2019 Annual Report

Aimmune Therapeutics, Inc. is a biopharmaceutical company with a mission to improve the lives of people with food allergies. Aimmune is developing and commercializing oral treatments for potentially life-threatening food allergies. The Company's Characterized Oral Desensitization ImmunoTherapy (CODIT™) approach is intended to provide meaningful levels of protection against allergic reactions resulting from accidental exposure to food allergens by desensitizing patients with defined, precise amounts of key allergens. Aimmune has one FDA-approved medicine for peanut allergy and other investigational therapies in development to treat other food allergies.

Forward Looking Statements

Statements contained in this report regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding: Aimmune's expectations regarding the potential benefits of PALFORZIA, AR201 and AIMab7195; Aimmune's expectations regarding the commercial launch of PALFORZIA; Aimmune's expectations regarding the timing of a potential acceptance and applicable review period of the MAA for AR101 by the EMA and by Swissmedic; Aimmune's expectations on the timing of completing a phase 2 clinical trial for AR201; Aimmune's expectations on the planned timing for the announcement of the completion of the POSEIDON clinical trial for PALFORZIA; Aimmune's expectations on the mechanisms of action of AIMab7195; Aimmune's expectations regarding the timing and availability of the full amount of proceeds under its loan agreement with KKR; Aimmune's expectations regarding the sufficiency of its cash resources; and Aimmune's expectations regarding potential applications of the CODIT™ approach to treating life-threatening food allergies. Risks and uncertainties that contribute to the uncertain nature of the forward-looking statements include: the expectation that Aimmune will need additional funds to finance its operations; Aimmune's dependence on the success of PALFORZIA; Aimmune's ability to build a commercial field organization and distribution network; the degree of acceptance of PALFORZIA among physicians, patients, healthcare payors, patient advocacy groups and the general medical community; Aimmune's ability to obtain favorable coverage and reimbursement from third-party payors for PALFORZIA; Aimmune's reliance on third parties for the manufacture of PALFORZIA; Aimmune's ability to implement and comply with REMS for PALFORZIA; possible regulatory developments in the United States and foreign countries; and Aimmune's ability to attract and retain senior management personnel. These and other risks and uncertainties are described more fully in Aimmune's most recent filings with the Securities and Exchange Commission, including its Annual Report on Form 10-K for the year ended December 31, 2019 and filed on February 27, 2020. All forward-looking statements contained in this report speak only as of the date on which they were made. Aimmune undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

This report concerns PALFORZIA, which has been approved for marketing in the United States by the FDA; AR101, a product candidate that is under clinical investigation in Europe; AR201, a product candidate under clinical investigation in the United States; and AIMab7195, a product candidate that Aimmune expects will be under clinical investigation. AR201 and AIMab7195 have not been approved for marketing by the FDA, the EMA or Swissmedic. AR101, in Europe, AR201 and AIMab7195 are currently limited to investigational use, and no representation is made as to their safety or effectiveness for the purposes for which they are being investigated.

April 9, 2020

Dear Shareholder,

The U.S. Food and Drug Administration's (FDA) approval of PALFORZIA™ on January 31, 2020 was a defining moment for the peanut allergy community and for Aimmune. The decision marks the first approved treatment for the serious health risk posed by peanut allergy – which affects more than 1.6 million children and teens in the United States – and the first approved treatment in the world for any form of food allergy. It is also notable in that the approval signifies the transformation of Aimmune from a clinical-stage organization to a fully integrated commercial-stage biotechnology company. I could not be more proud of this result. It is the culmination of years of focused and determined effort since Aimmune was founded by the food allergy community in 2011.

2019 was marked by significant work to ensure this outcome. We successfully navigated a federal government shutdown early in the year and a rigorous regulatory process with the FDA, achieving a remarkably positive outcome at the FDA Allergenic Products' Advisory Committee Meeting. In addition, we demonstrated the value of PALFORZIA at the Institute for Clinical and Economic Review's (ICER) Public Meeting which found PALFORZIA to be a cost-effective therapy for the treatment of peanut allergy.

Throughout the year, we were focused on building Aimmune into a strong commercial-stage company. We hired a number of important team members and developed a robust launch strategy for PALFORZIA. We made significant progress with physicians and payors, helping to pave the way for a successful PALFORZIA launch upon approval. In addition, we proactively planned for the safety measures that would be necessary to use our medicine appropriately and were able to quickly implement a Risk Evaluation and Mitigation (REMS) program, which was ultimately required by the FDA.

We made important progress in Europe where we estimate that approximately three million people have peanut allergy. In June 2019, we submitted a Marketing Authorization Application for PALFORZIA to the European Medicines Agency (EMA), and in October we submitted an application to Swissmedic, the Regulatory authority for Switzerland. Those applications are currently being reviewed, and we expect the EMA review to be completed in the fourth quarter of 2020 and the Swissmedic review to be completed mid-2021. In preparation for the potential approval and launch, we expanded our commercial leadership team in Europe with some key hires.

Finally, 2019 was significant for us as we expanded our Characterized Oral Desensitization ImmunoTherapy (CODIT™) pipeline beyond peanut allergy. We initiated a phase 2 clinical trial of AR201 for patients with egg allergy, and we have been working with regulatory authorities to determine next steps for a multi-tree nut allergy program.

We begin our journey as a commercial company from a position of financial strength. We ended 2019 with $158 million in cash, cash equivalents and investments and received a $200 million investment from Nestlé in February 2020, as well as a pre-arranged borrowing of an additional $85 million from KKR. The pro-forma cash at the beginning of 2020 was $443 million including these new funds. The new Nestlé investment brings Nestlé's total investment in Aimmune to date to $473 million, and the new KKR loan brings total debt to $125 million plus accrued interest.

Our achievements would not be possible without the many contributions from the food allergy community—the advocates, the patients and families who participated in our trials, and the allergists and staffs who served as investigator sites—along with our hard-working and talented employees, global regulatory authorities, and our shareholders. In so many ways, we are just getting started. I thank you all for your continued support and I look forward to a productive 2020.

Yours truly,

Jayson Dallas, M.D.
President and Chief Executive Officer

AIMMUNE THERAPEUTICS, INC.
8000 Marina Blvd., Suite 300
Brisbane, California 94005

NOTICE OF ANNUAL MEETING OF STOCKHOLDERS
TO BE HELD ON MAY 27, 2020

To the Stockholders of Aimmune Therapeutics, Inc.:

NOTICE IS HEREBY GIVEN that the Annual Meeting of Stockholders (the "Annual Meeting") of Aimmune Therapeutics, Inc., a Delaware corporation (the "Company"), will be held on May 27, 2020, at 3:00 p.m. local time. The Annual Meeting will be held entirely online due to the emerging public health impact of the coronavirus outbreak (COVID-19) and to support the health and well-being of our partners, employees and stockholders. You will be able to attend and participate in the Annual Meeting online by visiting www.virtualshareholdermeeting.com/AIMT2020, where you will be able to listen to the meeting live, submit questions and vote. The Annual Meeting will be held for the following purposes:

1. To elect three Class II directors to hold office until the 2023 annual meeting of stockholders or until their successors are elected;
2. To ratify the selection, by the Audit Committee of the Company's Board of Directors, of KPMG LLP, as the independent registered public accounting firm of the Company for its fiscal year ending December 31, 2020;
3. To approve, on a non-binding, advisory basis, the compensation of the Company's named executive officers as disclosed in the Proxy Statement accompanying this Notice of Annual Meeting of Stockholders; and
4. To transact such other business as may properly come before the Annual Meeting or any adjournment or postponement thereof.

The foregoing items of business are more fully described in the Proxy Statement accompanying this Notice of Annual Meeting of Stockholders. Only stockholders who owned common stock of the Company at the close of business on March 31, 2020 (the "Record Date") can vote at this meeting or any adjournments that take place.

The Board of Directors recommends that you vote as follows on the matters to be presented to stockholders at the Annual Meeting:

1. **FOR** the election of the director nominees named in Proposal No. 1 of the Proxy Statement;
2. **FOR** the ratification of the appointment of KPMG LLP, as the independent registered public accounting firm, as described in Proposal No. 2 of the Proxy Statement; and
3. **FOR** the advisory vote to approve the compensation of the Company's named executive officers, as described in Proposal No. 3 of the Proxy Statement.

YOUR VOTE IS IMPORTANT. WHETHER OR NOT YOU PLAN TO ATTEND THE ANNUAL MEETING ONLINE, WE ENCOURAGE YOU TO READ THE ACCOMPANYING PROXY STATEMENT AND OUR ANNUAL REPORT ON FORM 10-K FOR THE YEAR ENDED DECEMBER 31, 2019, AND SUBMIT YOUR PROXY AS SOON AS POSSIBLE USING ONE OF THE THREE CONVENIENT VOTING METHODS DESCRIBED IN THE "INFORMATION ABOUT THE PROXY PROCESS AND VOTING" SECTION IN THE PROXY STATEMENT. IF YOU RECEIVE MORE THAN ONE SET OF PROXY MATERIALS OR NOTICE OF INTERNET AVAILABILITY BECAUSE YOUR SHARES ARE REGISTERED IN DIFFERENT NAMES OR ADDRESSES, EACH PROXY SHOULD BE SIGNED AND SUBMITTED TO ENSURE THAT ALL OF YOUR SHARES WILL BE VOTED.

By Order of the Board of Directors

/s/ Jayson Dallas
Jayson D.A. Dallas, M.D.
President and Chief Executive Officer

Brisbane, California
April 9, 2020

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AIMMUNE THERAPEUTICS, INC.
8000 Marina Blvd., Suite 300
Brisbane, California 94005

PROXY STATEMENT

FOR THE 2020 ANNUAL MEETING OF STOCKHOLDERS
MAY 27, 2020

We have sent you this Proxy Statement and the enclosed Proxy Card because the Board of Directors (the "Board") of Aimmune Therapeutics, Inc. (referred to herein as the "Company", "Aimmune", "we", "us" or "our") is soliciting your proxy to vote at our 2020 Annual Meeting of Stockholders (the "Annual Meeting") to be held on Wednesday, May 27, 2020, at 3:00 p.m. local time. The Annual Meeting can be accessed by visiting www.virtualshareholdermeeting.com/AIMT2020, where you will be able to listen to the meeting live, submit questions and vote.

- This Proxy Statement summarizes information about the proposals to be considered at the Annual Meeting and other information you may find useful in determining how to vote.
- The Proxy Card is the means by which you actually authorize another person to vote your shares in accordance with your instructions.

In addition to solicitations by mail, our directors, officers and regular employees, without additional remuneration, may solicit proxies by telephone, e-mail and personal interviews. We may retain outside consultants to solicit proxies on our behalf as well. All costs of solicitation of proxies will be borne by us. Brokers, custodians and fiduciaries will be requested to forward proxy soliciting material to the owners of stock held in their names, and we will reimburse them for their reasonable out-of-pocket expenses incurred in connection with the distribution of proxy materials.

Pursuant to the rules adopted by the Securities and Exchange Commission (the "SEC"), we have elected to provide access to our Annual Meeting materials, which include this Proxy Statement and our Annual Report on Form 10-K for the year ended December 31, 2019 (the "Form 10-K"), over the internet in lieu of mailing printed copies. We will begin mailing the Notice of Internet Availability to our stockholders of record as of March 31, 2020 (the "Record Date") for the first time on or about April 16, 2020. The Notice of Internet Availability will contain instructions on how to access and review the Annual Meeting materials and will also contain instructions on how to request a printed copy of the Annual Meeting materials. In addition, we have provided brokers, dealers, banks, voting trustees and their nominees, at our expense, with additional copies of our proxy materials and the Form 10-K so that our record holders can supply these materials to the beneficial owners of shares of our common stock as of the Record Date. The Form 10-K is also available in the "Financial Information" section of our website at http://ir.aimmune.com.

The only outstanding voting securities of Aimmune are shares of common stock, $0.0001 par value per share (the "common stock"), of which there were 65,222,917 shares outstanding as of the Record Date (excluding any treasury shares). The holders of a majority in voting power of the shares of common stock issued and outstanding and entitled to vote, present in attendance online or represented by proxy, are required to hold the Annual Meeting.

INFORMATION ABOUT THE PROXY PROCESS AND VOTING

Why am I receiving these materials?

We have made this Proxy Statement and Proxy Card available to you on the internet or, upon your request, have delivered printed proxy materials to you, because the Board is soliciting your proxy to vote at the Annual Meeting, including at any adjournments or postponements of the Annual Meeting. You are invited to attend the Annual Meeting online to vote on the proposals described in this Proxy Statement by following the instructions at www.virtualshareholdermeeting.com/AIMT2020. However, you do not need to attend the Annual Meeting to vote your shares. Instead, you may simply complete, sign and return the Proxy Card, or follow the instructions below to submit your proxy over the telephone or on the internet.

This Proxy Statement, the Notice of Internet Availability, the Notice of Annual Meeting and accompanying Proxy Card will be first made available for access by our stockholders on or about April 16, 2020 to all stockholders of record entitled to vote at the Annual Meeting.

Who can vote at the Annual Meeting?

Only stockholders of record at the close of business on the Record Date will be entitled to vote at the Annual Meeting. At the close of business on the Record Date, there were 65,222,917 shares of common stock issued and outstanding and entitled to vote.

Stockholder of Record: Shares Registered in Your Name

If, on the Record Date, your shares were registered directly in your name with the transfer agent for our common stock, EQ Shareowner Services, then you are a stockholder of record. As a stockholder of record, you may vote at the Annual Meeting by attending the Annual Meeting online and following the instructions posted at www.virtualshareholdermeeting.com/AIMT2020 or vote by proxy. Whether or not you plan to attend the Annual Meeting online, we encourage you to fill out and return the Proxy Card or vote by proxy over the telephone or on the internet as instructed below to ensure your vote is counted.

Beneficial Owner: Shares Registered in the Name of a Broker, Bank or Other Agent

If, on the Record Date, your shares were held in an account at a brokerage firm, bank, dealer or other similar organization, then you are the beneficial owner of shares held in "street name" and these proxy materials are being forwarded to you by that organization. The organization holding your account is considered the stockholder of record for purposes of voting at the Annual Meeting. As a beneficial owner, you have the right to direct your broker or other agent on how to vote the shares in your account. You are also invited to attend the Annual Meeting online at www.virtualshareholdermeeting.com/AIMT2020. However, since you are not the stockholder of record, you may not vote your shares at the Annual Meeting by attending the Annual Meeting online unless you request and obtain a valid Proxy Card from your broker or other agent.

What am I being asked to vote on?

You are being asked to vote on three proposals:

- Proposal 1—the election of three Class II directors to hold office until our 2023 annual meeting of stockholders;
- Proposal 2—the ratification of the selection, by the Audit Committee of our Board, of KPMG LLP, as our independent registered public accounting firm for the year ending December 31, 2020; and
- Proposal 3—a non-binding, advisory vote on the compensation of our named executive officers.

In addition, you are entitled to vote on any other matters that are properly brought before the Annual Meeting.

How do I attend the Virtual Annual Meeting?

This year's Annual Meeting will be held entirely online due to the emerging public health impact of the coronavirus outbreak (COVID-19) and to support the health and well-being of our partners, employees and stockholders. Stockholders of record as of March 31, 2020 will be able to attend and participate in the Annual Meeting online by accessing www.virtualshareholdermeeting.com/AIMT2020. To join the Annual Meeting, you will need to have your 16-digit control number which is included on your Notice and your proxy card.

Even if you plan to attend the Annual Meeting online, we recommend that you also vote by proxy as described herein so that your vote will be counted if you decide not to attend the Annual Meeting.

Access to the Audio Webcast of the Annual Meeting. The live audio webcast of the Annual Meeting will begin promptly at 3:00 p.m. local time on May 27, 2020. Online access to the audio webcast will open approximately fifteen minutes prior to the start of the Annual Meeting to allow time for you to log in and test the computer audio system. We encourage our stockholders to access the meeting prior to the start time.

Log in Instructions. To attend the online Annual Meeting, log in at www.virtualshareholdermeeting.com/AIMT2020. Stockholders will need their unique 16-digit control number which appears on the Notice (printed in the box and marked by the arrow) and the instructions that accompanied the proxy materials. In the event that you do not have a control number, please contact your broker, bank, or other nominee as soon as possible and no later than May 1, 2020, so that you can be provided with a control number and gain access to the meeting.

Submitting Questions at the virtual Annual Meeting. Stockholders may submit questions in writing during the Annual Meeting on www.virtualshareholdermeeting.com/AIMT2020. Stockholders will need their unique control number which appears on their Notice, the proxy card (printed in the box and marked by the arrow) and the instructions that accompanied the proxy materials.

As part of the Annual Meeting, we will hold a live question and answer session, during which we intend to answer questions submitted during the meeting in accordance with the Annual Meeting's Rules of Conduct that are pertinent to the Company and the meeting matters, as time permits. Answers to any such questions that are not addressed during the meeting will be published following the meeting on the Company's website at www.aimmune.com under the "Investors" link. Questions and answers will be grouped by topic and substantially similar questions will be grouped and answered once. In order to promote fairness, efficient use of the Company's resources and in order to ensure all stockholders are responded to, we will respond to up to two questions from a single stockholder.

Technical Assistance. Beginning 30 minutes prior to the start of and during the virtual Annual Meeting, we will have support team ready to assist stockholders with any technical difficulties they may have accessing or hearing the virtual meeting.

If you encounter any difficulties accessing the virtual meeting during the check-in or meeting time, you should call our support team at 1-800-586-1548 (US Domestic Toll Free); 1-303-562-9288 (International).

Availability of live webcast to team members and other constituents. The live audio webcast will be available to not only our stockholders, but also our team members and other constituents.

How do I vote?

- For Proposal 1, you may either vote "For" all the nominees to the Board or you may "Withhold" your vote for any nominee you specify.
- For Proposal 2, you may either vote "For" or "Against" or abstain from voting.
- For Proposal 3, you may either vote "For" or "Against" or abstain from voting.

Please note that by casting your vote by proxy you are authorizing the individuals listed on the Proxy Card to vote your shares in accordance with your instructions and in their discretion with respect to any other matter that properly comes before the Annual Meeting or any adjournments or postponements thereof.

The procedures for voting are as follows:

Stockholder of Record: Shares Registered in Your Name

If you are a stockholder of record, you may vote online at the Annual Meeting by attending the Annual Meeting online and following the instructions posted at www.virtualshareholdermeeting.com/AIMT2020. Alternatively, you may vote by proxy by using the accompanying Proxy Card, over the internet or by telephone. Whether or not you plan to attend the Annual Meeting online, we encourage you to vote by proxy to ensure your vote is counted. Even if you have submitted a proxy before the Annual Meeting, you may still attend the Annual Meeting and vote online by following the instructions posted at www.virtualshareholdermeeting.com/AIMT2020. In such case, your previously submitted proxy will be disregarded.

- To vote at the Annual Meeting, attend the Annual Meeting online and follow the instructions posted at www.virtualshareholdermeeting.com/AIMT2020.
- To vote using the Proxy Card, simply complete, sign and date the accompanying Proxy Card and return it promptly in the envelope provided. If you return your signed Proxy Card to us before the Annual Meeting, we will vote your shares in accordance with the Proxy Card.
- To vote by proxy over the internet, follow the instructions provided on the Notice of Internet Availability.
- To vote by telephone, you may vote by proxy by calling the toll-free number found on the Notice of Internet Availability.

Beneficial Owner: Shares Registered in the Name of Broker, Bank or Other Agent

If you are a beneficial owner of shares registered in the name of your broker, bank or other agent, you should have received a voting instruction card and voting instructions with these proxy materials from that organization rather than from us. Simply complete and mail the voting instruction card to ensure that your vote is counted. To vote online at the Annual Meeting, you must obtain a valid proxy from your broker, bank or other agent. Follow the instructions from your broker, bank or other agent included with these proxy materials, or contact your broker, bank or other agent to request a proxy form.

We provide internet proxy voting to allow you to vote your shares online, with procedures designed to ensure the authenticity and correctness of your proxy vote instructions. However, please be aware that you must bear any costs associated with your internet access, such as usage charges from internet access providers and telephone companies.

Who counts the votes?

Broadridge Financial Solutions, Inc. ("Broadridge") has been engaged as our independent agent to tabulate stockholder votes, or Inspector of Election. If you are a stockholder of record, your executed Proxy Card is returned directly to Broadridge for tabulation. As noted above, if you hold your shares through a broker, your broker returns one Proxy Card to Broadridge on behalf of all its clients.

How are votes counted?

Votes will be counted by the Inspector of Election appointed for the Annual Meeting. The Inspector of Election will separately count "For" votes for all proposals, and, with respect to Proposals 2 and 3, "Against" votes, abstentions and broker non-votes. In addition, with respect to Proposal 1, the election of directors, the Inspector of Election will count the number of "Withheld" votes and broker non-votes received. If your shares are held by your broker as your nominee (that is, in "street name"), you will need to obtain a proxy form from the institution that holds your shares and follow the instructions included on that form regarding how to instruct your broker to vote your shares. If you do not give instructions to your broker, your broker can vote your shares with respect to "routine" items, but not with respect to "non-routine" items. See below for more information regarding: "**What are "broker non-votes"?**" and "**Which ballot measures are considered "routine" or "non-routine"?**"

What are "broker non-votes"?

Broker non-votes occur when a beneficial owner of shares held in "street name" does not give instructions to the broker or nominee holding the shares as to how to vote on matters deemed "non-routine." Generally, if shares are held in street name, the beneficial owner of the shares is entitled to give voting instructions to the broker or nominee holding the shares. If the beneficial owner does not provide voting instructions, the broker or nominee can still vote the shares with respect to matters that are considered to be "routine," but not with respect to "non-routine" matters. In the event that a broker, bank, custodian, nominee or other record holder of common stock indicates on a proxy that it does not have discretionary authority to vote certain shares on a particular proposal, then those shares will be treated as broker non-votes with respect to that proposal. Accordingly, if you own shares through a nominee, such as a broker or bank, please be sure to instruct your nominee how to vote to ensure that your vote is counted on each of the proposals.

Which ballot measures are considered "routine" or "non-routine?"

The ratification of the appointment of KPMG LLP, as our independent registered public accounting firm for the year ending December 31, 2020 (Proposal 2) is considered routine under applicable rules. A broker or other nominee may generally vote on routine matters, and therefore no broker non-votes are expected to exist in connection with Proposal 2. The election of directors (Proposal 1) and the non-binding advisory vote on the compensation of our named executive officers (Proposal 3) are considered non-routine under applicable rules. A broker or other nominee cannot vote without instructions on non-routine matters, and therefore there may be broker non-votes on Proposals 1 and 3.

How many votes are needed to approve the proposal?

With respect to Proposal 1, the election of directors, the three nominees receiving the highest number of "For" votes will be elected.

With respect to Proposal 2, the affirmative vote of the majority of votes cast (excluding abstentions and broker non-votes) is required for approval. This is a routine proposal and therefore we do not expect any broker non-votes.

With respect to Proposal 3, the affirmative vote of the majority of votes cast (excluding abstentions and broker non-votes) is required for approval. While the vote on this resolution is advisory and not binding on us, our Compensation Committee and our Board will consider the outcome of the vote on this resolution when considering future executive compensation decisions.

How many votes do I have?

On each matter to be voted upon, you have one vote for each share of common stock you own as of the Record Date.

What if I return a Proxy Card but do not make specific choices?

If we receive a signed and dated Proxy Card and the Proxy Card does not specify how your shares are to be voted, your shares will be voted as follows:

- "For" the election of each of the three nominees for director;
- "For" the ratification of the appointment of KPMG LLP, as our independent registered public accounting firm for the fiscal year ending December 31, 2020; and
- "For" the non-binding, advisory vote regarding the compensation of our named executive officers.

If any other matter is properly presented at the Annual Meeting, your proxy (one of the individuals named on your Proxy Card) will vote your shares in his or her discretion.

Who is paying for this proxy solicitation?

We will pay for the entire cost of soliciting proxies. In addition to these mailed proxy materials, our directors, officers and employees may also solicit proxies online, by telephone or by other means of communication. Directors, officers and employees will not be paid any additional compensation for soliciting proxies. We may also reimburse brokerage firms, banks and other agents for the cost of forwarding proxy materials to beneficial owners.

What does it mean if I receive more than one set of materials?

If you receive more than one set of materials, your shares are registered in more than one name or are registered in different accounts. In order to vote all the shares you own, you must either sign and return all of the Proxy Cards or follow the instructions for any alternative voting procedure on each of the Proxy Cards.

Can I change my vote after submitting my proxy?

Yes. You can revoke your proxy at any time before the final vote at the Annual Meeting. If you are the record holder of your shares, you may revoke your proxy in any one of three ways:

- You may submit another properly completed proxy with a later date.
- You may send a written notice that you are revoking your proxy to our Corporate Secretary at 8000 Marina Blvd., Suite 300, Brisbane, California 94005.
- You may attend the Annual Meeting online and vote by following the instructions posted at www.virtualshareholdermeeting.com/AIMT2020. Simply attending the Annual Meeting online will not, by itself, revoke your proxy.

If your shares are held by your broker, bank or other agent, you should follow the instructions provided by them.

When are stockholder proposals due for next year's Annual Meeting?

To be considered for inclusion in next year's proxy materials, your proposal must be submitted in writing by December 11, 2020, to our Corporate Secretary at 8000 Marina Blvd., Suite 300, Brisbane, California 94005; provided that if the date of the annual meeting is more than 30 days from May 27, 2020, the deadline is a reasonable time before we begin to print and send our proxy materials for next year's annual meeting. Pursuant to the bylaws, in order for a stockholder to present a proposal for next year's annual meeting, other than proposals to be included in the proxy statement as described above, or to nominate a director, you must do so between January 27, 2021 and February 26, 2021; provided that if the date of that annual meeting is more than 30 days before or more than 60 days after May 27, 2020, you must give notice not later than the 90th day prior to the annual meeting date or, if later, the 10th day following the day on which public disclosure of the annual meeting date is first made. You are also advised to review our bylaws, which contain additional requirements about advance notice of stockholder proposals and director nominations.

What is the quorum requirement?

A quorum of stockholders is necessary to hold a valid meeting. A quorum will be present if the holders of a majority in voting power of the shares of common stock issued and outstanding and entitled to vote are present in attendance online or represented by proxy at the Annual Meeting. On the Record Date, there were 65,222,917 shares outstanding and entitled to vote. Accordingly, 32,611,459 shares must be represented by stockholders present in attendance online at the Annual Meeting or by proxy to have a quorum.

Your shares will be counted toward the quorum only if you submit a valid proxy or vote at the Annual Meeting. Abstentions and broker non-votes will be counted toward the quorum requirement. If there is no quorum, either the chair of the Annual Meeting or a majority in voting power of the stockholders entitled to vote at the Annual Meeting, present in person or represented by proxy, may adjourn the Annual Meeting to another time or place.

How can I find out the results of the voting at the Annual Meeting?

Voting results will be announced by the filing of a Current Report on Form 8-K within four business days after the Annual Meeting. If final voting results are unavailable at that time, we will file an amended Current Report on Form 8-K within four business days of the day the final results are available.

PROPOSAL NO. 1
ELECTION OF DIRECTORS

Our Board is divided into three classes. Each class consists, as nearly as possible, of one-third of the total number of directors, and each class has a staggered, three-year term. Unless the Board determines that vacancies (including vacancies created by increases in the number of directors) shall be filled by the stockholders, and except as otherwise provided by law, vacancies on the Board may be filled only by the affirmative vote of a majority of the remaining directors. A director elected by the Board to fill a vacancy (including a vacancy created by an increase in the number of directors) shall serve for the remainder of the full term of the class of directors in which the vacancy occurred and until such director's successor is elected and qualified.

The Board currently consists of eight seated directors, divided into the three following classes:

- *Class I directors:* Jayson D.A. Dallas, M.D., Mark T. Iwicki and Greg Behar, whose current terms will expire at the annual meeting of stockholders to be held in 2022;
- *Class II directors:* Brett K. Haumann, M.D., Mark D. McDade and Stacey D. Seltzer, whose current terms will expire at the Annual Meeting; and
- *Class III directors:* Patrick G. Enright and Kathryn E. Falberg, whose current terms will expire at the annual meeting of stockholders to be held in 2021.

At each annual meeting of stockholders, the successors to directors whose terms will then expire will be elected to serve from the time of election and qualification until the third subsequent annual meeting of stockholders.

Messrs. Haumann and McDade and Ms. Seltzer have been nominated to serve as Class II directors and have each elected to stand for reelection. Each director to be elected will hold office from the date of their election by the stockholders until the third subsequent annual meeting of stockholders or until his or her successor is elected and has been qualified, or until such director's earlier death, resignation or removal.

Shares represented by executed proxies will be voted, if authority to do so is not withheld, for the election of the three nominees named below. In the event that any nominee should be unavailable for election as a result of an unexpected occurrence, such shares will be voted for the election of such substitute nominee as the Board may propose. Each person nominated for election has agreed to serve if elected, and management has no reason to believe that any nominee will be unable to serve. Directors are elected by a plurality of the votes cast at the meeting.

THE BOARD OF DIRECTORS RECOMMENDS A VOTE *FOR* THE ELECTION OF EACH NAMED NOMINEE.

The following table sets forth, for the Class II nominees (who are currently standing for re-election) and for our other current directors who will continue in office after the Annual Meeting, information with respect to their ages as of April 1, 2020 and position/office held within the Company:

Name	Age	Position/Office Held With the Company	Director Since
Class I Directors whose terms expire at the 2022 Annual Meeting of Stockholders			
Jayson D.A. Dallas, M.D.	52	President, Chief Executive Officer and Director	2018
Mark T. Iwicki[2][3]	53	Director	2015
Greg Behar	50	Director	2016
Class II Directors whose terms expire at the Annual Meeting			
Brett K. Haumann, M.D.[4]	50	Director	2018
Mark D. McDade[1][3]	64	Chair of the Board	2015
Stacey D. Seltzer[1][4]	43	Director	2015
Class III Directors whose terms expire at the 2021 Annual Meeting of Stockholders			
Patrick G. Enright[2][3]	58	Director	2013
Kathryn E. Falberg[1][2]	59	Director	2015

(1) Member of the Audit Committee.
(2) Member of the Compensation Committee.
(3) Member of the Nominating and Corporate Governance Committee.
(4) Member of the Research and Development Committee.

Set forth below is biographical information for the nominees and each person whose term of office as a director will continue after the Annual Meeting. The following includes certain information regarding our directors' individual experience, qualifications, attributes and skills that led the Board to conclude that they should serve as directors.

Nominees for Election to a Three-Year Term Expiring at the 2023 Annual Meeting of Stockholders

Brett K. Haumann, M.D. has served as a member of our Board since October 2018. Dr. Haumann is Chief Medical Officer and Senior Vice President, Clinical Development, and a member of the board of directors of Theravance Biopharma, Inc., which he joined in June 2014 in connection with Theravance Biopharma's spin-off from Theravance Inc., after joining Theravance Inc.as Vice President, Clinical Development, in October 2013. He became Vice President, Clinical Development and Operations of Theravance Inc.in March 2014 and became Senior Vice President, Clinical Development at Theravance Biopharma in December 2014. Dr. Haumann served as Chief Medical Officer at, and on the board of directors of Circassia Limited, a UK-based allergy biopharmaceutical company, from September 2012 to June 2013 and on the board of directors of Reacta Biotech Limited, a UK-based peanut allergy diagnostic company, from June 2014 to November 2016. Dr. Haumann held senior positions at GlaxoSmithKline from 2001 to 2012, including Medicines Development Leader and Vice President Clinical Development until August 2012. Dr. Haumann has more than 20 years of experience in the discovery and development of pulmonary and allergy medicines. Dr. Haumann completed his M.D. at the University of Witwatersrand Medical School, South Africa and holds an M.B.A. from Open University, United Kingdom. We believe that Dr. Haumann is qualified to serve on our Board due to his executive management and leadership experience in the life science industry, as well as his experience as a director of public companies

Mark D. McDade has served as the Chair of our Board since May 2015. Since January 2017, Mr. McDade has served as Managing Partner of the Qiming US Healthcare Fund, a venture capital firm. He previously served as Executive Vice President and Chief Operating Officer of UCB S.A., a Belgian biopharmaceutical company, from 2009 until his retirement from UCB S.A. in October 2016, after serving as Executive Vice President, Corporate Development since 2008. From 2002 to 2007, Mr. McDade served as Chief Executive Officer and as a member of the board of directors of PDL BioPharma, Inc., a biotechnology company. From 2000 to 2002, Mr. McDade was Chief Executive Officer of Signature BioScience, Inc., a drug discovery company. From 1994 to 2000, Mr. McDade served as Chief Operating Officer and as a director of Corixa Corporation, a biopharmaceutical company he co-founded. At Corixa, Mr. McDade also served as President from 1998 to 2000. He has served on the board of directors of Dermira, Inc., a biopharmaceutical company, since August 2014, which was acquired by Eli Lilly in February 2020. Mr. McDade also served on the board of directors of Five Prime Therapeutics, Inc., a biotechnology company, from 2006 to November 2018. Mr. McDade served as a member of the board of directors and as a member of the audit and conflicts committees for Phillips Edison Grocery Center REIT II, Inc., a non-traded real estate investment company, until November 2018 and has served as an Independent Director at Phillips Edison Grocery Center REIT III, Inc. from November 2018 until November 2019, when it was acquired by Phillips Edison & Company, Inc. Additionally, Mr. McDade is on the board of several privately-held companies. Mr. McDade received a B.A. in History from Dartmouth College and an M.B.A. from Harvard Business School. We believe that Mr. McDade is qualified to serve on our Board due

to his executive management and leadership experience in the life science industry, as well as his extensive experience as a director of public companies.

