply chain could materially adversely affect our business and delay or impede commercialization of PALFORZIA 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.

Finally, pursuant to our license agreement with Xencor, Inc., we have the right to develop, manufacture, and commercialize AIMab7195, a humanized monoclonal antibody. We have not previously developed manufacturing processes for an antibody. While we anticipate that we would outsource manufacturing of this antibody, the biologics manufacturing process is complex, and is susceptible to product loss due to problems with raw materials, contamination, equipment failure, improper installation or operation of equipment or vendor or operator error. Problems with manufacturing could result in delays in any clinical trials we may initiate for AIMab7195, as well as increased production costs, reduced production yields, product defects, and lost revenue.

Supplying our commercial and clinical supplies of PALFORZIA and clinical supplies of AR201 is a complex operation, and delays in the supply chain could harm the commercial success of PALFORZIA and our ongoing and planned clinical trials.

Supplying appropriate commercial and clinical trial materials for the commercial launch of PALFORZIA and our ongoing and planned clinical trials on a timely basis is a complex operation, and our ability to supply materials for clinical trials may eventually be affected by the COVID-19 pandemic. There are multiple doses in the dose escalation phase of PALFORZIA and for our AR201 clinical trial. 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 subjects. But this dosing flexibility also increases the complexity of supplying the appropriate doses to pharmacies and 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 in connection with the commercialization of PALFORZIA and as we continue to operate multiple large trials concurrently, including trials in Europe. 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. The complexity of our supply chain and logistics operations has been increased as a result of the COVID-19 pandemic. However, our manufacturing facilities remain operational and we believe we have sufficient product supply of PALFORZIA to meet demand in the near-term. Any delays or errors in our PALFORZIA supply chain logistics could delay or adversely affect our ability to commercialize PALFORZIA and our ongoing and planned clinical trials.

PALFORZIA, AR201 or any of our other product candidates may cause undesirable side effects or have other properties that could limit the commercial profile of an approved label and that could delay or prevent regulatory approval, or result in significant negative consequences following any regulatory approvals.

Undesirable side effects caused by PALFORZIA could cause us or the FDA to halt commercial sales or clinical trials of PALFORZIA, and undesirable side effects caused by our product candidates could cause the FDA or comparable 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. To date, patients treated with PALFORZIA have experienced drug-related side effects, which mainly include gastrointestinal issues ranging from itching of the lips to vomiting. Results of patients following the commercial launch of PALFORZIA or of patients enrolled in our clinical trials of PALFORZIA could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our commercial sales and/or clinical trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further commercial sales and development of or deny approval of PALFORZIA and our product candidates for any or all targeted indications. The drug-related side effects could affect commercialization as well as 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 PALFORZIA or AR201 will not be uncovered when a significantly larger number of patients are exposed to the drug, including following the commercialization of PALFORZIA. Further, we have not designed our clinical trials to determine the effect and safety consequences of taking PALFORZIA or AR201 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 PALFORZIA 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 PALFORZIA 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 PALFORZIA 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 PALFORZIA compared to none of the placebo-treated patients and 12.4% of patients ages 4-17 who received PALFORZIA 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. As a result of the foregoing, the PALFORZIA BLA proposed, and the FDA approval of PALFORZIA requires, a "black box" warning within the product labeling for risk of anaphylaxis, which is consistent with immunotherapies indicated to treat allergic conditions.

If safety problems relating to PALFORZIA are identified among the general population, in our clinical trials or in any clinical trials conducted by collaborators, or if we or others later identify undesirable side effects caused by PALFORZIA, the FDA or other regulatory authorities may require that we amend the labeling of PALFORZIA, require additional warnings, create a medication guide outlining the risks of such side effects for distribution to patients, order us to recall PALFORZIA or even withdraw regulatory approval for PALFORZIA. Similarly, if safety problems relating to AR201 or our other product candidates are identified prior to approval, the FDA or other regulatory authorities may not approve AR201 or any of our other product candidates, may limit the population it is used in or may require warnings on the label. 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 PALFORZIA and for AR201 or any of our other product candidates, if approved, and could have a material adverse effect on our business, results of operations, financial condition, prospects and stock price.

PALFORZIA, AR201 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, DBV Technologies S.A. is developing 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. In August 2019, DBV announced that it had resubmitted a BLA for Viaskin Peanut with a target action date of August 5, 2020.

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 and prevention of allergic reactions, including anaphylaxis, attributable to peanut allergy could harm our business and results of operations.

We may also face competition from physicians 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 PALFORZIA in the maintenance portion of our PALFORZIA treatment program. If we are unable to convince physicians, 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.

The regulatory approval process is lengthy, time-consuming and inherently unpredictable, and we may experience significant delays in obtaining additional regulatory approvals of PALFORZIA or regulatory approval of AR201 or our other product candidates, which could adversely impact our ability to generate revenue, and harm our business and our results of operations.

To gain approval to market a biologic product candidate, such as PALFORZIA, a BLA, MAA or other comparable foreign regulatory filing must be submitted to the FDA, the EMA or other comparable foreign regulatory authority. Such applications must include extensive clinical, non-clinical and manufacturing data that adequately demonstrate to the satisfaction of the FDA, the EMA or other comparable foreign regulatory authority the safety, purity, potency and effectiveness of the product for the intended indication sought in the BLA, the MAA or other relevant regulatory filing. A BLA, MAA or other comparable foreign regulatory filing must also include significant information regarding the chemistry, manufacturing and controls for the product. In January 2020, the FDA approved our BLA for PALFORZIA for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut in patients aged 4 to 17 years old with a confirmed diagnosis of peanut allergy and we have not commenced commercialization of the product. We submitted our PALFORZIA MAA to the EMA in June 2019.

Despite the FDA's approval of PALFORZIA, the FDA, the EMA or any other comparable foreign regulatory bodies can delay, limit or deny further approvals of PALFORZIA or any initial approvals of AR201 or our other product candidates for many reasons, including:

- disruptions caused by the COVID-19 pandemic;
- our inability to demonstrate to the satisfaction of the FDA that PALFORZIA or another relevant product candidate is safe, pure, potent and effective for the proposed indication or meets similar standards set by the EMA or other foreign authorities;
- the FDA, the EMA or other 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 PALFORZIA or another relevant product candidate outweigh any safety or other perceived risks;
- the FDA, the EMA or other 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 PALFORZIA or another relevant product candidate;
- the contract research organizations, or 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, the EMA or other applicable foreign regulatory authority may not approve or may disagree with the formulation, packaging, labeling and/or the specifications of a product candidate;
- the FDA's Allergenic Products Advisory Committee's may recommend the inclusion of limitations on approved labeling (including a "black box" warning) as well as certain distribution and use restrictions;
- the extent and nature of any protocol deviations in any of our completed, ongoing or future clinical trials;
- the FDA requires that we implement a REMS;
- our inability to demonstrate that the manufacturing process for a product candidate is adequately controlled to ensure that all product produced meets required quality standards and regulatory requirements;
- disruptions at the FDA, the EMA or other regulatory authorities that are unrelated to our products, such as government shutdowns, that cause delays in the regulatory approval process;
- the FDA, the EMA or other 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, the EMA or other 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 approval processes of the FDA, the EMA or other foreign regulatory authorities and are commercialized. While we obtained approval to market PALFORZIA in January 2020, it is the first drug approved for mitigating allergic reactions to food through desensitization and the first drug approved based on clinical findings of efficacy as measured by a double-blind, placebo-controlled food challenge, or DBPCFC, which is the testing mechanism for determining the desensitization efficacy of PALFORZIA. As such, the approval of PALFORZIA by the FDA does not guarantee that we will be able to obtain approval of PALFORZIA outside the United States or obtain approval of our other product candidates both within and outside the United States. Even if we receive approval of a BLA, MAA or other comparable foreign regulatory submission, the FDA, the EMA or other applicable foreign regulatory authority may grant approval contingent on the performance of costly additional clinical trials. The FDA, the EMA or other applicable foreign regulatory authority may also approve such product candidates for a more limited indication and/or a narrower patient population than we originally request, and the FDA, the EMA or other applicable foreign regulatory authority may not approve the labeling that we believe is necessary or desirable for the successful commercialization. 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 PALFORZIA outside the United States or of our other product candidates both within and outside the United States and would materially adversely impact our business and prospects.

If we do not achieve our commercialization and projected development in the timeframes we announce and expect, the commercialization of PALFORZIA, AR201 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 commercial, scientific, clinical, regulatory and other product development objectives. These milestones may include our expectations regarding commercialization objectives or the commencement or completion of scientific studies and clinical trials, the submission of regulatory filings. 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:

- the continued adverse impact of the COVID-19 pandemic on our operations and commercialization of PALFORZIA, as well as on our distribution systems and expenses;
- 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 physicians and collaborators;
- our ability to identify and enroll patients who meet clinical trial eligibility criteria;
- the classifications of our product candidates by the FDA, the EMA or other regulatory authorities;
- our receipt of approvals by the EMA or 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 PALFORZIA and any additional product candidates may be delayed, and our business and results of operations may be harmed.

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

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials and of similar academic research studies.

For example, the positive top-line results generated in our PALISADE, RAMSES and ARTEMIS trials for PALFORZIA, as well as our prior clinical trials, do not ensure that our roll-over studies for such trials, any future clinical trials or widespread use following commercialization will demonstrate similar results. Commercial products and 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 following commercial launch or 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 though we have completed PALISADE, RAMSES and ARTEMIS, the results may not be sufficient to obtain regulatory approval or commercial acceptance for certain patient populations. For example, while the majority of adults who completed the PALISADE trial in the PALFORZIA 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 Intent to Treat, or 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 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 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 PALFORZIA, AR201 or any of our other product candidates 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.

Disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. For example, our POSEIDON (ARC005) Phase 3 clinical trial to explore the efficacy and safety of PALFORZIA in young peanut-allergic children ages 1 to <4 years is ongoing. In addition, as a cost savings measure and in light of the ongoing impacts of COVID-19, we have decided to end enrollment in our Phase 2 clinical trial of AR201.

In addition, 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. Furthermore, our third-party contractors, including CROs, are being and may continue to be impacted in their ability to conduct our work as a result of the COVID-19 pandemic.

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 Europe 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 EU.

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. For example, pandemics and public health emergencies, such as the COVID-19 pandemic, have disrupted and delayed and could in the future disrupt or delay enrollment in our clinical trials in the United States and Europe. Our success will depend, in part, on our ability to overcome the challenges we encounter with respect to these risks and other factors affecting U.S. companies with global operations.

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, including our Phase 2 clinical trial of AR201 in subjects with hen egg allergy, 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, "topline" 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 publicly disclose preliminary or topline data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We may also make assumptions, estimations, calculations and conclusions as part of our analysis of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. Potential disruptions caused by the COVID-19 pandemic could exacerbate these challenges. As a result, the topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or

considerations may qualify such results, once additional data have been received and fully evaluated. Topline 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, topline data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock after this offering.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

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 PALFORZIA, or obtain any regulatory approval for or commercialize AR201 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 obtaining approval for and commercializing PALFORZIA outside the United States or obtaining approval for and commercializing AR201 or our other future product candidates within and outside the United States.

Furthermore, certain of our clinical trials must be conducted with product produced under 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 Europe. 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.

PALFORZIA and AR201 are regulated as biological products, or biologics, and any additional product candidates could be regulated as 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 PALFORZIA 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 PALFORZIA 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 PALFORZIA to be eligible for reference product exclusivity, potentially creating the opportunity for competition sooner than anticipated. In addition, even if PALFORZIA 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 PALFORZIA and any product 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. Formulary adoption conversations with payers regarding PALFORZIA are proceeding virtually. We anticipate that these interactions will continue and lead to additional formulary coverage decisions by payers later this year. Until PALFORZIA is formally covered on formularies, allergists can initiate patients on treatment via the use of the medical exception processes provided by payers. However, the impact of the COVID-19 pandemic on formulary coverage for PALFORZIA is hard to assess due the rapidly evolving nature of the situation and it is possible that formulary coverage may be delayed.

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 treatment regimen for PALFORZIA and the anticipated treatment regimen for AR201 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 physicians for the time spent on the visits. We may decide to seek the creation of new codes and associated reimbursement rates to ensure that physicians 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, physicians may be deterred from offering PALFORZIA, AR201 or any of our other product candidates 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 PALFORZIA, AR201 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 PALFORZIA, AR201 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 PALFORZIA, AR201 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 PALFORZIA, AR201 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.

We intend to expand our insurance coverage to include the sale of PALFORZIA. However, we may be unable to obtain this liability insurance on commercially reasonable terms, if at all.

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

As of June 30, 2020, we had 339 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 PALFORZIA, AR201 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. These challenges have been made more difficult by the COVID-19 pandemic and resulting shelter-in-place and stay-at-home restrictions.