Stacey D. Seltzer has served as a member of our Board since January 2015. Ms. Seltzer is currently a partner at Aisling Capital, where she previously served as principal since joining in September 2008. From 2004 to 2008, Ms. Seltzer held various positions at Schering-Plough Corporation, a pharmaceutical company, including U.S. Schering-Plough Brand Lead for Zetia, Associate Director, U.S. Marketing, Senior Manager, Global Licensing and Management Associate. From 2001 to 2002, Ms. Seltzer served as Director of Business Development for Akceli, Inc., a biotechnology company. Ms. Seltzer has served on the board of directors of Promentis Pharmaceuticals, Inc., a biopharmaceutical company, since November 2016. Ms. Seltzer is currently a board observer for Prolacta Bioscience Inc., a biopharmaceutical company. She previously served on the board of directors of Miramar Labs, Inc., and as a board observer for Agile Therapeutics, Inc., a pharmaceutical company, Durata Therapeutics, Inc., a pharmaceutical company, and Zeltiq Aesthetics, Inc. a medical equipment supplier. Ms. Seltzer received a B.S. and M.S. in Molecular Biophysics and Biochemistry from Yale University and an M.B.A. from the Wharton School at the University of Pennsylvania. We believe that Ms. Seltzer is qualified to serve on our Board due to her investment and management experience in the life science industry.

THE BOARD OF DIRECTORS RECOMMENDS A VOTE *FOR* THE ELECTION OF EACH OF THE ABOVE-NAMED NOMINEES

Directors Continuing in Office Until the 2021 Annual Meeting of Stockholders

Patrick G. Enright has served as a member of our Board since April 2013. Mr. Enright is a founder of Longitude Capital, a venture capital firm focused on investments in pharmaceutical and medical technology companies and has served as its Managing Director since 2006. From 2002 through 2006, Mr. Enright was a Managing Director of Pequot Ventures, a venture capital investment firm, where he co-led the life sciences investment practice. He currently serves on the board of directors and as a member of the audit and compensation committees of Jazz Pharmaceuticals plc and as chair of the board of directors and as member of the audit committee of Aptinyx Inc., both public pharmaceutical companies. Mr. Enright previously served on the board of directors and as a member of the audit committee of Corcept Therapeutics Incorporated, a pharmaceutical company, and as a member of the board of directors and as chair of the audit committee of Esperion Therapeutics, Inc., a pharmaceutical company. Mr. Enright is also on the board of several privately-held companies. Mr. Enright received a B.S. in Biological Sciences from Stanford University and an M.B.A. from the Wharton School at the University of Pennsylvania. We believe that Mr. Enright is qualified to serve on our Board due to his experience serving on the board of directors of clinical-stage biotechnology companies and his investment experience in the life science industry.

Kathryn E. Falberg has served as a member of our Board since May 2015. She previously served as Executive Vice President and Chief Financial Officer of Jazz Pharmaceuticals plc, a biopharmaceutical company, from March 2012 to March 2014, after serving as Senior Vice President and Chief Financial Officer since December 2009. From 2001 to 2009, Ms. Falberg worked with several smaller companies while serving as a corporate director and audit committee chair for several companies. From 1995 to 2001, Ms. Falberg was with Amgen Inc., a biotechnology company, where she served as Senior Vice President, Finance and Strategy and Chief Financial Officer, and prior to that as Vice President, Chief Accounting Officer and Vice President, Treasurer. Ms. Falberg also serves as a member of the board of directors for biopharmaceutical companies UroGen Pharma Ltd., Tricida Inc. and Arcus Biosciences Inc., and as a member of the board of directors of The Trade Desk Inc., a public technology company. She previously served on the board of directors of biotechnology companies Axovant Sciences Ltd., BioMarin Pharmaceutical, Inc., aTyr Pharma, Inc., Medivation, Inc., and Halozyme Therapeutics, Inc. Ms. Falberg received a B.A. in Economics and M.B.A. from the University of California, Los Angeles and is a certified public accountant (inactive). We believe that Ms. Falberg is qualified to serve on our Board due to her extensive background in financial and accounting matters for public companies and her leadership experience in the biotechnology industry.

Directors Continuing in Office Until the 2022 Annual Meeting of Stockholders

Jayson D.A. Dallas, M.D. has served as our President and Chief Executive Officer and as a member of our Board since June 2018. Dr. Dallas joined Aimmune from Ultragenyx Pharmaceutical Inc., a public biopharmaceutical company, where he had served as Executive Vice President since January 2016 and Chief Commercial Officer since August 2015. Between August 2015 and January 2016, he served as Senior Vice President of Ultragenyx. Prior to Ultragenyx, Dr. Dallas served as General Manager of Roche Holding (UK) Limited, a public healthcare company, in the United Kingdom from July 2012 to July 2015. Prior to that, he held two different positions at Genentech, Inc., a public pharmaceutical company, as Head of Global Oncology Launch Excellence and Biosimilar Strategy and Head of Global Product Strategy for Immunology and Ophthalmology from May 2010 to June 2012. Prior to joining Genentech, Dr. Dallas worked at Novartis AG and Pharmacia Corporation in the United States and, prior to that, at Roche in

Switzerland. Dr. Dallas has also served as a board member of Arena Pharmaceuticals Inc., a public biopharmaceutical company, since February 2017. Dr. Dallas holds an M.D. from the University of the Witwatersrand, Johannesburg, South Africa and an M.B.A. from Ashridge Business School in the United Kingdom. We believe that Dr. Dallas is qualified to serve on our Board due to his executive management and operational experience in the life science industry.

Mark T. Iwicki has served as a member of our Board since May 2015. Mr. Iwicki currently serves as the Chairman and Chief Executive Officer of Kala Pharmaceuticals, Inc., a biopharmaceutical company, which he joined in April 2015. Mr. Iwicki also currently serves as the Chairman of the board of directors and a member of the compensation committee of Pulmatrix, Inc., a biopharmaceutical company, a member of the board of directors and member of the compensation committee of Merus B.V., a biopharmaceutical company, chair of the board of directors of Akero Therapeutics, a biotechnology company, and a member of the board of directors of Oxeia Biopharmaceuticals and Nimbus Therapeutics LLC, biotechnology companies. Previously, Mr. Iwicki served as President and Chief Executive Officer and a member of the board of directors of Civitas Therapeutics, Inc., a biopharmaceutical company, from January 2014 until its acquisition by Acorda Therapeutics, Inc., a biotechnology company, in September 2014. From December 2012 to January 2014, Mr. Iwicki served as President and Chief Executive Officer and director at Blend Therapeutics, Inc., a biopharmaceutical company. From 2007 to June 2012, Mr. Iwicki served in several roles, including Chief Commercial Officer, President and Chief Operating Officer and Director and Chief Executive Officer at Sunovion Pharmaceuticals, Inc., formerly Sepracor, Inc., a pharmaceutical company. From 1998 to 2007, Mr. Iwicki held executive positions, including Vice President and Business Unit Head, at Novartis Pharmaceuticals Corporation, a pharmaceuticals company. Mr. Iwicki has also held management positions at Astra Merck Inc. and Merck & Co., Inc., pharmaceutical companies. Mr. Iwicki received a B.A. in Business Administration from Ball State University and an M.B.A. from Loyola University. We believe that Mr. Iwicki is qualified to serve on our Board due to his executive management and operational experience in the life science industry.

Greg Behar joined our Board in November 2016 in connection with the equity investment in Aimmune by Nestlé Health Science US Holdings, Inc. Mr. Behar currently serves as Chief Executive Officer of Nestlé Health Science, a global business of Nestlé S.A. ("Nestlé"), a nutrition, health and wellness company, which he joined in July 2014. Previously, Mr. Behar was President and Chief Executive Officer of Boehringer Ingelheim Pharmaceuticals Inc. (USA), a pharmaceutical company, from 2011 to June 2014 and Corporate Vice President Region NECAR (North European Union, Canada and Australasia) for Boehringer Ingelheim GmbH, a pharmaceutical company, from 2010 to 2011. He also spent seven years in marketing and sales leadership in various roles at Novartis AG, a healthcare company, following earlier work at Nestlé. Mr. Behar also serves on the boards of Seres Therapeutics, Inc., a microbiome therapeutics platform company, Cerecin, Inc., a clinical development company, Axcella Health, Inc., an amino acids therapeutics company, and Prometheus Biosciences, Inc., a biopharmaceutical company. Mr. Behar received a B.S. in Mechanical Engineering from the University of California, Los Angeles, an M.S. in Mechanical Engineering from EPFL in Switzerland and an M.B.A. from INSEAD in France. We believe that Mr. Behar is qualified to serve on our Board due to his extensive global management and leadership experience in the life science industry.

PROPOSAL NO. 2
RATIFICATION OF SELECTION OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Audit Committee of our Board has engaged KPMG LLP ("KPMG"), as our independent registered public accounting firm for the year ending December 31, 2020 and is seeking ratification of such selection by our stockholders at the Annual Meeting. KPMG has audited our financial statements for each of our fiscal years since the fiscal year ended December 31, 2013. Representatives of KPMG are expected to be present online at the Annual Meeting. They will have an opportunity to make a statement if they so desire and will be available to respond to appropriate questions.

Neither our bylaws nor other governing documents or law require stockholder ratification of the selection of KPMG as our independent registered public accounting firm. However, the Audit Committee is submitting the selection of KPMG to our stockholders for ratification as a matter of good corporate practice. If our stockholders fail to ratify the selection, the Audit Committee will reconsider whether or not to retain KPMG. Even if the selection is ratified, the Audit Committee in its discretion may direct the appointment of a different independent registered public accounting firm at any time during the year if they determine that such a change would be in the best interests of the Company and our stockholders.

Principal Accountant Fees and Services

The following table provides information regarding the fees incurred to KPMG during the years ended December 31, 2019 and 2018. The Audit Committee approved all of the fees described below.

	Year Ended December 31,	
	2019	2018
	(In thousands)	
Audit Fees[1]	$ 916	$ 726
Tax Fees	—	—
Audit-Related Fees[2]	65	92
All Other Fees	—	—
Total Fees	$ 981	$ 818

(1) Audit fees of KPMG for the years ending December 31, 2019 and 2018 were for professional services rendered for the audits of our financial statements, including accounting consultation, reviews of quarterly financial statements.

(2) Fees for 2018 include services associated with our follow on offering of common stock in February 2018.

Pre-Approval Policies and Procedures

The Audit Committee or a delegate of the Audit Committee pre-approves or provides pursuant to pre-approvals policies and procedures for the pre-approval of, all audit and non-audit services provided by its independent registered public accounting firm. This policy is set forth in the charter of the Audit Committee and is available at http://ir.aimmune.com.

The Audit Committee approved all of the audit, audit-related, tax and other services provided by KPMG for 2019 and all of the audit, audit-related, tax and other services provided by KPMG in 2018 and, in each case, the estimated costs of those services. Actual amounts billed, to the extent in excess of the estimated amounts, are periodically reviewed and approved by the Audit Committee.

THE BOARD OF DIRECTORS RECOMMENDS A VOTE *FOR* RATIFICATION OF OUR INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM.

REPORT OF THE AUDIT COMMITTEE OF THE BOARD OF DIRECTORS

The material in this report is not "soliciting material," is not deemed "filed" with the SEC and is not to be incorporated by reference into any filing of Aimmune under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.

The primary purpose of the Audit Committee is to oversee our financial reporting processes on behalf of our Board. The Audit Committee's functions are more fully described in its charter, which is available on our website at http://ir.aimmune.com. Management has the primary responsibility for our financial statements and reporting processes, including our systems of internal controls. In fulfilling its oversight responsibilities, the Audit Committee reviewed and discussed with management Aimmune's audited financial statements as of and for the year ended December 31, 2019.

The Audit Committee has discussed with KPMG LLP, the Company's independent registered public accounting firm, the matters required to be discussed by Statement on Auditing Standards 61, as amended, "Communications with Audit Committees," as adopted by the Public Company Accounting Oversight Board (the "PCAOB"). In addition, the Audit Committee discussed with KPMG LLP their independence, and received from KPMG LLP the written disclosures and the letter required by Ethics and Independence Rule 3526 of the PCAOB. Finally, the Audit Committee discussed with KPMG LLP, with and without management present, the scope and results of KPMG LLP's audit of such financial statements.

Based on these reviews and discussions, the Audit Committee has recommended to our Board that such audited financial statements be included in our Annual Report on Form 10-K for the year ended December 31, 2019 for filing with the SEC. The Audit Committee also has engaged KPMG LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2020 and is seeking ratification of such selection by the stockholders.

Audit Committee
Kathryn E. Falberg, Chair
Mark D. McDade
Stacey D. Seltzer

PROPOSAL NO. 3
NON-BINDING, ADVISORY VOTE TO APPROVE THE COMPENSATION OF OUR NAMED EXECUTIVE OFFICERS

Summary

The Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 enables our stockholders to vote to approve as required pursuant to Section 14A of the Exchange Act, on an advisory, non-binding basis, the compensation of our named executive officers as disclosed in this Proxy Statement in accordance with the compensation disclosure rules of the SEC, commonly known as a "Say-on-Pay" vote. Accordingly, we are seeking a non-binding, advisory vote to approve the compensation of our named executive officers as described in the "Compensation Discussion and Analysis" section of this proxy statement and the compensation tables and accompanying narrative disclosures that follow.

Board Recommendation

Our Compensation Committee and the Board believe that the information provided in the "Compensation Discussion and Analysis" section of this proxy statement, compensation tables and accompanying narrative disclosures demonstrates that our executive compensation program is designed appropriately, emphasizes pay for performance and aligns management's interests with our stockholders' interests to support long-term value creation.

Accordingly, our Board recommends that stockholders vote "FOR" the following resolution:

> RESOLVED, that stockholders of Aimmune Therapeutics, Inc. (the "Company") approve, on an advisory basis, the compensation of the Company's named executive officers, as disclosed in "Compensation Discussion and Analysis," compensation tables and the accompanying narrative disclosures of this Proxy Statement.

While the vote on this resolution is advisory and not binding on us, the Compensation Committee, or our Board, the Compensation Committee and our Board values thoughtful input from stockholders and will consider the outcome of the vote on this resolution when considering future executive compensation decisions. Our Board has adopted a policy of providing for annual advisory votes from stockholders on executive compensation. Unless our Board modifies its policy on the frequency of future Say-on-Pay advisory votes, the next Say-on-Pay advisory vote will be held at the 2021 annual meeting of stockholders.

THE BOARD OF DIRECTORS RECOMMENDS THAT STOCKHOLDERS VOTE, ON A NON-BINDING ADVISORY BASIS, *FOR* THE RESOLUTION TO APPROVE THE COMPENSATION OF OUR NAMED EXECUTIVE OFFICERS.

CORPORATE GOVERNANCE

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics that applies to all of our employees, officers and directors, including those officers responsible for financial reporting. The code of business conduct and ethics is available on our website at http://ir.aimmune.com. We expect that any amendments to the code, or any waivers of its requirements, will be disclosed on our website. The reference to our web address does not constitute incorporation by reference of the information contained at or available through our website.

Corporate Governance Guidelines

We believe in sound corporate governance practices and have adopted formal Corporate Governance Guidelines to enhance our effectiveness. Our Board adopted these Corporate Governance Guidelines in order to ensure that it has the necessary practices in place to review and evaluate our business operations as needed and to make decisions that are independent of our management. The Corporate Governance Guidelines are also intended to align the interests of directors and management with those of our stockholders. The Corporate Governance Guidelines set forth the practices our Board follows with respect to Board and committee composition and selection, Board meetings, Chief Executive Officer performance evaluation and succession planning. A copy of our Corporate Governance Guidelines is available on our website at http://ir.aimmune.com.

Independence of the Board of Directors

As required under the Nasdaq Global Select Market ("Nasdaq") rules and regulations, a majority of the members of a listed company's board of directors must qualify as "independent," as affirmatively determined by such board. The Board consults with the Company's counsel to ensure that the Board's determinations are consistent with all relevant securities and other laws and regulations regarding the definition of "independent," including those set forth in pertinent Nasdaq listing standards, as in effect from time to time.

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

As required under Nasdaq rules and regulations, our independent directors meet in regularly scheduled executive sessions at which only independent directors are present. Each of the Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee of our Board are comprised entirely of directors determined by the Board to be independent within the meaning of Nasdaq and SEC rules and regulations applicable to the members of such committees.

Leadership Structure of the Board

Our bylaws and Corporate Governance Guidelines provide our Board with flexibility to combine or separate the positions of Chair of the Board and Chief Executive Officer and/or the implementation of a lead director in accordance with its determination that utilizing one or the other structure would be in the best interests of the Company. Mr. McDade currently serves as the Chair of our Board. In that role, Mr. McDade presides over the executive sessions of the Board in which Dr. Dallas does not participate, serves as a liaison to Dr. Dallas and management on behalf of the Board and performs such other duties and exercises such other powers as may from time to time be assigned by the bylaws or the Board.

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

Role of Board in Risk Oversight Process

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

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

Board Committees

Audit Committee

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

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

The current members of our Audit Committee are Kathryn E. Falberg, Mark D. McDade and Stacey D. Seltzer. Ms. Falberg serves as the chair of the committee. All members of our Audit Committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and Nasdaq. Our Board has determined that Ms. Falberg is an Audit Committee financial expert as defined under the applicable rules of the SEC and has the requisite financial sophistication as defined under the applicable rules and regulations of Nasdaq. Under the rules of the SEC, members of the Audit Committee must also meet heightened independence standards. Our Board has determined that each of Ms. Falberg, Mr. McDade and Ms. Seltzer are independent under the applicable rules of the SEC and Nasdaq.

The Audit Committee operates under a written charter that satisfies the applicable standards of the SEC and Nasdaq. A copy of the Audit Committee charter is available to security holders on the Company's website at http://ir.aimmune.com.

Compensation Committee

Our Compensation Committee oversees policies relating to compensation and benefits of our officers and employees. The Compensation Committee reviews and determines or, if applicable, recommends to our Board corporate goals and objectives relevant to the compensation of our executive officers, including the Chief Executive Office, evaluates the performance of these officers in light of those goals and objectives and approves the compensation of these officers based on such evaluations. The Compensation Committee also approves the grant of stock options and other equity awards under our stock plans. The Compensation Committee will

review and evaluate, at least annually, the performance of the Compensation Committee and its members, including compliance by the Compensation Committee with its charter.

The current members of our Compensation Committee are Patrick G. Enright, Kathryn E. Falberg and Mark T. Iwicki. Mr. Enright serves as the chair of the committee. Each of the members of our Compensation Committee is independent under the applicable rules and regulations of Nasdaq and is a "non-employee director" as defined in Rule 16b-3 promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act").

Our executive officers submit proposals to the board and the Compensation Committee regarding our executive compensation. Our Chief Executive Officer also annually reviews the performance of each executive officer and makes recommendations regarding their compensation. The Compensation Committee considers those recommendations in determining base salaries, adjustments to base salaries, annual cash bonus program targets and awards and equity awards, if any, for the executive officers and other members of senior management.

Our Compensation Committee has retained Radford, Inc. ("Radford"), a nationally-recognized compensation consulting firm, to serve as its independent compensation consultant and to conduct market research and analysis on our various executive positions, to assist the committee in developing appropriate incentive plans for our executives on an annual basis, to provide the committee with advice and ongoing recommendations regarding material executive compensation decisions, and to review compensation proposals of management. Radford reports directly to the Compensation Committee and does not provide any non-compensation related services to the Company. The Compensation Committee reviewed the independence of Radford, employing the independence factors specified in the listing requirements of Nasdaq. Based on this assessment, the Compensation Committee determined that the engagement of Radford does not raise any conflicts of interest or similar concerns. In addition, the Compensation Committee evaluated the independence of its other outside advisors to the Compensation Committee, including outside legal counsel, considering the same independence factors and concluded their work for the Compensation Committee does not raise any conflicts of interest.

The Compensation Committee operates under a written charter that satisfies the applicable standards of the SEC and Nasdaq rules. A copy of the Compensation Committee charter is available to security holders on the Company's website at http://ir.aimmune.com.

Nominating and Corporate Governance Committee

The Nominating and Corporate Governance Committee is responsible for making recommendations to our Board regarding candidates for directorships and the size and composition of our Board. In addition, the Nominating and Corporate Governance Committee is responsible for overseeing our corporate governance policies and reporting and making recommendations to our Board concerning governance matters.

The current members of our Nominating and Corporate Governance Committee are Patrick G. Enright, Mark D. McDade and Mark T. Iwicki. Mr. McDade serves as the chair of the committee. Each of the members of our Nominating and Corporate Governance Committee is an independent director under the applicable rules and regulations of Nasdaq relating to Nominating and Corporate Governance Committee independence.

The Nominating and Corporate Governance Committee operates under a written charter that satisfies the applicable standards of the SEC and Nasdaq rules. A copy of the Nominating and Corporate Governance Committee charter is available to security holders on the Company's website at http://ir.aimmune.com.

Our Nominating and Corporate Governance Committee is responsible for reviewing with the Board, on an annual basis, the appropriate characteristics, skills and experience required for the Board as a whole and its individual members. In evaluating the suitability of individual candidates (both new candidates and current members), the Nominating and Corporate Governance Committee, in recommending candidates for election, and the Board, in approving (and, in the case of vacancies, appointing) such candidates, may take into account many factors, including but not limited to the following: diversity of personal and professional background, perspective and experience; personal and professional integrity, ethics and values; experience in corporate management, operations or finance, such as serving as an officer or former officer of a publicly-held company, and a general understanding of marketing, finance and other elements relevant to the success of a publicly-traded company in today's business environment; experience relevant to our industry and with relevant social policy concerns; experience as a board member or executive officer of another publicly-held company; relevant academic expertise or other proficiency in an area of our operations; practical and mature business judgment, including ability to make independent analytical inquiries; promotion of a diversity of business or career experience relevant to the success of our company; and any other relevant qualifications, attributes or skills.

The Board evaluates each individual in the context of the Board as a whole, with the objective of assembling a group that can best maximize the success of the business and represent stockholder interests through the exercise of sound judgment using its diversity of experience in these various areas.

The Nominating and Corporate Governance Committee will consider director candidates recommended by stockholders. For a stockholder to make any nomination for election to the Board at an annual meeting, the stockholder must provide notice to the Company, which notice must be delivered to, or mailed and received at, the Company's principal executive offices not less than 90 days and not more than 120 days prior to the one-year anniversary of the preceding year's annual meeting; provided, that if the date of the annual meeting is more than 30 days before or more than 60 days after such anniversary date, the stockholder's notice must be delivered, or mailed and received, not later than 90 days prior to the date of the annual meeting or, if later, the 10th day following the date on which public disclosure of the date of such annual meeting is made. Further updates and supplements to such notice may be required at the times, and in the forms, required under our bylaws. As set forth in our bylaws, submissions must include the name and address of the proposed nominee, information regarding the proposed nominee that is required to be disclosed in a proxy statement or other filings in a contested election pursuant to Section 14(a) under the Exchange Act, information regarding the proposed nominee's indirect and direct interests in shares of the Company's common stock, and a completed and signed questionnaire, representation and agreement of the proposed nominee. Our bylaws also specify further requirements as to the form and content of a stockholder's notice. We recommend that any stockholder wishing to make a nomination for director review a copy of our bylaws, as amended and restated to date, which is available, without charge, from our Corporate Secretary, at 8000 Marina Blvd., Suite 300, Brisbane, California 94005.

Research and Development Committee

The Research and Development Committee reviews, evaluates and advises the Board on the overall strategy, objectives and progress of our research and development programs. This includes regularly reviewing and making recommendations to the Board and management with respect to the Company's research and development goals, strategies and measures, as well as assessing progress and performance, of the Company's clinical programs and research and development activities, performing strategic reviews of the Company's key clinical and preclinical research and development programs, understanding emerging or evolving regulatory, research or scientific issues of importance to us and assisting the Board in understanding our intellectual property position in connection with the foregoing and otherwise, and periodically reviewing the Company's scientific capability, infrastructure, resources, competency, talent, and output of the Company's scientific advisory board(s).

The current members of our Research and Development Committee are Brett K. Haumann, M.D. and Stacey D. Seltzer. Dr. Haumann serves as the chairperson of the committee.

Meetings of the Board of Directors, Board and Committee Member Attendance and Annual Meeting Attendance

Our Board met eleven times and acted by unanimous written consent five times during 2019. The Audit Committee met five times and did not act by unanimous written consent. The Compensation Committee met six times and acted by unanimous written consent seven times. The Nominating and Corporate Governance Committee met three times and did not act by unanimous written consent. During 2019, each Board member attended at least 75% of the aggregate number of meetings of the Board and of the committees of the Board on which he or she served, in each case, to the extent appointed as a Board member or committee member at the relevant time of each meeting, with the following exceptions: Greg Behar attended 55% of the aggregate number of meetings of the Board. We encourage all of our directors and nominees for director to attend our annual meeting of stockholders; however, attendance is not mandatory. Seven members of our Board attended our 2019 Annual Meeting.

Stockholder Communications with the Board of Directors

Should stockholders wish to communicate with the Board or any specified individual directors, such correspondence should be sent to the attention of the Corporate Secretary, at 8000 Marina Blvd., Suite 300, Brisbane, California 94005. The Corporate Secretary will forward the communication to the Board members.

Compensation Committee Interlocks and Insider Participation

During 2019, our Compensation Committee included Mr. Enright, Mr. Iwicki and Ms. Falberg. None of the members of our Compensation Committee has at any time been one of our officers or employees. None of our executive officers currently serves, or in the past fiscal year has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers on our Board or Compensation Committee.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

We describe below transactions and series of similar transactions, since January 1, 2019, to which we were a party or will be a party, in which:

- the amounts involved exceeded or will exceed $120,000; and
- any of our directors, executive officers or holders of more than 5% of our common stock, or an affiliate or immediate family member thereof, had or will have a direct or indirect material interest.

Director and Executive Officer Compensation

See "Director Compensation," "Compensation Discussion and Analysis" and "Executive Compensation Tables" for information regarding the compensation of our directors and executive officers.

Employment Agreements

We have entered into employment agreements with our executive officers. For more information regarding these agreements, see "Compensation Discussion and Analysis."

Indemnification Agreements and Directors' and Officers' Liability Insurance

We have entered into indemnification agreements with each of our directors and executive officers. These agreements, among other things, require us to indemnify each director and executive officer to the fullest extent permitted by Delaware law, including indemnification of expenses such as attorneys' fees, judgments, penalties, fines and settlement amounts incurred by the director or executive officer in any action or proceeding, including any action or proceeding by or in right of us, arising out of the person's services as a director or executive officer.

Investor Rights Agreement

We entered into an amended and restated investor rights agreement with certain of our investors, including entities with which certain of our directors are or were affiliated, prior to our initial public offering in August 2015. As of December 31, 2019, the holders of approximately 6.0 million shares of our common stock, including the shares of common stock issuable upon exercise of outstanding options, are entitled to rights with respect to the registration of their shares under the Securities Act.

Collaboration with Nestle Health Science

In November 2016, we entered into a two-year strategic collaboration with an affiliate of Nestle Health Science US Holdings, Inc. for the advancement of food allergy therapeutics and issued and sold to Nestle Health Science US Holdings, Inc. (together with its affiliate, Nestle Health Science) 7,552,084 shares of common stock in a private placement at a price of $19.20 per share, which represented approximately 15.1% of our outstanding shares at the time of the transaction. Subject to certain limited exceptions, Nestle Health Science agreed to a two-year market standoff provision under which it agreed not to sell or transfer any of our common stock or other securities. Subject to certain limited exceptions, Nestle Health Science also agreed to a two-year standstill agreement under which Nestle Health Science agreed not to acquire us through any means. We agreed to register the resale of the shares that Nestle Health Science purchased on a registration statement to be filed with the SEC upon the request of Nestle Health Science, which cannot make the request prior to the 45th day preceding the end of the market standoff provision. The investment and the collaboration do not include any development milestones, product marketing rights or royalties.

In November 2018, we entered into an extension of the strategic collaboration on similar terms and issued and sold an additional 3,237,529 shares of our common stock in a private placement at a price of $30.27 per share for aggregate proceeds of $98.0 million, increasing Nestlé Health Science's ownership of Aimmune to approximately 19%. The transaction documents include the extension of the registration rights, standstill rights and market standoff provisions. We are not subject to any partnership, collaboration, or negotiation restrictions under the extension agreements. In addition, we retain all rights to our current and future pipeline assets, and we and Nestlé Health Science expect to continue to collaborate towards the successful development of such assets.

The initial investment launched a two-year strategic collaboration, which was extended for an additional two years in November 2018, between us and Nestle Health Science, the terms of which enable both parties to discuss our current and future oral immunotherapy development programs through a newly established pipeline forum. Nestle Health Science will provide ongoing scientific, regulatory, and commercial expertise and advice to us through the pipeline forum. Any information disclosed in the collaboration will remain our confidential information, and any new ideas or inventions that arise that relate to our products will be our solely owned intellectual property. During the term of the collaboration, and for so long as Nestle Health Science holds not less

than fourteen percent of our outstanding common stock, Nestle Health Science will be entitled to designate one nominee to serve as a director on our Board of Directors. In November 2016, Greg Behar joined our Board of Directors on behalf of Nestle Health Science. The strategic collaboration agreement contains a non-competition covenant pursuant to which Nestle Health Science has agreed not to engage in certain activities relating to OIT for the treatment of food allergies. For the year ended December 31, 2019, we neither paid nor received any amounts to or from Nestle Health Science in connection with activities carried out in connection with the collaboration.

In February 2020, we announced a $200.0 million equity investment by Nestle Health Science S.A. and the extension of our existing strategic collaboration designed to enable the development and commercialization of innovative food allergy therapies, which will terminate in November 2021.

In connection with the February 2020 equity investment, we entered into a Securities Purchase Agreement (the "Purchase Agreement"), dated as of February 4, 2020 (the "Effective Date"), by and between the Company and Nestle Health Science US Holdings, Inc., a Delaware corporation ("NHSc US"). In connection with the extension of the existing strategic collaboration, we entered into an Amended and Restated Strategic Collaboration Agreement (the "Strategic Collaboration Agreement"), dated as of the Effective Date, with Société des Produits Nestlé S.A., a company organized and existing under the laws of Switzerland and the successor to Nestec Ltd. ("Nestlé"), which is a research and development subsidiary of Swiss food, nutrition and wellness company, Nestlé. Pursuant to the Purchase Agreement, we and NHSc US also entered into an Amended and Restated Standstill Agreement (the "Standstill Agreement") and an Amended and Restated Registration Rights Agreement (the "Registration Rights Agreement"), each dated as of the Effective Date. Pursuant to the Strategic Collaboration Agreement, we and Nestlé (through itself and one or more affiliated entities) agreed to continue to collaborate with one another in connection with the development of our products.

Pursuant to the Purchase Agreement, we agreed to issue and sell to NHSc US (i) 1,000,000 shares of our common stock for an aggregate cash purchase price of $31,970,000.00, representing approximately 1.5% of our outstanding common stock and (ii) 525,634 shares of our Series A Preferred Stock for an aggregate cash purchase price of $168,032,048.95 (collectively, the "NHSc Shares"). The NHSc Shares were issued and sold to NHSc US at a price per share of commons stock of $31.97 and a price per share of Series A Preferred Stock of $319.675.

Policies and Procedures for Related Party Transactions

Our Board has adopted a written related person transaction policy setting forth the policies and procedures for the review and approval or ratification of related person transactions. This policy covers, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act of 1933, as amended, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships in which we were or are to be a participant, where the amount involved exceeds $120,000 and a related person had or will have a direct or indirect material interest, including, without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our Audit Committee is tasked to consider all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction with an unrelated third party and the extent of the related person's interest in the transaction.

REPORT OF THE COMPENSATION COMMITTEE OF THE BOARD OF DIRECTORS

The material in this report is not "soliciting material," 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.

The Compensation Committee reviewed and discussed with management the "Compensation Discussion and Analysis" included in this Proxy Statement. Based on those reviews and discussions, the Compensation Committee recommended to the Board that the "Compensation Discussion and Analysis" be included in this Proxy Statement.

Compensation Committee
Patrick G. Enright, Chair
Mark T. Iwicki
Kathryn E. Falberg

DIRECTOR COMPENSATION

We maintain a compensation policy for our non-employee directors (the "Director Compensation Program"), which was last amended by the Board in May 2019, upon recommendation by the Compensation Committee following its review of a competitive assessment prepared, and recommendations made, by Radford, our independent compensation consultant. Pursuant to the Director Compensation Program, each non-employee director receives an annual retainer of $40,000 and a non-employee director serving as Chair of the Board receives an additional annual retainer of $30,000. Non-employee directors who serve on one or more committees are eligible to receive the following annual committee fees:

Committee	Chair	Other Member
Audit Committee	$ 20,000	$ 10,000
Compensation Committee	15,000	7,500
Nominating and Corporate Governance Committee	10,000	5,000
Research and Development Committee	11,000	5,500

Under the Director Compensation Program, each non-employee director who is elected or appointed to our Board will automatically be granted an option to purchase our common stock having a grant date fair value of $225,000, calculated based on the 30-day average closing price of our common stock as of the trading day immediately preceding the date of grant and using assumptions published in our most recent periodic report as of the date of grant, and a number of restricted stock units ("RSUs") calculated by dividing $225,000 by the 30-day average closing price of our common stock as of the trading day immediately preceding the date of grant, in each case, with such grant to be made upon the director's initial appointment or election to our Board, referred to as the Initial Grant. In addition, each non-employee director who is serving on our Board immediately following an annual stockholder's meeting will automatically be granted an option to purchase our common stock having a grant date fair value of $132,500, calculated based on the 30-day average closing price of our common stock as of the trading day immediately preceding the date of grant and using assumptions published in our most recent periodic report as of the date of grant, and that number of RSUs calculated by dividing $132,500 by the 30-day average closing price of our common stock as of the trading day immediately preceding the date of grant, in each case, with such grant to be made on the date of such annual stockholder's meeting, referred to as the Annual Grant. The option underlying the Initial Grant will vest as to 1/36th of the shares subject to the option each month following the applicable grant date and the RSUs underlying the Initial Grant will vest as to 1/3rd of the RSUs on each anniversary of the applicable grant date, in each case, subject to continued service through the applicable vesting date. The Annual Grant will vest as to all of the shares subject to the Annual Grant on the earlier of the first anniversary of the applicable grant date or the next annual stockholders' meeting, subject to continued service through the vesting date. All equity awards, including any Initial Grants and Annual Grants, held by our non-employee directors will vest in full immediately prior to the occurrence of a change in control. Our non-employee directors received Annual Grants pursuant to the amended Director Compensation Program at our 2019 annual meeting of stockholders.

Director Compensation Table

The following table sets forth information concerning the compensation earned by our non-employee directors during the year ended December 31, 2019.

Name	Fees Earned or Paid in Cash[1]	Option Awards[2]	RSU Awards	Total
Greg Behar	$ 43,041	$ 126,406	$ 128,196	$ 297,643
Patrick G. Enright	62,041	126,406	128,196	316,643
Kathryn E. Falberg	70,166	126,406	128,196	324,768
Brett K. Haumann, M.D. [3]	—	—	—	—
Mark T. Iwicki	54,916	126,406	128,196	309,518
Mark D. McDade	92,541	126,406	128,196	347,143
Stacey D. Seltzer	57,166	126,406	128,196	311,768

(1) The amounts reported in this column represent the aggregate dollar amount of all fees earned or paid in cash to each non-employee director in fiscal 2019 for their service as a director, including any annual retainer fees, committee and/or chair fees.

(2) The amounts reported in this column represent the grant date fair value calculated in accordance with the provisions of Accounting Standards Codification ("ASC") Topic 718, *Compensation – Stock Compensation*. The valuation assumptions used in determining such amounts are described in Note 8 to our consolidated financial statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019.

(3) Dr. Haumann was elected as a Class II director on October 31, 2018. Dr. Haumann has waived any right to receive compensation from us pending a change in his visa status that permits the payment of compensation for services provided in the United States.

At December 31, 2019, our non-employee directors held the following outstanding options and restricted stock units:

Name	Shares Subject to Outstanding Options (#)	Shares Subject to Outstanding Restricted Stock Units (#)
Greg Behar	75,942	6,442
Patrick G. Enright	174,457	6,442
Kathryn E. Falberg	56,187	6,442
Mark T. Iwicki	195,976	6,442
Mark D. McDade	161,029	6,442
Stacey D. Seltzer	108,608	6,442

EXECUTIVE OFFICERS

The following is biographical information for our executive officers, including their ages as of April 1, 2020.

Name	Age	Position(s)
Jayson D.A. Dallas, M.D.	52	President, Chief Executive Officer and Director
Eric H. Bjerkholt	60	Chief Financial Officer
Daniel C. Adelman, M.D.	62	Chief Medical Officer
Andrew Oxtoby	46	Chief Commercial Officer
Douglas T. Sheehy	53	General Counsel and Secretary

Executive Officers

Dr. Dallas' biographical information is included above under "Proposal No. 1 Election of Directors."

Eric H. Bjerkholt has served as our Chief Financial Officer since April 2017. Prior to joining Aimmune, he was CFO at Sunesis Pharmaceuticals, Inc., where, over 13 years with the company, his role expanded to oversee business development and multiple aspects of governance and corporate relations. Prior to Sunesis, Mr. Bjerkholt was CFO at IntraBiotics Pharmaceuticals, Inc., and LifeSpring Nutrition, Inc. He began his healthcare career at J.P. Morgan & Co. as an investment banker in New York and then launched the company's Western U.S. healthcare practice. Mr. Bjerkholt holds a Cand. Oecon. (master's) degree in economics from the University of Oslo and an MBA from Harvard Business School. He has served on the boards of directors of several publicly-traded companies and is currently a member of the board of directors of Cerus Corporation.

Daniel C. Adelman, M.D. has served as our Chief Medical Officer since June 2016. From 2009 to September 2015, Dr. Adelman served as Chief Medical Officer and Senior Vice President of Development of Alvine Pharmaceuticals, Inc., a biopharmaceutical company. Additionally, Dr. Adelman was a member of the Research Advisory Board of Food Allergy Research & Education (FARE), Inc., a non-profit organization, from 2011 to June 2016. From 2003 to 2008, Dr. Adelman served as Chief Medical Officer and Senior Vice President of Development at Sunesis Pharmaceuticals, Inc., a pharmaceutical company. From 1998 to 2003, Dr. Adelman held various positions at Pharmacyclics, Inc., a pharmaceutical company, including Vice President of Clinical Operations and Biometrics. From 1994 to 1998, Dr. Adelman served as Clinical Scientist at Genentech. Dr. Adelman is also currently an Adjunct Professor of Medicine at the University of California, San Francisco, where he has taught and practiced for more than 25 years. Dr. Adelman received an A.B. degree in Biology from the University of California, Berkeley, and an M.D. from the University of California, Davis. Dr. Adelman is a co-founder of Sixal, Inc., and serves as a member of its board of directors and chair of the scientific advisory board.

Andrew Oxtoby has served as our Chief Commercial Officer since January 2019. Prior to joining Aimmune, Mr. Oxtoby was the Vice President US Diabetes Connected Care & Insulins at Eli Lilly & Company ("Lilly") from July 2018 to January 2019. Prior to this, Mr. Oxtoby held a number of leadership roles at Lilly in both the US and Europe, including Vice President US Diabetes Sales from March 2017 to June 2018, Vice President International Oncology from January 2015 to February 2017, Global R&D Leader for Thoracic Oncology Products from May 2012 to December 2014, and Managing Director of Lilly Netherlands from December 2009 to April 2012. Prior to joining Lilly, Mr. Oxtoby worked at Procter & Gamble from 1996 to 2000 and held positions in engineering and R&D in multiple business units. Mr. Oxtoby earned his undergraduate degree in Mechanical Engineering from Purdue University and his MBA from Harvard Business School.

Douglas T. Sheehy has served as our General Counsel and Secretary since April 2016. Prior to joining Aimmune, Mr. Sheehy served as Executive Vice President, Chief Administrative Officer, General Counsel and Secretary of Codexis, Inc., a protein engineering company that develops biocatalysts for the pharmaceutical and fine chemical industries, from February 2014 to April 2016, as Senior Vice President, General Counsel and Secretary from 2009 to February 2014 and as Vice President, General Counsel and Secretary from 2007 to 2009. Prior to Codexis, Mr. Sheehy spent five years in key legal roles at CV Therapeutics, Inc., a publicly-held biopharmaceutical company that was subsequently acquired by Gilead Sciences, Inc. in 2009. He began his legal career as a corporate attorney at Gunderson Dettmer LLP. Mr. Sheehy holds a B.A. in history from Dartmouth College and a J.D. from American University, where he was Editor-in-Chief of the American University Law Review.

COMPENSATION DISCUSSION AND ANALYSIS

General

The following Compensation Discussion and Analysis ("CD&A") provides information on the compensation arrangements for our Named Executive Officers (our Chief Executive Officer, our Chief Financial Officer and our other three most highly compensated executive officers serving at the end of fiscal 2019, collectively our "NEOs") and is intended to provide context for the decisions underlying the compensation paid to our NEOs in 2019. This CD&A should be read together with the compensation tables and related disclosures set forth below. Our NEOs for 2019 and their positions with the Company as of December 31, 2019 were as follows:

- Dr. Jayson D.A. Dallas, President and Chief Executive Officer;
- Eric H. Bjerkholt, Chief Financial Officer;
- Dr. Daniel C. Adelman, Chief Medical Officer;
- Andrew A. Oxtoby, Chief Commercial Officer; and
- Douglas T. Sheehy, General Counsel and Secretary.

Executive Summary

2019 Performance Highlights and Pay for Performance. Our executive compensation programs are designed to deliver pay in accordance with corporate and individual performance, rewarding superior performance and providing consequences for underperformance. We believe that compensation of our NEOs for fiscal year 2019 was aligned with the Company's performance during 2019. Highlights of that performance include, but are not limited to:

- In September 2019, the FDA Allergenic Products Advisory Committee voted to support use of PALFORZIA for peanut allergy; this positive outcome supported the FDA's approval of PALFORZIA in January 2020 as the first approved treatment for patients with peanut allergy.
- In December 2019, we had substantially prepared the Company to launch PALFORZIA in the United States shortly after approval by the FDA.
- In June 2019, we submitted a marketing authorization application, or MAA, to the European Medicines Agency, or EMA, for PALFORZIA for the treatment of peanut allergy.
- In March 2019, we announced that our Phase 3 ARTEMIS clinical trial of AR101 for the treatment of peanut allergy met its primary efficacy endpoint.
- In March 2019, we announced that the biologics license application, or BLA, for PALFORZIA had been accepted for review by the FDA.
- In August 2019, we enrolled the first patient in a Phase 2 clinical trial of AR201 for the treatment of egg allergy.

In order to align pay with performance, a significant portion of our NEOs' compensation is delivered in the form of equity awards and annual cash incentives, each of which depends on our actual performance. For fiscal year 2019, 83% of the total target direct compensation for our NEOs was in the form of stock options, RSUs and annual cash incentives.

2019 Compensation Highlights. Consistent with our compensation philosophy, key compensation decisions for 2019 included the following:

- *Base Salaries and Target Annual Cash Incentive Opportunities.* The 2019 base salaries for our NEOs (other than Mr. Oxtoby) were increased between 3.5% and 7.5%, consistent with the overall budgeted increase for our executives. The 2019 target bonuses for each of our NEOs (other than Mr. Oxtoby) remained at their 2018 levels. Mr. Oxtoby's base salary and target bonus were established by our Compensation Committee in connection with his hiring following its review of a compensation study and recommendations by Radford.
- *Annual Cash Incentives.* For 2019, our Compensation Committee selected 10 primary performance goals for our performance-based annual bonus program that were intended to promote our business plan and short-term goals, including with respect to AR101, cash and financing, commercial launch readiness and pipeline progress, as well as two strategic "kicker" goals that could result in achievement over any primary goals. Our NEOs' annual bonus payouts were the result of our 106.5% achievement of the corporate goals as well as each NEOs' individual performance in 2019.

- *Equity-Based Long-Term Incentives.* In 2019, we granted 75% of the target direct compensation of our NEOs as equity-based compensation in the form of stock options and RSUs. We believe that stock options and RSUs effectively align the interests of our executives with those of our stockholders by directly linking compensation to the value of our common stock. Stock options require an increase in stockholder value in order for our NEOs to realize any value, and RSUs provide additional retentive value.

Compensation Governance and Best Practices. We are committed to having strong governance standards with respect to our compensation programs, procedures and practices. Our key compensation practices include the following:

- *Pay for performance.* A significant portion of executive compensation is "at risk" based on corporate performance, and additionally is equity-based, in order to align the interests of our executive officers with stockholders.
- *Strong link between performance measures and strategic objectives.* Performance measures for incentive compensation are linked to operating priorities designed to create long-term stockholder value.
- *Independent compensation consultant.* The Compensation Committee retains Radford, an independent compensation consultant, to review, and make recommendations regarding, our executive compensation program and practices.
- *No guaranteed annual salary increases or bonuses.* Our NEOs' salary increases are based on individual evaluations and their annual cash incentives are tied to corporate performance.
- *Limited tax gross ups.* We do not provide any tax gross ups other than limited gross ups of taxes incurred in connection with relocation expense reimbursements.
- *Limited perquisites.* We do not provide any perquisites or personal benefits to our NEOs, other than in limited circumstances.
- *No hedging or pledging.* We prohibit our employees and directors from hedging or pledging any Company securities.

Stockholder Advisory Vote on Executive Compensation

At our 2019 annual meeting of stockholders, our stockholders voted in a non-binding, advisory vote to approve the compensation of our named executive officers. Our compensation committee reviewed the result of this vote, and, in light of the approval by a substantial majority of our stockholders of the compensation programs described in our 2019 proxy statement (representing over 93% of the shares cast), did not implement any significant changes to our executive compensation program as a result of the vote. At our 2018 annual meeting of stockholders, our stockholders voted in a non-binding, advisory vote in favor of having a non-binding stockholder vote on executive compensation once every year. Consistent with the stated preference of a majority of our stockholders (representing approximately 99.9% of the shares cast), our next advisory vote on our named executive officers' compensation will be held at this 2020 annual meeting, pursuant to Proposal No. 3.

Executive Compensation Objectives and Philosophy

The key objective in our executive compensation program is to attract, motivate and reward leaders with the skills and experience necessary to successfully execute on our strategic plan to maximize stockholder value. Our executive compensation program is designed to:

- attract and retain talented and experienced executives in a competitive and dynamic market;
- motivate our NEOs to help the Company achieve the best possible financial and operational results;
- provide reward opportunities consistent with our performance on both a short-term and long-term basis; and
- align the long-term interests of our NEOs with those of our stockholders.

We strive to set our overall total compensation at a competitive level. Executives may be compensated above or below the targeted market position based on factors such as experience, performance, scope of position and the competitive demand for proven executive talent, as described further below under "*Determination of Executive Compensation*."

Determination of Executive Compensation

Our Compensation Committee is responsible for establishing and overseeing our executive compensation programs and annually reviews and determines the compensation to be provided to our NEOs. In setting executive compensation, the Compensation Committee considers a number of factors, including the recommendations of our Chief Executive Officer (other than with respect to himself), current and past total compensation, competitive market data and analysis provided by the Compensation Committee's independent compensation consultant, Company performance and each executive's impact on performance, each executive's relative

scope of responsibility and potential, each executive's individual performance and demonstrated leadership and internal equity pay considerations. Our Chief Executive Officer's recommendations are based on his evaluation of each other NEO's individual performance and contributions. Our Compensation Committee makes decisions regarding our Chief Executive Officer's compensation with input from the full Board of Directors.

Competitive Market Data and Independent Compensation Consultant

In order to design a competitive executive compensation program that will continue to attract top executive talent, our Compensation Committee engages an independent compensation consultant to provide a competitive review of executive compensation, including base salary, annual incentives and equity compensation as compared with market data. Our Compensation Committee has retained Radford to provide these services.

In consultation with Radford, in September 2018, our Compensation Committee approved a new peer group (the "2018 Peer Group") based on the following general criteria: (i) U.S.-based biotechnology companies, with an emphasis on recently public companies and in biotech "hub" markets; (ii) pre-commercial companies, with similar disease focus where possible; (iii) market capitalization between $500 million and $4.5 billion; and (iv) companies with between 40 to 400 full-time employees. The 2018 Peer Group was comprised of the following companies:

- Acceleron Pharma
- Adamas Pharmaceuticals
- Aerie Pharmaceuticals
- Agios Pharmaceuticals
- Akebia Therapeutics
- Atara Biotherapeutics
- ChemoCentryx
- Dynavax Technologies
- Enanta Pharmaceuticals
- Epizyme
- FibroGen
- Five Prime Therapeutics
- Flexion Therapeutics
- Global Blood Therapeutics
- Karyopharm
- MyoKardia
- Portola Pharmaceuticals
- Revance Therapeutics
- Sangamo Therapeutics
- Spark Therapeutics
- Ultragenyx Pharmaceuticals
- Xencor

As of August 2018, as compared to the 2018 Peer Group, we were at the 47th percentile for 30-day average market capitalization and the 24th percentile for headcount. In October 2018, our Compensation Committee reviewed Radford's analysis of our 2018 executive compensation program with respect to the most recently filed proxy information for the 2018 Peer Group and the Radford 2018 Life Sciences Industry Survey, which included a select cut of our peer companies and public U.S. pre-commercial bio/pharma companies with headcount between 40 and 400, market capitalization between $500 million and $4.5 billion, and revenues under $50 million. Our Compensation Committee was not aware of the constituent companies in the broader survey data. Radford's analysis did not include Mr. Oxtoby, who was hired in January 2019. Based on this analysis and consistent with our compensation approach for 2018, Dr. Adelman's target cash compensation was between the 50th and 75th percentile of market, and our other NEOs' target cash compensation (excluding Mr. Oxtoby) was between the 25th and 50th percentiles of market. In addition, our NEOs' annual equity grant values (excluding Mr. Oxtoby), were between the 50th and >75th percentiles of market.

Our Compensation Committee generally uses the peer group to help structure a competitive executive compensation program, position executive compensation by considering market data, and make individual compensation decisions based on comparable positions at companies with which we compete for talent. While the Compensation Committee does not establish compensation levels solely based on a review of competitive data, it believes such data is a useful tool in its deliberations as our compensation policies and practices must be competitive in the marketplace for us to be able to attract, motivate and retain qualified executive officers.

Components of Compensation

The primary elements of our NEOs' compensation and the main objectives of each are:

- *Base Salary.* Base salary attracts and retains talented executives, recognizes individual roles and responsibilities and provides stable income.
- *Annual Performance-Based Incentive Compensation.* Annual performance bonuses promote short-term performance objectives and reward executives for their contributions toward achieving those objectives.
- *Equity-Based Long-Term Incentive Compensation.* Equity compensation, provided in the form of stock options and RSUs, aligns executives' interests with our stockholders' interests, emphasizes long-term financial and operational performance, and helps retain executive talent.

In addition, our NEOs are eligible to participate in our health and welfare programs and our 401(k) plan on the same basis as our other employees. We are also party to employment agreements that provide for severance and change in control benefits, which aid in attracting and retaining executive talent and help executives to remain focused and dedicated during potential transition periods due to a change in control. Each of these elements of compensation for 2019 is described further below.

Base Salary

Base salaries provide our NEOs with a reasonable degree of financial certainty and stability. Our Compensation Committee annually reviews and determines the base salaries of our executives and evaluates the base salaries of new hires at the time of hire. In February 2019, our Compensation Committee approved salary increases for our then-serving NEOs in a range of 3.5% to 4.0%, consistent with the budgeted base salary increase for all of our executives. The base salary for Dr. Dallas was set by the Compensation Committee at the time of his hire in June 2018 following the review of a compensation study by Radford summarizing his compensation arrangement with his prior employer and the compensation levels paid by the 2017 Peer Group. Following such determinations, our NEOs' 2019 base salaries were as set forth below:

Name	2018 Annualized Base Salary	2019 Annualized Base Salary
Dr. Jayson D.A. Dallas	$ 535,000	$ 575,000
Eric H. Bjerkholt	414,000	436,500
Dr. Daniel C. Adelman	430,600	445,700
Andrew Oxtoby	—	420,000
Douglas T. Sheehy	374,980	401,300

Annual Performance-Based Incentive Compensation

We have adopted the Aimmune Therapeutics Company Bonus Plan pursuant to which we establish annual performance-based bonus programs in order to motivate our executives to meet or exceed company-wide short-term performance objectives. Our annual bonus program provides for the payment of cash bonuses based on each NEOs' target annual bonus and our achievement of corporate performance objectives and each NEO's individual performance in a given year.

In February 2019, our Compensation Committee determined not to increase the target bonus of each of our then-serving NEOs, which for each of our NEOs was 40% of base salary, other than our Chief Executive Officer whose target bonus was 60% of base salary. Mr. Oxtoby's target bonus was set at 40% of his base salary at the time he was hired in January 2019, consistent with our other NEOs.

For fiscal year 2019, our Compensation Committee approved 11 primary performance goals under our annual bonus program relating to the following areas: (i) products; (ii) performance; (iii) pipeline and lifecycle management; and (iv) people. Our 2019 annual bonus program also included two strategic "kicker" goals, which could result in an aggregate overachievement of 20% at target achievement for such kicker goals. The products goals included progress towards approval for AR101 in the U.S., readiness to launch AR101 in the U.S. and the filing of an MAA with the EMA by pre-established target deadlines. The performance goals included AR101 net revenue, management of 2019 cash spend in accordance with our forecast and ending 2019 with a certain number of months of funding, payor education objectives and investor and media outreach objectives. The pipeline and lifecycle management goals included screening the first patient for an egg allergy candidate in a Phase 2 study, finalizing a strategy for a multi-nut product and AR101 product advancement objectives. The people goal included continuing to build a strong employee experience at the company. The kicker goals related to certain corporate development activities and collaboration objectives. Given that some of our non-financial goals are related to our business strategy and are highly confidential, we do not publicly disclose them at all or in full detail. We believe their disclosure would provide our competitors, customers and other third parties with significant insights regarding our confidential business strategies that could cause us substantial competitive harm. These goals were set by our Compensation Committee at a level our Compensation Committee determined would require substantial effort to be achieved, such that the goals would not be expected to be achieved with average or below average performance.

For fiscal year 2019, our Compensation Committee allocated specific weightings to each performance goal. For most of the goals, the Compensation Committee established only a target level, corresponding to percentage achievement at 100%. However, for certain of the goals, the Committee also established threshold and stretch goals, corresponding to percentage achievement of 75% and 125%, respectively. The maximum attainable percentage achievement of our primary goals was 120%, and the maximum attainable percentage achievement of both our primary goals and kicker goals was 144%. Our corporate goals, their applicable weightings and actual achievement for 2019 are set forth in the table below:

Performance Area	Weight	Weighted Achievement
Products (3 sub goals)	30%	30.0%
Performance (4 sub goals)	40%	37.5%
Pipeline & Lifecycle Management (2 sub goals)	20%	18.0%
People (1 sub goals)	10%	8.0%
Total (primary goals)	**100%**	**93.5%**
"Kicker" (2 sub goals)	20%	10.0%
Total	**120%**	**103.5%**

Corporate goals and performance targets are reviewed and approved by the Compensation Committee, which seeks input from the Board prior to any allocation of the bonus. In February 2020, the Compensation Committee reviewed our 2019 company-wide performance and determined that the corporate goals had been achieved at 103.5% as detailed in the table above. The Compensation Committee also considered corporate achievements which were not captured in the corporate goals for fiscal year 2019, including efforts related to securing FDA approval of AR101, and increased the achievement factor of the corporate goals with respect to determining bonuses to executive officers of 106.5%.

Individual bonus payouts were determined 80% based on our company-wide achievement, and 20% based on our Compensation Committee's assessment of the NEO's individual performance except for the Chief Executive Officer, whose bonus payout was determined 100% based on our company-wide achievement. The Compensation Committee did not establish specific individual goals for our NEOs, but rather evaluated each in a holistic manner based on his or her area of responsibility and contributions to the Company, taking into account the recommendations of our Chief Executive Officer with respect to each NEO. Based on this evaluation, our Compensation Committee determined that each of our NEOs had achieved individual performance as follows: Mr. Bjerkholt, 100%; Dr. Adelman, 90%; Mr. Oxtoby, 120%; and Mr. Sheehy, 125%. The dollar amount of our NEOs' 2019 performance bonuses are set forth in the column entitled "Non-Equity Incentive Plan Compensation" in the "2019 Summary Compensation Table" below.

Equity-Based Long-Term Incentive Awards

Our Compensation Committee believes it is essential to provide equity-based compensation to our executive officers in order to link the interests and risks of our executive officers with those of our stockholders, reinforcing our commitment to ensuring a strong linkage between company performance and pay. During 2019, we granted each of our NEOs stock options and RSUs.

In connection with the commencement of Mr. Oxtoby's employment with us, in January 2019, we granted Mr. Oxtoby an option to purchase 150,000 shares of our common stock and 12,000 RSUs. The option vests as to 25% of the total number of shares subject to the option on the first anniversary of Mr. Oxtoby's commencement of employment with us and as to 1/48th of the total number of shares subject to the option on each monthly anniversary of his commencement of employment thereafter, subject to his continued service through the applicable vesting date. The RSUs vest as to 1/4th of the total number of RSUs on each anniversary of Mr. Oxtoby's commencement of employment with us, subject to his continued service through the applicable vesting date.

In February 2019, we made the following grants of stock options and RSUs to our NEOs (other than Mr. Oxtoby):

Name	Number of Shares Underlying Stock Options	Number of Shares Underlying Restricted Stock Units
Dr. Jayson D.A. Dallas	210,000	35,000
Eric H. Bjerkholt	78,750	13,125
Dr. Daniel C. Adelman	71,250	11,875
Douglas T. Sheehy	75,000	12,500

The stock option awards vest as to 1/48th of the total number of shares subject to the option on each monthly anniversary of March 1, 2019, subject to continued service through the applicable vesting date. The RSU awards vest as to 1/4th of the total number of RSUs on each anniversary of March 1, 2019, subject to continued service through the applicable vesting date.

Consistent with our compensation philosophy for 2019, these equity award grants were approved following consideration of the 50th to 75th percentile of market, internal pay equity among executive officers with similar levels of responsibility, and retention value.

Retirement Savings, Health and Welfare Benefits

Our NEOs participate in our company-sponsored benefit programs on generally the same basis as other salaried employees, including a standard complement of health and welfare benefit plans and a 401(k) plan, which is intended to qualify under Section 401(k) of the Code, such that a portion of their eligible compensation may be deferred on a pre-tax basis. Under the 401(k) plan, employees may elect to reduce their current compensation by up to the statutorily prescribed annual limit and to have the amount of such reduction contributed to the 401(k) plan. During 2019, the Company matched contributions up to an annual maximum of $2,000 with immediate vesting.

Perquisites and Other Personal Benefits

We do not view perquisites or other personal benefits as a significant component of our executive compensation program. We currently provide perquisites or other personal benefits to our NEOs in limited circumstances where we believe it is appropriate to assist an individual executive officer in the performance of his or her duties, to make our executive officers more efficient and effective or for recruitment, motivation, or retention purposes. All current and future practices with respect to perquisites or other personal benefits have been and will be approved by the Compensation Committee.

Employment and Severance Arrangements

We have entered into employment agreements with each of our NEOs, which set forth the terms and conditions of employment of each named executive officer, including base salary, target bonus, initial equity award grants, and standard employee benefit plan participation. The agreements also include certain change and control severance provisions, which our Compensation Committee believes are necessary to attract and retain executive talent and are a customary component of executive compensation. In particular, such provisions can serve to mitigate a potential disincentive for them when they are evaluating a potential acquisition of the Company and can encourage retention through the conclusion of the transaction. The change in control and severance payments and benefits provided under our executive employment agreements are designed to provide our NEOs with treatment that is competitive with market practices. A description of these provisions, as well as information on the estimated payments and benefits that our NEOs would have been eligible to receive as of December 31, 2019, are set forth under "*Potential Payments Upon Termination or Change in Control*" below.

Employment Agreement with Mr. Oxtoby

In connection with the appointment of Mr. Oxtoby as our Chief Commercial Officer effective January 22, 2019, we entered into an employment agreement with him, which provides for an initial annual base salary of $420,000 and an annual target bonus of 40% of annual base salary. Pursuant to the employment agreement, Mr. Oxtoby also received a new hire equity award, comprised of (i) an option to purchase 150,000 shares of Company common stock and (ii) 12,000 RSUs. The option vests as to 25% of the total number shares subject to the option on January 22, 2020 and as to 1/48th of the total number of shares subject to the option on each monthly anniversary thereafter, subject to his continued service through the applicable vesting date. The RSUs vest in equal installments on each of the first four anniversaries of January 22, 2019, subject to his continued service through each applicable vesting date.

Other Policies and Considerations

Derivatives Trading, Hedging, and Pledging Policies

Our Insider Trading Policy provides that no employee, officer, or director may acquire, sell, or trade in any interest or position relating to the future price of Company securities, such as a put option, a call option or a short sale (including a short sale "against the box"), or engage in hedging transactions (including "cashless collars"). In addition, our Insider Trading Policy provides that no employee, officer, or director may pledge Company securities as collateral to secure loans. This prohibition means, among other things, that these individuals may not hold Company securities in a "margin" account, which would allow the individual to borrow against their holdings to buy securities.

Deductibility of Compensation

Section 162(m) of the Internal Revenue Code disallows a tax deduction for any publicly-held corporation for individual compensation exceeding $1 million in any taxable year for all current and former named executive officers. While our Board and Compensation Committee may take the deductibility of compensation into account when making compensation decisions, we believe that maintaining the discretion to provide compensation that is non-deductible allows us to provide compensation tailored to the needs of our Company and our named executive officers and is an important part of our responsibilities and benefits our stockholders.

Nonqualified Deferred Compensation

The Compensation Committee takes into account whether components of the compensation for our executive officers will be adversely impacted by the penalty tax imposed by Section 409A of the Code and aims to structure these components to be compliant with or exempt from Section 409A to avoid such potential adverse tax consequences.

"Golden Parachute" Payments

Sections 280G and 4999 of the Code provide that certain executive officers and other service providers who are highly compensated or hold significant equity interests may be subject to an excise tax if they receive payments or benefits in connection with a change in control of the company that exceeds certain prescribed limits, and that we, or a successor, may forfeit a deduction on the amounts subject to this additional tax. We are not obligated to provide any NEO with a "gross-up" or other reimbursement payment for any tax liability that he or she might owe as a result of the application of Sections 280G or 4999.

Accounting for Share-Based Compensation

We follow ASC Topic 718 for our share-based compensation awards. ASC Topic 718 requires companies to measure the compensation expense for all share-based payment awards made to employees and directors, including stock options, based on the grant date "fair value" of these awards. This calculation is performed for accounting purposes and reported in the compensation tables below, even though our executive officers may never realize any value from their awards. ASC Topic 718 also requires companies to recognize the compensation cost of their share-based compensation awards in their income statements over the period that an executive officer is required to render service in exchange for the option or other award.

EXECUTIVE COMPENSATION TABLES

2019 Summary Compensation Table

The following table sets forth total compensation earned by our NEOs for the fiscal years presented.