If we fail to attract and retain senior management, we may be unable to successfully commercialize PALFORZIA or develop and conduct clinical trials of AR201 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 commercialization of PALFORZIA and our ongoing clinical trials of AR201 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, pay adjustments due to COVID-19 may negatively affect our ability to attract and retain key personnel, including senior management. In addition, 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 commercialization, continued clinical testing and potential approval outside the United States of PALFORZIA, an important element of our strategy is to expand our product portfolio by identifying, developing and commercializing additional therapies including additional therapies using our CODIT therapeutic approach, such as product candidates for the treatment of egg allergy and multi-nut allergy. We initiated enrollment of a Phase 2 clinical trial of AR201 in subjects with hen egg allergy in August 2019. 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 PALFORZIA, 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 separately as well as in combination with any of our CODIT product candidates. 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 PALFORZIA.

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 PALFORZIA 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 PALFORZIA with adjunctive dupilumab in peanut-allergic patients in a Phase 2 trial sponsored by Regeneron, which was initiated in October 2018. In addition, in February 2020, we in-licensed AIMab7195 (formerly XmAb7195) from Xencor, Inc., or Xencor. Initially, we plan to develop AIMab7195 as a potential adjunctive treatment for use with our existing CODIT pipeline assets, including PALFORZIA, and we plan to explore treatment outcomes, including the potential to induce remission in patients with food allergies. In the future we may seek additional collaboration arrangements with pharmaceutical or biotechnology companies for the development or commercialization of PALFORZIA 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;
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings; and
- a collaborator may be adversely impacted by COVID-19 or other unforeseen events and public health emergencies.

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 United States 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 PALFORZIA, AR201 or any of our other product candidates outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

We submitted our PALFORZIA MAA to the EMA in June 2019. If we or a collaborator seek to commercialize PALFORZIA, AR201 or any of our other product candidates 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 PALFORZIA, AR201 or any of our other product candidates;
- 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 EU;
- 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 withdrawal from the EU may have a negative effect on global economic conditions, financial markets and our business.

Following a national referendum and enactment of legislation by the government of the United Kingdom, the United Kingdom formally withdraw from the EU on January 31, 2020 and entered into a transition period during which it will continue its ongoing and

complex negotiations with the EU relating to the future trading relationship between the parties. Significant political and economic uncertainty remains about whether the terms of the relationship will differ materially from the terms before withdrawal, as well as about the possibility that a so-called "no deal" separation will occur if negotiations are not completed by the end of the transition period. 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, restrict the ability of key market participants to operate in certain financial markets or restrict our access to capital.

We submitted our PALFORZIA MAA to the EMA in June 2019 and we have ongoing business in the United Kingdom and the EU, including employees in the United Kingdom. Further, our ARTEMIS study was conducted solely in Europe. Our MAA for PALFORZIA was filed and any other product candidate that we may file in the future must be filed by an entity located in a EU member nation. While we are already in the process of establishing a network of subsidiary undertakings in Europe and our MAA for PALFORZIA has been 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 EU laws to replace or replicate now that withdrawal has occurred, 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 EU 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 PALFORZIA and the effect of the 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 as a result of the withdrawal.

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 ongoing global financial crisis caused by the COVID-19 pandemic has already caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn 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 PALFORZIA is located in Florida, which has historically and very recently experienced severe hurricanes. In addition, the source material for PALFORZIA 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. As a result of the COVID-19 pandemic, we may face increased risks of a Security Event due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. 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 and commercialization of PALFORZIA and AR201, 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 In addition, 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 PALFORZIA and AR201, 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. These challenges could be exacerbated by the COVID-19 pandemic.

Risks Related to Government Regulation

The regulatory approval process is highly uncertain and we may not obtain regulatory approval for the commercialization of PALFORZIA outside the United States or of AR201 or any additional product candidates within or outside the United States.

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. In January 2020, the FDA approved our Biologics License Application, or BLA, for PALFORZIA for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut in patients aged 4 to 17 years old with a confirmed diagnosis of peanut allergy, and we have not commenced commercialization of the product. However, we will not be permitted to market PALFORZIA in other countries until we receive regulatory approvals in those countries and neither we nor any future collaboration partner will be permitted to market AR201 or any additional product candidate in the United States until we receive approval of a BLA from the FDA. 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 PALFORZIA either prior to, in the case of other regulatory authorities, or post-approval, such as additional trials in specific patient subpopulations or to establish a larger safety database of patients who have been administered PALFORZIA. 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 product candidate for many reasons, including, but not limited to, the following:

- a product candidate may not be deemed safe, pure, potent, or effective for its intended uses;

- 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 PALFORZIA fails to demonstrate safety and efficacy in clinical trials to gain regulatory approval outside the United States, or if AR201 or any additional product candidate fails to demonstrate sufficient safety and efficacy in clinical trials to gain regulatory approval within or outside the United States, our business and results of operations will be materially and adversely harmed. Additionally, the FDA has placed limitations on PALFORZIA in our label (including any "black box" warning) and, if the FDA or other regulatory authorities require that we conduct additional clinical trials, delay approval to market PALFORZIA outside the United States or further limit the use of PALFORZIA, our business and results of operations may be harmed.

Even though PALFORZIA has been approved by the FDA, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, PALFORZIA and any additional 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.

Following the approval of a drug, 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.

PALFORZIA is 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 authorities 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 PALFORZIA. 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 PALFORZIA 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 and our partners may be subject to federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address data privacy and security). In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations (e.g., Section 5 of the FTC Act), that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996, as amended, or HIPAA. Depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. We are also subject to 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 the California Consumer Privacy Act and other upcoming U.S. laws. 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 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.

Recent legal developments in Europe have created complexity and uncertainty regarding transfers of personal data from the EEA to the U.S. For example, on July 16, 2020, the Court of Justice of the European Union ("CJEU") invalidated the EU-US Privacy Shield Framework ("Privacy Shield") under which personal data could be transferred from the EEA to U.S. entities which had self-certified under the Privacy Shield scheme. While the CJEU upheld the adequacy of the standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism, and potential alternative to the

Privacy Shield), it made clear that reliance on them alone may not necessarily be sufficient in all circumstances. Use of the standard contractual clauses must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals and additional measures and/or contractual provisions may need to be put in place, however, the nature of these additional measures is currently uncertain. The CJEU went on to state that if a competent supervisory authority believes that the standard contractual clauses cannot be complied with in the destination country and the required level of protection cannot be secured by other means, such supervisory authority is under an obligation to suspend or prohibit that transfer. These recent developments will require us to review and amend the legal mechanisms by which we transfer personal data from the EEA to the U.S. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the standard contractual clauses cannot be used, or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

On January 31, 2020, or the Exit Date, the UK left the EU and entered a transition period, which is currently scheduled to end on December 31, 2020. Following the withdrawal of the UK from the EU, the relationship between the UK and EU in relation to certain aspects of data protection law remains unclear. Personal data exports from the EU and EEA to the UK can continue without change until the end of the transition period. However, at this time, we may be required to find alternate 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 text of the e-Privacy Regulation is still under development, a recent European court decision and regulators' recent guidance are driving increased attention to cookies and tracking technologies. If regulators start to enforce the strict approach in recent guidance, this could lead to substantial costs and require significant systems change.

We are also subject to a wide variety of other laws in the United States and other jurisdictions. Laws, regulations and standards governing issues such as worker classification, labor and employment, anti-discrimination, whistleblowing and worker confidentiality obligations, product liability, intellectual property, taxation, privacy, data security and competition, are often complex and subject to varying interpretations, in many cases due to their lack of specificity. As a result, their application in practice may change or develop over time through judicial decisions or as new guidance or interpretations are provided by regulatory and governing bodies, such as federal, state and local administrative agencies. For example, in the United States, California enacted the California Consumer Privacy Act, or the CCPA, on June 28, 2018, which took effect on January 1, 2020. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the United States, which could increase our potential liability and adversely affect our business.

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.

PALFORZIA and AR201 or any additional products, if approved, 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 PALFORZIA. For example, in our PALISADE clinical trial, of patients ages 4-17, 12.4% of patients from the PALFORZIA treatment arm and 2.4% of patients from the placebo-treatment arm discontinued due to investigator-reported adverse events. Additionally, eight PALFORZIA-treated patients in the PALISADE trial experienced a total of ten severe adverse events, and four of these patients discontinued treatment. As a condition of the approval of PALFORZIA, the FDA require, and foreign regulatory authority regulations may 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.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, 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, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. 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 biologics, or modifications to licensed biologics, 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.

Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products, and subsequently, on March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. We submitted a MAA for PALFORZIA with the EMA in June 2019 and the application is currently under review. We do not believe that the pandemic has to date caused, or will going forward cause, a significant delay in the review and potential approval of our MAA by the EMA or our MAA by Swissmedic. However, the impact of the COVID-19 pandemic is hard to assess due the rapidly evolving nature of the situation and it is possible that the review process for our applications may be delayed.

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

In order to market any product in the European Economic Area, or EEA (which is composed of the 27 Member States of the EU plus Norway, Iceland and Liechtenstein, and the United Kingdom until the end of the transition period on December 31, 2020 provided for in the Withdrawal Agreement between the EU and the UK), and many other foreign jurisdictions, separate regulatory approvals are required. In the EEA, medicinal products can only be commercialized after obtaining a MAA. Before granting the MAA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy. We submitted our PALFORZIA MAA to the EMA in June 2019.

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 United States 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;

- 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. 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 Act;

- 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 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 (as defined by statute), other healthcare providers beginning in 2022, 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;

- 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 United States, 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 participate in a number of federal and state government pricing programs in the United States 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 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 inseverable 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. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, although it is unclear when the Supreme Court will make a decision. It is also unclear how such litigation and other efforts to challenge, repeal or replace the Affordable Care Act will impact the law or our business.

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 2030 unless additional Congressional action is taken, with the exception of a temporary suspension from May 1, 2020 through December 31, 2020 implemented by the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, which was signed into law on March 27, 2020. In addition, 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. Furthermore, there has been increased interest by third party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

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 PALFORZIA, AR201 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 PALFORZIA and any additional product candidates. We intend to rely upon a combination of patents, trademarks, trade secrets and confidentiality agreements to protect PALFORZIA and 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 PALFORZIA and 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 five issued patents in the United States covering certain of our manufacturing methods, methods of treatment and the formulation for PALFORZIA, and four issued patents in foreign countries covering certain of our manufacturing methods for PALFORZIA, we do not anticipate that we will be able to obtain a composition of matter patent over the active pharmaceutical ingredient in PALFORZIA, AR201 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 PALFORZIA and certain of our other product candidates. We cannot assure our stockholders that these applications will result in any additional issued patents in the United States 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 PALFORZIA, AR201 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 product 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 PALFORZIA, AR201 or other product candidates, the period of time during which we could exclusively market PALFORZIA, AR201 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 PALFORZIA, AR201 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 PALFORZIA, AR201 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 PALFORZIA and AR201, without infringing third-party patent rights. If the breadth or strength of protection provided by any patents we obtain with respect to PALFORZIA, AR201 or any additional product candidates is successfully challenged, then our ability to commercialize PALFORZIA, AR201 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 PALFORZIA, AR201 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 PALFORZIA, AR201 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 PALFORZIA, AR201 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 PALFORZIA, AR201 or any additional product candidates. If a patent holder believes PALFORZIA, AR201 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 PALFORZIA, AR201 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 PALFORZIA, AR201 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 PALFORZIA, AR201 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 PALFORZIA, AR201 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:

- delays in the commercialization of PALFORZIA, or any of our product candidates if approved;
- announcements of regulatory approval or disapproval of PALFORZIA outside the United States or any of our product candidates;
- changes in revenue and earnings estimates or recommendations by securities analysts;

- changes in financial estimates or guidance, including our ability to meet our future revenue and operating profit or loss estimates or guidance;
- results of, or delays in, our clinical trials;
- delays in our product development timelines;
- limitations to specific label indications or patient populations for PALFORZIA use, or changes or delays in the regulatory review process of PALFORZIA outside the Unites States or any of our product candidates;
- severe adverse events in our trials, in any clinical trials with PALFORZIA 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 PALFORZIA, AR201 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 June 30, 2020, 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 ⅔% of the shares entitled to vote to remove a director for cause, and the prohibition on removal of directors without cause;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;
- the ability of our board of directors to alter our bylaws without obtaining stockholder approval;
- the required approval of at least 66 ⅔% of the shares entitled to vote at an election of directors to adopt, amend or repeal our bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by the chairman of the board of directors, the chief executive officer, the president or the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from

conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

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

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

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 two or three women on our board of directors 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 $522.3 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 Nestlé 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.

Reduction in Base Salary of Executive Officers

In light of the disruption and uncertainty created by the evolving COVID-19 pandemic and its anticipated impact on the Company's operations, all of its named and other executive officers, including the Company's Chief Executive Officer, Jayson D.A. Dallas, M.D., and Chief Financial Officer, Eric H. Bjerkholt, took a 25 percent reduction in cash base salary, effective May 16, 2020 through August 31, 2020.

Item 6. Exhibits

a) Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	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 February 4, 2020, by and between the Company and Nestle Health Science US Holdings, Inc.	8-K	2/5/2020	4.1	
4.5	Amended and Restated Standstill Agreement, dated February 4, 2020, by and between the Company and Nestle Health Science US Holdings, Inc.	8-K	2/5/2020	4.2	
4.6	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock.	8-K	2/5/2020	3.1	
4.7	Description of Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.	10-K	2/27/2020	4.7	
10.1(a)#	2015 Equity Incentive Annual Plan.	S-8	8/11/2015	99.2(a)	
10.1(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)	
10.1(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)	
10.1(d)#	Form of Global Stock Option Grant Notice and Award Agreement.				X
10.1(e)#	Form of Global Restricted Stock Unit Grant Notice and Award Agreement.				X
10.2#	Aimmune Therapeutics, Inc. Employee Stock Purchase Plan.	S-8	8/11/2015	99.3	
10.3#	Non-Employee Director Compensation Program.	10-Q	5/11/2020	10.3#	
10.4#	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
101.INS	Inline 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	Inline XBRL Taxonomy Extension Schema Document				X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document				X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document				X

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document				X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document				X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)				X

# Indicates management contract or compensatory plan.

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

SIGNATURES

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

Aimmune Therapeutics, Inc.

Date: July 30, 2020

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

Aimmune Therapeutics, Inc.

Date: July 30, 2020

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

AIMMUNE THERAPEUTICS, INC.
2015 EQUITY INCENTIVE AWARD PLAN

GLOBAL STOCK OPTION GRANT NOTICE

Aimmune Therapeutics, Inc., a Delaware corporation, (the "Company"), pursuant to its 2015 Equity Incentive Award Plan, as may be amended from time to time (the "Plan"), hereby grants to the holder listed below (the "Participant"), an option to purchase the number of shares of the Company's common stock ("Stock"), set forth below (the "Option"). This Option is subject to all of the terms and conditions set forth herein, as well as in the Plan and the Global Stock Option Agreement, including any special terms and conditions for the Participant's country set forth in the appendix attached hereto as Exhibit A (the "Appendix") (collectively, the "Agreement"), each of which are incorporated herein by reference. Unless otherwise defined herein, the terms defined in the Plan shall have the same defined meanings in this Global Stock Option Grant Notice (the "Grant Notice") and the Agreement.

Participant:	«Participant»
Grant Date:	«Grant_Date»
Vesting Commencement Date:	«VCD»
Exercise Price per Share:	$[ ]
Total Exercise Price:	«Total_Price»
Total Number of Shares Subject to the Option:	«Shares» shares
Expiration Date:	«Expiration»
Vesting Schedule:	«Vesting_Schedule»
Type of Option:	Incentive Stock Option Non-Qualified Stock Option

By accepting the Option via the Company's online acceptance procedure, the Participant agrees to be bound by the terms and conditions of the Plan, the Agreement, and this Grant Notice. The Participant has reviewed the Agreement, the Plan and this Grant Notice in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Grant Notice and fully understands all provisions of this Grant Notice, the Agreement and the Plan. The Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator upon any questions arising under the Plan, this Grant Notice or the Agreement. The Participant further consents to receive Plan documents by electronic delivery and to participate in the Plan through an online or electronic system established and maintained by the Company or another third party designated by the Company.

AIMMUNE THERAPEUTICS, INC.

GLOBAL STOCK OPTION AGREEMENT

Pursuant to the Global Stock Option Grant Notice (the "Grant Notice") to which this Global Stock Option Agreement, including any special terms and conditions for the Participant's country set forth in the appendix attached hereto as Exhibit A (the "Appendix") (collectively, this "Agreement"), is attached, Aimmune Therapeutics, Inc., a Delaware corporation (the "Company"), has granted to the Participant an Option under the Company's 2015 Equity Incentive Award Plan, as may be amended from time to time (the "Plan"), to purchase the number of shares of Stock indicated in the Grant Notice.

ARTICLE 1.

GENERAL

1.1 Defined Terms. Wherever the following terms are used in this Agreement they shall have the meanings specified below, unless the context clearly indicates otherwise. Capitalized terms not specifically defined herein shall have the meanings specified in the Plan and the Grant Notice.

1.2 Incorporation of Terms of Plan. The Option is subject to the terms and conditions of the Plan which are incorporated herein by reference. In the event of any inconsistency between the Plan and this Agreement, the terms of the Plan shall control.

ARTICLE 2.

GRANT OF OPTION

2.1 Grant of Option. Effective as of the Grant Date set forth in the Grant Notice (the "Grant Date"), the Company irrevocably grants to the Participant the Option to purchase any part or all of an aggregate of the number of shares of Stock set forth in the Grant Notice, upon the terms and conditions set forth in the Plan and this Agreement, subject to adjustments as provided in Section 14.2 of the Plan. Unless designated as a Non-Qualified Stock Option in the Grant Notice, the Option shall be an Incentive Stock Option to the maximum extent permitted by law.

2.2 Exercise Price. The exercise price of the shares of Stock subject to the Option shall be as set forth in the Grant Notice, without commission or other charge; *provided*, *however*, that the price per share of the shares of Stock subject to the Option shall not be less than 100% of the Fair Market Value of a share of Stock on the Grant Date. Notwithstanding the foregoing, if this Option is designated as an Incentive Stock Option and Participant is a Greater Than 10% Stockholder as of the Date of Grant, the exercise price per share of the shares of Stock subject to the Option shall not be less than 110% of the Fair Market Value of a share of Stock on the Grant Date.

ARTICLE 3.

PERIOD OF EXERCISABILITY

3.1 Commencement of Exercisability.

(a) Subject to Sections 3.2, 3.3, 5.11 and 5.17 hereof, the Option shall become vested and exercisable in such amounts and at such times as are set forth in the Grant Notice.

(b) No portion of the Option which has not become vested and exercisable at the date of the Participant's Termination of Service shall thereafter become vested and exercisable, except as may be otherwise provided by the Administrator or as set forth in a written agreement between the Company and the Participant.

(c) Notwithstanding Sections 3.1(a) hereof and the Grant Notice, but subject to Section 3.1(b) hereof, in the event of a Change in Control the Option shall be treated pursuant to Section 14.2 of the Plan.

3.2 Duration of Exercisability. The installments provided for in the vesting schedule set forth in the Grant Notice are cumulative. Each such installment which becomes vested and exercisable pursuant to the vesting schedule set forth in the Grant Notice shall remain vested and exercisable until it becomes unexercisable under Section 3.3 hereof.

3.3 Expiration of Option. The Option may not be exercised to any extent by anyone after the first to occur of the following events:

(a) The Expiration Date set forth in the Grant Notice, which shall in no event be more than ten (10) years from the Grant Date;

(b) If this Option is designated as an Incentive Stock Option and Participant, at the time the Option was granted, was a Greater Than 10% Stockholder, the expiration of five (5) years from the Grant Date;

(c) The expiration of three (3) months from the date of the Participant's Termination of Service, unless such termination occurs by reason of the Participant's death or disability; or

(d) The expiration of one (1) year from the date of the Participant's Termination of Service by reason of the Participant's death or disability.

3.4 Termination of Service. For purposes of the Option and the Participant's participation in the Plan, the Participant's Termination Service will be considered to be the date the Participant is no longer actively providing services to the Company or any of its Affiliate (regardless of the reason for such termination and whether or not later found to be invalid or in breach of employment laws in the jurisdiction where the Participant is employed or the terms of the Participant's employment agreement, if any), and unless otherwise expressly provided in this Agreement or determined by the Company, (i) the Participant's right to vest in the Option under the Plan, if any, will terminate as of such date and will not be extended by any notice period (*e.g.*, the Participant's period of service would not include any contractual notice period or any period of "garden leave" or similar period mandated under employment laws in the jurisdiction where the Participant is employed or the terms of the Participant's employment agreement, if any), and (ii) the period (if any) during which the Participant may exercise the Option after a Termination of Service will commence on the date the Participant ceases to actively provide services and will not be extended by any notice period mandated under employment laws in the jurisdiction where the Participant is employed or terms of his or her employment agreement, if any; the Administrator shall have the exclusive discretion to determine when the Participant is no longer actively providing services for purposes of the Option.

3.5 Special Tax Consequences. The Participant acknowledges that, to the extent that the aggregate Fair Market Value (determined as of the time the Option is granted) of all shares of Stock with respect to which Incentive Stock Options, including the Option (if applicable), are exercisable for the first time by the Participant in any calendar year exceeds $100,000, the Option and such other options shall be Non-Qualified Stock Options to the extent necessary to comply with the limitations imposed by

Section 422(d) of the Code. The Participant further acknowledges that the rule set forth in the preceding sentence shall be applied by taking the Option and other "incentive stock options" into account in the order in which they were granted, as determined under Section 422(d) of the Code and the Treasury Regulations thereunder. The Participant also acknowledges that an Incentive Stock Option exercised more than three (3) months after the Participant's Termination of Employment, other than by reason of death or disability, will be taxed as a Non-Qualified Stock Option.

3.6 Responsibility for Taxes.

(a) The Participant acknowledges that, regardless of any action the Company or, if different, the Affiliate that employs the Participant or for which the Participant otherwise provides services (the "Service Recipient"), the ultimate liability for all income tax, social insurance, payroll tax, fringe benefits tax, payment on account or other tax-related items related to the Participant's participation in the Plan and legally applicable to the Participant ("Tax-Related Items") is and remains the Participant's responsibility and may exceed the amount, if any, actually withheld by the Company or the Service Recipient. The Participant further acknowledges that the Company and the Service Recipient (i) make no representations or undertakings regarding the treatment of any Tax-Related Items in connection with any aspect of the Option, including the grant of the Option, the vesting or exercise of the Option, the subsequent sale of any shares Stock acquired pursuant to the Option and the receipt of any dividends and (ii) do not commit to structure the terms of the grant or any aspect of the Option to reduce or eliminate the Participant's liability for Tax-Related Items. Further, if the Participant is subject to Tax-Related Items in more than one jurisdiction, the Participant acknowledges that the Company and/or the Service Recipient (or former service recipient, as applicable) may be required to withhold or account for Tax-Related Items in more than one jurisdiction.

(b) Prior to any relevant taxable or tax withholding event, as applicable, the Participant agrees to make arrangements satisfactory to the Company and/or the Service Recipient to satisfy all Tax-Related Items. In this regard, the Participant authorizes the Company and/or the Service Recipient to satisfy any applicable withholding obligations with regard to any Tax-Related Items by one or a combination of the following: withholding from proceeds of the sale of shares of Stock under the Plan, either through a voluntary sale or through a mandatory sale arranged by the Company (on the Participant's behalf pursuant to this authorization without further consent). In the event that such withholding by sale of Shares is not advisable or desirable by the Company (in its sole and absolute discretion), the Participant authorizes the Company and/or the Service Recipient to satisfy the applicable withholding obligations by one or a combination of the following: (i) withholding from the Participant's wages or other cash compensation payable to the Participant by the Company and/or the Service Recipient, (ii) withholding a sufficient number of whole shares of Stock that would otherwise be issued to the Participant upon exercise of the Option having an aggregate value sufficient to pay the Tax-Related Items, or (iii) any other method determined by the Company and compliant with applicable law, provided, however, that if the Participant is a Section 16 officer of the Company under the Exchange Act, then the obligation for Tax-Related Items will be satisfied by one or a combination of, the following: withholding from (i) the proceeds from the sale of Shares or (ii) the Participant's wages or cash compensation, unless otherwise determined by the Committee (as constituted to satisfy Rule 16b-3 of the Exchange Act) in advance of the withholding event.

(c) The Company may withhold or account for Tax-Related Items by considering applicable minimum statutory withholding rates or other applicable withholding rates, including maximum rates in the jurisdictions applicable to the Participant, in which case the Participant may receive a refund of any over-withheld amount in cash and will have no entitlement to the equivalent in shares of Stock. Further, if the obligation for Tax-Related Items is satisfied by withholding in shares of Stock, the Participant will be deemed to have been issued the full number of Shares subject to the Option, notwithstanding that a number of shares of Stock is held back solely for the purpose of paying Tax-Related Items.

(d) The Participant agrees to pay to the Company or the Service Recipient any amount of Tax-Related Items that the Company or the Service Recipient may be required to withhold or account for as a result of the Participant's participation in the Plan that cannot be satisfied by the means described in this Section. The Company may refuse to issue or deliver the shares of Stock, or the proceeds of the sale of shares of Stock, if the Participant fails to comply with his or her obligations in connection with the Tax-Related Items.

ARTICLE 4.