Name and Principal Position	Year	Salary ($)	Bonus ($)[1]	Stock Awards ($)[2]	Option Awards ($)[2]	Non-Equity Incentive Plan Compensation ($) [3]	All Other Compensation ($) [4]	Total ($)
Dr. Jayson D.A. Dallas	2019	575,000	10,350	830,200	2,969,484	357,075	2,000	4,744,109
Chief Executive Officer	2018	287,562	—	1,840,800	6,781,145	337,000	—	9,246,507
Eric H. Bjerkholt	2019	436,500	4,190	311,325	1,113,557	179,489	2,000	2,047,061
Chief Financial Officer	2018	411,667	—	319,406	1,200,251	175,500	2,000	2,108,824
	2017	268,333	56,800	—	3,417,012	116,000	—	3,858,145
Dr. Daniel C. Adelman	2019	445,700	4,279	281,675	1,007,504	179,706	2,000	1,920,864
Chief Medical Officer	2018	427,333	—	319,406	1,200,251	182,600	2,000	2,131,590
	2017	411,667	—	—	1,158,858	177,800	—	1,748,325
Andrew Oxtoby[5]	2019	396,667	3,298	263,280	1,972,710	169,456	145,968	2,951,379
Chief Commercial Officer								
Douglas T. Sheehy	2019	401,300	3,852	296,500	1,060,530	173,041	2,000	1,937,223
General Counsel and Secretary	2018	372,883	—	1,107,275	1,600,335	165,000	2,000	3,247,493
General Counsel and Secretary	2017	360,250	58,000	—	1,158,858	155,600	—	1,732,708

(1) The amounts reported in the Bonus column represent the discretionary amount paid under the Company's annual bonus program based on corporate achievement outside of the pre-established goals under the annual bonus program.

(2) For the stock and option awards columns, amounts shown represent the grant date fair value of the awards granted as calculated in accordance with ASC Topic 718. See Note 8 to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2019 for the assumptions used in calculating this amount.

(3) The amounts reported in the Non-Equity Incentive Plan Compensation column represent the annual performance-based cash bonuses earned by our NEOs based on the achievement of certain company performance objectives and individual performance. For 2019, these amounts were paid to the NEOs in February 2020. See the descriptions of the annual performance bonuses paid to our NEOs under "*Annual Performance-Based Incentive Compensation*" above.

(4) Amounts represent Company contributions of $2,000 under our 401(k) plan for each of our NEOs, except for Mr. Oxtoby. Amounts reported for Mr. Oxtoby of $145,968 include $82,452 for costs for temporary housing, $9,989 for other relocation-related costs, and $53,528 for tax gross-up payments on relocation benefits.

(5) Mr. Oxtoby commenced employment with us on January 22, 2019.

2019 Grants of Plan-Based Awards

The following table summarizes information about the non-equity incentive plan compensation and equity-based awards granted to our NEOs in 2019.

		Estimated Future Payouts Under Non-Equity Incentive Plan Awards[1]						
Name	Grant Date[2]	Threshold ($)	Target ($)	Maximum ($)	All Other Stock Awards: (#) of Shares of Stock or Units	All Other Option Awards: (#) of Securities Underlying Options	Exercise or Base Price of Option Awards ($/Share)	Grant Date Fair Value of Stock and Option Awards ($) [3]
Dr. Jayson D.A. Dallas		258,750	345,000	431,250				
	2/22/2019				35,000			830,200
	2/22/2019					210,000	23.72	2,969,484
Eric H. Bjerkholt		130,950	174,600	218,250				
	2/22/2019				13,125			311,325
	2/22/2019					78,750	23.72	1,113,557
Dr. Daniel C. Adelman		133,710	178,280	222,850				
	2/22/2019				11,875			281,675
	2/22/2019					71,250	23.72	1,007,504
Andrew Oxtoby		126,000	168,000	210,000				
	1/22/2019				12,000			263,280
	1/22/2019					150,000	21.94	1,972,710
Douglas T. Sheehy		120,390	160,520	200,650				
	2/22/2019				12,500			296,500
	2/22/2019					75,000	23.72	1,060,530

(1) Amounts shown in these columns represent each NEOs' threshold, target and maximum amounts under our non-equity incentive plan compensation, assuming 75%, 100% and 125% achievement percentages, respectively, for our corporate goals where applicable, and 100% achievement percentage with respect to each NEO's individual performance.

(2) The vesting of the options and RSUs is described below in the footnotes to the Outstanding Equity Awards at 2019 Fiscal Year End.

(3) Amounts shown represents the grant date fair value of awards granted as calculated in accordance with ASC Topic 718. See Note 8 to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2019 for the assumptions used in calculating this amount.

Outstanding Equity Awards at 2019 Fiscal Year End

The following table lists all outstanding equity awards held by our NEOs as of December 31, 2019.

		Option Awards				Stock Awards	
Name	Vesting Commencement Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested($)[1]
Dr. Jayson D.A. Dallas	6/19/2018(2)	131,250	218,750	30.68	6/19/2028		
	6/19/2018(3)	—				45,000	1,506,150
	2/22/2019(4)	43,750	166,250	23.72	2/22/2029		
	2/22/2019(3)	-				35,000	1,171,450
Eric H. Bjerkholt	4/28/2017(2)	180,000	90,000	19.44	4/28/2027		
	3/1/2018(4)	24,609	31,641	34.07	3/2/2028		
	3/1/2018(3)					7,031	235,328
	2/22/2019(4)	16,406	62,344	23.72	2/22/2029		
	2/22/2019(3)					13,125	439,294
Dr. Daniel C. Adelman	6/24/2016(2)	138,750	31,250	11.45	6/24/2026		
	2/24/2017(4)	63,750	26,250	19.63	2/24/2027		
	3/1/2018(4)	24,609	31,641	34.07	3/2/2028		
	3/1/2018(3)					7,031	235,328
	2/22/2019(4)	14,843	56,407	23.72	2/22/2029		
	2/22/2019(3)					11,875	397,456
Andrew Oxtoby	1/22/2019(2)	—	150,000	21.94	1/22/2029		
	1/22/2019(3)					12,000	401,640
Douglas T. Sheehy	4/4/2016(2)	44,482	9,167	12.95	4/29/2026		
	2/24/2017(4)	41,250	26,250	19.63	2/24/2027		
	3/1/2018(4)	32,812	42,188	34.07	3/2/2028		
	3/1/2018(3)					24,375	815,831
	2/22/2019(4)	15,625	59,375	23.72	2/22/2029		
	2/22/2019(3)					12,500	418,375

(1) Based on the closing price of our common stock on December 31, 2019 of $33.47.

(2) Represents stock options which vest as to 25% of the total number of shares subject to the option on the first anniversary of the vesting commencement date and with respect to 1/48th of the total number of shares subject to the option on each monthly anniversary thereafter, subject to the applicable holder's continued service through the applicable vesting date.

(3) Represents RSUs which vest with respect to 1/4th of the RSUs on each anniversary of the vesting commencement date, subject to the applicable holder's continued service through the applicable vesting date.

(4) Represents stock options which vest with respect to 1/48th of the total number of shares subject to the option on each monthly anniversary of the vesting commencement date, subject to the applicable holder's continued service through the applicable vesting date.

2019 Option Exercises and Stock Vested

The following table summarizes the stock options exercised and stock awards vested during the year ended December 31, 2019, and the value realized upon exercise or vesting by our NEOs.

	Options Awards		Stock Awards	
Name	Number of Shares Acquired on Exercise (#)	Value Realized Upon Exercise ($)[1]	Number of Shares Acquired on Vesting (#)	Value Realized Upon Vesting ($)[2]
Dr. Jayson D.A. Dallas..	—	—	15,000	301,050
Eric H. Bjerkholt.....	—	—	2,344	58,342
Dr. Daniel C. Adelman .	20,000	371,716	2,344	58,342
Andrew Oxtoby.....	—	—	—	—
Douglas T. Sheehy	10,000	200,822	8,125	202,231

(1) Amounts are calculated by multiplying the number of shares acquired on exercise by the closing trading price of a share of our common stock price on the exercise date, less the exercise price.

(2) Amounts are calculated by multiplying the number of shares acquired upon vesting by the closing trading price of a share of our common stock on the date of vesting.

Pension Benefits and Nonqualified Deferred Compensation Plans

We do not have any plans with any of our NEOs that provide for payments or other benefits at, following, or in connection with retirement. We also do not have any defined contribution or other plan with any of our NEOs that provides for the deferral of compensation on a basis that is not tax-qualified.

Potential Payments Upon Termination or Change in Control

Executive Employment Agreements

Under the employment agreements with each of our NEOs, in the event that the applicable executive is terminated by us without "cause" or resigns for "good reason", then in exchange for providing us a general release of claims, the executive is entitled to receive (i) continued base salary payments for nine months or, in the case of Dr. Dallas, twelve months, (ii) reimbursement of premiums for (or, in the case of Ms. Barrowcliffe, if she receives private medical insurance, provision of) continued healthcare coverage for nine months or, in the case of Dr. Dallas, twelve months, (iii) six months', or in the case of Dr. Dallas, twelve months', accelerated vesting of equity awards, including stock options, held by the executive (with any vested stock options remaining exercisable for up to twelve months after his termination of employment or resignation), and (iv) in the case of Dr. Dallas only, his new hire stock option and RSU awards will accelerate in full.

If the termination or resignation occurs during the period commencing three months prior to a change in control and ending twelve months after a change in control, then, in lieu of the foregoing benefits, each executive is entitled to receive (a) a cash lump sum payment equal to one times, or in the case of Dr. Dallas, one and one-half times, the sum of the executive's base salary and target bonus, (b) reimbursement of premiums for continued healthcare coverage for twelve months or, in the case of Dr. Dallas, eighteen months, and (c) full accelerated vesting of each equity award, including stock options, held by the executive (with any vested stock options remaining exercisable for up to twelve months following such termination or resignation).

The employment agreements also include a Section 280G "best pay" provision, which provides that if any amount received by the executive pursuant to the agreement or otherwise that would be subject to the excise tax imposed by Section 4999 of the Code, the executive would receive the full amount of the payments and benefits or an amount reduced so that no portion would be subject to the excise tax, whichever would result in the largest payment to the executive on an after-tax basis.

Under Dr. Dallas' employment agreement, in the event of Dr. Dallas' death, his new hire stock option and RSU awards will accelerate in full, and in the event of Dr. Dallas' termination due to permanent disability, he will receive 12 months' accelerated vesting of his new hire stock option and RSU awards, subject to his execution and delivery of a release of claims.

For the purposes of the employment agreements, "cause" means any of the following events: (a) the executive's theft, dishonesty or falsification of any employment or company records that is non-trivial in nature; (b) the executive's malicious or reckless disclosure of our confidential or proprietary information or any material breach by the executive of his obligations under the proprietary information and invention assignment agreement with us; (c) the conviction of the executive of a felony (excluding motor vehicle violations) or the commission of gross negligence or willful misconduct, where a majority of the non-employee members of our Board reasonably determines that such act or misconduct has (i) seriously undermined the ability of the Board or management to entrust the executive with important matters or otherwise work effectively with the executive, (ii) substantially contributed to our loss of significant revenues or business opportunities, or (iii) significantly and detrimentally affected our business or reputation; and/or (d) the

willful failure or refusal by the executive to follow the reasonable and lawful directives of our Board, provided such willful failure or refusal continues after the executive's receipt of reasonable notice in writing of such failure or refusal and a reasonable opportunity of not less than 30 days to correct the problem.

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

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

Estimated Potential Payments

The following table shows the payments and benefits that would be made to our NEOs assuming a termination without cause or a resignation for good reason (each, a "Qualifying Termination"), a Qualifying Termination within the period commencing three months prior to and ending 12 months following a change in control, and for Dr. Dallas, terminations due to death and disability, in each case, assuming the triggering events occurred on December 31, 2019.

Name	Base Salary and Target Bonus ($)	COBRA Premiums/ Continued Healthcare ($)	Equity Acceleration ($)[1]	Extended Option Exercise Period ($)[2]	Total Potential Payments ($)[3]
Dr. Jayson D.A. Dallas					
Qualifying Termination	575,000	35,589	1,172,913	867,623	2,651,125
Qualifying Termination in Connection with a CIC	1,284,000	53,383	4,908,850	1,862,201	8,108,434
Death Disability	—	—	4,908,850	1,862,201	6,771,051
Permanent Disability	—	—	1,550,913	1,100,398	2,651,311
Eric H. Bjerkholt					
Qualifying Termination	327,375	25,027	757,794	376,868	1,487,064
Qualifying Termination in Connection with a CIC	579,600	33,369	2,545,175	636,754	3,794,898
Dr. Daniel C. Adelman					
Qualifying Termination	334,275	12,577	1,108,494	269,393	1,724,739
Qualifying Termination in Connection with a CIC	623,980	16,770	2,234,177	503,684	3,378,611
Andrew Oxtoby					
Qualifying Termination	315,000	18,149	712,941	71,147	1,117,237
Qualifying Termination in Connection with a CIC	588,000	24,198	2,131,140	200,886	2,944,224
Douglas T. Sheehy					
Qualifying Termination	300,975	26,691	811,751	304,005	1,443,422
Qualifying Termination in Connection with a CIC	561,820	35,589	2,364,519	564,948	3,526,876

(1) With respect to options, the value of equity acceleration was calculated by (i) multiplying the number of accelerated shares of common stock underlying the options by $33.47, the closing trading price of our common stock on December 31, 2019 and (ii) subtracting the exercise price for the options. With respect to RSUs, the value of equity acceleration was calculated by multiplying the number of accelerated RSUs by $33.47, the closing trading price of our common stock on December 31, 2019.

(2) Amount represents the incremental aggregate value due to the extension of the option exercise period and was calculated by multiplying the number of accelerated shares of common stock underlying the options by the difference between the Black-Scholes value of an option with a one-year exercise period and a three-month exercise period.

(3) Amounts shown are the maximum potential payment the NEO would have received as of December 31, 2019. Amounts of any reduction pursuant to the 280G best pay provision, if any, would be calculated upon actual termination of employment.

Compensation Risk Assessment

Consistent with the SEC's disclosure requirements, we have assessed our compensation programs for all employees. We have concluded that our compensation policies and practices do not create risks that are reasonably likely to have a material adverse effect on us. In consultation with Radford, we have evaluated our executive and employee compensation and benefits programs to determine if these programs' provisions and operations create undesired or unintentional risk of a material nature. The risk assessment process includes a review of program policies and practices; analysis to identify risks and risk controls related to our compensation programs; and determinations as to the sufficiency of risk identification, the balance of potential risk to potential reward, the effectiveness of our risk controls and the impacts of our compensation programs and their risks to our strategy. In 2019, our assessment focused on the following areas: (i) philosophy and peer group development; (ii) total direct compensation and benchmarking; (iii) incentive plan risk; (iv) equity plan risk; (v) change in control polices; (vi) plan re-evaluation frequency; and (v) institutional investor risk. In relation to this, we believe that our incentive compensation arrangements provide incentives that do not encourage risk taking beyond our ability to effectively identify and manage significant risks and are compatible with effective internal controls and our risk management practices.

The Compensation Committee monitors our compensation programs on an annual basis and expects to make modifications as necessary to address any changes in our business or risk profile.

CEO Pay Ratio

As required by Section 953(b) of the Dodd-Frank Wall Street Reform and Consumer Protection Act, and Item 402(u) of Regulation S-K, we are providing information about the relationship of the annual total compensation of our employees and the annual total compensation of our Chief Executive Officer. For 2019, our last completed fiscal year, the total compensation in 2019 of our Chief Executive Officer was approximately 17 times the median total compensation in 2019 of all of our other employees (the "Pay Ratio"). The median of the annual total compensation of all employees of our Company (other than our Chief Executive Officer) was $285,956 and the annual total compensation of our Chief Executive Officer was $4,744,109.

The Company chose December 1, 2018 as the date for establishing the employee population used in identifying the median employee. We identified the median employee using annual base salary or annual wages as of December1, 2018 for each of our U.S. and non-U.S. employees, all of whom were permanent, full-time employees. We captured all employees as of December 1, 2018, consisting of approximately 205 individuals globally, with approximately 81% of these individuals located in the U.S. and approximately 19% located outside of the U.S. Earnings of our employees outside the U.S. were converted to U.S. dollars using the spot exchange rate as of December 31, 2018. No cost-of-living adjustments were made. The annual total compensation of the median employee and the annual total compensation of our CEO for the year-ended December 31, 2019 were calculated in accordance with the requirements of Item 402(c)(2)(x) of Regulation S-K.

Equity Compensation Plan Information

The following table provides certain information as of December 31, 2019, with respect to all of our equity compensation plans in effect on that date.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)		Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights		Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))	
Equity Compensation Plan Approved by Stockholders [1][2][3]	8,160,618	[4]	$ 21.52	[5]	6,902,802	[6]
Equity Compensation Plan Not Approved by Stockholders	—		—		—	

(1) Includes the 2015 Equity Incentive Award Plan, the 2013 Stock Plan, as amended, and the 2015 Employee Stock Purchase Plan.

(2) The 2015 Equity Incentive Award Plan contains an "evergreen" provision, pursuant to which the number of shares of common stock reserved for issuance or transfer pursuant to awards under the 2015 Equity Incentive Award Plan shall be increased on the first day of each year beginning in 2016 and ending in 2025, equal to the lesser of (A) four percent (4.0%) of the shares of common stock outstanding (on an as converted basis) on the last day of the immediately preceding fiscal year and (B) such smaller number of shares of stock as determined by our Board; provided, however, that no more than 35,000,000 shares of stock may be issued upon the exercise of incentive stock options.

(3) The 2015 Employee Stock Purchase Plan contains an "evergreen" provision, pursuant to which the maximum number of shares of our common stock authorized for sale under the 2015 Employee Stock Purchase Plan shall be increased on the first day of each year beginning in 2016 and ending in 2025, equal to the lesser of (A) one percent (1.0%) of the shares of common stock outstanding (on an as converted basis) on the last day of the immediately preceding fiscal year and (B) such number of shares of common stock as determined by our Board; provided, however, no more than 8,000,000 shares of our common stock may be issued thereunder.

(4) Consists of 7,629,823 shares of common stock underlying outstanding options, 530,795 shares of common stock underlying outstanding restricted stock units.

(5) Represents the weighted average exercise price of outstanding options and is calculated without taking into account the 530,795 shares of common stock subject to outstanding restricted stock units that become issuable without the payment of a purchase price as those units vest.

(6) Includes 2,303,797 shares that were available for future issuance as of December 31, 2019 under the 2015 Employee Stock Purchase Plan (of which up to 80,294 shares may be issued under the offering period in effect as of December 31, 2019, which offering period ends on May 15, 2020).

INFORMATION ABOUT STOCK OWNERSHIP

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table presents information as to the beneficial ownership of our common stock as of April 1, 2020 for:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock;
- each named executive officer as set forth in the summary compensation table above;
- each of our directors; and
- all executive officers and directors as a group.

Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Unless otherwise indicated below, to our knowledge, the persons and entities named in the table have sole voting and sole investment power with respect to all shares beneficially owned, subject to community property laws where applicable. Shares of our common stock subject to options that are currently exercisable or exercisable within 60 days of April 1, 2020 are deemed to be outstanding and to be beneficially owned by the person holding the stock options for the purpose of computing the percentage ownership of that person, but are not treated as outstanding for the purpose of computing the percentage ownership of any other person.

Percentage ownership of our common stock in the table is based on 65,222,917 shares of our common stock issued and outstanding on April 1, 2020. This table is based upon information supplied by officers, directors and principal stockholders and Schedules 13D and Schedules 13G, if any, filed with the SEC. Unless otherwise indicated, the address of each of the individuals and entities named below is c/o Aimmune Therapeutics, Inc., 8000 Marina Blvd., Suite 300, Brisbane, California 94005.

	Shares of Common Stock Beneficially Owned[1]			
Name of Beneficial Owner	**Common Stock**	**Securities Exercisable**	**Number of Shares Beneficially Owned**	**Percentage**
5% Stockholders:				
Nestle Health Science US Holdings, Inc.[2]	12,727,113	—	12,727,113	19.51%
Longitude Venture Partners II, L.P.[3]	6,013,134	—	6,013,134	9.22%
T. Rowe Price Associates, Inc.[4]	5,622,538	—	5,622,538	8.62%
The Vanguard Group[5]	4,040,835	—	4,040,835	6.20%
BlackRock, Inc.[6]	3,676,895	—	3,676,895	5.64%
Palo Alto Investors LP[7]	3,380,441	—	3,380,441	5.18%
NEOs and Directors:				
Dr. Jayson D.A. Dallas[8]	17,978	233,333	251,311	*
Greg Behar[9]	10,192	82,384	92,576	*
Patrick G. Enright[10]	6,183,695	174,457	6,358,152	9.72%
Kathryn E. Falberg[11]	128,644	62,629	191,273	*
Brett Haumann[12]	—	—	—	*
Mark T. Iwicki[13]	33,125	202,418	235,543	*
Mark D. McDade[14]	20,410	167,471	187,881	*
Stacey D. Seltzer[15]	3,779	115,050	118,829	*
Dr. Daniel C. Adelman[16]	4,952	270,649	275,601	*
Eric H. Bjerkholt[17]	20,051	263,202	283,253	*
Andrew Oxtoby[18]	1,765	50,000	51,765	*
Douglas T. Sheehy[19]	14,623	167,936	182,559	*
All executive officers and directors as a group (12 persons)[20]	6,439,214	1,789,529	8,228,743	12.28%

* Represents beneficial ownership of less than one percent of the outstanding shares of common stock.

(1) Represents shares of common stock held and options held by such individuals that were exercisable within 60 days of April 1, 2020. Includes shares held in the beneficial owner's name or jointly with others, or in the name of a bank, nominee or trustee for the beneficial owner's account. Reported numbers do not include options that vest more than 60 days after April 1, 2020.

(2) As reported on Schedule 13D/A filed with the SEC on February 11, 2020. The shares are held by Nestle Health Science US Holdings, Inc. Nestle Health Science US Holdings, Inc. is a wholly-owned subsidiary of NIMCO US, Inc., which is a wholly-owned subsidiary of Nestle S.A., a publicly-traded company. Each of these entities may be deemed to share voting and investment power with respect to all shares held by Nestle Health Science US Holdings, Inc. Each of NIMCO US, Inc. and Nestle S.A. disclaims beneficial ownership of such shares except to the extent of its pecuniary interest therein. The address of Nestle Health Science US Holdings, Inc. is 383 Main Avenue, 5th Floor, Norwalk, CT 06851.

(3) As reported on Schedule 13G/A filed with the SEC on February 12, 2020 and the Statement of Change in Beneficial Ownership on Form 4 filed with the SEC on December 1, 2016, in each case, by Longitude Venture Partners II, L.P. ("Longitude Venture II"), Longitude Capital Partners II, LLC ("Longitude Capital II"), Patrick G. Enright and Juliet Tammenoms Bakker. Longitude Venture II holds 6,013,134 shares of common stock. Longitude Capital II is the general partner of Longitude Venture II. Longitude Capital II and Longitude Venture II may be deemed to have sole voting, investment and dispositive power over the shares held by Longitude Venture II. Patrick G. Enright and Juliet Tammenoms Bakker are the managing members of Longitude Capital II and in their capacity as such, may be deemed to exercise shared voting and investment power with respect to such shares. Each of Ms. Bakker and Mr. Enright disclaim beneficial ownership of such shares except to the extent of his or her pecuniary interest therein. The address of Longitude Venture Partners II, L.P. is 800 El Camino Real, Suite 220 Menlo Park, CA 94025.

(4) As reported on Schedule 13G/A filed with the SEC on February 14, 2020 T. Rowe Price Associates, Inc. holds 5,622,538 shares of common stock. T. Rowe Price Associates, Inc. has sole voting power of 1,147,419 shares of common stock and sole dispositive power of 5,622,538 shares of common stock. The address of T. Rowe Price Associates, Inc. is 100 E. Pratt Street, Baltimore, MD 21202.

(5) As reported on Schedule 13G/A filed with the SEC on February 12, 2020, The Vanguard Group holds 4,040,835 shares of common stock. The Vanguard Group has sole dispositive power of 3,949,729 shares of common stock and shared dispositive power of 91,106 shares of common stock. The address of The Vanguard Group is 100 Vanguard Blvd., Malvern, PA 19355.

(6) As reported on Schedule 13G/A filed with the SEC on February 5, 2020, BlackRock, Inc. holds 3,676,895 shares of common stock. BlackRock, Inc. has sole voting power of 3,586,649 shares of common stock and sole dispositive power of 3,676,895 shares of common stock. The address of BlackRock, Inc. is 55 East 52nd Street, New York, NY 10055.

(7) As reported on Schedule 13G filed with the SEC on February 14, 2020, Dr. Patrick Lee, Dr. Anthony Joonkyoo Yun, Palo Alto Investors LP ("PAI") and PAI LLC ("PAI GP") hold 3,380,441 shares of common stock and each hold shared voting power and dispositive power with respect to such shares. PAI is a registered investment adviser and investment adviser of investment limited partnerships and is the investment adviser to other investment funds. PAI GP is the general partner of investment limited partnerships. PAIs clients have the right to receive or the power to direct the receipt of dividends from, or the proceeds from the sale of, the shares. Dr. Lee and Dr. Yun co-manage PAI and in their capacity as such, may be deemed to exercise shared voting and investment power with respect to such shares. Each of Dr. Patrick Lee, Dr. Anthony Joonkyoo Yun, Palo Alto Investors LP and PAI LLC disclaims beneficial ownership of the Stock except to the extent of their respective pecuniary interest therein. The address of Palo Alto Investors LP is 470 University Avenue, Palo Alto, CA 94301.

(8) Consists of (a) 17,978 shares of common stock and (b) 233,333 shares of common stock that may be acquired pursuant to the exercise of stock options with 60 days of April 1, 2020.

(9) Consists of (a) 10,192 shares of common stock and (b) 82,384 shares of common stock that may be acquired pursuant to the exercise of stock options with 60 days of April 1, 2020.

(10) Consists of (a) 70,561 shares of common stock, (b) 174,457 shares of common stock that may be acquired pursuant to the exercise of stock options within 60 days of April 1, 2020, and (c) the securities beneficially owned by Longitude Venture Partners II, L.P. as set forth in footnote (3). Mr. Enright disclaims beneficial ownership of the shares listed in footnote (3), except to the extent of his pecuniary interest therein.

(11) Consists of (a) 128,644 shares of common stock and (b) 62,629 shares of common stock that may be acquired pursuant to the exercise of stock options with 60 days of April 1, 2020.

(12) Dr. Haumann was elected as a Class II director by the Board on October 31, 2018. In connection with his election, he became entitled to receive compensation in accordance with our Director Compensation Program, including the Initial Equity Grant; however, he declined to receive such compensation absent a change in his U.S. visa status that allows him to accept the compensation.

(13) Consists of (a) 33,125 shares of common stock and (b) 202,418 shares of common stock that may be acquired pursuant to the exercise of stock options within 60 days of April 1, 2020.

(14) Consists of (a) 20,410 shares of common stock and (b) 167,471 shares of common stock that may be acquired pursuant to the exercise of stock options within 60 days of April 1, 2020.

(15) Consists of (a) 3,779 shares of common stock and (b) 115,050 shares of common stock that may be acquired pursuant to the exercise of stock options within 60 days of April 1, 2020, for which Ms. Seltzer disclaims beneficial ownership of, including any pecuniary interest therein, as a result of an existing contractual relationship between Ms. Seltzer and Aisling Capital.

(16) Consists of (a) 4,952 shares of common stock and (b) 270,649 shares of common stock that may be acquired pursuant to the exercise of stock options within 60 days of April 1, 2020.

(17) Consists of (a) 20,051 shares of common stock and (b) 263,202 shares of common stock that may be acquired pursuant to the exercise of stock options within 60 days of April 1, 2020.

(18) Consists of (a) 1,765 shares of common stock and (b) 50,000 shares of common stock that may be acquired pursuant to the exercise of stock options within 60 days of April 1, 2020.

(19) Consists of (a) 14,623 shares of common stock and (b) 167,936 shares of common stock that may be acquired pursuant to the exercise of stock options within 60 days of April 1, 2020.

(20) Consists of the shares described in notes 8 through 19 above.

SECTION 16(a) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Section 16(a) of the Exchange Act requires the Company's directors and executive officers, and persons who own more than 10% of a registered class of the Company's equity securities, to file with the SEC initial reports of ownership and reports of changes in ownership of common stock and other equity securities of the Company. Officers, directors and greater than 10% stockholders are required by SEC regulations to furnish the Company with copies of all Section 16(a) forms they file.

To the Company's knowledge, based solely on a review of the copies of such reports furnished to the Company and written representations that no other reports were required, the Company believes that all Section 16(a) filing requirements applicable to our officers, directors and greater than 10% beneficial owners were complied with during the year ended December 31, 2019.

ADDITIONAL INFORMATION

Householding of Proxy Materials

The SEC has adopted rules that permit companies and intermediaries (*e.g.*, brokers) to satisfy the delivery requirements for proxy statements and annual reports with respect to two or more stockholders sharing the same address by delivering a single proxy statement addressed to those stockholders. This process, which is commonly referred to as "householding," potentially means extra convenience for stockholders and cost savings for companies.

Brokers with account holders who are Aimmune stockholders may be "householding" our proxy materials. A single proxy statement may be delivered to multiple stockholders sharing an address unless contrary instructions have been received from the affected stockholders. Once you have received notice from your broker that it will be "householding" communications to your address, "householding" will continue until you are notified otherwise or until you notify your broker or the Company that you no longer wish to participate in "householding."

If, at any time, you no longer wish to participate in "householding" and would prefer to receive a separate proxy statement and annual report, you may (1) notify your broker, (2) direct your written request to: 8000 Marina Blvd., Suite 300, Brisbane, California 94005 or (3) request from the Company by calling 650-614-5220. Stockholders who currently receive multiple copies of this Proxy Statement at their address and would like to request "householding" of their communications should contact their broker. In addition, the Company will promptly deliver, upon written or oral request to the address or telephone number above, a separate copy of the Form 10-K, Proxy Statement, Proxy Card or Notice of Internet Availability of Proxy Materials to a stockholder at a shared address to which a single copy of the documents was delivered.

Other Matters

As of the date of this Proxy Statement, the Board does not intend to present any matters other than those described herein at the Annual Meeting and is unaware of any matters to be presented by other parties. If other matters are properly brought before the Annual Meeting for action by the stockholders, proxies will be voted in accordance with the recommendation of the Board or, in the absence of such a recommendation, in the discretion of the proxy holder.

We have filed our Annual Report on Form 10-K for the year ended December 31, 2019 with the SEC. It is available free of charge at the SEC's web site at www.sec.gov. Upon written request by a Aimmune stockholder, we will mail without charge a copy of our Annual Report on Form 10-K, including the financial statements and financial statement schedules, but excluding exhibits to the Annual Report on Form 10-K. Exhibits to the Annual Report on Form 10-K are available upon payment of a reasonable fee, which is limited to our expenses in furnishing the requested exhibit. All requests should be directed to the Corporate Secretary, 8000 Marina Blvd., Suite 300, Brisbane, California 94005.

By Order of the Board of Directors

/s/ Jayson Dallas

Jayson D.A. Dallas, M.D.
President and Chief Executive Officer

April 9, 2020

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2019

OR

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

FOR THE TRANSITION PERIOD FROM TO

Commission File Number 001-37519

AIMMUNE THERAPEUTICS, INC.

(Exact name of Registrant as specified in its Charter)

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

8000 Marina Blvd Suite #300
Brisbane, CA 94005
(Address of principal executive offices)

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

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

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

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

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

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

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

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	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 ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant based on the closing price of shares of common stock on The Nasdaq Stock Market on June 30, 2019 was $919,670,159.

The number of shares of Registrant's Common Stock outstanding as of February 14, 2020 was 65,041,825.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Definitive Proxy Statement relating to the 2020 Annual Meeting of Shareholders, scheduled to be held on May 27, 2020, are incorporated by reference into Part III of this Annual Report on Form 10-K to the extent stated herein. The Definitive Proxy Statement will be filed within 120 days of the Registrant's fiscal year ended December 31, 2019.

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Forward-Looking Statements

This Annual Report on Form 10-K, including "Business" in Part I, Item I and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II, Item 7, contains "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical facts contained in this Annual Report on Form 10-K are statements that could be deemed forward-looking statements reflecting the current beliefs and expectations of management with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. These statements are often identified by the use of words such as "may," "will," "expect," "believe," "anticipate," "intend," "could," "should," "estimate," or "continue," and similar expressions or variations. The risks and uncertainties referred to above include, without limitation, risks related to our research and development efforts, need for future capital, timely completion of our clinical trials, uncertainty of clinical trial results or regulatory approvals or clearances, manufacturing of our product candidates at scales and costs appropriate for commercialization, enforcement of our patent and proprietary rights, potential competition and other risks that are described herein and that are otherwise described from time to time in our Securities and Exchange Commission, or SEC, reports including, but not limited to, the factors described in Item 1A, "Risk Factors," of this Annual Report on Form 10-K. Given these risks and uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

This Annual Report on Form 10-K also contains estimates, projections and other information concerning our industry, our business and the markets for certain drugs, including data regarding the estimated size of those markets, their projected growth rates and the incidence of certain medical conditions. Information that is based on estimates, forecasts, projections or similar methodologies is inherently subject to uncertainties, and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by third parties, industry, medical and general publications, government data and similar sources. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires.