EXERCISE OF OPTION

4.1 Person Eligible to Exercise. Except as provided in Section 5.3 hereof, during the lifetime of the Participant, only the Participant may exercise the Option or any portion thereof, unless it has been disposed of pursuant to a DRO. After the death of the Participant, any exercisable portion of the Option may, prior to the time when the Option becomes unexercisable under Section 3.3 hereof, be exercised by the deceased Participant's personal representative or by any person empowered to do so under the deceased Participant's will or under the then applicable laws of descent and distribution.

4.2 Partial Exercise. Any exercisable portion of the Option or the entire Option, if then wholly exercisable, may be exercised in whole or in part at any time prior to the time when the Option or portion thereof becomes unexercisable under Section 3.3 hereof. However, the Option shall not be exercisable with respect to fractional shares of Stock.

4.3 Manner of Exercise. The Option, or any exercisable portion thereof, may be exercised solely by delivery to the Secretary of the Company (or any third party administrator or other person or entity designated by the Company; for the avoidance of doubt, delivery shall include electronic delivery), during regular business hours, of all of the following prior to the time when the Option or such portion thereof becomes unexercisable under Section 3.3 hereof:

(a) An exercise notice in a form specified by the Administrator, stating that the Option or portion thereof is thereby exercised, such notice complying with all applicable rules established by the Administrator. The notice shall be signed by the Participant or other person then entitled to exercise the Option or such portion of the Option;

(b) The receipt by the Company of full payment for the shares of Stock with respect to which the Option or portion thereof is exercised, including payment of any applicable Tax-Related Items, which Tax-Related Items may be satisfied by one or more of the withholding methods set forth in Section 3.6;

(c) Any other written representations or documents as may be required in the Administrator's sole discretion to evidence compliance with the Securities Act, the Exchange Act or any other applicable law, rule or regulation; and

(d) In the event the Option or portion thereof shall be exercised pursuant to Section 4.1 hereof by any person or persons other than the Participant, appropriate proof of the right of such person or persons to exercise the Option.

Notwithstanding any of the foregoing, the Company shall have the right to specify all conditions of the manner of exercise, which conditions may vary by country and which may be subject to change from time to time.

4.4 Method of Payment. Payment of the exercise price shall be by any of the following, or a combination thereof, at the election of the Participant:

(a) Cash or check;

(b) With the consent of the Administrator, surrender of shares of Stock (including, without limitation, shares of Stock otherwise issuable upon exercise of the Option) held for such period of time as may be required by the Administrator in order to avoid adverse accounting consequences and having a Fair Market Value on the date of delivery equal to the aggregate exercise price of the Option or exercised portion thereof; or

(c) Other legal consideration acceptable to the Administrator (including, without limitation, through the delivery of a notice that the Participant has placed a market sell order with a broker with respect to shares of Stock then issuable upon exercise of the Option, and that the broker has been directed to pay a sufficient portion of the net proceeds of the sale to the Company in satisfaction of the Option exercise price; *provided* that payment of such proceeds is then made to the Company at such time as may be required by the Company, but in any event not later than the settlement of such sale).

4.5 Conditions to Issuance of Stock. The shares of Stock deliverable upon the exercise of the Option, or any portion thereof, may be either previously authorized but unissued shares of Stock or issued shares of Stock which have then been reacquired by the Company. Such shares of Stock shall be fully paid and nonassessable. The Company shall not be required to issue or deliver any shares of Stock purchased upon the exercise of the Option or portion thereof prior to fulfillment of all of the conditions in Section 12.4 of the Plan and following conditions:

(a) The admission of such shares of Stock to listing on all stock exchanges on which such Stock is then listed;

(b) The completion of any registration or other qualification of such shares of Stock under any state or federal law or under rulings or regulations of the U.S. Securities and Exchange Commission ("SEC") or of any other governmental regulatory body, which the Administrator shall, in its absolute discretion, deem necessary or advisable;

(c) The obtaining of any approval or other clearance from any state, federal or foreign governmental agency which the Administrator shall, in its absolute discretion, determine to be necessary or advisable;

(d) The receipt by the Company of full payment for such shares of Stock, including payment of any applicable Tax-Related Items, which may be in one or more of the forms of consideration permitted under Section 4.4 hereof; and

(e) The lapse of such reasonable period of time following the exercise of the Option as the Administrator may from time to time establish for reasons of administrative convenience.

4.6 Rights as Stockholder. The holder of the Option shall not be, nor have any of the rights or privileges of, a stockholder of the Company, including, without limitation, voting rights and rights to dividends, in respect of any shares of Stock purchasable upon the exercise of any part of the Option unless and until such shares of Stock shall have been issued by the Company and held of record by such holder (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company). No adjustment will be made for a dividend or other right for which the record date is prior to the date the shares of Stock are issued, except as provided in Section 14.2 of the Plan.

ARTICLE 5.

OTHER PROVISIONS

5.1 Administration. The Administrator shall have the power to interpret the Plan and this Agreement and to adopt such rules for the administration, interpretation and application of the Plan as are consistent therewith and to interpret, amend or revoke any such rules. All actions taken and all interpretations and determinations made by the Administrator in good faith shall be final and binding upon the Participant, the Company and all other interested persons. No member of the Committee or the Board shall be personally liable for any action, determination or interpretation made in good faith with respect to the Plan, this Agreement or the Option.

5.2 Whole Shares. The Option may only be exercised for whole shares of Stock.

5.3 Option Not Transferable.

(a) Subject to Section 4.1 hereof, the Option may not be sold, pledged, assigned or transferred in any manner other than by will or the laws of descent and distribution or, subject to the consent of the Administrator, pursuant to a DRO, unless and until the Option has been exercised and the shares of Stock underlying the Option have been issued, and all restrictions applicable to such shares of Stock have lapsed. Neither the Option nor any interest or right therein shall be liable for the debts, contracts or engagements of the Participant or his or her successors in interest or shall be subject to disposition by transfer, alienation, anticipation, pledge, hypothecation, encumbrance, assignment or any other means whether such disposition be voluntary or involuntary or by operation of law by judgment, levy, attachment, garnishment or any other legal or equitable proceedings (including bankruptcy) unless and until the Option has been exercised, and any attempted disposition thereof prior to exercise shall be null and void and of no effect, except to the extent that such disposition is permitted by the preceding sentence.

(b) During the lifetime of the Participant, only the Participant may exercise the Option (or any portion thereof), unless it has been disposed of pursuant to a DRO; after the death of the Participant, any exercisable portion of the Option may, prior to the time when such portion becomes unexercisable under the Plan or this Agreement, be exercised by the Participant's personal representative or by any person empowered to do so under the deceased Participant's will or under the then-applicable laws of descent and distribution.

(c) Notwithstanding any other provision in this Agreement, the Participant may, if permitted and in the manner determined by the Administrator, designate a beneficiary to exercise the rights of the Participant and to receive any distribution with respect to the Option upon the Participant's death. A beneficiary, legal guardian, legal representative, or other person claiming any rights pursuant to the Plan is subject to all terms and conditions of the Plan and this Agreement, except to the extent the Plan and this Agreement otherwise provide, and to any additional restrictions deemed necessary or appropriate by the Administrator. If the Participant is married or a domestic partner in a domestic partnership qualified under Applicable Law and resides in a community property state, a designation of a person other than the Participant's spouse or domestic partner, as applicable, as his or her beneficiary with respect to more than 50% of the Participant's interest in the Option shall not be effective without the prior written consent of the Participant's spouse or domestic partner. If no beneficiary has been designated or survives the Participant, or if the Administrator does not permit a beneficiary to be designated, payment shall be made to the person entitled thereto pursuant to the Participant's will or the laws of descent and distribution. Subject to the foregoing, a beneficiary designation may be changed or revoked by the Participant at any time provided the change or revocation is filed with the Administrator prior to the Participant's death.

5.4 Tax and Legal Consultation. The Participant understands that Participant may suffer adverse tax consequences as a result of the grant, vesting and/or exercise of the Option, and/or with the purchase or disposition of the shares of Stock subject to the Option. The Participant acknowledges that the Participant should consult with his or her tax, legal and financial consultants in connection with the purchase or disposition of such shares of Stock and that the Participant is not relying on the Company for any tax or legal advice.

5.5 Binding Agreement. Subject to the limitation on the transferability of the Option contained herein, this Agreement will be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.

5.6 Adjustments Upon Specified Events. The Administrator may accelerate the vesting of the Option in such circumstances as it, in its sole discretion, may determine. In addition, upon the occurrence of certain events relating to the Stock contemplated by Section 14.2 of the Plan (including, without limitation, an extraordinary cash dividend on such Stock), the Administrator shall make such adjustments the Administrator deems appropriate in the number of shares of Stock subject to the Option, the exercise price of the Option and the kind of securities that may be issued upon exercise of the Option. The Participant acknowledges that the Option is subject to adjustment, modification and termination in certain events as provided in this Agreement and Section 14.2 of the Plan.

5.7 Notices. Any notice to be given under the terms of this Agreement to the Company shall be addressed to the Company in care of the Secretary of the Company at the Company's principal office, and any notice to be given to the Participant shall be addressed to the Participant at the Participant's last address reflected on the Company's records. By a notice given pursuant to this Section 5.7, either party may hereafter designate a different address for notices to be given to that party. Any notice which is required to be given to the Participant shall, if the Participant is then deceased, be given to the person entitled to exercise his or her Option pursuant to Section 4.1 hereof by written notice under this Section 5.7. Any notice shall be deemed duly given when sent via email or when sent by certified mail (return receipt requested) and deposited (with postage prepaid) in a post office or branch post office regularly maintained by the United States Postal Service.

5.8 Titles. Titles are provided herein for convenience only and are not to serve as a basis for interpretation or construction of this Agreement.

5.9 Governing Law. The laws of the State of Delaware, United States of America, shall govern the interpretation, validity, administration, enforcement and performance of the terms of this Agreement regardless of the law that might be applied under principles of conflicts of laws. Any action, lawsuit or other proceedings brought to enforce this Agreement, relating to it, or arising from it, or relating to or arising from the Plan, may be brought only in the state or federal courts located in the Northern District of California where this grant is made and/or to be performed, and the parties to this Agreement hereby submit to and consent to the sole and exclusive jurisdiction of such courts, and no other courts.

5.10 Conformity to Securities Laws. Participant acknowledges that the Plan and this Agreement are intended to conform to the extent necessary with all provisions of the Securities Act and the Exchange Act and any Applicable Law. Notwithstanding any other provision of the Plan or this Agreement, unless there is an exemption from any registration, qualification or other legal requirement applicable to the shares of Stock the Company shall not be required to deliver any shares of Stock issuable upon exercise of the Option prior to the completion of any registration or qualification of the shares of Stock under any local, state, federal or foreign securities or exchange control law or under rulings or regulations of the SEC or of any other governmental regulatory body, or prior to obtaining any approval or other clearance from any local, state, federal or foreign governmental agency, which registration, qualification or approval the

Company shall, in its absolute discretion, deem necessary or advisable. The Participant understands that the Company is under no obligation to register or qualify the shares with the SEC or any state or foreign securities commission or to seek approval or clearance from any governmental authority for the issuance or sale of the shares of Stock. Further, the Participant agrees that the Company shall have unilateral authority to amend the Agreement without his or her consent to the extent necessary to comply with securities or other laws applicable to issuance of shares of Stock.

5.11 Amendment, Suspension and Termination. To the extent permitted by the Plan, this Agreement may be wholly or partially amended or otherwise modified, suspended or terminated at any time or from time to time by the Administrator or the Board; *provided, however,* that, except as may otherwise be provided by the Plan, no amendment, modification, suspension or termination of this Agreement shall adversely affect the Option in any material way without the prior written consent of the Participant.

5.12 Successors and Assigns. The Company may assign any of its rights under this Agreement to single or multiple assignees, and this Agreement shall inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer herein set forth in Section 5.3 hereof, this Agreement shall be binding upon the Participant and his or her heirs, executors, administrators, successors and assigns.

5.13 Notification of Disposition. If this Option is designated as an Incentive Stock Option, the Participant shall give prompt notice to the Company of any disposition or other transfer of any shares of Stock acquired under this Agreement if such disposition or transfer is made (a) within two (2) years from the Grant Date with respect to such shares of Stock or (b) within one (1) year after the transfer of such shares of Stock to the Participant. Such notice shall specify the date of such disposition or other transfer and the amount realized, in cash, other property, assumption of indebtedness or other consideration, by the Participant in such disposition or other transfer.

5.14 Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan or this Agreement, if Participant is subject to Section 16 of the Exchange Act, the Plan, the Option and this Agreement shall be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3 of the Exchange Act) that are requirements for the application of such exemptive rule. To the extent permitted by Applicable Law, this Agreement shall be deemed amended to the extent necessary to conform to such applicable exemptive rule.