Trademarks

This Annual Report on Form 10-K includes trademarks, service marks and trade names owned by us or other companies. All trademarks, service marks and trade names included in this Annual Report on Form 10-K are the property of their respective owners.

PART I

Item 1. Business.

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 **C**haracterized **O**ral **D**esensitized **I**mmunology **T**herapy, 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. 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, that may occur with 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.

In addition to the approved indication, we are evaluating 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 expect to complete enrolment of this trial in the second half of 2020. We also 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. We expect the EMA to issue a decision on the application in the fourth quarter of 2020.

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, which we expect to be complete in the first half of 2021. We are also exploring a product candidate designed to treat multi-nut allergy, including walnut allergy.

In February 2020, we in-licensed AIMab7195 (formerly XmAb7195) from Xencor, Inc., or Xencor. 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.

We maintain worldwide commercial rights to PALFORZIA and all of our product candidates. 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.

Our Strategy

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

- *Commercialize PALFORZIA in the United States for the treatment of peanut allergy:* We recently commenced marketing activities for PALFORZIA in the United States through a specialty field force of approximately 80 Practice Account Managers targeting a subset of the approximately 5,000 practicing allergists in the United States.
- *Commercialize PALFORZIA in Europe through our own specialty field force*: We own worldwide commercial rights to PALFORZIA and all of our product candidates. If PALFORZIA is approved by the EMA and Swissmedic for the treatment of peanut allergy, we intend to commercialize it by developing a specialty field force targeting allergy-focused clinicians in the major European markets. We anticipate that this field force could also support the commercialization of additional CODIT product candidates, if approved.

- *Expand the PALFORZIA label:* We are conducting a Phase 3 clinical trial for young children aged one to less than four years old. We expect to complete enrolment of this trial in the second half of 2020. If the trial is successful, we intend to submit the results to the FDA under a sBLA with the goal to extend the approved label to this age group.
- *Leverage the CODIT system to develop additional proprietary product candidates for the treatment of food allergies*: Leveraging the expertise we have gained developing PALFORZIA, we are currently evaluating AR201 as a treatment for egg allergy in a randomized Phase 2 clinical trial in subjects with hen egg allergy and expect to complete this trial in the first half of 2021.
- *Develop new modalities to treat food allergies*: We are motivated to advance the field of food allergy by exploring other treatment modalities beyond our CODIT system. For example, we are exploring the adjunctive use of monoclonal antibodies in combination with PALFORZIA through the development of proprietary drug candidates, such as AIMab7195, as well as through collaborations with other pharmaceutical and biotechnology companies.

PALFORZIA Program Overview

Peanut allergy is a life-threatening disease. Based on a 2014 study published in the Journal of Allergy and Clinical Immunology, 40% to 50% of the people with peanut allergy in the United States are sensitive to an exposure of 100 mg or less of peanut protein, the equivalent of less than half of a peanut kernel (one peanut kernel typically contains approximately 250 mg to 300 mg of peanut protein). In addition, people with peanut allergy are often sensitive to as little as 10 mg of peanut protein. Strict dietary avoidance is hard to achieve and accidental exposure to food allergens is common, resulting in approximately 200,000 emergency room visits per year in the United States. The burden and anxiety for patients and their families is significant and a highly motivating force in seeking out therapy. There is a particularly high unmet need in young children who spend a significant portion of their day away at school where parental control is diminished and in adolescents who face peer pressure from their friends and classmates and may begin to engage in risk-taking behaviors.

Allergists have long used immunotherapy approaches to successfully treat patients with environmental allergies. Published studies have shown oral immunotherapy, or OIT, to be a potentially promising approach to desensitizing patients with peanut, milk, egg, tree nut and other food allergies. This approach involves a dose escalation phase in which the food allergen is gradually introduced orally to reduce the immune response to that allergen. After reaching a target dose, daily ingestion of the allergen at a fixed therapeutic dose continues immunomodulation. With CODIT, we are the first company to develop an OIT-based therapeutic approach to treat food allergies that has undergone the rigorous development required by the FDA for other approved pharmaceuticals. We believe that our first product developed with our CODIT approach, PALFORZIA, has the potential to fulfill the need for a consistent and scalable OIT-based approach to peanut allergy.

Clinical Trial Results

Clinical Trial Results Included in PALFORZIA U.S. Approved Package Insert

The efficacy of PALFORZIA for the mitigation of allergic reactions, including anaphylaxis, in patients with peanut allergy was investigated in PALISADE. PALISADE was a Phase 3, randomized, double-blind, placebo-controlled study of the efficacy and safety of PALFORZIA in patients with peanut allergy aged 4 through 55 years in the United States, Canada, and Europe. The primary analysis population consisted of 496 subjects (PALFORZIA, N = 372; placebo, N = 124) aged 4 through 17 years in the intent-to-treat, or ITT, population who received at least one dose of study treatment. After an initial dose escalation ranging from 0.5 mg to 6 mg on day 1 and confirmation of tolerability of the 3 mg dose on day 2, subjects underwent up-dosing for 20 to 40 weeks starting at 3 mg until the 300 mg dose was reached. The up-dosing period varied for each subject depending on how the dose was tolerated. Subjects then underwent 24 to 28 weeks of maintenance immunotherapy with 300 mg PALFORZIA until the end of the study. At the end of the maintenance period, subjects completed an exit double-blind, placebo-controlled food challenge, or DBPCFC, to approximate an accidental exposure to peanut and to assess their ability to tolerate increasing amounts of peanut protein with no more than mild allergic symptoms. The primary efficacy endpoint was the percentage of subjects tolerating a single dose of 600 mg peanut protein in the exit DBPCFC with no more than mild allergic symptoms after six months of maintenance treatment. The primary efficacy endpoint was considered met if the lower bound of the 95% confidence interval, or CI, for the difference in response rates between the treatment and the placebo groups was greater than the prespecified margin of 15%. Key secondary endpoints included the comparisons of the response rates after single doses of 300 mg and 1000 mg peanut protein as well as a comparison of the maximum severity of symptoms at any challenge dose of peanut protein during the exit DBPCFC. The key secondary endpoints were to be evaluated for statistical significance (two-sided $p < 0.05$) only if the primary endpoint and all the preceding tests in the hierarchy were statistically significant in favor of PALFORZIA. Response rates at the exit DBPCFC for the ITT population are shown in Table 1. The maximum severity of symptoms at any challenge is shown in Table 2.

Table 1: Response Rates at the Exit DBPCFC in PALISADE (ITT Population, 4 through 17 Years)

Peanut challenge dose, single dose	300 mg **[1]**	600 mg **[2]**	1000 mg **[1]**
PALFORZIA (N = 372)	76.6%	67.2%	50.3%
Placebo (N = 124)	8.1%	4.0%	2.4%
Treatment difference (95% CI)	68.5% (58.6%, 78.5%)	63.2% (53.0%, 73.3%)	47.8% (38.0%, 57.7%)
P-value	< 0.0001	< 0.0001	< 0.0001

Subjects without an exit DBPCFC were counted as non-responders.
[1] Secondary endpoint was considered met if the Farrington-Manning test for a non-zero treatment difference was significant at the two-sided 0.05 level.
[2] The primary efficacy endpoint was considered met if the lower bound of the Farrington-Manning 95% CI was greater than the prespecified margin of 15 percentage points.
CI, confidence interval, DBPCFC, double-blind, placebo-controlled food challenge; ITT, intent-to-treat.

The completer population consisted of all subjects aged 4 through 17 years in the ITT population who stayed on treatment and had an evaluable exit DBPCFC (296 PALFORZIA, 116 placebo). In the completer population, the proportion of subjects who tolerated single highest doses of 300 mg, 600 mg, and 1000 mg with no more than mild symptoms at the exit DBPCFC were 96.3%, 84.5%, and 63.2%, respectively for PALFORZIA-treated subjects compared with 8.6%, 4.3%, and 2.6% for placebo-treated subjects.

Table 2: Maximum Severity of Symptoms at Any Challenge Dose During the Exit DBPCFC (ITT Population, 4 through 17 Years)

Symptom Severity	**PALFORZIA N = 372**	**Placebo N = 124**
None	37.6%	2.4%
Mild	32.0%	28.2%
Moderate	25.3%	58.9%
Severe **[1]**	5.1%	10.5%

Subjects without an exit DBPCFC were assigned the maximum severity during the screening DBPCFC, which equates to no change from screening.
P-value < 0.0001; treatment difference was tested using the Cochran-Mantel-Haenszel statistic (with equally spaced scores) stratified by geographic region (North America, Europe).
[1] Includes severe symptoms and life-threatening or fatal reactions. No subjects had symptoms considered life-threatening or fatal.
DBPCFC, double-blind, placebo-controlled food challenge; ITT, intent-to-treat.

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in clinical trials of a drug cannot be directly compared with the adverse reaction rates in clinical trials of another drug and may not reflect the rates observed in practice. The clinical data for PALFORZIA reflect exposure in 709 peanut-allergic subjects enrolled in two Phase 3, double-blind, placebo-controlled trials (PALISADE and RAMSES), and in long-term, open-label, follow-on studies. In PALISADE, subjects were up-dosed for 20 to 40 weeks followed by maintenance dosing for 24 to 28 weeks. In RAMSES, subjects were up-dosed for 20 to 40 weeks up to a 300 mg daily dose with no extended maintenance dosing. In these studies, subjects recorded adverse reactions daily in an electronic diary card throughout the study duration. PALISADE (NCT02635776) was a randomized, double-blind, placebo-controlled efficacy and safety study conducted in the United States, Canada, and Europe evaluating PALFORZIA versus placebo in 555 subjects aged 4 through 55 years with peanut allergy. Subjects were required to have serum IgE to peanut ≥ 0.35 kUA/L within 12 months before study entry and/or a mean wheal diameter on skin-prick test to peanut ≥ 3 mm greater than the negative control. The primary analysis population was aged 4 through 17 years, 78% white and 57% male. At study entry, subjects reacted at 100 mg or less of peanut protein in a double-blind, placebo-controlled food challenge (DBPCFC). The primary analysis was conducted in 496 subjects aged 4 through 17 years (PALFORZIA, N = 372; placebo, N = 124). Of the subjects aged 4 through 17 years treated with PALFORZIA, 72% had a medical history of anaphylactic reactions to peanut, 66% reported multiple food allergies, 63% had a medical history of atopic dermatitis, and 53% had a present or previous diagnosis of asthma. Subjects with severe persistent or uncontrolled asthma were excluded. RAMSES was a randomized, double-blind, placebo-controlled safety study conducted in the United States and Canada evaluating PALFORZIA versus placebo in 506 subjects aged 4 through 17 years with peanut allergy. Subjects were required to have a clinical history of peanut allergy including onset of characteristic allergic signs and symptoms within 2 hours of known oral exposure to peanut, serum IgE to peanut of ≥ 14 kUA/L and a mean wheal diameter on skin prick test ≥ 8 mm greater than the negative control at screening. Subjects were not required to complete a DBPCFC for study entry. The study duration was approximately 6 months and compared the safety and tolerability of PALFORZIA (N = 337) with placebo (N = 168). Most subjects were male (63%) and white (79%). Of the subjects treated with PALFORZIA, 60.5% had a medical history of anaphylactic reactions, 65.0% reported multiple food allergies, 57.9% had a medical history of atopic dermatitis, and 52.2% had a present or previous diagnosis of asthma. Subjects with severe persistent or uncontrolled asthma were excluded. Across these two Phase 3, double-blind, placebo-controlled, randomized clinical studies, the most common adverse reactions in subjects treated with

PALFORZIA (incidence ≥ 5% and at least 5 percentage points greater than in subjects treated with placebo) were gastrointestinal, respiratory, and skin symptoms commonly associated with allergic reactions, as shown in Table 3.

Table 3: Treatment-Emergent Adverse Reactions in ≥ 5% of PALFORZIA-Treated Subjects and ≥ 5% Percentage Points Greater Than Placebo-Treated Subjects in any Dosing Phase (Aged 4 through 17 Years)

System Organ Class / Preferred Term [2]	Study 1 & Study 2 IDE PALFORZIA (N = 709)	Study 1 & Study 2 IDE Placebo (N = 292)	Study 1 & Study 2 Up-Dosing PALFORZIA (N = 693)	Study 1 & Study 2 Up-Dosing Placebo (N = 289)	Study 1 [1] 300 mg PALFORZIA (N = 310)	Study 1 [1] 300 mg Placebo (N = 118)
Gastrointestinal disorders						
Abdominal pain [3]	185 (26.1%)	24 (8.2%)	465 (67.1%)	100 (34.6%)	90 (29.0%)	20 (16.9%)
Vomiting	22 (3.1%)	2 (0.7%)	253 (36.5%)	47 (16.3%)	50 (16.1%)	14 (11.9%)
Nausea	60 (8.5%)	2 (0.7%)	224 (32.3%)	41 (14.2%)	45 (14.5%)	8 (6.8%)
Oral pruritus [4]	62 (8.7%)	9 (3.1%)	216 (31.2%)	30 (10.4%)	51 (16.5%)	7 (5.9%)
Oral paresthesia	13 (1.8%)	7 (2.4%)	94 (13.6%)	11 (3.8%)	23 (7.4%)	2 (1.7%)
Respiratory, thoracic, and mediastinal disorders						
Throat irritation	66 (9.3%)	15 (5.1%)	279 (40.3%)	49 (17.0%)	43 (13.9%)	11 (9.3%)
Cough	18 (2.5%)	1 (0.3%)	221 (31.9%)	68 (23.5%)	61 (19.7%)	22 (18.6%)
Rhinorrhea	9 (1.3%)	4 (1.4%)	145 (20.9%)	50 (17.3%)	46 (14.8%)	9 (7.6%)
Sneezing	24 (3.4%)	8 (2.7%)	140 (20.2%)	31 (10.7%)	33 (10.6%)	5 (4.2%)
Throat tightness	18 (2.5%)	3 (1.0%)	98 (14.1%)	8 (2.8%)	20 (6.5%)	0 (0.0%)
Wheezing	4 (0.6%)	0 (0.0%)	85 (12.3%)	21 (7.3%)	19 (6.1%)	10 (8.5%)
Dyspnea	2 (0.3%)	1 (0.3%)	53 (7.6%)	5 (1.7%)	17 (5.5%)	1 (0.8%)
Skin and subcutaneous tissue disorders						
Pruritus	56 (7.9%)	16 (5.5%)	225 (32.5%)	59 (20.4%)	45 (14.5%)	14 (11.9%)
Urticaria	28 (3.9%)	10 (3.4%)	197 (28.4%)	54 (18.7%)	63 (20.3%)	17 (14.4%)
Immune system disorders						
Anaphylactic reaction [5]	5 (0.7%)	1 (0.3%)	63 (9.1%)	10 (3.5%)	27 (8.7%)	2 (1.7%)
Ear and labyrinth disorders						
Ear pruritus	5 (0.7%)	1 (0.3%)	41 (5.9%)	2 (0.7%)	7 (2.3%)	0 (0.0%)

At each level of summarization (any event, system organ class, or preferred term) subjects with more than 1 adverse reaction were counted only once within each study period.
[1] In Study 2, no adverse reactions ≥ 5% were reported in subjects following treatment with 300 mg PALFORZIA (N = 265).
[2] Adverse events were coded to system organ class and preferred term using the MedDRA, version 19.1.
[3] Includes preferred terms of abdominal pain, abdominal pain upper, and abdominal discomfort.
[4] Includes preferred terms of oral pruritus, tongue pruritis, and lip pruritus.
[5] The anaphylactic reaction preferred term includes systemic allergic reactions of any severity, of which severe anaphylaxis was reported in 4 PALFORZIA-treated subjects (0.6%) during up-dosing and 1 PALFORZIA-treated subject (0.3%) during maintenance.
IDE, initial dose escalation; MedDRA, Medical Dictionary for Regulatory Activities.

A total of 155 (21.9%) PALFORZIA-treated subjects and 19 (6.5%) placebo-treated subjects discontinued for any reason. Adverse reactions led to study discontinuation in 9.2% PALFORZIA-treated subjects and 1.7% placebo-treated subjects during initial dose escalation and up-dosing combined, and 1.0% PALFORZIA-treated subjects and no placebo-treated subjects during maintenance dosing in Study 1. Gastrointestinal reactions were the most common reason leading to discontinuation of study product during initial dose escalation and up-dosing combined (6.5% PALFORZIA, 1.0% placebo), followed by respiratory disorders (2.3% PALFORZIA, 1.0% placebo).

Additional Clinical Data Included in European MAA

In February 2018, we completed enrollment of 175 patients in our European Phase 3 efficacy trial designed with a higher efficacy bar of tolerating 1,000 mg of peanut protein in an exit food-challenge without anything more than mild, transient symptoms, which we refer to as the ARTEMIS (AR101 Trial in Europe Measuring Oral Immunotherapy Success) trial. In June 2019, we announced positive results from ARTEMIS. Efficacy results for the ITT group are summarized in Table 4 below:

Table 4: Response Rates at the Exit DBPCFC in ARTEMIS (ITT Population, 4 through 17 Years)

Peanut challenge dose, single dose	300 mg	600 mg	1000 mg
PALFORZIA (N = 132)	73.5%	68.2%	58.3%
Placebo (N = 43)	16.3%	9.3%	2.3%
Treatment difference (95% CI)	57.2% (41.2%, 69.1%)	58.9% (44.2%, 69.3%)	56.0% (44.1%, 65.2%)
P-value	< 0.0001	< 0.0001	< 0.0001

Subjects without an exit DBPCFC were counted as non-responders.
CI, confidence interval, DBPCFC, double-blind, placebo-controlled food challenge; ITT, intent-to-treat.

The safety profile observed in ARTEMIS was largely consistent with that seen in the PALISADE and RAMSES trials. The results of the ARTEMIS trial were submitted to the EMA as part of the MAA for Europe.

Food Allergy Overview

Food Allergies are a Significant and Growing Health Problem

Food allergies are a significant and growing health problem in the United States, Europe and throughout the developed world. It is estimated that over 30 million people in the United States and Europe have a food allergy, and one in 13 children are affected in the United States. According to a study published in JAMA Pediatrics in 2013, the economic cost of food allergies in the United States is estimated to equal approximately $25 billion per year, of which approximately $4 billion is associated with direct medical expenses. Food allergies are a particularly urgent issue for children and adolescents because of the greater prevalence of food allergies in those age groups and because of the increased risk of accidental exposures leading to a serious allergic reaction. A large-scale study conducted in 2011 concluded that approximately 8% of children and adolescents in the United States have a food allergy and that approximately 39% of that group had a history of at least one severe allergic reaction. We estimate that over 50% of patients with peanut allergy experience a severe allergic reaction each year.

Peanut allergy is one of the most common food allergies in the world, affecting more than 1.6 million children and teens in the United States alone. It can be a chronic and life-long condition, and reactions to peanut can range from mild to potentially life-threatening, with one in four peanut-allergic patients visiting emergency rooms each year due to accidental exposures. Among children with food allergies in the United States, approximately 25% are allergic to peanuts, with other common food allergies being milk (21%), shellfish (17%), tree nut (13%, of which walnut represents 40%)) and egg (10%). We estimate that there are approximately three million people in the United States and three million people in Europe with peanut allergy, including over three million children. The prevalence of peanut allergy in children in the United States is estimated to have increased at a constant annual growth rate of approximately 10% between 1997 and 2008, and experts believe it has continued to rise since 2008.

Risks Associated with Allergic Reactions

Allergic reactions to food are painful, frightening and potentially deadly. Symptoms of an allergic reaction include hives, swelling, vomiting, abdominal pain, wheezing, breathlessness, and lowered blood pressure. Severe and potentially life-threatening reactions are referred to as anaphylaxis and such reactions require urgent medical attention and often result in treatment at hospital emergency departments. Food-related allergic reactions are estimated to result in approximately 200,000 emergency room visits and over 10,000 hospital admissions each year in the United States.

Allergic reactions, including severe allergic reactions, can be triggered by exposure to minute quantities of the relevant food allergen. For example, of the over two million people with peanut allergy in the United States, 40% to 50% are sensitive to an exposure of 100 mg or less of peanut protein, the equivalent of less than half of a peanut kernel (one peanut kernel typically contains approximately 250 mg to 300 mg of peanut protein). In addition, people with peanut allergy are often sensitive to as little as 10 mg of peanut protein, the equivalent of approximately 1/25th of a peanut kernel. As a result, accidental exposure arising from contamination of a food source or the inaccurate or confusing labeling of food products occurs regularly and can result in severe allergic reactions.

Causes of Allergic Reactions

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

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

Challenges in the Current Treatment and Management of Food Allergies

The most common practices to manage food allergies are strict avoidance of food allergens and emergency treatment of allergy symptoms in the event of an accidental exposure. These options have substantial limitations, and the burdens of practicing avoidance and stress caused by the limited availability of effective treatment options for accidental exposure can have a substantial negative impact on the quality of life of food-allergic patients and their families. For example, food-allergic patients and their caregivers often have difficulties managing their social and day-to-day lives and live with an ongoing fear of accidental exposure and anaphylaxis. One study found that children with peanut allergy reported a poorer quality of life than children with insulin-dependent diabetes mellitus. A separate study found that the parents of peanut-allergic children reported more disruption in their family's lives than the parents of children with rheumatological disease.

Limitations of Practicing Avoidance of Food Allergens

Successfully practicing avoidance can be very difficult and requires careful reading of food labels, care in the storage and preparation of foods, awareness of product recalls for mislabeling and contamination, and oftentimes avoidance of cuisines where the food allergen is known to be common. In addition, activities such as attending a sporting event, traveling by airplane or visiting public spaces become difficult and stressful for food-allergic patients and their families. Practicing avoidance can be particularly difficult on food-allergic children as parents often attempt to prevent accidental exposures by limiting their child's participation in everyday activities, including social activities, eating outside the home and sometimes even choosing to home school their child because such food-allergic children may not have the awareness or self-regulation skills to practice avoidance by themselves. As children move into adolescence and young adulthood, decreased parental supervision and increased societal pressures often complicate the practice of avoidance.

Limitations of Emergency and Symptomatic Treatments

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

Limitations of Current Desensitization Treatments

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

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

- *Sublingual Immunotherapy*: Involves the administration of increasing amounts of food extract under a patient's tongue. This approach has been shown to be safe, but it appears to induce only a modest degree of desensitization.
- *Epicutaneous Desensitization*: Involves the use of a patch that causes allergens to be absorbed by the skin. Clinical trials are ongoing to explore the potential viability of this approach and there is currently one product for the potential treatment of peanut allergy with a biologics license application, or BLA, under review by the FDA.
- *Oral Immunotherapy (OIT)*: Involves the oral consumption of increasing doses of a food-based product on a daily basis over a period of months. This approach has the potential to produce a high degree of desensitization, but adoption has been hampered by lack of standardization for products and protocols.

We believe the most effective form of desensitization therapy for food allergy is OIT. PALFORZIA, using OIT, is the first and only FDA-approved therapy for the mitigation of food allergy reactions.

Immunology of Oral Desensitization

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

The initial step in an immune response is the presentation of an allergenic protein by an antigen presenting cell, such as a dendritic cell, and subsequent recognition of the allergenic protein by T-cells. A subset of T-cells, known as Th2 cells, upon binding to an antigen secrete a set of pro-inflammatory proteins called cytokines, such as IL-4, IL-5 and IL-13, which are important in cellular activation and signaling. Secretion of this group of cytokines promotes B-cell maturation and production of IgE antibodies. These IgE antibodies cross-link at the surface of the mast cells by binding with the antigen, which results in the mast cells releasing histamines, proteases and other chemical mediators of inflammation, all of which elicit symptoms of an allergic reaction.

In oral desensitization, the step-wise increasing of doses of an allergen, starting with very low levels of such allergen that are generally insufficient to trigger a large IgE-mediated allergic reaction, has been shown over time to induce regulatory T-cells. These regulatory T-cells dampen the Th2 immune response. At the same time, the increasing levels of allergen exposure induce B-cells to produce IgG4 antibodies, which compete with IgE antibodies to bind with the allergen, thereby decreasing allergen-induced mast cell degranulation. Ultimately, these immunomodulatory T-cell and B-cell responses result in a decreased clinical response to allergen exposure. To realize the full potential of OIT, patients may need to stay on therapy for several years.

Our Solution

Our CODIT approach for the treatment of food allergies leverages and improves upon the extensive independent scientific research supporting OIT. Based on our clinical development to date, including our Phase 3 PALISADE, RAMSES and ARTEMIS trials of PALFORZIA, we believe that our CODIT approach has the potential to be widely adopted by allergists and to appeal to patients and parents as a result of the following key anticipated attributes:

- *Standardized Products*: Our proprietary biologic product candidates are derived from natural food products and are designed to contain precisely defined dosages of well-characterized food proteins so that each dosage is consistent for total protein and relative allergen content. In addition, we expect each of our product candidates, if approved, to be provided to patients as a convenient, orally administered, once daily therapy.
- *Well-Defined Treatment Regimens to Support Safety and Efficacy*: We expect each CODIT product candidate to feature clearly defined clinical protocols with gradual dose escalation and practical fixed therapeutic dosing regimens designed to enhance safety, tolerability and efficacy. We intend to demonstrate the safety and efficacy of each CODIT product candidate in large scale, well-controlled clinical trials.
- *Clinically Meaningful Desensitization*: We expect each approved CODIT product candidate to provide patients with protection from food allergens at a level that exceeds the amount typically encountered in an accidental exposure, to impart real world safety.
- *Compatibility with Clinical Practice*: We expect our protocols for each CODIT product candidate to be similar to treatment regimens currently utilized by allergists for non-food allergies.
- *Tailored Support Services*: We intend to provide physician education, patient guidance and other support services to facilitate the administration of each approved CODIT product candidate.

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

Additional Food Allergy Research and Development

We intend to leverage the expertise we gained in the clinical development of PALFORZIA to advance additional CODIT candidates for a range of food allergy biotherapeutics to address high unmet need. We expect to leverage our expertise in the formulation and pharmaceutical development of biologic drug products from naturally available food protein to accomplish this goal. As with PALFORZIA, we expect this process to require the identification of key protein antigens and allergenic protein epitopes, the development of analytic methods, the creation of usable and stable formulations and the ability to manufacture supplies within strict pharmaceutical processes.

AR201 for Egg Allergy

Our egg CODIT product candidate, AR201, is designed for the treatment of egg allergy in pediatric and young adult patients. Egg allergy is one of the most common food allergies in infants and young children. Published studies indicate that egg allergy is prevalent in approximately 1% of young children but resolves by age 16 in nearly 70% of patients and is therefore significantly less prevalent in the adult population. Based on our epidemiological analysis, we estimate the prevalence for egg allergy in two key markets, the United States and the EU, to be approximately 1.5 million patients in the aggregate. Worldwide, we estimate that there are more than 6 million people with egg allergy, with a significant patient base in China and Japan, where egg is the most common food allergy. Allergists have observed that patients who have egg allergy that persist beyond childhood tend to be higher risk patients with more severe reactions, a population that is especially vulnerable to severe reactions in the case of accidental exposure. The ubiquity of egg in staple foods along with a lack of strict food labeling requirements make adherence to an avoidance diet especially difficult. Despite conscientious label reading, egg allergens can be present due to errors in food packaging and formulation as well as undisclosed ingredient substitutions.

These practical challenges along with the lack of proactive treatment represent a significant unmet need.

As a result, we believe there would be strong demand for an FDA-approved egg CODIT product candidate. We enrolled the first patient in a Phase 2 clinical trial in subjects with hen egg allergy in August 2019 and expect to complete the trial in the first half of 2021.

Other Research and Development Programs

We are exploring additional research and development programs evaluating the potential application of CODIT in other food allergies, including walnuts and other tree nuts and cow's milk.

We believe that approximately 0.4% - 0.6% of the U.S. population is allergic to walnuts. In addition, a high proportion of people who are allergic to walnuts are also allergic to pecans and other tree nuts due to preserved homology in allergenic epitopes. Tree nut allergy was estimated to be prevalent in approximately 2.3 million, or approximately 1%, of people ages 1-55 in the United States in 2017. Similar to the dynamic of peanut allergy, tree nuts can be difficult to avoid. Strict avoidance, supported by first line defense medication, such as epinephrine, is the standard of care. We are currently exploring the feasibility of a multi-nut formulation to desensitize against several tree nut allergies and plan to meet with the FDA to discuss this program in the first half of 2020.

In February 2020, we completed the in-licensing of AIMab7195 (formerly XmAb7195) from Xencor. Initially, we intend to develop AIMab7195 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. AIMab7195 is an anti-IgE monoclonal antibody with enhanced binding to the Fc gamma receptor IIb (FcγRIIb). IgE recognizes and interacts with allergens and, as a result, can activate immune cells, such as mast cells and basophils, that drive an allergic response in patients. AIMab7195 is designed to clear IgE rapidly from circulation, to prevent the production of IgE by preventing the activation of IgE-positive B cells, and to block IgE from interacting with its receptor on immune cells. AIMab7195 has been evaluated in two phase 1 studies that enrolled more than 100 healthy volunteers and patients with allergy and atopic disease. We will be solely responsible for costs related to the development of AIMab7195.

Collaborations

Regeneron

In October 2017, we entered into a clinical collaboration with Regeneron and its strategic alliance collaborator, Sanofi, to study PALFORZIA treatment with adjunctive dupilumab in peanut-allergic patients in a Phase 2 clinical trial. Regeneron initiated the Phase 2 clinical trial in October 2018. The primary objective is to assess whether dupilumab, as adjunct to PALFORZIA, improves desensitization at the completion of up-dosing, defined as an increase in the proportion of participants who pass a DBPCFC at week 28 compared to placebo. The study also includes a proposed exploration of sustained remission after discontinuation of therapy in another DBPCFC. Sustained remission is achieved when, after a break in treatment, peanut-allergic patients are able to tolerate a defined amount of peanut protein with no more than mild allergic symptoms. Regeneron is sponsoring the clinical trial, and we will provide clinical supply of PALFORZIA and food challenge materials.

Nestlé Health Science

In November 2016, we entered into a two-year strategic collaboration with an affiliate of Nestlé Health Science US Holdings, Inc. for the advancement of food allergy therapeutics and issued and sold to Nestlé Health Science US Holdings, Inc. (together with its affiliate, Nestlé Health Science) 7,552,084 shares of common stock in a private placement at a price of $19.20 per share, which represented approximately 15.1% of our outstanding shares at the time of the transaction, for a total of $145.0 million. Subject to certain limited exceptions, Nestlé Health Science agreed to a two-year market standoff provision under which it agreed not to sell or transfer any of our common stock or other securities. Subject to certain limited exceptions, Nestlé Health Science also agreed to a two-year standstill agreement under which Nestlé Health Science agreed not to acquire us through any means. We agreed to register the resale of the shares that Nestlé Health Science purchased on a registration statement to be filed with the SEC upon the request of Nestlé Health Science, which cannot make the request prior to the 45th day preceding the end of the market standoff provision. The investment and the collaboration did not include any development milestones, product marketing rights or royalties.

In November 2018, Nestlé Health Science made an additional equity investment of $98.0 million for 3,237,529 newly issued shares of our common stock at $30.27 per share, increasing Nestlé Health Science's ownership of Aimmune to approximately 19%. We also entered into a two-year extension of the original two-year strategic collaboration agreement, focused on offering innovative food allergy therapies, with Nestlé Health Science. The agreement does not contain any partnership, collaboration, or negotiation restrictions on Aimmune. Aimmune retains all rights to its current and future pipeline assets, and Aimmune and Nestlé Health Science will collaborate towards successful development of such assets.

The initial investment launched a two-year strategic collaboration, which was extended for an additional two years in November 2018, between us and Nestlé Health Science, the terms of which enable both parties to discuss our current and future oral immunotherapy development programs through a newly established pipeline forum. Nestlé Health Science will provide ongoing scientific, regulatory, and commercial expertise and advice to us through the pipeline forum. Any information disclosed in the collaboration will remain our confidential information, and any new ideas or inventions that arise that relate to our products will be our solely owned intellectual property. If we elect to seek a partner or collaborator for one of our oral immunotherapy development programs during the two-year term of the collaboration, Nestlé Health Science will have a three-month period to negotiate exclusively with us. During the term of the collaboration, and for so long as Nestlé Health Science holds not less than ten percent of our outstanding common stock, Nestlé Health Science will be entitled to designate one nominee to serve as a director on our Board of Directors. In November 2016, Greg Behar joined our Board of Directors on behalf of Nestlé Health Science. The strategic collaboration agreement contains a non-competition covenant pursuant to which Nestlé Health Science has agreed not to engage in certain activities relating to OIT for the treatment of food allergies.