5.15 Not a Contract of Service Relationship. Nothing in this Agreement or in the Plan shall be interpreted as forming or amending an employment or service contract with the Company or any of its Affiliates or interfere with or restrict in any way with the right of the Company or any of its Affiliates, which rights are hereby expressly reserved, to discharge or to terminate for any reason whatsoever, with or without cause, the services of the Participant's at any time

5.16 Entire Agreement. The Plan, the Grant Notice and this Agreement constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and the Participant with respect to the subject matter hereof.

5.17 Section 409A. This Option is not intended to constitute "nonqualified deferred compensation" within the meaning of Section 409A of the Code (together with any Department of Treasury regulations and other interpretive guidance issued thereunder, including without limitation any such regulations or other guidance that may be issued after the date hereof, "Section 409A"). However, notwithstanding any other provision of the Plan, the Grant Notice or this Agreement (or any Exhibits hereto), if at any time the Administrator determines that the Option (or any portion thereof) may be subject to Section 409A, the Administrator shall have the right in its sole discretion (without any obligation to do so or to indemnify Participant or any other person for failure to do so) to adopt such amendments to the Plan,

the Grant Notice or this Agreement (or any Exhibits hereto), or adopt other policies and procedures (including amendments, policies and procedures with retroactive effect), or take any other actions, as the Administrator determines are necessary or appropriate either for the Option to be exempt from the application of Section 409A or to comply with the requirements of Section 409A.

5.18 Limitation on Participant's Rights. Participation in the Plan confers no rights or interests other than as herein provided. This Agreement creates only a contractual obligation on the part of the Company as to amounts payable and shall not be construed as creating a trust. Neither the Plan nor any underlying program, in and of itself, has any assets. The Participant shall have only the rights of a general unsecured creditor of the Company with respect to amounts credited and benefits payable, if any, with respect to the Option, and rights no greater than the right to receive the Stock as a general unsecured creditor with respect to options, as and when exercised pursuant to the terms hereof.

5.19 Nature of Grant. In accepting the grant, the Participant acknowledges, understands and agrees that:

(a) the Plan is established voluntarily by the Company, it is discretionary in nature and it may be modified, amended, suspended or terminated by the Company at any time, to the extent permitted by the Plan;

(b) the grant of the Option is exceptional, voluntary and occasional and does not create any contractual or other right to receive future grants of options, or benefits in lieu of options, even if options have been granted in the past;

(c) all decisions with respect to future options or other grants, if any, will be at the sole discretion of the Company;

(d) the Participant is voluntarily participating in the Plan;

(e) the Option and the shares of Stock subject to the Option, and the income from and value of same, are not intended to replace any pension rights or compensation;

(f) the Option and the shares of Stock subject to the Option, and the income from and value of same, are not part of normal or expected compensation for purposes of, including but not limited to, calculating any severance, resignation, termination, redundancy, dismissal, end-of-service payments, bonuses, holiday pay, long-service awards, pension or retirement or welfare benefits or similar payments;

(g) unless otherwise agreed with the Company in writing, the Option and the shares of Stock subject to the Option, and the income from and value of same, are not granted as consideration for, or in connection with, the service the Participant may provide as a director of a subsidiary of the Company;

(h) the future value of the underlying shares of Stock is unknown, indeterminable and cannot be predicted with certainty;

(i) if the underlying shares of Stock do not increase in value, the Option will have no value;

(j) if the Participant exercises the Option and acquires shares of Stock, the value of such shares of Stock may increase or decrease in value, even below the exercise price;

(k) no claim or entitlement to compensation or damages shall arise from forfeiture of the Option resulting from the termination of the Participant's employment or other service relationship (for any reason whatsoever, whether or not later found to be invalid or in breach of employment laws in the jurisdiction where the Participant is employed or the terms of the Participant's employment agreement, if any); and

(l) neither the Company, the Service Recipient nor any other Affiliate of the Company shall be liable for any foreign exchange rate fluctuation between the Participant's local currency and the United States Dollar that may affect the value of the Option or of any amounts due to the Participant pursuant to the exercise of the Option or the subsequent sale of any shares of Stock acquired upon exercise.

5.20 **Data Privacy**. ***By participating in the Plan via the Company's acceptance procedure, the Participant is declaring that the Participant agrees with the data processing practices described herein and consents to the collection, processing and use of Personal Data (as defined below) by the Company and the transfer of Personal Data to the recipients mentioned herein, including recipients located in countries which do not adduce an adequate level of protection from a European (or other) data protection law perspective, for the purposes described herein.***

(a) ***Declaration of Consent. The Participant understands that the Participant needs to review the following information about the processing of the Participant's personal data by or on behalf of the Company, the Service Recipient and/or any Affiliate as described in this Agreement and any other Plan materials (the "Personal Data") and declare his or her consent. As regards the processing of the Participant's Personal Data in connection with the Plan and this Agreement, the Participant understands that the Company is the controller of the Participant's Personal Data.***

(b) ***Data Processing and Legal Basis. The Company collects, uses and otherwise processes Personal Data for the purposes of allocating shares of Stock and implementing, administering and managing the Plan. The Participant understands that this Personal Data may include, without limitation, the Participant's name, home address and telephone number, email address, date of birth, social insurance number, passport number or other identification number (e.g., resident registration number), salary, nationality, job title, any shares of stock or directorships held in the Company or any of its Affiliates, details of all awards or any other entitlement to shares of stock or equivalent benefits awarded, canceled, exercised, vested, unvested or outstanding in the Participant's favor. The legal basis for the processing of the Participant's Personal Data, where required, will be the Participant's consent.***

(c) ***Stock Plan Administration Service Providers. The Participant understands that the Company transfers the Participant's Personal Data, or parts thereof, to E*TRADE (and its affiliated companies), an independent service provider based in the United States which assists the Company with the implementation, administration and management of the Plan. In the future, the Company may select a different service provider and share the Participant's Personal Data with such different service provider that serves the Company in a similar manner. The Participant understands and acknowledges that the Company's service provider will open an account for the Participant to receive and trade shares of Stock acquired under the Plan and that the Participant will be asked to agree on separate terms and data processing practices with the service provider, which is a condition of the Participant's ability to participate in the Plan.***

(d) ***International Data Transfers. The Participant understands that the Company and, as of the date hereof, any third parties assisting in the implementation, administration and management of the Plan, such as E*TRADE, are based in the United States. If the Participant is located outside the United States, the Participant understands and acknowledges that the Participant's country may have enacted data privacy laws that are different from the laws of the United States. For example,***

the European Commission has issued only a limited adequacy finding with respect to the United States that applies solely if and to the extent that companies self-certify and remain self-certified under the EU/U.S. Privacy Shield program, which is open to companies subject to Federal Trade Commission jurisdiction and in which the Company participates with respect to employee data. The Company's legal basis for the transfer of the Participant's Personal Data, where required, is the Participant's consent.

(e) ***Data Retention.*** ***The Participant understands that the Company will use the Participant's Personal Data only as long as is necessary to implement, administer and manage the Participant's participation in the Plan, or to comply with legal or regulatory obligations, including under tax and securities laws. In the latter case, the Participant understands and acknowledges that the Company's legal basis for the processing of the Participant's Personal Data would be compliance with the relevant laws or regulations. When the Company no longer needs the Participant's Personal Data for any of the above purposes, the Participant understands the Company will remove it from its systems.***

(f) ***Voluntariness and Consequences of Denial/Withdrawal of Consent.*** ***The Participant understands that the Participant's participation in the Plan and the Participant's consent is purely voluntary. The Participant may deny or later withdraw the Participant's consent at any time, with future effect and for any or no reason. If the Participant denies or later withdraws his or her consent, the Company can no longer offer participation in the Plan to the Participant or offer other equity awards to the Participant or administer or maintain such awards and the Participant would no longer be able to participate in the Plan. The Participant further understands that denial or withdrawal of the Participant's consent would not affect the Participant's status or salary as an employee or service provider or the Participant's career and that the Participant would merely forfeit the opportunities associated with the Plan.***

(g) ***Data Subject Rights.*** ***The Participant understands that data subject rights regarding the processing of Personal Data vary depending on the applicable law and that, depending on where the Participant is based and subject to the conditions set out in the applicable law, the Participant may have, without limitation, the rights to (i) inquire whether and what kind of Personal Data the Company holds about the Participant and how it is processed, and to access or request copies of such Personal Data, (ii) request the correction or supplementation of Personal Data about the Participant that is inaccurate, incomplete or out-of-date in light of the purposes underlying the processing, (iii) obtain the erasure of Personal Data no longer necessary for the purposes underlying the processing, processed based on withdrawn consent, processed for legitimate interests that, in the context of the Participant's objection, do not prove to be compelling, or processed in non-compliance with applicable legal requirements, (iv) request the Company to restrict the processing of the Participant's Personal Data in certain situations where the Participant feels its processing is inappropriate, (v) object, in certain circumstances, to the processing of Personal Data for legitimate interests, and to (vi) request portability of the Participant's Personal Data that the Participant has actively or passively provided to the Company (which does not include data derived or inferred from the collected data), where the processing of such Personal Data is based on consent or the Participant's employment and is carried out by automated means. In case of concerns, the Participant understands that the Participant may also have the right to lodge a complaint with the competent local data protection authority. Further, to receive clarification of, or to exercise any of, the Participant's rights, the Participant understands that the Participant should contact his or her local human resources representative.***

5.21 Language. The Participant acknowledges that he or she is proficient in the English language, or has consulted with an advisor who is proficient in the English language, so as to enable the Participant to understand the provisions of this Agreement and the Plan. If the Participant has received this Agreement or any other document related to the Plan translated into a language other than English and if the meaning of the translated version is different than the English version, the English version will control.

5.22 Electronic Delivery and Participation. The Company may, in its sole discretion, decide to deliver any documents related to current or future participation in the Plan by electronic means. The Participant hereby consents to receive such documents by electronic delivery and agree to participate in the Plan through an on-line or electronic system established and maintained by the Company or a third party designated by the Company.

5.23 Severability. The provisions of this Agreement are severable and if any one or more provisions are determined to be illegal or otherwise unenforceable, in whole or in part, the remaining provisions shall nevertheless be binding and enforceable.

5.24 Country-Specific Provisions. The Participant's participation in the Plan shall be subject to any special terms and conditions set forth in the Appendix attached hereto for the Participant's country. Moreover, if the Participant relocates to one of the countries included in the Appendix, the special terms and conditions for such country will apply to the Participant to the extent the Company determines that the application of such terms and conditions is necessary or advisable for legal or administrative reasons. The Appendix constitutes part of this Agreement.

5.25 Imposition of Other Requirements. The Company reserves the right to impose other requirements on the Participant's participation in the Plan, on the Option and on any shares of Stock acquired under the Plan, to the extent the Company determines it is necessary or advisable for legal or administrative reasons, and to require the Participant to sign any additional agreements, consents, authorizations or undertakings that may be necessary to accomplish the foregoing.

5.26 Waiver. The Participant acknowledges that a waiver by the Company of breach of any provision of this Agreement shall not operate or be construed as a waiver of any other provision of this Agreement, or of any subsequent breach, whether or like or different nature.

5.27 Exchange Control, Foreign Asset/Account and/or Tax Reporting. The Participant acknowledges that there may be certain exchange control, foreign asset/account and/or tax reporting requirements which may affect the Participant's ability to acquire or hold shares of Stock or cash received from participating in the Plan (including the proceeds from the sale of shares of Stock and the receipt of any dividends paid on shares of Stock) in a brokerage or bank account outside the Participant's country. The Participant may be required to report such accounts, assets or related transactions to the tax or other authorities in the Participant's country. The Participant also may be required to repatriate sale proceeds or other funds received as a result of participating in the Plan to the Participant's country within a certain time after receipt. The Participant acknowledges that it is the Participant's responsibility to comply with such regulations and that the Participant should speak to his or her personal advisor on this matter.

5.28 Insider Trading/Market Abuse. The Participant may be subject to insider trading restrictions and/or market abuse laws based on the exchange on which the shares of Stock are listed and in applicable jurisdictions, including the United States, the Participant's country and the designated broker's country, which may affect the Participant's ability to accept, acquire, sell or otherwise dispose of shares of Stock, rights to shares of Stock (*e.g.*, the Option) or rights linked to the value of shares of Stock under the Plan during such times that the Participant is considered to have "inside information" regarding the Company (as defined by the laws or regulations in the Participant's country). Any restrictions under these laws or regulations are separate from and in addition to any restrictions that may be imposed under any applicable Company insider trading policy. The Participant acknowledges that it is the Participant's responsibility to comply with any applicable restrictions and that the Participant should speak to his or her personal advisor on this matter.

EXHIBIT A

Country-Specific Provisions for Participants Outside the U.S.

Capitalized terms used but not defined in this Exhibit A (the "Appendix") shall have the same meanings assigned to them in the Grant Notice, the Agreement and the Plan.