In February 2020, we announced a $200.0 million equity investment by Nestle Health Science S.A. and the extension of their existing strategic collaboration designed to enable the development and commercialization of innovative food allergy therapies, which will terminate in November 2021

License Agreement with Xencor

In February 2020, we entered into a license agreement, or the License Agreement, with 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. Under the License Agreement, Xencor granted to us an exclusive, worldwide, royalty-bearing sublicensable license under certain patent rights and a non-exclusive, royalty-bearing sublicensable license under certain know-how rights to develop, manufacture, and commercialize AIMab7195 Products for the diagnosis, treatment, or prevention of human diseases and conditions.

In connection with the entry into the License Agreement, we will pay Xencor an upfront payment of $5.0 million, and we issued to Xencor 156,238 shares of Common Stock, pursuant to a Securities Issuance Agreement with Xencor, dated February 4, 2020.

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 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 the 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.

Research and Development Expenses

A significant portion of our operating expenses relates to the development and manufacturing of PALFORZIA. For the years ended December 31, 2019, 2018 and 2017, our research and development costs were $124.0 million, $133.4 million, and $89.3 million, respectively, and are included in the research and development expense line item in our Consolidated Statements of Operations and Comprehensive Loss. For further detail about the research and development activities, refer to the research and development section in the "Management's Discussion and Analysis" in this Annual Report on Form 10-K.

Sales and Marketing

We intend to commercialize PALFORZIA in the United States and, subject to regulatory approval, commercialize PALFORZIA in Europe, by developing a specialty sales force targeting a subset of the approximately 5,000 practicing allergists in the United States as well as allergy-focused clinicians in major European markets. We anticipate that this sales force could also support the commercialization of additional CODIT product candidates, if approved. We intend to focus our sales efforts on patients with more moderate to severe food allergies, particularly children and adolescents. We do not anticipate that a DBPCFC will be a requirement for prescribing PALFORZIA as DBPCFCs are not widely used as a diagnostic tool in current clinical practice. Our CODIT therapeutic approach for food allergies may encompass providing a range of services, including telephone and e-mail support for patients, physician awareness and education activities, reimbursement assistance, benefit navigation and co-pay and patient assistance programs. Based on the estimated direct medical expenses associated with peanut allergy and the estimated number of people with peanut allergy in the United States, we believe the potential market opportunity for approved peanut allergy treatments in the United States could exceed one billion dollars annually.

Manufacturing

We contract with and rely on third-party manufacturers to produce the food product and final biologic product for PALFORZIA and our product candidates and to package PALFORZIA and our product candidates. We have completed construction of a manufacturing facility for PALFORZIA in a leased building in Clearwater, Florida, at the site of one of our current contract manufacturers and installed equipment and qualified the operating systems in this new facility. This manufacturing facility became operational in November 2018. We plan to continue to rely on the contract manufacturer that is located at the same site to manage the operations of this new manufacturing facility. We plan to rely on this contract manufacturer and other contract manufacturers to produce supply for our clinical trials, for commercial supply of PALFORZIA and other product candidates.

Our commercial product and product candidates are manufactured in accordance with stringent manufacturing processes. Our processes are designed to ensure that that the total protein content of each formulation and the relative concentrations of particular proteins are consistent. Through our contract manufacturers, we are capable of producing dosages for certain product candidates with protein content as small as 0.2 mg and have developed advanced analytical methods to help ensure each dose contains precisely defined amounts of multiple well-characterized allergenic proteins. Our formulations are also designed to help ensure that the drug product is acceptably stable and can be easily mixed with food.

PALFORZIA is currently produced for us by a contract manufacturer using our proprietary process. This process involves several blending and characterization steps intended to help ensure that each dose contains a precise amount of peanut flour containing a specific concentration of peanut protein. Because peanut flour is a sensitizing agent, PALFORZIA must be produced on a manufacturing line that is physically separated from other manufacturing lines and that has its own ventilation system.

We also rely on separate contract manufacturers to provide packaging services for PALFORZIA. We plan on using blister packs and sachets as the final packaging configuration for our commercial launch of PALFORZIA. Stability testing of PALFORZIA in the blister pack and sachet configurations is ongoing. Any complications with the stability testing in the blister pack or sachet configuration could delay the timing of our regulatory filings for PALFORZIA and could result in a limited shelf life of the commercial product at the time of launch. In addition, 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.

Supplying appropriate clinical trial materials for the commercial launch of PALFORZIA, as well as for our ongoing and planned clinical trials, on a timely basis is a complex operation. There are multiple doses in the dose escalation for 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 PALFORZIA and for 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. 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.

Contract manufacturers often encounter difficulties involving production yields, quality control and quality assurance, as well as shortages of qualified personnel. Qualifying manufacturers and providers of packaging services is a lengthy process. If at any time, one or more of our qualified contract organizations were not able to manufacture or package our commercial product or drug product candidate or provide other requisite services, our business and financial condition could be materially adversely affected.

Our third-party suppliers (other than Golden Peanut Company, or GPC), their facilities and all lots of commercial product and product candidates used in our clinical trials are required to be in compliance with current Good Manufacturing Practices, or cGMP. The cGMP regulations include requirements relating to organization and personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports, and returned or salvaged products. The manufacturing facilities for our products must be in compliance with these regulations to the FDA's satisfaction before any product is approved and we can manufacture commercial products. Our third-party manufacturers are also subject to periodic inspections of facilities by the FDA and other authorities, which may include the evaluation of procedures and operations used in the testing and manufacture of our products to assess compliance with applicable regulations. Further, producing commercial quantities of PALFORZIA has required us to scale up our existing manufacturing process and design and institute rigorous quality control and assurance procedures in our new manufacturing facility. These procedures include qualification of the manufacturing equipment and building utility systems and validation of the manufacturing process at commercial scale. Designing and implementing these procedures are time-consuming and complex operations. Any aspects of this new manufacturing facility that do not meet the cGMP requirements to the FDA's satisfaction or the periodic inspections of facilities by the FDA and other authorities could interfere with the commercialization of PALFORZIA.

Suppliers

Our lead product candidate, PALFORZIA, contains peanut flour and pharmaceutical-grade ingredients. We source the peanut flour from GPC, a wholly-owned subsidiary of Archer Daniels Midland. We chose to use peanut flour from GPC as the basis for PALFORZIA because its peanut flour has been used in most of the leading academic studies of peanut allergy OIT and because we believe that the widespread use of GPC peanut products in the United States may make their peanut flour representative of the type of peanut protein that patients are most likely to encounter in an accidental exposure. The other ingredients in PALFORZIA, such as diluents, glidants and lubricants, are sourced from established producers of pharmaceutical grade ingredients. In order to develop PALFORZIA as an FDA-approved biological product, we took the further step of characterizing the protein signature of GPC flour. Independent scientific research has identified numerous peanut proteins that are the allergens that cause allergic reactions to peanuts. Three of these proteins appear to be the most significant and representative of the levels of the other proteins. Our characterization of PALFORZIA is based on measuring total protein amount and the relative concentrations of those three key proteins as well as their potencies in an antibody binding assay.

We purchase standard food-grade peanut flour from GPC pursuant to a long-term exclusive commercial supply agreement, which was expanded and extended in January 2018. Under the terms of the restated agreement, we are obligated to purchase peanut flour exclusively from GPC, provided that GPC is able to supply the peanut flour in a timely manner with the quantity of peanut flour that we require. GPC is not allowed to sell several peanut flour products to any third party worldwide for use in OIT for the treatment or cure of peanut allergy, provided that we are in compliance with our exclusive purchase obligation and meet specified annual purchase commitments. The restated agreement remains in effect until ten years after the first delivery to us of peanut flour for commercial use and includes an option for us to extend the term for an additional five years. The restated agreement requires GPC to notify its wholesalers and distributors that the peanut flour products subject to the restated agreement cannot be used in OIT for the treatment or cure of peanut allergy. We also have a right of first refusal to obtain rights to new or existing GPC peanut flour products that are not already covered by the restated agreement if a third party intends to use the new or existing GPC product in OIT for the treatment of or cure of peanut allergy. We may terminate the restated agreement at any time for any reason upon providing 60 days' written notice to GPC. Either party may terminate the restated agreement if the other party fails to cure their material breach within 30 days of receiving notice of such breach from the non-breaching party or if the other party fails to perform their obligations under the agreement for a continuous period of 120 days due to a force majeure event or an insolvency or bankruptcy-related events.

In connection with the amendment and restatement of the agreement, we issued Archer Daniels Midland Company 300,000 shares of our common stock, vesting over a 3.5-year period. Subject to certain exceptions, in the event that the price per share of our common stock were to fall below a specified level, the restated agreement provides that GPC would only be prohibited from selling one peanut flour product to any third party in the United States, Mexico, Canada, the EU or Japan for use in OIT for the treatment or cure of peanut allergy.

In May 2019, we entered into a Commercial Supply Agreement, or the Commercial Supply Agreement, pursuant to which CoreRx, Inc. agreed to manufacture commercial supply of PALFORZIA, if approved. Under the Commercial Supply Agreement, we are required to purchase a minimum percentage of our PALFORZIA commercial supply requirements in each of the first six years of the Commercial Supply Agreement, subject to certain conditions and restrictions, ranging from 100% in 2019 and decreasing to a majority in 2024. We are also required to purchase a minimum percentage of our PALFORZIA supply requirements for release testing in each of the first six year of the Commercial Supply Agreement, ranging from 100% in 2019 and decreasing to a significant majority in 2024. The initial term of the Commercial Supply Agreement began upon execution of the Commercial Supply Agreement and will continue until December 31, 2024. The Commercial Supply Agreement then automatically renews for successive two-year terms, unless earlier terminated pursuant to its terms, or upon either party's notice of termination to the other.

In November 2019, we entered into a commercial packaging agreement, or the Commercial Packaging Agreement, with AndersonCrecon Inc. doing business as PCI of Illinois, or PCI, pursuant to which PCI package bulk product in accordance with our specifications, applicable laws and the terms and conditions of the Commercial Packaging Agreement. The initial term of the Commercial Packaging Agreement is for four contract years following the effective date. Contract Year one means the period beginning on the effective date of the Commercial Packaging Agreement and ending on December 31, 2019. Each contract year thereafter is the 12-month period from January 1 to December 31. The Commercial Packaging Agreement will automatically be renewed for one-year terms after the end of the Initial Term unless and until one party gives the other party at least three (3) years prior written notice of its desire to terminate as of the end of the then-current term, or is otherwise terminated in accordance with the other terms of the Commercial Packaging Agreement.

From time to time, we have and may, in the ordinary course of business, continue to enter into commercial supply agreements with third-parties for the supply of ingredients and proteins necessary for our other product candidates in the ordinary course of business. For example, in December 2018, we entered into an exclusive supply agreement for egg protein with Michael Foods, Inc. Pursuant to the agreement, we have exclusive access to the clinical and commercial use of Michael Foods' egg products for any egg allergy treatment, prevention or cure for a period of up to 15 years beyond the potential approval of AR201.

Intellectual Property

We have filed patent applications in the United States and foreign countries as well as international patent applications pursuant to the Patent Cooperation Treaty relating to PALFORZIA and certain of our other product candidates. Five patents, covering the formulation, methods of treatment, and certain of our manufacturing methods for PALFORZIA, have been issued in the United States, and four patents have issued in foreign countries covering certain of our manufacturing methods for PALFORZIA. There is no assurance that any additional patents will be issued from any of our pending patent applications. Even if patents do issue, there can be no assurance that the scope of the claims contained in the patents will be broad enough to provide protection from potentially competing products. Our patents and patent applications relating to PALFORZIA have expiration dates ranging from 2034 to 2040 without taking into account any potential patent term extensions. Our patents and patent applications seek protection relating to our formulations, methods of manufacture and improved methods for treating food allergies. We do not own or license, and do not anticipate that we will be able to obtain, a composition of matter patent over the active pharmaceutical ingredient in PALFORZIA or for any other product candidates that are based on widely or readily available food products. We have also licensed intellectual

property from Xencor relating to AIMab7195. The licensed intellectual property incudes issued U.S. and foreign patents covering AIMab7195.

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

Competition

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

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

Currently, other than PALFORZIA, there are no FDA-approved medical therapies for the treatment of food allergies. In October 2017, DBV Technologies S.A. announced results from its completed Phase 3 clinical trial evaluating Viaskin Peanut, a patch technology that epicutaneously delivers food allergens to the patient with the goal of desensitizing the patient to the allergens, in peanut-allergic patients (4 to 11 years of age). DBV submitted, and then subsequently withdrew, a BLA for this product. However, DBV resubmitted the BLA in August 2019, and it was accepted for review by the FDA in October 2019. PALFORZIA and/or any additional product candidate of ours may face competition from DBV's product candidates, if approved.

We may also face competition from allergists who decide to provide OIT and other desensitization therapies to their patients using their own formulations of food allergens and treatment protocols rather than adopting our product candidates or we may face competition from companies that develop their own OIT products, other desensitization therapy products or products intended to prevent the onset of food allergies in infants or young children. In addition, peanut allergic patients may attempt to use food products as a substitute for PALFORZIA in the fixed dosing portion of our PALFORZIA treatment program.

In the future, we may face competition from competitors seeking to use PALFORZIA as a reference product while developing a biosimilar product candidate using the FDA's abbreviated approval pathway for biosimilar products. The abbreviated regulatory pathway created pursuant to the Biologics Price Competition and Innovation Act of 2009, or BPCIA, establishes legal authority for the FDA to review and approve biosimilar biologics. To be considered a biosimilar, a product candidate must be highly similar to the reference product notwithstanding minor differences in clinically inactive components. In addition, there can be no clinically meaningful differences between the product candidate and the reference product in terms of the safety, purity, and potency of the product. We believe that the relative concentrations of relevant proteins in the peanut flour we source pursuant to our exclusive contract with the GPC are significantly different from the concentrations of proteins found in other commercially available sources of 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. 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.

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

Coverage and Reimbursement

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. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the drug products for a particular indication. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the studies required to obtain regulatory approvals. In the United States, decisions regarding the extent of coverage and amount of reimbursement to be provided for our products, if approved, will be made on a payor by payor basis. Each payor determines whether or not it will provide coverage for a drug, what amount it will pay for the drug, and on what tier of its formulary the drug will be placed. The drug's formulary placement generally determines the out-of-pocket costs to a patient in order to obtain the drug and can strongly influence the adoption of a drug by patients and physicians. Patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost of our products and related services.

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

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

Currently, there is no dedicated reimbursement code for the administration of oral immunotherapy today as allergists can use several different reimbursement coding options to seek reimbursement for their time in administrating the service. However, with such codes, there is no guarantee that a third-party payor will provide reimbursement for such codes as that decision is solely at the payor's discretion and must be negotiated on a case-by-case basis between providers and payors. Most recently as of November 2019, both the American Academy of Allergy, Asthma, and Immunology and the American College of Allergy, Asthma, and Immunology have issued a joint guidance on how to code for services related to PALFORZIA, specifically around the dose escalation and up-dosing phases of treatment. However, it was also acknowledged that allergy practices should follow health plan and payer policies as they may differ from what was recommended. In markets outside of the United States, we will need to evaluate clinician compensation mechanisms in each market to determine whether there is appropriate payment of physicians for administration of the treatment regimens.

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Healthcare Reform

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

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

In March 2010, the Affordable Care Act was signed into law, which substantially changed the way healthcare is financed by both governmental and private insurers. The Affordable Care Act, among other things, established: an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents; revised the methodology by which rebates owed by manufacturers for covered outpatient drugs under the Medicaid Drug Rebate Program are calculated; increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; extended the Medicaid Drug Rebate program to utilization of certain injectable outpatient drugs, as well as prescriptions of individuals enrolled in Medicaid managed care organizations.

We expect that 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. Since its enactment, there have also been other judicial and Congressional challenges to certain aspects of the Affordable Care Act. As a result, there have been delays in the implementation of, and action taken to repeal or replace, certain aspects of the Affordable Care Act. Recently, the Tax Cuts and Jobs Act (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. Further, 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. While the Trump Administration and the Centers for Medicare & Medicaid Services have both stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, if any, will impact the law. Any changes will likely take time to unfold and it is uncertain if any such changes may impact our business.

In addition, recently, there has been heightened governmental 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, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for medical products. Individual states in the United States have also become increasingly aggressive 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.

In addition, third-party payors may revise the payment methodologies used to determine reimbursement amounts. This includes annual updates to payments to physicians for the procedures performed using our products, which could directly impact the demand for any of our product candidates that may be approved.

In the future, there may continue to be additional proposals relating to the reform of the United States healthcare system, some of which could further limit the prices we are able to charge for our products candidates or increase the co-pay obligations of patients.

Government Regulation

Government Regulation in the United States

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

Overview of Biologics Regulation in the United States

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

- completion of pre-clinical laboratory tests and animal studies performed in accordance with the FDA's Good Laboratory Practices, or GLP, regulations;
- submission to the FDA of an IND which must become effective before human clinical trials may begin and must be updated annually;
- approval by an independent Institutional Review Board, or IRB, or ethics committee at each clinical site before the trial is initiated;
- performance of adequate and well-controlled clinical trials to establish the safety, purity and potency of the proposed biologic product candidate for its intended purpose;
- preparation, and submission to the FDA, of a BLA after completion of clinical trials;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMP requirements, and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency; and
- FDA review and approval of the BLA prior to any commercial marketing or sale of the product in the United States.

Pre-clinical Studies and IND Application

Prior to beginning the first clinical trial with a product candidate, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical trials. The IND also generally includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. We filed an IND for AR201 in December 2018 for use in oral desensitization therapy for egg allergy in children and adults. We filed an IND for PALFORZIA in April 2013 for use in oral desensitization therapy for peanut allergy in children and adults. Because there are no robust animal models of egg or peanut allergy, we did not conduct any pre-clinical efficacy studies of AR201 or PALFORZIA. In addition, because AR201 and PALFORZIA are based on food products, the FDA did not require us to submit any pre-clinical toxicology data before authorizing us to proceed with clinical trials under our IND for AR201.

Clinical Trials

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

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

- *Phase 1*. The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to evaluate the safety, dosage tolerance, metabolism and pharmacologic actions of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.
- *Phase 2*. The investigational product is administered to a limited patient population to evaluate dosage tolerance and optimal dosage, identify possible adverse side effects and safety risks and preliminarily evaluate efficacy.
- *Phase 3*. The investigational product is administered to an expanded patient population, generally at geographically dispersed clinical study sites to generate enough data to statistically evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the investigational product, and to provide an adequate basis for product licensure.
- *Phase 4*. In some cases, the FDA may condition approval of a BLA for a product candidate on the sponsor's agreement to conduct additional clinical trials after approval. In other cases, a sponsor may voluntarily conduct additional clinical trials after approval to gain more information about the product. Such post-approval studies are typically referred to as Phase 4 clinical trials.

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

Review and Approval of a BLA

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, detailed information regarding the investigational product is submitted to the FDA in the form of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent pre-clinical and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of the product, or from a number of alternative sources, including studies initiated by investigators. Under federal law, the submission of most BLAs is subject to an application user fee, and the sponsor of an approved BLA is also subject to annual program user fees. These fees are typically increased annually. A waiver of user fees may be obtained under certain limited circumstances. Applications for certain products, such as allergenic extracts, are exempt from such user fees and may not be subject to review under the same timelines as applications for user-fee-paying products.

Once a BLA has been submitted, the FDA's goal is generally to review the application within ten months after it accepts the application for filing, or, if the application receives priority review, six months after the FDA accepts the application for filing However, these review timelines may not apply to BLAs submitted for allergenic extract products. Moreover, the review process is often significantly extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity and potency.

Before approving a BLA, the FDA typically will inspect the facility or facilities at which the product is manufactured. The FDA will not approve the application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP requirements. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in

the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

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

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

Expedited Review and Approval Programs

A sponsor may seek approval of its product candidate under programs designed to accelerate the FDA's review and approval of new drugs and biological products that meet certain criteria. Specifically, new drugs and biological products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for that disease or condition. For a Fast Track product, the FDA may consider sections of the BLA for review on a rolling basis before the complete application is submitted if relevant criteria are met. PALFORZIA was granted Fast Track designation in September 2014.

A product candidate may also qualify for priority review, under which the FDA generally sets the target date for FDA action on the BLA that is subject to the prescription drug user fee amendments, or PDUFA, goals at six months after the FDA accepts the application for filing, or for drugs that are not new chemical entities, six months after the FDA receives the application. Priority review is granted when there is evidence that the proposed product would be a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious condition. If criteria are not met for priority review, the application is subject to the standard FDA PDUFA review period of 10 months after the FDA accepts the application for filing, or for drugs that are not new chemical entities, 10 months after FDA receives the application. Priority review designation does not change the scientific or medical standard for approval or the quality of evidence necessary to support approval.

Under the accelerated approval program, the FDA may approve a BLA on the basis of either a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Post-marketing studies or completion of ongoing studies after regulatory approvals are generally required to verify the biologic's clinical benefit in relationship to the surrogate endpoint or ultimate outcome in relationship to the clinical benefit. Biologics granted accelerated approval may be subject to expedited withdrawal procedures if the product sponsor fails to conduct the required post-marketing studies, or if such post-marketing studies fail to verify a clinical benefit.

The FDA may also designate a product candidate as a Breakthrough Therapy if it is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough Therapy designation includes all of the Fast Track program features, as well as more intensive FDA interaction and guidance. The Breakthrough Therapy designation is a distinct status from both accelerated approval and priority review, which can also be granted to the same biologic if relevant criteria are met. If a product is designated as breakthrough therapy, the FDA will work to expedite the development and review of such product.

Fast Track designation, Breakthrough Therapy designation and priority review do not change the standards for approval but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Post-Approval Requirements

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

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

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

The FDA strictly regulates the marketing, labeling, advertising, and promotion of biologics. A company may make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturers' communications on the subject of off-label use of their products.

Abbreviated Licensure Pathway of Biological Products as Biosimilar or Interchangeable

The Affordable Care Act, or ACA, signed into law on March 23, 2010, included the BPCIA, which amended the PHSA and established a regulatory scheme authorizing the FDA to approve biosimilars and interchangeable biosimilars. The FDA has issued several guidance documents outlining its current approach to the review and approval of biosimilars.

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

products administered multiple times) that the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

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

Other Healthcare Laws in the United States

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

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

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

The federal Civil Monetary Penalties Law prohibits, among other things, the offering or transferring of remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of Medicare or Medicaid payable items or services. Noncompliance with such beneficiary inducement provision of the federal Civil Monetary Penalties Law can result in civil money penalties for each wrongful act, assessment of three times the amount claimed for each item or service and exclusion from the federal healthcare programs

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

There has also been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, among other things, imposed new reporting requirements on drug manufacturers for payments

made by them to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit required information may result in civil monetary penalties for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Drug manufacturers are required to submit reports to the government by the 90th day of each calendar year. Certain states also mandate implementation of compliance programs, impose restrictions on drug manufacturer marketing practices and/or require the tracking and reporting of marketing expenditures and pricing information as well as gifts, compensation and other remuneration to physicians.

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

The U.S. is also increasingly introducing new general data privacy and security legislation, including notably the recent California Consumer Privacy Act, which comes into force in 2020 and regulates the collection of personal information about California residents regardless of the industry in which the business operates.

Federal and state government price reporting laws require manufacturers to calculate and report complex pricing metrics to government programs. Such reported prices may be used in the calculation of reimbursement and/or discounts on marketed products. Participation in these programs and compliance with the applicable requirements subject manufacturers to potentially significant discounts on products, increased infrastructure costs, and potentially limit the ability to offer certain marketplace discounts.

Government Regulation in Europe and European laws regarding the protection of personal data

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), medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA.

There are two types of MAs:

- The Community MA, which is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the EMA, and which is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, and medicinal products that contain a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU. Under the Centralized Procedure the maximum timeframe for the evaluation of a marketing authorization application is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP). Accelerated evaluation might be granted by the CHMP in exceptional cases, when the authorization of a medicinal product is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. Under the accelerated procedure the standard 210 days review period is reduced to 150 days.
- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member States through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure.

Under the above described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

In the EEA, new products authorized for marketing, or reference products, qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. The data exclusivity period prevents generic or biosimilar applicants from relying on the pre-clinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until 10 years have elapsed from the initial authorization of the reference product in the EU. The 10-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those 10 years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

In the EEA, marketing authorization applications for new medicinal products not authorized have to include the results of studies conducted in the pediatric population, in compliance with a pediatric investigation plan, or PIP, agreed with the EMA's Pediatric Committee, or PDCO. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which marketing authorization is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data is not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the marketing authorization is obtained in all Member States of the EU and study results are included in the product information, even when negative, the product is eligible for six months' supplementary protection certificate extension. For orphan-designated medicinal products, the 10-year period of market exclusivity is extended to 12 years.

The collection and processing of personal data – including health data –EEA (including the EU), is currently governed by the General Data Protection Regulation, or GDPR, which became enforceable on May 25, 2018, replacing the Data Protection Directive 95/46/EC. The GDPR implements more stringent operational requirements for processors and controllers of personal data, including, for example, expanded disclosures about how personal information is collected and used, limitations on retention of information, increased requirements pertaining to health data and pseudonymised (*i.e.*, key-coded) data, mandatory data breach notification requirements, more robust rights for individuals in regard to their personal data and higher standards for controllers to demonstrate that they have obtained valid consent for certain data processing activities. The GDPR provides that EU and EEA Member States may make their own further laws and regulations, which may impose further limitations, including in relation to the processing of genetic, biometric or health data, which may result in differences between Member State laws, limit our ability to use and share personal data, cause our costs to increase, and/or harm our business and/or financial condition.

We are also subject to strict rules on the transfer of personal data out of the EEA, including to the United States. The GDPR only permits exports of personal data outside the EEA where there is a suitable data transfer solution in place to safeguard the personal data (e.g., the EU Commission approved Standard Contractual Clauses or, in relation to exports to the US, the EU-US Privacy Shield) or where the country receiving such data is approved by the EU Commission as providing adequate protection for personal data. Where we transfer personal data out of the EEA, we rely on a number of data transfer solutions including in regard to transfers of personal data (HR data and non-HR data) to the US (and Switzerland), we are certified under the EU-US (and Swiss-US) Privacy Shield. If it were to be determined that we were not complying with our obligations under the EU-US (and/or Swiss-US) Privacy Shield framework(s) and we were to lose our applicable Privacy Shield certification from the US Department of Commerce, we will need to find an alternative solution for transferring personal data from EU to the US.

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, after 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.

Failure to comply with the GDPR may result in fines of up to €20.0 million or up to 4% of the total worldwide annual turnover of the preceding financial year (whichever is higher) and other administrative penalties, as well as enforcement notices, assessment notices (for a compulsory audit), orders to cease/ change our processing of our data, regulatory investigations and potential civil

claims including class action type litigation where individuals suffer harm, which may be onerous and adversely affect our clinical trials, business, reputation, financial condition, operations and prospects.

We are also subject to evolving EU data 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 effective 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 €20.0 million 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 changes.

Other Regulations

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

Employees

As of December 31, 2019, we had 275 full-time employees. Of these employees, 129 are engaged in research and development. Our employees are not represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Segment Information

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

Corporate Information

We were founded on June 24, 2011 as a Delaware corporation under the name Allergen Research Corporation. In May 2015, we changed our name to Aimmune Therapeutics, Inc. We completed our initial public offering in August 2015. Our common stock is currently listed on The Nasdaq Global Select Market under the symbol "AIMT." Our principal executive offices are located at 8000 Marina Blvd, Suite 300, Brisbane, CA 94005 and our telephone number is (650) 614-5220. Our website address is www.aimmune.com. The information on, or that can be accessed through, our website is not incorporated by reference into this Annual Report on Form 10-K or any other filings we make with the U.S. Securities and Exchange Commission, or SEC.

Available Information

We make available on or through our website, www.aimmune.com, certain reports and amendments to those reports that we file with, or furnish to, the SEC in accordance with the Securities Exchange Act of 1934, as amended, or the Exchange Act. These include our Annual Reports on Form 10-K, our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act. We make this information available on or through our website free of charge as soon as reasonably practicable after we electronically file the information with, or furnish it to, the SEC. The SEC maintains a website that contains reports, proxy and information statements, and other information regarding our filings, at www.sec.gov. The information on, or that can be accessed through, our website is not incorporated by reference into this Annual Report on Form 10-K or any other filings we make with the SEC.

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 Annual Report on Form 10-K, including our audited financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations." The occurrence of any of the events or developments described below could have a material adverse effect on our business, results of operations, financial condition, prospects and stock price. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

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

We have a limited operating history, have incurred significant losses since our inception and anticipate that we will continue to incur losses for the foreseeable future. We just received approval to market our product PALFORZIA™, and have not yet commercially launched the product, 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, and we have not commenced commercialization of the product. We are not profitable and have incurred losses each year since our inception in June 2011. We have only a limited operating history upon which you can evaluate our business and prospects. In addition, we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the pharmaceutical industry. We have not generated any revenue from product sales and, as a result, we have incurred significant losses. We incurred a net loss of $248.5 million, $210.8 million, and $131.3 million for the years ended December 31, 2019, 2018, 2017 respectively. As of December 31, 2019, our accumulated deficit was $724.7 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 our product candidates, if approved, which 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 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 or 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 require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development, other operations or commercialization efforts.

Since commencing our operations in 2011, substantially all of our efforts have been focused on research, development and the advancement of our CODIT therapeutic approach, PALFORZIA and researching and developing additional CODIT product candidates. As of December 31, 2019, we had capital resources consisting of cash, cash equivalents and investments of $158.2 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 AR201 for egg allergy and for other 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 loan tranche from KKR of $85.0 million in February 2020, we anticipate that these financial resources will fully fund us based on our current business plan. However, our operating plan may change as a result of many factors, including factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity, debt financings or other sources, such as strategic collaborations. Such financing may result in dilution to stockholders, imposition of debt covenants and repayment obligations or other restrictions that may affect our business. If we raise additional capital through strategic collaboration agreements, we may have to relinquish valuable rights to our product candidates including possible future revenue streams. In addition, any fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize 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;
- 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 building 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 developing 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 foreign 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 PALFORIZIA 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 commercialize PALFORZIA, 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 December 31, 2019, there was approximately $44.0 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. Any delay or 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 lenders' 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.

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 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. However, we are not permitted to market or promote PALFORZIA outside the United States before we receive regulatory approval from the European Medicines Agency, or 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 Marketing Authorization Application, or 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.

We have not commenced commercialization of the product and 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 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 U.S. 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 and the inclusion of the "black box" warning could make it more difficult for PALFORZIA 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 we only recently 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 expect to complete deployment of a specialty commercial field organization with technical expertise and supporting distribution capabilities to commercialize PALFORZIA in February 2020. Such deployment will be expensive and time-consuming.

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 in the development of our internal commercial field, marketing and distribution capabilities would adversely impact the commercialization of these products. Further, given our lack of prior experience in commercializing pharmaceutical products, our estimates of the number of commercial field employees needed to commercialize 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 expect to implement a training program to educate physicians and patients on the safe use of PALFORZIA and its approved indication. 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 began deployment of our medical science liaison, or MSL, organization in the third quarter of 2018, and this team continues to grow. The MSL team is a field-based part of our medical affairs group. The role of MSLs is to serve as a liaison to members of the medical, scientific and patient advocate communities and to provide scientific expertise and clinical insights from health care practitioners to internal colleagues. The activities of MSLs are subject to extensive statutory and regulatory requirements and enforcement, in the United States, by the federal government and the states and, outside the United States, by the governments of the countries where we deploy MSLs. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our MSL activities could be subject to challenge under one or more of such laws or regulations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to market our products and adversely impact our financial results.