Terms and Conditions

This Appendix, which is part of the Agreement, includes additional terms and conditions that govern the Option granted to the Participant under the Plan if the Participant works and/or resides in one of the countries listed below. If the Participant is a citizen or resident of a country other than the one in which the Participant is currently working (or is considered as such for local law purposes), or if the Participant transfers employment or residency to a different country after the Grant Date, the Company will, in its discretion, determine the extent to which the terms and conditions contained herein will be applicable to the Participant.

Notifications

This Appendix also includes information regarding securities laws, exchange controls and certain other issues of which the Participant should be aware with respect to participating in the Plan. The information is based on the securities, exchange controls and other laws in effect in the respective countries as of February 2020. Such laws are often complex and change frequently. As a result, the Participant should not rely on the information noted herein as the only source of information relating to the consequences of participating in the Plan because the information may be out-of-date at the time the Participant exercises the Option, acquires shares of Stock under the Plan or subsequently sell such shares of Stock.

In addition, the information contained in this Appendix is general in nature and may not apply to the Participant's particular situation, and the Company is not in a position to assure the Participant of any particular result. Accordingly, the Participant should seek appropriate professional advice as to how the relevant laws in the Participant's country may apply to the Participant's situation.

If the Participant is a citizen or resident of a country other than the one in which the Participant is currently working (or is considered as such for local law purposes), or the Participant transfers employment or residency to a different country after the Grant Date, the notifications contained in this Appendix may not be applicable to the Participant in the same manner.

FRANCE

Terms and Conditions

Option Not Tax-Qualified. The Option is not intended to qualify for specific tax or social security treatment in France.

Language Consent. By accepting the grant of the Option, the Participant confirms having read and understood the documents related to the grant (the Grant Notice, the Agreement and the Plan), which were provided in the English language. The Participant accepts the terms of those documents accordingly.

Consentement Relatif à la Langue. *En acceptant l'attribution d'Option, le Participant confirme avoir lu et compris les documents relatifs à l'attribution (l'Avis d'Attribution, le Contrat et le Plan) qui ont été fournis en langue anglaise. Le Participant accepte les dispositions de ces documents en connaissance de cause.*

Notifications

Foreign Asset / Account Reporting Notification. French residents may hold shares of Stock acquired under the Plan outside France, provided they declare all foreign accounts, whether open, current, or closed, in the their income tax return.

GERMANY

Notifications

Exchange Control Notification. Cross-border payments in excess of €12,500 (including transactions made in connection with the sale of securities) must be reported monthly to the German Federal Bank (*Bundesbank*). If the Participant is a German resident and he or she makes or receives a payment in excess of this amount in connection with the Participant's participation in the Plan, the Participant must report the payment to Bundesbank electronically using the "General Statistics Reporting Portal" ("*Allgemeines Meldeportal Statistik*") available via Bundesbank's website (www.bundesbank.de).

IRELAND

There are no country-specific provisions

SWITZERLAND

Notifications

Securities Law Notification. Neither this document nor any other materials relating to the Option (i) constitute a prospectus according to articles 35 et seq. of the Swiss Federal Act on Financial Services ("FinSA"), (ii) may be publicly distributed or otherwise made publicly available in Switzerland to any person other than an employee of the Company or (iii) has been or will be filed with, or approved or supervised by, any Swiss reviewing body according to article 51 FinSA or any Swiss regulatory authority, including the Swiss Financial Market Supervisory Authority (FINMA).

UNITED KINGDOM

Terms and Conditions

Responsibility for Taxes**.** The following provision supplements Section 3.6 of the Agreement:

The Participant agrees to indemnify the Company and/or the Service Recipient for all Tax-Related Items that they are required to pay or withhold or have paid or will pay to Her Majesty's Revenue & Customs ("HMRC") (or any other relevant authority) on the Participant's behalf and authorizes the Company and/or the Service Recipient to recover such amounts by any of the means set out in Section 3.6 of the Agreement. The Participant also agrees to be liable for any Tax-Related Items related to the Option and legally applicable to him or her, and hereby covenants to pay any such Tax-Related items as and when requested by the Company, the Service Recipient or by HMRC (or any other relevant authority).

Notwithstanding the foregoing, if the Participant is an executive officer or director (as within the meaning of Section 13(k) of the Exchange Act), the terms of the immediately foregoing provision will not apply. In the event that the Participant is an executive officer or director and the income tax is not collected from or paid by the Participant within ninety (90) days of the end of the U.K. tax year in which an event giving rise to the indemnification described above occurs, the amount of any uncollected income tax may constitute a

benefit to the Participant on which additional income tax and national insurance contributions may be payable. The Participant acknowledges that he or she will be responsible for reporting and paying any income tax due on this additional benefit directly to the HMRC under the self-assessment regime and for paying the Company or the Service Recipient, as applicable, for the value of any employee national insurance contributions due on this additional benefit.

AIMMUNE THERAPEUTICS, INC.
2015 EQUITY INCENTIVE AWARD PLAN

GLOBAL RESTRICTED STOCK UNIT AWARD GRANT NOTICE

Aimmune Therapeutics, Inc., a Delaware corporation, (the "Company"), pursuant to its 2015 Equity Incentive Award Plan, as amended from time to time (the "Plan"), hereby grants to the holder listed below (the "Participant"), an award of restricted stock units ("Restricted Stock Units" or "RSUs"). Each Restricted Stock Unit represents the right to receive, in accordance with the Global Restricted Stock Unit Award Agreement, including any special terms and conditions for the Participant's country set forth in the appendix attached hereto as Exhibit A (the "Appendix") (collectively, the "Agreement"), one share of Common Stock ("Share"). This award of Restricted Stock Units is subject to all of the terms and conditions set forth herein and in the Agreement and the Plan, each of which are incorporated herein by reference. Unless otherwise defined herein, the terms defined in the Plan shall have the same defined meanings in this Global Restricted Stock Unit Award Grant Notice (the "Grant Notice") and the Agreement.

Participant:	[ ]
Grant Date:	[ ]
Total Number of RSUs:	[ ]
Vesting Commencement Date:	[ ]
Vesting Schedule:	[ ]
Termination:	If the Participant experiences a Termination of Service prior to the applicable vesting date, all RSUs that have not become vested on or prior to the date of such Termination of Service (after taking into consideration any vesting that may occur in connection with such Termination of Service, if any) will cease to vest and thereupon be automatically forfeited by the Participant without payment of any consideration therefor.

By accepting this award of Restricted Stock Units via the Company's online acceptance procedure, the Participant agrees to be bound by the terms and conditions of the Plan, the Agreement and this Grant Notice. The Participant has reviewed the Agreement, the Plan and this Grant Notice in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Grant Notice and fully understands all provisions of this Grant Notice, the Agreement and the Plan. The Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator upon any questions arising under the Plan, this Grant Notice or the Agreement. The Participant further consents to receive Plan documents by electronic delivery and to participate in the Plan through an online or electronic system established and maintained by the Company or another third party designated by the Company.

AIMMUNE THERAPEUTICS, INC.

GLOBAL RESTRICTED STOCK UNIT AWARD AGREEMENT

Pursuant to the Global Restricted Stock Unit Award Grant Notice (the "Grant Notice") to which this Restricted Stock Unit Award Agreement, including any special terms and conditions for the Participant's country set forth in the appendix attached hereto as Exhibit A (the "Appendix") (collectively, this "Agreement"), is attached, Aimmune Therapeutics, Inc., a Delaware corporation (the "Company"), has granted to the Participant the number of restricted stock units ("Restricted Stock Units" or "RSUs") set forth in the Grant Notice under the Company's 2015 Equity Incentive Award Plan, as amended from time to time (the "Plan"). Each Restricted Stock Unit represents the right to receive one share of Common Stock ("Share"). Capitalized terms not specifically defined herein shall have the meanings specified in the Plan and Grant Notice.

ARTICLE I.

GENERAL

1.1 Incorporation of Terms of Plan. The RSUs are subject to the terms and conditions of the Plan, which are incorporated herein by reference. In the event of any inconsistency between the Plan and this Agreement, the terms of the Plan shall control.

ARTICLE II.

GRANT OF RESTRICTED STOCK UNITS

2.1 Grant of RSUs. Pursuant to the Grant Notice and upon the terms and conditions set forth in the Plan and this Agreement, effective as of the Grant Date set forth in the Grant Notice, the Company hereby grants to the Participant an award of RSUs under the Plan.

2.2 Unsecured Obligation to RSUs. Unless and until the RSUs have vested in the manner set forth in Article 2 hereof, the Participant will have no right to receive Shares under any such RSUs. Prior to actual payment of any vested RSUs, such RSUs will represent an unsecured obligation of the Company, payable (if at all) only from the general assets of the Company.

2.3 Vesting Schedule. Subject to Section 2.5 hereof, the RSUs shall vest and become nonforfeitable with respect to the applicable portion thereof according to the vesting schedule set forth in the Grant Notice (rounding down to the nearest whole Share).

2.4 Forfeiture, Termination and Cancellation upon Termination of Service.

(a) Notwithstanding any contrary provision of this Agreement or the Plan, upon the Participant's Termination of Service for any or no reason, all Restricted Stock Units which have not vested prior to or in connection with such Termination of Service (after taking into consideration any accelerated vesting which may occur in connection with such Termination of Service (if any)) shall thereupon automatically be forfeited, terminated and cancelled as of the applicable termination date without payment of any consideration by the Company, and the Participant, or the Participant's beneficiary or personal representative, as the case may be, shall have no further rights hereunder. No portion of the RSUs which has not become vested as of the date on which the Participant incurs a Termination of Service shall thereafter become vested.

(b) For purposes of the Restricted Stock Units and the Participant's participation in the Plan, the Participant's Termination Service will be considered to be the date the Participant is no longer actively providing services to the Company or any of its Affiliate (regardless of the reason for such termination and whether or not later found to be invalid or in breach of employment laws in the jurisdiction where the Participant is employed or the terms of the Participant's employment agreement, if any), and unless otherwise expressly provided in this Agreement or determined by the Company, the Participant's right to vest in the Restricted Stock Units under the Plan, if any, will terminate as of such date and will not be extended by any notice period (*e.g.*, the Participant's period of service would not include any contractual notice period or any period of "garden leave" or similar period mandated under employment laws in the jurisdiction where the Participant is employed or the terms of the Participant's employment agreement, if any); the Administrator shall have the exclusive discretion to determine when the Participant is no longer actively providing services for purposes of the Restricted Stock Units.

2.5 Issuance of Common Stock upon Vesting. As soon as administratively practicable following the vesting of any Restricted Stock Units pursuant to Section 2.3 hereof, but in no event later than thirty (30) days after such vesting date (for the avoidance of doubt, this deadline is intended to comply with the "short term deferral" exemption from Section 409A of the Code), the Company shall deliver to the Participant (or any transferee permitted under Section 3.2 hereof) a number of Shares (either by delivering one or more certificates for such Shares or by entering such Shares in book entry form, as determined by the Company in its sole discretion) equal to the number of RSUs subject to this Award that vest on the applicable vesting date, unless such RSUs terminate prior to the given vesting date pursuant to Section 2.4(b) hereof. Notwithstanding the foregoing, in the event Shares cannot be issued pursuant to Section 12.4 of the Plan, the Shares shall be issued pursuant to the preceding sentence as soon as administratively practicable after the Administrator determines that Shares can again be issued in accordance with such Section.

2.6 Conditions to Delivery of Shares. The Shares deliverable hereunder may be either previously authorized but unissued Shares, treasury Shares or issued Shares which have then been reacquired by the Company. Such Shares shall be fully paid and nonassessable. The Company shall not be required to issue or deliver any certificates or make any book entries evidencing Shares deliverable hereunder prior to fulfillment of the conditions set forth in Section 12.4 of the Plan.

2.7 Rights as Stockholder. The holder of the RSUs shall not be, nor have any of the rights or privileges of, a stockholder of the Company, including, without limitation, voting rights and rights to dividends, in respect of the RSUs and any Shares underlying the RSUs and deliverable hereunder unless and until such Shares shall have been issued by the Company and held of record by such holder (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company). No adjustment shall be made for a dividend or other right for which the record date is prior to the date the Shares are issued, except as provided in Section 14.2 of the Plan.

2.8 Responsibility for Taxes.

(a) The Participant acknowledges that, regardless of any action the Company or, if different, the Affiliate that employs the Participant or for which the Participant otherwise provides services (the "Service Recipient"), the ultimate liability for all income tax, social insurance, payroll tax, fringe benefits tax, payment on account or other tax-related items related to the Participant's participation in the Plan and legally applicable to the Participant ("Tax-Related Items") is and remains the Participant's responsibility and may exceed the amount, if any, actually withheld by the Company or the Service Recipient. The Participant further acknowledges that the Company and the Service Recipient (i) make no representations or undertakings regarding the treatment of any Tax-Related Items in connection with any aspect of the RSUs, including the grant of the RSUs, the vesting of the RSUs, the subsequent sale of any Shares acquired pursuant to the RSU and the receipt of any dividends and (ii) do not commit to structure

the terms of the grant or any aspect of the RSUs to reduce or eliminate the Participant's liability for Tax-Related Items. Further, if the Participant is subject to Tax-Related Items in more than one jurisdiction, the Participant acknowledges that the Company and/or the Service Recipient (or former service recipient, as applicable) may be required to withhold or account for Tax-Related Items in more than one jurisdiction.