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 our 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 commercialize or 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 intend to use blister packs and sachets as the final packaging configuration for our commercial launch of PALFORZIA. Stability testing of PALFORZIA in the blister pack and sachet configurations is ongoing. Any complications with the stability testing in the blister pack or sachet configurations could extend the timelines for our regulatory filings for PALFORZIA and could limit the shelf life of the commercial product at the time of launch. In addition, 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 as well as for our ongoing and planned clinical trials on a timely basis is a complex operation. There are multiple doses in the dose escalation phase of 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. 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, in October 2017, DBV Technologies S.A. announced results from

its completed Phase 3 clinical trial evaluating Viaskin Peanut, a patch technology that epicutaneously delivers food allergens to the patient with the goal of desensitizing the patient to the allergens, in peanut-allergic patients (4 to 11 years of age). DBV submitted, and then subsequently withdrew, a BLA for this product. In August 2019, DBV announced that it had resubmitted a BLA for Viaskin Peanut.

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 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. 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:

- 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:

- 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 have not yet been 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.

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

Conducting clinical trials in foreign countries, as we have done for our ARTEMIS trial, and are doing or plan to do for our ARC004, ARC005 and ARC008 trials, presents additional risks that may delay completion of our clinical trials. These risks include a foreign regulatory authority imposing additional requirements prior to the commencement of clinical trials in a foreign country, the failure of physicians or enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, complying with data privacy regulations in the EU 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 EU 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 physicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating.

In addition, certain sub-groups of patients may be more difficult to recruit than others. For example, to date, we have enrolled 57 patients above the age of 17, and we believe the adult patient population is more difficult to recruit than younger patients. The FDA has concluded that additional safety and efficacy data is required for the adult patient subgroup and any initial approval that we may obtain will not include an indication for patients of such subgroup. If we are not able to recruit patients to participate in our clinical trials in a timely manner, our business and results of operations could be adversely affected.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs or foreign equivalents of the institutions in which such studies are being conducted, by an independent Safety Review Board for such clinical trial, or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, failure to pass inspections of the clinical trial operations or trial site by the FDA or other regulatory authorities, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using the product, changes in governmental regulations or administrative actions, issues with the quality of or the manufacturing process used to produce our clinical trial materials or lack of adequate funding to continue the clinical trial. For example, the protocols for certain of our clinical trials require that patients participate in food challenges where they receive increasing amounts of the food to which they are allergic. In our clinical trials, participation in these food challenges has resulted in allergic reactions severe enough to require treatment with epinephrine. It is possible that patients could have allergic reactions severe enough to require hospitalization or even cause death. In such an event, we could be required to suspend or terminate our clinical trials.

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

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

In accordance with our food allergy clinical trial protocols, in certain clinical trials, 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 also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. 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 further 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, especially, the EU. Failure to comply with these data privacy regulations could prevent us from using clinical data, and subject us to penalties and fines, which could delay or impair review and potential approval of marketing approval applications for our product candidates. Moreover, these third parties may also have relationships with other commercial entities, some of which may compete with us. In addition, our agreements with third parties may typically be terminated by such third parties upon as little as 30 days' prior written notice or, in certain cases, under certain other circumstances, including our insolvency. If the third parties conducting our clinical trials do not perform their contractual duties or obligations, experience work stoppages, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical trial protocols, GCPs or data privacy requirements, we may need to enter into new arrangements with alternative third parties, which could be difficult, costly or impossible, and our clinical trials may be extended, delayed or terminated or may need to be repeated. If any of the foregoing were to occur, we may not be able to obtain regulatory approval for or commercialize the product candidate being tested in such studies.

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. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States. In the United States, private third-party payors often rely upon Medicare coverage and reimbursement policies and payment limitations in setting their own coverage and reimbursement policies. Our inability to promptly obtain adequate coverage, reimbursement and profitable payment rates from both government funded and private payors for new products that we develop could have a material adverse effect on our business, results of operations, financial condition, prospects and stock price.

In addition, the 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 December 31, 2019, we had 275 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:

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

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

If we fail to attract and retain senior management, we may be unable to successfully 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 and planned 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, 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 and AR201, 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 physicians, 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 further 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 the future we may seek additional collaboration arrangements with pharmaceutical or biotechnology companies for the further 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; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

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

We may attempt to acquire businesses, technologies, services, products or product candidates that we believe are a strategic fit with our business. If we do undertake any acquisitions, the process of integrating an acquired business, technology, service, products or product candidates into our business may result in unforeseen operating difficulties and expenditures, including diversion of resources and management's attention from our core business. In addition, we may fail to retain key executives and employees of the companies we acquire, which may reduce the value of the acquisition or give rise to additional integration costs. Future acquisitions could result in additional issuances of equity securities that would dilute the ownership of existing stockholders. Future acquisitions could also result in the incurrence of debt, contingent liabilities or the amortization of expenses related to other intangible assets, any of which could adversely affect our operating results. In addition, we may fail to realize the anticipated benefits of any acquisition.

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

We are subject to income and other taxes in the U.S. and foreign jurisdictions. Changes in laws and policy relating to taxes or trade may have an adverse effect on our business, financial condition and results of operations. For example, the U.S. government recently enacted significant tax reform, and certain provisions of the new law may adversely affect us. Changes include, but are not limited to, a federal corporate tax rate decrease from 34% to 21% for tax years beginning after December 31, 2017, the transition of U.S. international taxation from a worldwide tax system to a more generally territorial system, and a one-time transition tax on the

mandatory deemed repatriation of foreign earnings. The legislation is unclear in many respects and could be subject to potential amendments and technical corrections and will be subject to interpretations and implementing regulations by the Treasury and Internal Revenue Service, any of which could mitigate or increase certain adverse effects of the legislation. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation. Generally, future changes in applicable U.S. or foreign tax laws and regulations, or their interpretation and application could have an adverse effect on our business, financial conditions and results of operations.

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

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

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

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

Furthermore, our contract manufacturer and integral parties in our supply chain, are operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen and severe adverse events. In particular, our manufacturing facility for 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. 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 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.

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 sufficient 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 a "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 are subject to numerous U.S. federal and state laws both generally and specifically in relation to protected health information, including the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, and related laws, and European laws and regulations, including the General Data Protection Regulation, or GDPR, and the e-Privacy Directive (2002/58/EC), soon to be replaced by an e-Privacy Regulation, and the EU national laws implementing or supplementing the GDPR or e-Privacy Directive, as well as 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 repealed the Data Protection Directive (95/46/EC) and is directly applicable in all EU member states since its effective date of May 25, 2018. The GDPR applies to companies established (for data processing purposes) in the EU or EEA as well as companies that are not so established in the EU or EEA and which collect and use personal data in relation to offering goods or services to, or monitoring the behavior of, individuals located in the EU or EEA, including, for example, through the conduct of clinical trials (whether the trials are conducted directly by us or through a clinical vendor or collaborator). The GDPR sets out requirements that must be complied with when handling personal data including: providing detailed disclosures about how data subjects' personal data will be used; demonstrating that they have an appropriate legal basis in place to justify their data processing activities; appointing data protection officers in certain circumstances; enhancing existing rights and granting rights for data subjects in regard to their personal data (including the right to be "forgotten", to data access and to data portability); strengthening the obligation to notify data protection regulators or supervisory authorities (and in certain cases, affected individuals) of data security breaches; and complying with principal of accountability and complying with the obligation to demonstrate compliance through policies, procedures, training and audit.

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

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

We are also subject to EU and EEA laws on data export, where we transfer personal data outside the E.E.A. to group companies or third parties. The GDPR only permits exports of personal data outside EEA where there is a suitable data transfer solution in place to safeguard the personal data (e.g., the EU Commission approved Standard Contractual Clauses or, in relation to exports of personal data to the US, the EU-US- Privacy Shield) or where the country receiving such data is approved by the EU Commission as providing adequate protection for personal data. Where we transfer personal data out of the EU or EEA, we rely on a number of data transfer solutions including in regard to transfers of personal data (HR data and non-HR data) to the US (and Switzerland), we are certified under the EU-US (and Switzerland-US) Privacy Shield. In addition, if it were to be determined that we were not complying with our obligations under the Privacy Shield framework and we were to lose our Privacy Shield certification from the Department of Commerce, we will need to find an alternative solution for transferring data out of the EEA to the U.S.

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, after 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 changes.

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 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 requires, 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.

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

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

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

Our failure to obtain regulatory approvals in foreign jurisdictions for 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 U.S. by the federal government and the states and by the governments of other countries where we conduct our business. The laws that will affect our ability to operate as a commercial organization include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the false claims laws;
- U.S. federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;
- U.S. federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them to have committed a violation;
- U.S. federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;
- U.S. federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- the U.S. federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information;
- the U.S. federal physician sunshine requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the Affordable Care Act, which requires certain manufacturers of drugs, devices, biologics, and medical supplies to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members;
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers;
- state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources;
- state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; and state laws governing the privacy and security of health information (or personal information generally) in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts;
- state laws that require drug manufacturers to obtain licenses prior to distribution or sale of pharmaceutical products in that state; and
- European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers.

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

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

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

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

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

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

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

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

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

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

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. These changes include the Budget Control Act of 2011, which resulted in aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2029 unless additional Congressional action is taken, as well as the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Recently, there has also been heightened government scrutiny over the manner in which manufacturers set prices for their marketed products, which has

resulted in several Congressional inquiries and proposed and enacted legislation designed to, among other things, reform government program reimbursement methodologies. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. 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 U.S. or foreign countries. Even if any such additional patents issue, we cannot assure our stockholders that they or any other patents we obtain will include any claims with a scope sufficient to protect 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 or commercialization 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:

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

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

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

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;

- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- the required approval of at least 66 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 at least one woman on our board of directors by the end of 2019, and two or three women on our board by the end of 2021, depending on the size of our board at the time. While we currently have two women on our board and intend to continue to comply with this California law, recruiting and retaining board members carries uncertainty, and failure to comply with this requirement could result in financial penalties.

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

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

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

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

Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership over a rolling three-year period, the corporation's ability to use its pre-change net operating loss, or NOL, carryforwards to offset its post-change taxable income may be limited. Limitations may also apply to the utilization of other pre-change tax attributes as a result of an ownership change. As of December 31, 2019, we had generated NOL carryforwards for federal income tax purposes of $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 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our corporate headquarters is located in Brisbane, California where we lease a total of approximately 58,000 square feet. The lease for this office space expires on June 30, 2024. We also lease office space in Durham, North Carolina and London, United Kingdom.

In addition, we lease approximately 30,000 square feet of manufacturing space in Clearwater, Florida pursuant to a lease that expires in 2025.

We believe that our existing facilities and other available properties will be sufficient for our needs for the foreseeable future.

For additional information, see Contractual Obligations and Other Commitments in Part II, Item 7 of this Annual Report on Form 10-K.

Item 3. Legal Proceedings.

We are currently not party to any material legal proceedings; however, we may from time to time be involved in various legal proceedings incident to the ordinary course of our business.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock has been listed on The Nasdaq Global Select Market under the symbol "AIMT" since our initial public offering, or IPO, of our common stock on August 6, 2015. Prior to that time, there was no public market for our common stock.

Holders of Record

On February 14, 2020, there were approximately 15 stockholders of record of our common stock and the closing price of our common stock was $27.97 per share as reported by The Nasdaq Global Select Market. Since many of our shares of common stock are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

Dividend Policy

We have never declared or paid cash dividends on our capital stock. We intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. In addition, the Securities Purchase Agreement we entered into with Nestle Health Science US Holdings, Inc. in February 2020, contractually prevents us from using any of the proceeds from the sale and issuance of the shares of our common stock as a cash dividend or distribution until the second anniversary of the closing date. Further, we are currently subject to covenants under our credit agreement with an affiliate of KKR, LLC that place restrictions on our ability to pay dividends. Any future determination related to dividend policy will be made at the discretion of our board of directors.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

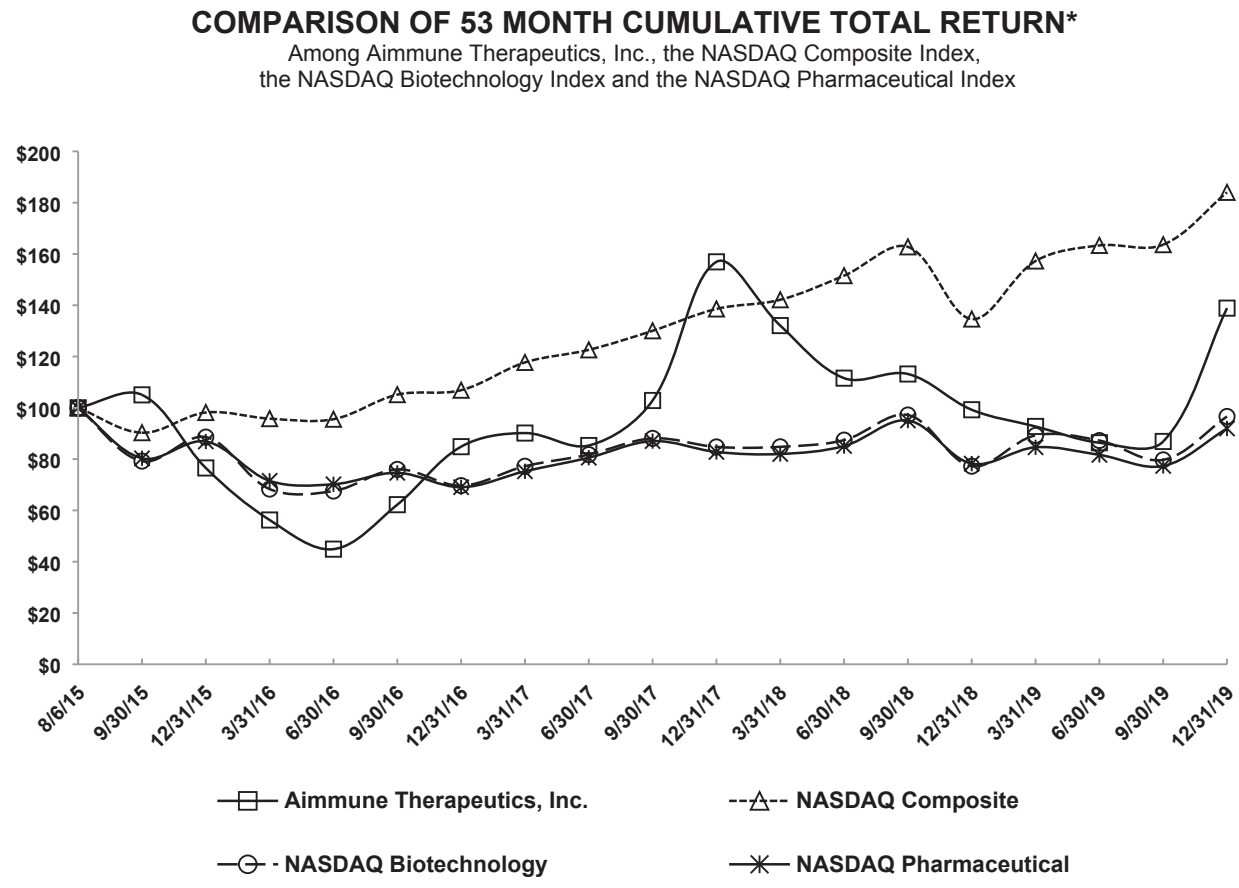
None.

Sales of Unregistered Securities

There were no sales of unregistered securities during the year ended December 31, 2019.

Stock Performance Graph

The following graph illustrates a comparison of the total cumulative stockholder return on our common stock since August 6, 2015, which is the date our common stock first began trading on The Nasdaq Global Select Market, to three indices: the Nasdaq Composite Index, the Nasdaq Biotechnology Index and the Nasdaq Pharmaceutical Index. The stockholder return shown in the graph below is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns. This graph shall not be deemed "soliciting material" or be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any of our filings under the Securities Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.



*$100 invested on 8/6/15 in stock or 7/31/15 in index, including reinvestment of dividends.
Fiscal year ending December 31.

Item 6. Selected Financial Data.

The following selected financial data are derived from the consolidated financial statements. The data presented below should be read in conjunction with the consolidated financial statements of the Company, the notes to the consolidated financial statements, and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this Annual Report on Form 10-K. The selected consolidated statement of operations data for the years ended December 31, 2019, 2018 and 2017 and the selected consolidated balance sheet data as of December 31, 2019 and 2018 are derived from our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. The selected consolidated statement of operations data for the years ended December 31, 2016 and 2015 and the selected consolidated balance sheet data as of December 31, 2017, 2016 and 2015 are derived from our audited consolidated financial statements not included in this Annual Report on Form 10-K. Our historical results are not necessarily indicative of the results that may be expected in the future.

	Year Ended December 31,				
	2019	2018	2017	2016	2015
	(In thousands, except per share amounts)				
Operating expenses					
Research and development	$ 123,987	$ 133,420	$ 89,325	$ 54,642	$ 19,816
General and administrative	125,817	81,921	43,949	26,885	16,181
Total operating expenses	249,804	215,341	133,274	81,527	35,997
Loss from operations	(249,804)	(215,341)	(133,274)	(81,527)	(35,997)
Interest income	5,851	4,984	2,190	918	217
Interest expense	(4,916)	(113)	(114)	(97)	(36)
Other income (expense), net	1,088	(221)	(71)	(118)	—
Loss before provision for income taxes	(247,781)	(210,691)	(131,269)	(80,824)	(35,816)
Provision for income taxes	716	61	56	—	—
Net loss	$(248,497)	$(210,752)	$(131,325)	$ (80,824)	$ (35,816)
Net loss per share, basic and diluted	$ (3.97)	$ (3.67)	$ (2.61)	$ (1.89)	$ (1.88)
Weighted average shares used in computing net loss per share, basic and diluted	62,558	57,403	50,401	42,751	19,041

	Year Ended December 31,				
	2019	2018	2017	2016	2015
	(In thousands)				
Balance Sheet Data:					
Cash and cash equivalents	$ 79,880	$ 107,511	$ 73,487	$ 124,010	$ 76,777
Working capital	101,629	274,607	162,512	240,230	192,359
Total assets	204,369	339,555	206,934	298,789	212,361
Accumulated deficit	(724,680)	(476,234)	(265,482)	(134,157)	(53,333)
Total stockholders' equity	104,024	298,947	177,805	285,972	206,251

Item 7. 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 audited financial statements and related notes included elsewhere in this Annual Report on Form 10-K. This discussion and other parts of this Annual Report on Form 10-K 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 Annual Report of on Form 10-K 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 **C**haracterized **O**ral **D**esensitized **I**mmunology **T**herapy, 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. 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, that may occur with 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 expect to commence 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 expect to complete enrolment of this trial in the second half of 2020. We also 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. We expect the EMA to issue a decision on the application in the fourth quarter of 2020. We maintain worldwide commercial rights to PALFORZIA and all of our product candidates. 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.

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, which we expect to be fully enrolled for in the second half of 2020. We are also exploring a product candidate designed to treat multi-nut allergy, including walnut allergy.

Since commencing our operations in 2011, substantially all our efforts have been focused on research, development and commercialization of PALFORZIA. We have not generated any revenue from product sales and, as a result, we have incurred significant losses. We incurred net losses of $248.5 million, $210.8 million and $131.3 million for the years ended December 31, 2019, 2018, and 2017, respectively, and used $195.4 million of cash in operations for the year ended December 31, 2019. As of December 31, 2019, our accumulated deficit was $724.7 million. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase as we begin to commercialize PALFORZIA and as we continue to develop other product candidates.

In February and March 2018, we issued and sold an aggregate of 6,325,000 shares of our common stock in an underwritten public offering at a price to the public of $32.00 per share, including the closing of the full exercise of the underwriters' option to purchase an additional 825,000 shares of common stock. In addition, in November 2018, we sold an additional 3,237,529 shares of our common stock to Nestlé Health Science at a price of $30.27 per share, for aggregate proceeds of $98.0 million.

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 PALFORIZA 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 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 and supply future clinical trials of AR101. This manufacturing facility became operational in November 2018. We plan to continue to rely on the contract manufacturer that is located at the same site to manage the operations of this new manufacturing facility. Additionally, we currently utilize specialized clinical vendors, clinical trial sites, consultants, and clinical research organizations, or CROs, to ensure the proper and timely conduct of our clinical trials. We expect to continue to significantly increase our investment in our manufacturing process and commercial organization as we launch PALFORZIA commercially in the United States and as we prepare for the potential approval of the MAA with the EMA for PALFORZIA.

Credit Agreement with KKR

In January 2019, we entered into a Credit Agreement with KKR Peanut Aggregator L.P., an affiliate of KKR LLC, which we refer to, together with the several banks and other financial institutions from time to time party to the Credit Agreement, collectively as the Lenders, and Cortland Capital Market Services LLC, as the administrative agent and the collateral agent, or Agent. The Credit Agreement consists of a six-year term loan facility for an up to aggregate principal amount of $170.0 million, which we refer to as the Term Loans. The Credit Agreement provided for an initial Term Loan of $40.0 million, which was funded in January 2019. We drew an additional $85.0 million of the Term Loans in February 2020 following FDA approval of PALFORZIA and satisfaction of other customary borrowing conditions. At our option and, subject to the fulfillment of customary conditions precedent, including our achievement of aggregate net sales (as defined in the agreement) for PALFORIZA by July 31, 2020 in an amount of at least $30.0 million, we may draw the remaining $45.0 million of the Term Loans. The Term Loans under the Credit Agreement bear interest through maturity, at our election, with respect to (a) ABR Loans, 6.50% per annum and (b) LIBOR Loans, 7.50% per annum. We began accruing interest on the outstanding Term Loans on March 31, 2019, and continue to accrue interest on the outstanding Term loans on the last business day of each March, June, September and December thereafter while any Term Loan is outstanding, as well as on the final maturity date of the Term Loans. For each interest payment date until and including the fiscal quarter ending June 30, 2020, we have the option to elect whether the interest payments due on such interest payment date shall be paid in cash or paid in kind and capitalized. We have selected to pay in kind and have the interest capitalized for the year ending December 31, 2019.

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

If all or any of the Term Loans are prepaid or required to be prepaid under the Credit Agreement, then we will pay, in addition to such prepayment, a prepayment premium equal to (i) with respect to any such prepayment paid on or prior to January 3, 2021, the amount, if any, by which (a) the present value as of such date of determination of (x) 105.00% of the principal amount of the Term Loans prepaid plus (y) all required interest payments that would have been due on the principal amount of the Term Loans prepaid through and including January 3, 2021, computed using a discount rate equal to the treasury rate most nearly equal to the period from such date of prepayment to January 3, 2021 plus 50 basis points exceeds (b) the principal amount of the Term Loans prepaid, (ii) with respect to any prepayment paid or required to be paid after January 3, 2021 but on or prior to January 3, 2022, 5.00% of the principal amount of the Term Loans prepaid, (iii) with respect to any prepayment paid or required to be paid after January 3, 2022 but on or prior to January 3, 2023, 2.00% of the principal amount of the Term Loans prepaid and (iv) with respect to any prepayment paid or required to be prepaid thereafter, 0.00% of the principal amount of the Term Loans prepaid.

Upon the prepayment or repayment of all or any of the Term Loans, we will pay an additional (in addition to the prepayment premium) exit fee in an amount equal to 4.00% of the principal amount of the Term Loans prepaid or repaid. In addition, we paid certain customary fees and expenses to the Agent and other service providers upon the closing of the transaction.

The obligations under the Credit Agreement are secured by a lien on substantially all of our tangible and intangible property. The Credit Agreement contains certain affirmative covenants, 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 each of 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.

Collaboration with Nestle Health Science

In November 2016, we entered into a two-year strategic collaboration with an affiliate of Nestle Health Science US Holdings, Inc. for the advancement of food allergy therapeutics and issued and sold to Nestle Health Science US Holdings, Inc. (together with its affiliate, Nestle Health Science) 7,552,084 shares of common stock in a private placement at a price of $19.20 per share, which represented approximately 15.1% of our outstanding shares at the time of the transaction. Subject to certain limited exceptions, Nestle Health Science agreed to a two-year market standoff provision under which it agreed not to sell or transfer any of our common stock or other securities. Subject to certain limited exceptions, Nestle Health Science also agreed to a two-year standstill agreement under which Nestle Health Science agreed not to acquire us through any means. We agreed to register the resale of the shares that Nestle Health Science purchased on a registration statement to be filed with the SEC upon the request of Nestle Health Science, which cannot make the request prior to the 45th day preceding the end of the market standoff provision. The investment and the collaboration do not include any development milestones, product marketing rights or royalties.

In November 2018, we entered into an extension of the strategic collaboration on similar terms and issued and sold an additional 3,237,529 shares of our common stock in a private placement at a price of $30.27 per share for aggregate proceeds of $98.0 million, increasing Nestlé Health Science's ownership of Aimmune to approximately 19%. The transaction documents include the extension of the registration rights, standstill rights and market standoff provisions. We are not subject to any partnership, collaboration, or negotiation restrictions under the extension agreements. In addition, we retain all rights to our current and future pipeline assets, and we and Nestlé Health Science expect to continue to collaborate towards the successful development of such assets.

The initial investment launched a two-year strategic collaboration, which was extended for an additional two years in November 2018, between us and Nestle Health Science, the terms of which enable both parties to discuss our current and future oral immunotherapy development programs through a newly established pipeline forum. Nestle Health Science will provide ongoing scientific, regulatory, and commercial expertise and advice to us through the pipeline forum. Any information disclosed in the collaboration will remain our confidential information, and any new ideas or inventions that arise that relate to our products will be our solely owned intellectual property. If we elect to seek a partner or collaborator for one of our oral immunotherapy development programs during the two-year term of the collaboration, Nestle Health Science will have a three-month period to negotiate exclusively with us. During the term of the collaboration, and for so long as Nestle Health Science holds not less than ten percent of our outstanding common stock, Nestle Health Science will be entitled to designate one nominee to serve as a director on our Board of Directors. In November 2016, Greg Behar joined our Board of Directors on behalf of Nestle Health Science. The strategic collaboration agreement contains a non-competition covenant pursuant to which Nestle Health Science has agreed not to engage in certain activities relating to OIT for the treatment of food allergies.

In February 2020, we announced a $200.0 million equity investment by Nestle Health Science S.A. and the extension of their existing strategic collaboration designed to enable the development and commercialization of innovative food allergy therapies, which will terminate in November 2021.

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 consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles, or GAAP, in the United States. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates. Our significant accounting policies are more fully described in Note 2 of Notes to Consolidated Financial Statements in Part II, Item 8 of this Annual Report on Form 10-K.

Accrued Research and Development Costs

We record expenses for our research and development activities conducted by third-party service providers, which include the conduct of pre-clinical studies and clinical trials, contract manufacturing activities and pre-approval inventory, based upon the estimated amount of services provided and work completed but not yet invoiced and in accordance with agreements established with these third-party service providers. We include these costs in accrued liabilities in the consolidated balance sheets and within research and development expenses in the consolidated statements of operations and comprehensive loss. These costs are a significant component of our research and development expenses.

We estimate the amount of work completed through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fee to be paid for such services. We make significant judgments and estimates in determining the accrued balance in each reporting period. As actual costs become known, we adjust our accrued estimates. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed, the number of patients enrolled and the rate of patient enrollment may vary from our estimates and could result in us reporting amounts that are too high or too low in any particular period. Our accrued expenses are dependent, in part, upon the receipt of timely and accurate reporting from clinical research organizations and other third-party service providers. To date, there have been no material differences from our accrued expenses to actual expenses.

Stock-Based Compensation

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

We recorded stock-based compensation expense of $32.9 million, $32.7 million and $16.7 million for the years ended December 31, 2019, 2018 and 2017, respectively.

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

- *Expected Term.* The expected term of stock-bases awards represents the weighted average period the stock-based awards are expected to be outstanding. We have opted to use the simplified method for estimating the expected term as provided by the Securities and Exchange Commission Staff Accounting Bulletin, or SAB, 110 as our stock-based awards are considered "plain vanilla". The simplified method calculates the expected term as the average time-to-vesting and the contractual life of the options. We plan to continue to use the simplified method under SAB 110 until we have sufficient exercise history as a publicly traded company.

- *Expected Volatility.* As we have limited trading history for our common stock, the expected stock price volatility assumption is determined based on the historical volatilities of a group of industry peers as well as the historical volatility of our own common stock since we began trading subsequent to our IPO in August 2015. Industry peers consist of several public companies in the biopharmaceutical industry with comparable characteristics including enterprise value, risk profiles and position within the industry. We intend to continue to consistently apply this process using the same or similar public companies until a sufficient amount of historical information regarding the volatility of our own common stock share price becomes available, or unless circumstances change such that the identified companies are no longer similar to us, in which case, more suitable companies whose share prices are publicly available would be utilized in the calculation.
- *Risk-Free Interest Rate.* The risk-free interest rate is based on the implied yield available on U.S. Treasury zero-coupon issues in effect at the time of grant for periods corresponding with the expected term of the stock-based award.
- *Expected Dividend Yield.* We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero for all years presented.

Restricted Stock Units, or 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).

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 grant date fair value of stock options granted were as follows:

	Year Ended December 31,		
	2019	2018	2017
Expected term (in years)	6.0	6.0	6.0
Expected volatility	62.4%	67.8%	73.1%
Risk free interest rate	2.3%	2.5%	2.0%
Dividend yield	—	—	—
Weighted average estimated fair value	$ 13.47	$ 19.53	$ 13.70

In addition to the Black-Scholes assumptions, we estimate our forfeiture rate based on an analysis of our actual forfeitures and will continue to evaluate the adequacy of the forfeiture rate based on actual forfeiture experience, analysis of employee turnover behavior and other factors. The impact from any forfeiture rate adjustment would be recognized in full in the period of adjustment, and if the actual number of future forfeitures differs from our estimates, we might be required to record adjustments to stock-based compensation in future periods. We will continue to use judgment in evaluating the expected volatility, expected terms and forfeiture rates utilized for our stock-based compensation expense calculations on a prospective basis.

As of December 31, 2019, we had $48.2 million and $7.9 million of unrecognized stock-based compensation expense related to unvested stock options and stock awards, respectively, which is expected to be recognized over an estimated weighted-average period of 2.7 years and 2.4 years, respectively. For stock options subject to ratable vesting, we recognize stock-based compensation expense on a straight-line basis over the service period for the entire award. In future periods, our stock-based compensation expense is expected to increase as a result of recognizing our existing unrecognized stock-based compensation for awards that will vest and as we issue additional stock-based awards to attract and retain our employees.

Recent Accounting Pronouncements

The information required by this item is included in Note 2, Summary of Significant Accounting Policies of the Notes to Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K.

Components of Results of Operations

Research and Development Expenses

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

General and Administrative Expenses

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

Results of Operations

Comparison of the years ended December 31, 2019 and 2018

	Year Ended December 31,			
	2019	2018	$ Change	% Change
	(In thousands)			
Operating expenses:				
Research and development	$ 123,987	$ 133,420	$ (9,433)	(7)%
General and administrative	125,817	81,921	43,896	54%
Total operating expenses	249,804	215,341	34,463	16%
Loss from operations	(249,804)	(215,341)	(34,463)	16%
Interest income	5,851	4,984	867	17%
Interest expense	(4,916)	(113)	(4,803)	4250%
Other income (expense), net	1,088	(221)	1,309	(592)%
Loss before provision for income taxes	(247,781)	(210,691)	(37,090)	18%
Provision for income taxes	716	61	655	1074%
Net loss	$ (248,497)	$ (210,752)	$ (37,745)	18%

Research and Development Expenses

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

	Year Ended December 31,			
	2019	2018	$ Change	% Change
	(In thousands)			
External clinical-related expenses	$ 68,262	$ 86,577	$ (18,315)	(21)%
Employee-related costs	31,644	27,903	3,741	13%
Stock-based compensation expense	11,245	9,945	1,300	13%
Facilities and other costs	12,836	8,995	3,841	43%
Total research and development	$ 123,987	$ 133,420	$ (9,433)	(7)%

Research and development expenses decreased by $9.4 million for the year ended December 31, 2019 compared to the year ended December 31, 2018, primarily due to decreased external clinical-related expenses, which were partially offset by higher employee-related costs, stock-based compensation expense and facilities and other costs. External costs decreased primarily due to the close-out of certain PALFORZIA clinical trials, including RAMSES, ARC009, ARTEMIS and ARC011, and were partially offset by an increase in manufacturing costs for the production of pre-approval inventory of PALFORZIA as well as costs related to our Phase 2 clinical trial of AR201 in subjects with hen egg allergy. Employee-related costs and stock-based compensation expense increased primarily due to increased headcount to support continued development of PALFORZIA. Facilities and other costs increased primarily due to the allocation of higher facilities and information technology costs, which are allocable from general and administrative to research and development expenses based on headcount.

We expect research and development expenses to 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. Following our receipt of regulatory approval of PALFORZIA in January 2020, future manufacturing costs will be capitalized as inventory and will subsequently be expensed as costs of goods sold when such inventory is sold.