(b) Prior to any relevant taxable or tax withholding event, as applicable, the Participant agrees to make arrangements satisfactory to the Company and/or the Service Recipient to satisfy all Tax-Related Items. In this regard, the Participant authorizes the Company and/or the Service Recipient to satisfy any applicable withholding obligations with regard to any Tax-Related Items by withholding from proceeds of the sale of Shares under the Plan, either through a voluntary sale or through a mandatory sale arranged by the Company (on the Participant's behalf pursuant to this authorization without further consent). In the event that such withholding by sale of Shares is not advisable or desirable by the Company (in its sole and absolute discretion), the Participant authorizes the Company and/or the Service Recipient to satisfy the applicable withholding obligations by one or a combination of the following: (i) withholding from the Participant's wages or other cash compensation payable to the Participant by the Company and/or the Service Recipient, (ii) withholding a sufficient number of whole Shares that would otherwise be issued to the Participant upon settlement of the RSUs having an aggregate value sufficient to pay the Tax-Related Items, or (iii) any other method determined by the Company and compliant with applicable law, provided, however, that if the Participant is a Section 16 officer of the Company under the Exchange Act, then the obligation for Tax-Related Items will be satisfied by one or a combination of, the following: withholding from (i) the proceeds from the sale of Shares or (ii) the Participant's wages or cash compensation, unless otherwise determined by the Committee (as constituted to satisfy Rule 16b-3 of the Exchange Act) in advance of the withholding event.

(c) The Company may withhold or account for Tax-Related Items by considering applicable minimum statutory withholding rates or other applicable withholding rates, including maximum rates in the jurisdictions applicable to the Participant, in which case the Participant may receive a refund of any over-withheld amount in cash and will have no entitlement to the equivalent in Shares. Further, if the obligation for Tax-Related Items is satisfied by withholding in Shares, the Participant will be deemed to have been issued the full number of Shares subject to the RSUs, notwithstanding that a number of Shares is held back solely for the purpose of paying Tax-Related Items.

(d) The Participant agrees to pay to the Company or the Service Recipient any amount of Tax-Related Items that the Company or the Service Recipient may be required to withhold or account for as a result of the Participant's participation in the Plan that cannot be satisfied by the means described in this Section. The Company may refuse to issue or deliver the Shares, or the proceeds of the sale of Shares, if the Participant fails to comply with his or her obligations in connection with the Tax-Related Items.

ARTICLE III.

OTHER PROVISIONS

3.1 Administration. The Administrator shall have the power to interpret the Plan and this Agreement and to adopt such rules for the administration, interpretation and application of the Plan as are consistent therewith and to interpret, amend or revoke any such rules. All actions taken and all interpretations and determinations made by the Administrator in good faith shall be final and binding upon the Participant, the Company and all other interested persons. No member of the Administrator or the Board shall be personally liable for any action, determination or interpretation made in good faith with respect to the Plan, this Agreement or the RSUs.

3.2 RSUs Not Transferable. The RSUs shall be subject to the restrictions on transferability set forth in Section 12.3 of the Plan; *provided, however*, that this Section 3.2 notwithstanding, with the consent of the Administrator, the RSUs may be transferred to one or more Permitted Transferees, subject to and in accordance with Section 12.3 of the Plan.

3.3 Tax and Legal Consultation. The Participant understands that the Participant may suffer adverse tax consequences in connection with the RSUs granted pursuant to this Agreement (and the Shares issuable with respect thereto). The Participant acknowledges that the Participant should consult with her tax, legal and financial consultants in connection with the RSUs and the issuance of Shares with respect thereto and that the Participant is not relying on the Company for any tax or legal advice.

3.4 Binding Agreement. Subject to the limitation on the transferability of the RSUs contained herein, this Agreement will be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.

3.5 Adjustments Upon Specified Events. The Administrator may accelerate the vesting of the RSUs in such circumstances as it, in its sole discretion, may determine. The Participant acknowledges that the RSUs are subject to adjustment, modification and termination in certain events as provided in this Agreement and Section 14.2 of the Plan.

3.6 Notices. Any notice to be given under the terms of this Agreement to the Company shall be addressed to the Company in care of the Secretary of the Company at the Company's principal office, and any notice to be given to the Participant shall be addressed to the Participant at the Participant's last address reflected on the Company's records. By a notice given pursuant to this Section 3.6, either party may hereafter designate a different address for notices to be given to that party. Any notice shall be deemed duly given when sent via email or when sent by certified mail (return receipt requested) and deposited (with postage prepaid) in a post office or branch post office regularly maintained by the United States Postal Service.

3.7 Participant's Representations. If the Shares issuable hereunder have not been registered under the Securities Act or any applicable state laws on an effective registration statement at the time of such issuance, the Participant shall, if required by the Company, concurrently with such issuance, make such written representations as are deemed necessary or appropriate by the Company and/or its counsel.

3.8 Titles. Titles are provided herein for convenience only and are not to serve as a basis for interpretation or construction of this Agreement.

3.9 Governing Law. The laws of the State of Delaware, United States of America, shall govern the interpretation, validity, administration, enforcement and performance of the terms of this Agreement regardless of the law that might be applied under principles of conflicts of laws. Any action, lawsuit or other proceedings brought to enforce this Agreement, relating to it, or arising from it, or relating to or arising from the Plan, may be brought only in the state or federal courts located in the Northern District of California where this grant is made and/or to be performed, and the parties to this Agreement hereby submit to and consent to the sole and exclusive jurisdiction of such courts, and no other courts.

3.10 Conformity to Securities Laws. The Participant acknowledges that the Plan and this Agreement are intended to conform to the extent necessary with all provisions of the Securities Act and the Exchange Act and Applicable Law. Notwithstanding any other provision of the Plan or this Agreement, unless there is an exemption from any registration, qualification or other legal requirement applicable to the Shares the Company shall not be required to deliver any Shares issuable upon settlement of the RSUs

prior to the completion of any registration or qualification of the Shares under any local, state, federal or foreign securities or exchange control law or under rulings or regulations of the U.S. Securities and Exchange Commission ("SEC") or of any other governmental regulatory body, or prior to obtaining any approval or other clearance from any local, state, federal or foreign governmental agency, which registration, qualification or approval the Company shall, in its absolute discretion, deem necessary or advisable. The Participant understands that the Company is under no obligation to register or qualify the shares with the SEC or any state or foreign securities commission or to seek approval or clearance from any governmental authority for the issuance or sale of the Shares. Further, the Participant agrees that the Company shall have unilateral authority to amend this Agreement without his or her consent to the extent necessary to comply with securities or other laws applicable to issuance of Shares.

3.11 Amendment, Suspension and Termination. To the extent permitted by the Plan, this Agreement may be wholly or partially amended or otherwise modified, suspended or terminated at any time or from time to time by the Administrator or the Board; *provided, however*, that, except as may otherwise be provided by the Plan, no amendment, modification, suspension or termination of this Agreement shall adversely affect the RSUs in any material way without the prior written consent of the Participant.

3.12 Successors and Assigns. The Company may assign any of its rights under this Agreement to single or multiple assignees, and this Agreement shall inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer herein set forth in Section 3.2 hereof, this Agreement shall be binding upon the Participant and his or her heirs, executors, administrators, successors and assigns.

3.13 Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan or this Agreement, if the Participant is subject to Section 16 of the Exchange Act, then the Plan, the RSUs and this Agreement shall be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3 of the Exchange Act) that are requirements for the application of such exemptive rule. To the extent permitted by Applicable Law, this Agreement shall be deemed amended to the extent necessary to conform to such applicable exemptive rule.

3.14 Not a Contract of Service Relationship. Nothing in this Agreement or in the Plan shall be interpreted as forming or amending an employment or service contract with the Company or any of its Affiliates or interfere with or restrict in any way with the right of the Company or any of its Affiliates, which rights are hereby expressly reserved, to discharge or to terminate for any reason whatsoever, with or without cause, the services of the Participant's at any time.

3.15 Entire Agreement. The Plan, the Grant Notice and this Agreement constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and the Participant with respect to the subject matter hereof.

3.16 Section 409A. This Award is not intended to constitute "nonqualified deferred compensation" within the meaning of Section 409A of the Code (together with any Department of Treasury regulations and other interpretive guidance issued thereunder, including without limitation any such regulations or other guidance that may be issued after the date hereof, "Section 409A"). However, notwithstanding any other provision of the Plan, the Grant Notice or this Agreement, if at any time the Administrator determines that this Award (or any portion thereof) may be subject to Section 409A, the Administrator shall have the right in its sole discretion (without any obligation to do so or to indemnify Participant or any other person for failure to do so) to adopt such amendments to the Plan, the Grant Notice or this Agreement, or adopt other policies and procedures (including amendments, policies and procedures with retroactive effect), or take any other actions, as the Administrator determines are necessary or

appropriate for this Award either to be exempt from the application of Section 409A or to comply with the requirements of Section 409A.

3.17 Limitation on Participant's Rights. Participation in the Plan confers no rights or interests other than as herein provided. This Agreement creates only a contractual obligation on the part of the Company as to amounts payable and shall not be construed as creating a trust. Neither the Plan nor any underlying program, in and of itself, has any assets. The Participant shall have only the rights of a general unsecured creditor of the Company and its Affiliates with respect to amounts credited and benefits payable, if any, with respect to the RSUs, and rights no greater than the right to receive the Common Stock as a general unsecured creditor with respect to RSUs, as and when payable hereunder.

3.18 Nature of Grant. In accepting the RSUs, the Participant acknowledges, understands and agrees that:

(a) the Plan is established voluntarily by the Company, it is discretionary in nature and it may be modified, amended, suspended or terminated by the Company at any time, to the extent permitted by the Plan;

(b) the grant of the RSUs is exceptional, voluntary and occasional and does not create any contractual or other right to receive future grants of RSUs, or benefits in lieu of RSUs, even if RSUs have been granted in the past;

(c) all decisions with respect to future RSU or other grants, if any, will be at the sole discretion of the Company;

(d) the Participant is voluntarily participating in the Plan;

(e) the RSUs and the Shares subject to the RSU, and the income from and value of same, are not intended to replace any pension rights or compensation;

(f) the RSUs and the Shares subject to the RSU, and the income from and value of same, are not part of normal or expected compensation for purposes of, including but not limited to, calculating any severance, resignation, termination, redundancy, dismissal, end-of-service payments, bonuses, holiday pay, long-service awards, pension or retirement or welfare benefits or similar payments;

(g) unless otherwise agreed with the Company in writing, the RSUs and the Shares subject to the RSUs, and the income from and value of same, are not granted as consideration for, or in connection with, the service the Participant may provide as a director of a subsidiary of the Company;

(h) the future value of the underlying Shares is unknown, indeterminable and cannot be predicted with certainty;

(i) no claim or entitlement to compensation or damages shall arise from forfeiture of the RSUs resulting from the termination of the Participant's employment or other service relationship (for any reason whatsoever, whether or not later found to be invalid or in breach of employment laws in the jurisdiction where the Participant is employed or the terms of the Participant's employment agreement, if any); and

(j) neither the Company, the Service Recipient nor any other Affiliate of the Company shall be liable for any foreign exchange rate fluctuation between the Participant's local currency and the

United States Dollar that may affect the value of the RSUs or of any amounts due to the Participant pursuant to the settlement of the RSUs or the subsequent sale of any Shares acquired upon settlement.

3.19 **Data Privacy**. ***By participating in the Plan via the Company's acceptance procedure, the Participant is declaring that the Participant agrees with the data processing practices described herein and consents to the collection, processing and use of Personal Data (as defined below) by the Company and the transfer of Personal Data to the recipients mentioned herein, including recipients located in countries which do not adduce an adequate level of protection from a European (or other) data protection law perspective, for the purposes described herein.***

(a) ***Declaration of Consent. The Participant understands that the Participant needs to review the following information about the processing of the Participant's personal data by or on behalf of the Company, the Service Recipient and/or any Affiliate as described in this Agreement and any other Plan materials (the "Personal Data") and declare his or her consent. As regards the processing of the Participant's Personal Data in connection with the Plan and this Agreement, the Participant understands that the Company is the controller of the Participant's Personal Data.***

(b) ***Data Processing and Legal Basis. The Company collects, uses and otherwise processes Personal Data for the purposes of allocating Shares and implementing, administering and managing the Plan. The Participant understands that this Personal Data may include, without limitation, the Participant's name, home address and telephone number, email address, date of birth, social insurance number, passport number or other identification number (e.g., resident registration number), salary, nationality, job title, any shares of stock or directorships held in the Company or any of its Affiliates, details of all awards or any other entitlement to shares of stock or equivalent benefits awarded, canceled, exercised, vested, unvested or outstanding in the Participant's favor. The legal basis for the processing of the Participant's Personal Data, where required, will be the Participant's consent.***

(c) ***Stock Plan Administration Service Providers. The Participant understands that the Company transfers the Participant's Personal Data, or parts thereof, to E*TRADE (and its affiliated companies), an independent service provider based in the United States which assists the Company with the implementation, administration and management of the Plan. In the future, the Company may select a different service provider and share the Participant's Personal Data with such different service provider that serves the Company in a similar manner. The Participant understands and acknowledges that the Company's service provider will open an account for the Participant to receive and trade Shares acquired under the Plan and that the Participant will be asked to agree on separate terms and data processing practices with the service provider, which is a condition of the Participant's ability to participate in the Plan.***

(d) ***International Data Transfers. The Participant understands that the Company and, as of the date hereof, any third parties assisting in the implementation, administration and management of the Plan, such as E*TRADE, are based in the United States. If the Participant is located outside the United States, the Participant understands and acknowledges that the Participant's country may have enacted data privacy laws that are different from the laws of the United States. For example, the European Commission has issued only a limited adequacy finding with respect to the United States that applies solely if and to the extent that companies self-certify and remain self-certified under the EU/U.S. Privacy Shield program, which is open to companies subject to Federal Trade Commission jurisdiction and in which the Company participates with respect to employee data. The Company's legal basis for the transfer of the Participant's Personal Data, where required, is the Participant's consent.***

(e) ***Data Retention. The Participant understands that the Company will use the Participant's Personal Data only as long as is necessary to implement, administer and manage the***

Participant's participation in the Plan, or to comply with legal or regulatory obligations, including under tax and securities laws. In the latter case, the Participant understands and acknowledges that the Company's legal basis for the processing of the Participant's Personal Data would be compliance with the relevant laws or regulations. When the Company no longer needs the Participant's Personal Data for any of the above purposes, the Participant understands the Company will remove it from its systems.

(f) ***Voluntariness and Consequences of Denial/Withdrawal of Consent. The Participant understands that the Participant's participation in the Plan and the Participant's consent is purely voluntary. The Participant may deny or later withdraw the Participant's consent at any time, with future effect and for any or no reason. If the Participant denies or later withdraws his or her consent, the Company can no longer offer participation in the Plan to the Participant or offer other equity awards to the Participant or administer or maintain such awards and the Participant would no longer be able to participate in the Plan. The Participant further understands that denial or withdrawal of the Participant's consent would not affect the Participant's status or salary as an employee or service provider or the Participant's career and that the Participant would merely forfeit the opportunities associated with the Plan.***

(g) ***Data Subject Rights. The Participant understands that data subject rights regarding the processing of Personal Data vary depending on the applicable law and that, depending on where the Participant is based and subject to the conditions set out in the applicable law, the Participant may have, without limitation, the rights to (i) inquire whether and what kind of Personal Data the Company holds about the Participant and how it is processed, and to access or request copies of such Personal Data, (ii) request the correction or supplementation of Personal Data about the Participant that is inaccurate, incomplete or out-of-date in light of the purposes underlying the processing, (iii) obtain the erasure of Personal Data no longer necessary for the purposes underlying the processing, processed based on withdrawn consent, processed for legitimate interests that, in the context of the Participant's objection, do not prove to be compelling, or processed in non-compliance with applicable legal requirements, (iv) request the Company to restrict the processing of the Participant's Personal Data in certain situations where the Participant feels its processing is inappropriate, (v) object, in certain circumstances, to the processing of Personal Data for legitimate interests, and to (vi) request portability of the Participant's Personal Data that the Participant has actively or passively provided to the Company (which does not include data derived or inferred from the collected data), where the processing of such Personal Data is based on consent or the Participant's employment and is carried out by automated means. In case of concerns, the Participant understands that the Participant may also have the right to lodge a complaint with the competent local data protection authority. Further, to receive clarification of, or to exercise any of, the Participant's rights, the Participant understands that the Participant should contact his or her local human resources representative.***

3.20 Language. The Participant acknowledges that he or she is proficient in the English language, or has consulted with an advisor who is proficient in the English language, so as to enable the Participant to understand the provisions of this Agreement and the Plan. If the Participant has received this Agreement or any other document related to the Plan translated into a language other than English and if the meaning of the translated version is different than the English version, the English version will control.

3.21 Electronic Delivery and Participation. The Company may, in its sole discretion, decide to deliver any documents related to current or future participation in the Plan by electronic means. The Participant hereby consents to receive such documents by electronic delivery and agrees to participate in the Plan through an online or electronic system established and maintained by the Company or a third party designated by the Company.

3.22 Severability. The provisions of this Agreement are severable and if any one or more provisions are determined to be illegal or otherwise unenforceable, in whole or in part, the remaining provisions shall nevertheless be binding and enforceable.

3.23 Country-Specific Provisions. The Participant's participation in the Plan shall be subject to any special terms and conditions set forth in the Appendix attached hereto for the Participant's country. Moreover, if the Participant relocates to one of the countries included in the Appendix, the special terms and conditions for such country will apply to the Participant to the extent the Company determines that the application of such terms and conditions is necessary or advisable for legal or administrative reasons. The Appendix constitutes part of this Agreement.

3.24 Imposition of Other Requirements. The Company reserves the right to impose other requirements on the Participant's participation in the Plan, on any RSUs granted under the Plan and on any Shares acquired under the Plan, to the extent the Company determines it is necessary or advisable for legal or administrative reasons, and to require the Participant to sign any additional agreements, consents, authorizations or undertakings that may be necessary to accomplish the foregoing.

3.25 Waiver. The Participant acknowledges that a waiver by the Company of breach of any provision of this Agreement shall not operate or be construed as a waiver of any other provision of this Agreement, or of any subsequent breach, whether of like or different nature.

3.26 Exchange Control, Foreign Asset/Account and/or Tax Reporting. The Participant acknowledges that there may be certain exchange control, foreign asset/account and/or tax reporting requirements which may affect the Participant's ability to acquire or hold Shares or cash received from participating in the Plan (including the proceeds from the sale of Shares and the receipt of any dividends paid on Shares) in a brokerage or bank account outside the Participant's country. The Participant may be required to report such accounts, assets or related transactions to the tax or other authorities in the Participant's country. The Participant also may be required to repatriate sale proceeds or other funds received as a result of participating in the Plan to the Participant's country within a certain time after receipt. The Participant acknowledges that it is the Participant's responsibility to comply with such regulations and that the Participant should speak to his or her personal advisor on this matter.

3.27 Insider Trading/Market Abuse. The Participant may be subject to insider trading restrictions and/or market abuse laws based on the exchange on which the Shares are listed and in applicable jurisdictions, including the United States, the Participant's country and the designated broker's country, which may affect the Participant's ability to accept, acquire, sell or otherwise dispose of Shares, rights to Shares (*e.g.*, RSUs) or rights linked to the value of Shares under the Plan during such times that the Participant is considered to have "inside information" regarding the Company (as defined by the laws or regulations in the Participant's country). Any restrictions under these laws or regulations are separate from and in addition to any restrictions that may be imposed under any applicable Company insider trading policy. The Participant acknowledges that it is the Participant's responsibility to comply with any applicable restrictions and that the Participant should speak to his or her personal advisor on this matter.

EXHIBIT A

Country-Specific Provisions for Participants Outside the U.S.

Capitalized terms used but not defined in this Exhibit A (the "Appendix") shall have the same meanings assigned to them in the Grant Notice, the Agreement and the Plan.

Terms and Conditions

This Appendix, which is part of the Agreement, includes additional terms and conditions that govern the RSUs granted to the Participant under the Plan if the Participant works and/or resides in one of the countries listed below. If the Participant is a citizen or resident of a country other than the one in which the Participant is currently working (or is considered as such for local law purposes), or if the Participant transfers employment or residency to a different country after the Grant Date, the Company will, in its discretion, determine the extent to which the terms and conditions contained herein will be applicable to the Participant.

Notifications

This Appendix also includes information regarding securities laws, exchange controls and certain other issues of which the Participant should be aware with respect to participating in the Plan. The information is based on the securities, exchange controls and other laws in effect in the respective countries as of February 2020. Such laws are often complex and change frequently. As a result, the Participant should not rely on the information noted herein as the only source of information relating to the consequences of participating in the Plan because the information may be out-of-date at the time the Participant acquires Shares under the Plan or subsequently sell such Shares.

In addition, the information contained in this Appendix is general in nature and may not apply to the Participant's particular situation, and the Company is not in a position to assure the Participant of any particular result. Accordingly, the Participant should seek appropriate professional advice as to how the relevant laws in the Participant's country may apply to the Participant's situation.

If the Participant is a citizen or resident of a country other than the one in which the Participant is currently working (or is considered as such for local law purposes), or the Participant transfers employment or residency to a different country after the Grant Date, the notifications contained in this Appendix may not be applicable to the Participant in the same manner.

FRANCE

Terms and Conditions

RSUs Not Tax-Qualified. The RSUs are not intended to qualify for specific tax or social security treatment in France.

Language Consent. By accepting the grant of the RSUs, the Participant confirms having read and understood the documents related to the grant (the Grant Notice, the Agreement and the Plan), which were provided in the English language. The Participant accepts the terms of those documents accordingly.

Consentement Relatif à la Langue. En acceptant l'attribution de droits sur des actions assujettis à des restrictions (« RSUs »), le Participant confirme avoir lu et compris les documents relatifs à l'attribution (l'Avis d'Attribution, le Contrat et le Plan) qui ont été fournis en langue anglaise. Le Participant accepte les dispositions de ces documents en connaissance de cause.

Notifications

Foreign Asset / Account Reporting Notification. French residents may hold Shares acquired under the Plan outside France, provided they declare all foreign accounts, whether open, current, or closed, in the their income tax return.

GERMANY

Notifications

Exchange Control Notification. Cross-border payments in excess of €12,500 (including transactions made in connection with the sale of securities) must be reported monthly to the German Federal Bank (*Bundesbank*). If the Participant is a German resident and he or she makes or receives a payment in excess of this amount in connection with the Participant's participation in the Plan, the Participant must report the payment to Bundesbank electronically using the "General Statistics Reporting Portal" ("*Allgemeines Meldeportal Statistik*") available via Bundesbank's website (www.bundesbank.de).

IRELAND

There are no country-specific provisions.

SWITZERLAND

Notifications

Securities Law Notification. Neither this document nor any other materials relating to the RSUs (i) constitute a prospectus according to articles 35 et seq. of the Swiss Federal Act on Financial Services ("FinSA"), (ii) may be publicly distributed or otherwise made publicly available in Switzerland to any person other than an employee of the Company or (iii) has been or will be filed with, or approved or supervised by, any Swiss reviewing body according to article 51 FinSA or any Swiss regulatory authority, including the Swiss Financial Market Supervisory Authority (FINMA).

UNITED KINGDOM

Terms and Conditions

Responsibility for Taxes. The following provision supplements Section 2.9 of the Agreement:

The Participant agrees to indemnify the Company and/or the Service Recipient for all Tax-Related Items that they are required to pay or withhold or have paid or will pay to Her Majesty's Revenue & Customs ("HMRC") (or any other relevant authority) on the Participant's behalf and authorizes the Company and/or the Service Recipient to recover such amounts by any of the means set out in Section 2.9 of the Agreement. The Participant also agrees to be liable for any Tax-Related Items related to the RSUs and legally applicable to him or her, and hereby covenants to pay any such Tax-Related items as and when requested by the Company, the Service Recipient or by HMRC (or any other relevant authority).

Notwithstanding the foregoing, if the Participant is an executive officer or director (as within the meaning of Section 13(k) of the Exchange Act), the terms of the immediately foregoing provision will not apply. In the event that the Participant is an executive officer or director and the income tax is not collected from or paid by the Participant within ninety (90) days of the end of the U.K. tax year in which an event giving rise to the indemnification described above occurs, the amount of any uncollected income tax may constitute a

benefit to the Participant on which additional income tax and national insurance contributions may be payable. The Participant acknowledges that he or she will be responsible for reporting and paying any income tax due on this additional benefit directly to the HMRC under the self-assessment regime and for paying the Company or the Service Recipient, as applicable, for the value of any employee national insurance contributions due on this additional benefit.

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: July 30, 2020

By: /s/ Jayson Dallas

Jayson Dallas, M.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, 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: July 30, 2020

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 June 30, 2020 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: July 30, 2020 By: /s/ Jayson Dallas

Jayson Dallas M.D.
President and Chief Executive Officer
(*Principal Executive Officer*)

Date: July 30, 2020 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.