General and Administrative Expenses

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

	Year Ended December 31,			
	2019	2018	$ Change	% Change
	(In thousands)			
Employee-related costs	$ 44,684	$ 22,949	$ 21,735	95%
Stock-based compensation expense	21,684	22,787	(1,103)	(5)%
External professional services	56,168	35,028	21,140	60%
Facilities and other costs	3,281	1,157	2,124	184%
Total general and administrative	$ 125,817	$ 81,921	$ 43,896	54%

General and administrative expenses increased by $43.9 million for the year ended December 31, 2019 compared to the year ended December 31, 2018, primarily due to increased employee-related costs, external professional services costs and facilities and other costs. Employee-related costs increased primarily due to increased headcount, which was for additional administrative support for the continued buildout of our infrastructure to support the commercialization of PALFORZIA, including the establishment of key commercial functions such as marketing, market access and our field teams and a medical science liaison organization. External professional services costs increased primarily due to consulting services for commercial planning, 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. Stock-based compensation expense decreased primarily due to lower expense from our stock issuance to an affiliate of GPC as a result of lower stock prices in 2019.

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

Interest Income

Interest income increased by $0.9 million for the year ended December 31, 2019 compared to the year ended December 31, 2018, primarily due to higher interest income resulting from higher average cash, cash equivalents, and investment balances.

Interest Expense

Interest expense increased by $4.8 million for the year ended December 31, 2019 compared to the year ended December 31, 2018, due to interest expense on long-term debt issued in January 2019.

Other income (expense), net

Other income (expense), net, increased by $1.3 million for the year ended December 31, 2019 compared to the year ended December 31, 2018, due to research and development credits related to our foreign subsidiaries.

Provision for Income Taxes

The provision for income taxes for the year ended December 31, 2019 resulted from our foreign subsidiaries.

Comparison of the years ended December 31, 2018 and 2017

Refer to our Annual Report on Form 10-K filed with the SEC on February 28, 2019 for a comparison of the results for the years ended December 31, 2018 and 2017.

Liquidity and Capital Resources

As of December 31, 2019, we had cash, cash equivalents and investments of $158.2 million. With the 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 February 2020, we anticipate that these financial resources will fully fund us based on our current business plan.

In February and March 2018, we issued and sold an aggregate of 6,325,000 shares of our common stock in an underwritten public offering at a price to the public of $32.00 per share, including the closing of the full exercise of the underwriters' option to purchase an additional 825,000 shares of common stock. In November 2018, we sold 3,237,529 shares of our common stock to Nestlé Health Science at a price of $30.27 per share, for aggregate proceeds of $98.0 million.

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 PALFORIZA 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 year ending December 31, 2019.

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 proceeds of $200.0 million.

With FDA approval in January 2020, we expect to commence 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. In addition, we intend to continue to make investments in the development of AR201 to treat egg allergy and explore other product candidates.

Summary Statement of Cash Flows

Comparison of the years ended December 31, 2019 and 2018

	Year Ended December 31,		
	2019	2018	Change
		(In thousands)	
Net cash provided by (used in):			
Operating activities	$ (195,408)	$ (169,128)	$ (26,280)
Investing activities	111,899	(96,010)	207,909
Financing activities	55,878	299,162	(243,284)
Net change in cash and cash equivalents	$ (27,631)	$ 34,024	$ (61,655)

Net Cash Used In Operating Activities

Net cash used in operating activities was $195.4 million for the year ended December 31, 2019, an increase of $26.3 million from $169.1 million for the year ended December 31, 2018. This increase was primarily due to higher net loss from operations resulting from increased general and administrative expenses.

Net Cash Provided By Investing Activities

Net cash provided by investing activities was $111.9 million for the year ended December 31, 2019, an increase of $207.9 million from net cash used in investing activities of $96.0 million for the year ended December 31, 2018. The increase was primarily due to the timing of net maturities of various investments and capitalized assets.

Net Cash Provided By Financing Activities

Net cash provided by financing activities was $55.9 million for the year ended December 31, 2019, a decrease of $243.3 million from $299.2 million for the year ended December 31, 2018. The decrease was primarily due to 6,325,000 shares issued and sold during our public offering in February 2018, which was partially offset by our net debt borrowing under the KKR agreement of $36.1 million in January 2019.

As of December 31, 2019, we had cash, cash equivalents and investments of $158.2 million.

Comparison of the years ended December 31, 2018 and 2017

Refer to our Annual Report on Form 10-K filed with the SEC on February 28, 2019 for a comparison of the results for the years ended December 31, 2018 and 2017.

Contractual Obligations and Other Commitments

The following table summarizes our future contractual obligations as of December 31, 2019:

	Years				
	Total	Less than 1	1–3	3–5	More than 5
			(In thousands)		
Operating leases	$ 17,506	$ 3,772	$ 7,868	$ 5,639	$ 227
Capital lease	78	34	44	—	—
Long-term debt [1]	44,004	—	—	44,004	—
Other purchase commitments and obligations [2], [3], [4], [5]	52,389	11,892	18,592	18,875	3,030
Total contractual obligations	$ 113,977	$ 15,698	$ 26,504	$ 68,518	$ 3,257

[1] 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. The loan can be prepaid at our discretion, at any time, subject to prepayment fees. The weighted-average interest rate is calculated based on the daily cost of borrowing, reflecting the relevant adjusted LIBOR 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 selected to pay in kind and have the interest capitalized for the year ending December 31, 2019.

In February 2020, $85.0 million was funded 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 PALFORIZA by July 31, 2020 in an amount of at least $30.0 million.

[2] We purchase standard food-grade peanut flour from Golden Peanut Company, or GPC, a wholly-owned subsidiary of Archer Daniels Midland, pursuant to a long-term exclusive commercial supply agreement, which was expanded and extended in January 2018. GPC is not allowed to sell several peanut flour products to any third party worldwide for use in OIT for the treatment or cure of peanut allergy, provided that we are in compliance with our exclusive purchase obligation and meet specified annual purchase commitments. The restated agreement remains in effect until ten years after the first delivery to us of peanut flour for commercial use and includes an option for us to extend the term for an additional five years. In connection with the expansion and extension of the agreement, we issued Archer Daniels Midland Company 300,000 shares of our common stock, vesting over a 3.5-year period.

Pursuant with the restated agreement, our purchase obligation commences with the first delivery of peanut flour for commercial use, which occurred in 2019. The aggregate purchase commitment under this agreement would be $5.6 million over a term of nine years.

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

[4] In May 2019, we entered into a commercial supply agreement, or the Commercial Supply Agreement, pursuant to which CoreRx, Inc. agreed to manufacture commercial supply of PALFORZIA, if approved. Under the Commercial Supply Agreement, we are required to purchase a minimum percentage of our PALFORZIA commercial supply requirements in each of the first six years of the Commercial Supply Agreement, subject to certain conditions and restrictions, ranging from 100% in 2019 and decreasing to a majority in 2024.We are also required to purchase a minimum percentage or our PALFORZIA supply requirements for release testing in each of the first six years of the Commercial Supply Agreement, ranging from 100% in 2019 and decreasing to a significant majority in 2024. As of December 31, 2019, the minimum aggregate purchase commitment under this agreement would be $43.8 million. The initial term of the Commercial Supply Agreement began upon execution of the Commercial Supply Agreement and will continue until December 31, 2024. The Commercial Supply Agreement then automatically renews for successive two-year terms, unless earlier terminated pursuant to its terms, or upon either party's notice of termination to the other.

(5) In November 2019, we entered into a commercial packaging agreement, or the Commercial Packaging Agreement, with AndersonCrecon Inc. doing business as PCI of Illinois, or PCI, pursuant to which PCI package bulk product in accordance with our specifications, applicable laws and the terms and conditions of the Commercial Packaging Agreement. The initial term of the Commercial Packaging Agreement is for four contract years following the effective date. Contract Year one means the period beginning on the effective date of the Commercial Packaging Agreement and ending on December 31, 2019. Each contract year thereafter is the 12-month period from January 1 to December 31. The Commercial Packaging Agreement will automatically be renewed for one-year terms after the end of the Initial Term unless and until one party gives the other party at least three (3) years prior written notice of its desire to terminate as of the end of the then-current term, or is otherwise terminated in accordance with the other terms of the Commercial Packaging Agreement. As of December 31, 2019, the minimum aggregate purchase commitment under this agreement would be $3.0 million.

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. We will be solely responsible for costs related to the development of AIMab7195.

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 milestone, 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 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. Our contractual obligations under the License Agreement are not reflected in the table above.

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.

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

Off-Balance Sheet Arrangements

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

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

As of December 31, 2019, we had cash, cash equivalents and investments of $158.2 million, which consisted primarily of money market funds, agency securities, corporate securities, U.S. government securities and commercial paper. Such interest-earning instruments carry a degree of interest rate risk. However, historical fluctuations of interest income have not been significant.

We do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate exposure. We have not historically been exposed to material risks due to changes in interest rates. Based on our investment positions as of December 31, 2019, a hypothetical 100 basis point change in interest rates would result in a $0.3 million change in the fair market value of the portfolio. Any changes would only be realized if we sold the investments prior to maturity.

As of December 31, 2019, we had approximately $44.0 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 9.2% on our long-term debt as of December 31, 2019, would result in a change in our annual interest expense impacting the financial statements by approximately $0.4 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 8. Financial Statements and Supplementary Data.

The following consolidated financial statements, and the related notes thereto, of Aimmune Therapeutics, Inc. and the Report of the Company's Independent Registered Public Accounting Firm are filed as a part of this Annual Report on Form 10-K.

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Aimmune Therapeutics, Inc.:

Opinions on the Consolidated Financial Statements and Internal Control Over Financial Reporting

We have audited the accompanying consolidated balance sheets of Aimmune Therapeutics, Inc. and subsidiaries (the Company) as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2019, and the related notes (collectively, the consolidated financial statements). We also have audited the Company's internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2019, in conformity with U.S. generally accepted accounting principles. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019 based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Changes in Accounting Principle

As discussed in Note 2 to the consolidated financial statements, the Company has changed its method of accounting for leases effective January 1, 2019 due to the adoption of Accounting Standards Update (ASU) 2016-02, *Leases* (Topic 842).

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's consolidated financial statements and an opinion on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding

prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness 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.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgment. The communication of a critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Assessment of accrual for research and development costs related to clinical trial activities

As discussed in Note 4 to the consolidated financial statements, the Company has accrued liabilities for research and development costs in the amount of $11.3 million as of December 31, 2019. This accrual includes liabilities for clinical trial activities which includes clinical studies. Clinical studies are primarily managed internally, with the assistance of third-party service providers, including contract research organizations and contract manufacturing organizations. The accrual for clinical trial activities is based on an estimate of the percentage of activities completed to date, contractual rates, and amounts invoiced and paid to date.

We identified the assessment of the accrual for research and development costs related to clinical trial activities as a critical audit matter. The percentage of activities completed to date requires subjective estimates based on discussions with and reports provided by the contract research organizations and contract manufacturing organizations, oversight of the activities and the overall project budgets. Testing of the estimates required a higher degree of auditor judgment to evaluate, and changes to the estimates could have a significant impact on the amount of accrued clinical trial expenses recorded by the Company.

The primary procedures we performed to address this critical audit matter included the following. We tested certain internal controls over the Company's accrued research and development process, including controls over the estimation of activities completed to date. For certain clinical trial studies, we assessed the Company's estimates of the activities completed to date by (1) inquiring with Company personnel responsible for overseeing the clinical trial activities to understand progress of the activities; (2) inspecting correspondence received directly from the contract research organizations and contract manufacturing organizations, including status reports, and comparing the reported amounts to the Company's estimates; (3) inspecting executed change orders and original contract terms, including the timeline and budget, and comparing them to the Company's estimated research activities completed to date; (4) inspecting the Company's accrual analysis and calculation and obtaining the third party reports detailing site visit and patient information and agreeing the inputs to the Company's calculation; (5) inspecting executed clinical trial agreements for the relevant rates and agreeing the rates to the Company's calculation; (6) testing the mathematical accuracy of the calculation; and (7) performing a lookback analysis by comparing the estimated accrual balance as of December 31, 2019 to the actual amounts that were ultimately invoiced to assess the Company's ability to estimate the accrual.

/s/ KPMG LLP

We have served as the Company's auditor since 2015.

San Francisco, California
February 27, 2020

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

	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 79,880	$ 107,511
Short-term investments	63,633	196,421
Prepaid expenses and other current assets	5,564	8,687
Total current assets	149,077	312,619
Long-term investments	14,661	—
Property and equipment, net	28,604	26,328
Operating lease right-of-use-assets	11,512	—
Prepaid expenses and other assets	515	608
Total assets	$ 204,369	$ 339,555
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 13,882	$ 8,833
Accrued liabilities	31,286	29,144
Operating lease liabilities, current	2,257	—
Other current liabilities	23	35
Total current liabilities	47,448	38,012
Long-term debt, net of discount	41,028	—
Operating lease liabilities	10,524	—
Other liabilities	1,345	2,596
Total liabilities	100,345	40,608
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, par value $0.0001 per share - 10,000 shares authorized at December 31, 2019 and 2018; 0 shares issued and outstanding at December 31, 2019 and 2018	—	—
Common stock, par value $0.0001 per share - 290,000 shares authorized as of December 31, 2019 and 2018; 63,779 and 62,142 shares issued and outstanding as of December 31, 2019 and 2018, respectively	6	6
Additional paid-in capital	828,618	775,283
Accumulated other comprehensive income (loss)	80	(108)
Accumulated deficit	(724,680)	(476,234)
Total stockholders' equity	104,024	298,947
Total liabilities and stockholders' equity	$ 204,369	$ 339,555

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,		
	2019	2018	2017
Operating expenses			
Research and development	$ 123,987	$ 133,420	$ 89,325
General and administrative	125,817	81,921	43,949
Total operating expenses	249,804	215,341	133,274
Loss from operations	(249,804)	(215,341)	(133,274)
Interest income	5,851	4,984	2,190
Interest expense	(4,916)	(113)	(114)
Other income (expense), net	1,088	(221)	(71)
Loss before provision for income taxes	(247,781)	(210,691)	(131,269)
Provision for income taxes	716	61	56
Net loss	(248,497)	(210,752)	(131,325)
Other comprehensive loss, net of tax:			
Unrealized gain (loss) on investments	188	—	(81)
Comprehensive loss	$ (248,309)	$ (210,752)	$ (131,406)
Net loss per share, basic and diluted	$ (3.97)	$ (3.67)	$ (2.61)
Weighted average shares used in computing net loss per common share, basic and diluted	62,558	57,403	50,401

See accompanying notes to consolidated financial statements.

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

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2016	50,204	$ 5	$ 420,151	$ (27)	$ (134,157)	$ 285,972
Issuance of common stock upon exercise of vested options and vesting of restricted stock units	887	—	6,520	—	—	6,520
Stock-based compensation	—	—	16,719	—	—	16,719
Other comprehensive loss	—	—	—	(81)	—	(81)
Net loss	—	—	—	—	(131,325)	(131,325)
Balance as of December 31, 2017	51,091	$ 5	$ 443,390	$ (108)	$ (265,482)	$ 177,805
Issuance of common stock upon exercise of vested options and vesting of restricted stock units	1,188	—	10,726	—	—	10,726
Issuance of common stock upon public offering	6,325	1	190,435	—	—	190,436
Issuance of common stock upon securities agreement	3,538	—	98,000	—	—	98,000
Stock-based compensation	—	—	32,732	—	—	32,732
Net loss	—	—	—	—	(210,752)	(210,752)
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	1,637	—	20,406	—	—	20,406
Stock-based compensation	—	—	32,929	—	—	32,929
Other comprehensive income	—	—	—	188	—	188
Accumulated depreciation upon adoption of ASU Topic 842					51	51
Net loss	—	—	—	—	(248,497)	(248,497)
Balance as of December 31, 2019	63,779	$ 6	$ 828,618	$ 80	$ (724,680)	$ 104,024

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,		
	2019	2018	2017
Cash flows from operating activities:			
Net loss	$ (248,497)	$ (210,752)	$ (131,325)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation expense	4,086	1,598	966
Stock-based compensation expense	32,929	32,732	16,719
Non-cash interest expense	4,626	—	—
Amortization of premium on investment securities	(1,631)	(886)	511
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	3,888	(1,995)	(1,435)
Accounts payable	6,200	2,688	2,315
Accrued liabilities	2,039	7,412	11,557
Other liabilities	952	75	1,087
Net cash used in operating activities	(195,408)	(169,128)	(99,605)
Cash flows from investing activities:			
Purchase of property and equipment	(8,047)	(9,420)	(6,425)
Purchase of investments	(166,321)	(261,293)	(129,534)
Maturities of investments	286,267	174,703	178,521
Net cash provided by (used in) investing activities	111,899	(96,010)	42,562
Cash flows from financing activities:			
Borrowings under debt agreement	40,000	—	—
Debt issuance costs	(3,856)	—	—
Proceeds from underwritten public offering, net of offering costs	—	288,435	6,520
Net cash proceeds from exercise of stock options, including early exercise	20,406	10,727	—
Tax withholdings related to net share settlements of restricted stock units	(672)	—	—
Net cash provided by financing activities	55,878	299,162	6,520
Net (decrease) increase in cash and cash equivalents	(27,631)	34,024	(50,523)
Cash and cash equivalents at the beginning of the year	107,511	73,487	124,010
Cash and cash equivalents at the end of the year	$ 79,880	$ 107,511	$ 73,487
Supplemental disclosure of non-cash investing and financing activities:			
Property and equipment purchases included in accounts payable and accrued liabilities	$ 1,048	$ 1,301	$ 1,355
Supplemental cash flow disclosures:			
Cash paid for taxes	$ —	$ 148	$ 39

See accompanying notes to 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 **C**haracterized **O**ral **D**esensitized **I**mmunology **T**herapy, 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 year ended December 31, 2019, we incurred a net loss of $248.5 million and used $195.4 million of cash in operations. As of December 31, 2019, we had an accumulated deficit of $724.7 million and we do not expect to experience positive cash flows in the near future. As of December 31, 2019, we had cash, cash equivalents and investments of $158.2 million. With the 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 February 2020, we anticipate that these financial resources will fully fund us based on our current business plan. 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 consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States, or U.S. GAAP, and include the accounts of our wholly-owned subsidiaries. All significant intercompany transactions have been eliminated. We operate in one reportable segment.

Foreign Currency Translation

Our functional currency and the functional currency of all of our subsidiaries is the United States dollar. Accordingly, monetary assets and liabilities in the non-functional currency of these subsidiaries are remeasured using exchange rates in effect at the end of the period. Costs in local 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 remeasurement gains and losses are included in the consolidated statements of operations and comprehensive loss as incurred and have not been material for all periods presented.

Use of Estimates

The preparation of the accompanying 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 consolidated financial statements, and the reported amounts of costs and expenses during the reporting period. We base our estimates and assumptions on historical experience when available and on various factors that we believe to be reasonable under the circumstances. We evaluate our estimates and assumptions on an ongoing basis. Our actual results could differ from these estimates under different assumptions or conditions.

Cash and Cash Equivalents

We consider all highly liquid investments with original maturities of three months or less from the date of purchase to be cash equivalents. Cash equivalents, which are carried at estimated fair value, consist primarily of money market funds and certain available-for-sale investments with maturities of three months or less.

Segment Reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker in making decisions regarding resource allocation and assessing performance. We operate in one reportable segment.

Concentration of Credit Risk

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

Investments

Our investments consist of available-for-sale securities. Investments with original maturities of greater than 90 days but less than one (1) year are classified as short-term on the consolidated balance sheets. Investments with original maturities greater than one (1) year are classified as long-term on the consolidated balance sheets.

Our investments in available-for-sale securities are reported at estimated fair value. Available-for-sale securities consist primarily of agency securities, corporate securities, U.S. government securities and commercial paper. Unrealized gains and losses related to changes in the fair value of securities are recognized in accumulated other comprehensive income or loss, net of tax, on our consolidated balance sheets. Changes in the fair value of available-for-sale securities impact the consolidated statements of operations and comprehensive loss only when such securities are sold or an other-than-temporary impairment is recognized. Realized gains and losses on the sale of securities are determined by specific identification of each security's cost basis. We regularly review our investment portfolio to determine if any security is other-than-temporarily impaired, which would require us to record an impairment charge in the period any such determination is made. We consider factors such as the duration, severity and the reason for the decline in value, the financial condition of the issuer and any changes thereto, the potential recovery period and our intent to sell. For debt securities, we also consider whether (i) it is more likely than not that we will be required to sell the debt securities before recovery of their amortized cost basis, and (ii) the amortized cost basis cannot be recovered as a result of credit losses. Our assessment on whether a security is other-than-temporarily impaired could change in the future due to new developments or changes in assumptions related to any particular security.

Property and Equipment

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

The useful lives of property and equipment are as follows:

Computer equipment	3 years
Furniture and office equipment	4 years
Manufacturing equipment	7 years
Buildings	25 years
Leasehold improvements	Shorter of remaining lease terms or useful life

Impairment of Long-Lived Assets

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

Leases

Leases are classified as either finance or operating leases based on the principle of whether or not the lease is effectively a finance purchase by us. Lease expense is recognized over the term of the lease based on an effective interest method for finance leases and on a straight-line basis for operating leases. We also record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification.

Research and Development

We expense research and development costs as incurred. We record accrued liabilities for estimated costs of research and development activities conducted by third-party service providers, which include the conduct of pre-clinical studies and clinical trials, contract manufacturing activities and pre-approval inventory. These costs are a significant component of our research and development expenses. We accrue for these costs based on factors such as estimates of the work completed and in accordance with agreements established with our third-party service providers under the service agreements. We make significant judgments and estimates in determining the accrued liabilities balance in each reporting period. As actual costs become known, we adjust our accrued liabilities. We have not experienced any material differences between accrued costs and actual costs incurred. However, the status and timing of actual services performed, number of patients enrolled and the rate of patient enrollments may vary from our estimates, resulting in adjustments to expense in future periods. Changes in these estimates that result in material changes to our accruals could materially affect our results of operations.

Stock-Based Compensation

We recognize compensation costs related to stock options granted to employees and directors based on the estimated fair value of the awards on the date of grant, net of estimated forfeitures. We estimate the grant date fair value using the Black-Scholes option-pricing model. The grant date fair value of the stock-based awards is generally recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective awards. The fair value of the shares granted pursuant to the 2015 Employee Stock Purchase Plan, or the 2015 ESPP, is expensed over the purchase period, which is generally six months, on a straight-line basis.

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

- *Expected Term.* The expected term of stock-based awards represents the weighted average period the stock-based awards are expected to be outstanding. We have opted to use the simplified method for estimating the expected term as provided by the Securities and Exchange Commission Staff Accounting Bulletin, or SAB, 110 as our stock-based awards are considered “plain vanilla”. The simplified method calculates the expected term as the average time-to-vesting and the contractual life of the options. We plan to continue to use the simplified method under SAB 110 until we have sufficient exercise history as a publicly traded company.
- *Expected Volatility.* As we have limited trading history for our common stock, the expected stock price volatility assumption is determined based on the historical volatilities of a group of industry peers as well as the historical volatility of our own common stock since we began trading subsequent to our IPO in August 2015. Industry peers consist of several public companies in the biopharmaceutical industry with comparable characteristics including enterprise value, risk

profiles and position within the industry. We intend to continue to consistently apply this process using the same or similar public companies until a sufficient amount of historical information regarding the volatility of our own common stock share price becomes available, or unless circumstances change such that the identified companies are no longer similar to us, in which case, more suitable companies whose share prices are publicly available would be utilized in the calculation.

- *Risk-Free Interest Rate.* The risk-free interest rate is based on the implied yield available on U.S. Treasury zero-coupon issues in effect at the time of grant for periods corresponding with the expected term of the stock-based award.
- *Expected Dividend Yield.* We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero for all years presented.

Restricted Stock Units, or 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 addition to the Black-Scholes assumptions, we estimate our forfeiture rate based on an analysis of our actual forfeitures and will continue to evaluate the adequacy of the forfeiture rate based on actual forfeiture experience, analysis of employee turnover behavior and other factors. The impact from any forfeiture rate adjustment would be recognized in full in the period of adjustment, and if the actual number of future forfeitures differs from our estimates, we might be required to record adjustments to stock-based compensation in future periods. We will continue to use judgment in evaluating the expected volatility, expected terms and forfeiture rates utilized for our stock-based compensation expense calculations on a prospective basis.

Income Taxes

We use the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of reported assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. We must then assess the likelihood that the resulting deferred tax assets will be realized. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. Due to our lack of earnings history, the net deferred tax assets have been fully offset by a valuation allowance. Tax benefits from uncertain tax positions are recognized when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on technical merits. The amount recognized is measured as the largest amount of tax benefit that is greater than 50% likely of being realized upon effective settlement.

Comprehensive Income or Loss

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

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**:**

	Year Ended December 31,		
	2019	**2018**	**2017**
Stock options	7,629,823	7,133,113	6,629,111
Restricted stock units	530,795	309,847	16,638

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.

Financial instruments include cash equivalents, investments, accounts payable, and accrued liabilities. Our cash equivalents and investments are carried at estimated fair value and remeasured on a recurring basis. The carrying value of accounts payable and accrued liabilities approximate their estimated fair value due to the relatively short-term nature of these instruments. 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.

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

Recently Adopted Accounting Pronouncements

We adopted Accounting Standards Update, or ASU No. 2016-02, *Leases (Topic 842)*, as of January 1, 2019 using the alternative modified retrospective approach provided in ASU No. 2018-11, *Lease (Topic 841): Targeted Improvements*. In doing so, we have continued to apply Accounting Standards Codification, or ASC 840 in the comparative periods and recognized the cumulative effect of applying Topic 842 to retained earnings on January 1, 2019. We elected a package of practical expedients for leases that commenced prior to January 1, 2019, which among other things, allowed us to carry forward the historical lease assessment for: (i) whether any expired or existing contracts are or contain leases; (ii) lease classification for any expired or existing leases; and (iii) initial direct costs capitalization for any existing leases. We have also elected a practical expedient, by class of underlying asset, not to separate non-lease components from lease components and instead to account for each separate lease component and the non-lease components associated with that lease component as a single lease component. We have made an accounting policy election to not apply the recognition requirements to leases with a lease term of 12 months or less. We have recognized those lease payments in the consolidated statements of operations and comprehensive loss on a straight-line basis over the lease term and variable lease payments in the period in which the obligation for those payments is incurred. Adoption of this standard has resulted in the recognition of operating lease right-of-use assets of $11.5 million and lease liabilities of $12.8 million as of December 31, 2019. The standard did not materially impact our consolidated statements of operations and comprehensive loss or our consolidated statements of cash flows.

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

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.

Recently Issued Accounting Pronouncements Not Yet Adopted

In August 2018, the Financial Accounting Standards Board, or FASB, issued ASU 2018-13, *Fair Value Measurement: Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement*, which adds and modifies certain

disclosure requirements for fair value measurements. Under the new guidance, entities will no longer be required to disclose the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, or valuation processes for Level 3 fair value measurements. However, public companies will be required to disclose the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and related changes in unrealized gains and losses included in other comprehensive income. ASU 2018-13 is effective for fiscal periods beginning after December 15, 2019, with early adoption permitted. We adopted this guidance on January 1, 2020. The adoption of ASU 2018-13 will not have a material impact on the disclosures in our consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments — Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which requires measurement and recognition of expected credit losses for financial assets held. ASU 2016-13 modifies the other-than-temporary impairment model for available-for-sale debt securities and requires an estimate of expected credit losses when the fair value is below the amortized cost of the asset. ASU 2016-13 is effective for fiscal years beginning after December 15, 2019 and interim periods within those fiscal years with early adoption permitted. We adopted this guidance on January 1, 2020. The adoption of ASU 2016-13 will not have a material impact on the disclosures in our consolidated financial statements.

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

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**):**

	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

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

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

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

	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

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

At December 31, 2019, all of the available-for-sale securities have contractual maturities within two years. We periodically review our available-for-sale investments for other-than-temporary impairment loss. We consider factors such as the duration, severity and the reason for the decline in value, the potential recovery period and our intent to sell. For debt securities, we also consider whether (i) it is more likely than not that we will be required to sell the debt securities before recovery of their amortized cost basis, and (ii) the amortized cost basis cannot be recovered as a result of credit losses. During the years ended December 31, 2019, 2018, and 2017 we did not recognize any other-than-temporary impairment losses. All marketable securities with unrealized losses have been in a loss position for less than twelve months.

The carrying value of 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

Property and Equipment, Net

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

	Year Ended December 31,	
	2019	2018
Furniture and equipment	$ 2,660	$ 2,221
Computer equipment	2,820	2,073
Manufacturing equipment	9,012	1,733
Leased equipment	100	100
Leasehold improvements	14,525	4,469
Buildings	—	688
Construction in progress	6,649	18,295
Property and equipment, gross	35,766	29,579
Less: accumulated depreciation	(7,162)	(3,251)
Property and equipment, net	$ 28,604	$ 26,328

Depreciation expense for the years ended December 31, 2019, 2018 and 2017 was $4.1 million, $1.6 million and $1.0 million, respectively.

Accrued Liabilities

Accrued liabilities consist of the following (in thousands**):**

	Year Ended December 31,	
	2019	2018
Compensation and benefits	$ 13,286	$ 8,912
Research and development	11,336	15,504
Professional and consulting	6,627	4,691
Other	37	37
Total accrued liabilities	$ 31,286	$ 29,144

5. Long-Term Debt, Net of Discounts

In January 2019, we entered into a loan agreement with an affiliate of KKR for up to $170.0 million in three tranches, or the KKR Loans. 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 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 PALFORIZA 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 for the year ending December 31, 2019. We began accruing interest on the 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.

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

The KKR Loans can be prepaid at our discretion, at any time, subject to prepayment fees. If all or any of the KKR Loans are prepaid or required to be prepaid, then we must pay, in addition to such prepayment, a prepayment premium (the "Prepayment Premium") equal to (i) with respect to any such prepayment paid on or prior to January 3, 2021, the amount, if any, by which (a) the present value as of such date of determination of (x) 105.00% of the principal amount of the KKR Loans prepaid plus (y) all required interest payments that would have been due on the principal amount of the KKR Loans prepaid through and including January 3, 2021, computed using a discount rate equal to the treasury rate most nearly equal to the period from such date of prepayment to January 3, 2021 plus 50 basis points exceeds (b) the principal amount of the KKR Loans prepaid, (ii) with respect to any prepayment paid or required to be paid after January 3, 2021 but on or prior to January 3, 2022, 5.00% of the principal amount of the KKR Loans prepaid, (iii) with respect to any prepayment paid or required to be paid after January 3, 2022 but on or prior to January 3, 2023, 2.00% of the principal amount of the KKR Loans prepaid and (iv) with respect to any prepayment paid or required to be prepaid thereafter, 0.00% of the principal amount of the KKR Loans prepaid. In addition, upon the occurrence of a change of control, we must prepay, the outstanding amount of the KKR Loans. Upon the prepayment or repayment of all or any of the KKR Loans, we must pay an additional (in addition to the Prepayment Premium) exit fee in an amount equal to 4.00% of the principal amount of the KKR Loans prepaid or repaid. In addition, we paid certain customary fees and expenses to the Agent and other service providers upon the closing of the transaction.

The obligations under the Credit Agreement are secured by a lien on substantially all of our tangible and intangible property. The Credit Agreement contains certain affirmative covenants, 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 each of 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 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 December 31, 2019, $44.0 million was outstanding under the KKR Loans. As of December 31, 2019, the interest rate on the KKR Loans was 9.20%.

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

	December 31, 2019
Principal amount of long-term debt	$ 44,004
Less: Current portion of long-term debt	—
Long-term debt, net of current portion	44,004
Unamortized discount relating to deferred financing costs	(3,234)
Accrued exit fee payment	258
Long-term debt, net of discounts and current portion	$ 41,028

Future principal payments of our long-term debt as of December 31, 2019 are as follows (in thousands):

Fiscal year ending December 31:	
2020	$ —
2021	—
2022	—
2023	22,002
2024	22,002
Thereafter	—
Total	$ 44,004

6. Commitments and Contingencies

Leases

Facility 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 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.

In 2015, we entered into lease agreements for our corporate headquarters in Brisbane, California for 38,000 square feet of office space, which was subsequently amended resulting in a total of approximately 58,000 square feet of office space being leased. The term for the entire office space terminates on June 30, 2024. We are responsible for operating expenses over base operating expenses as defined in the original lease agreement.

In June 2015, we signed a facility lease for a manufacturing facility in Clearwater, Florida for approximately 20,000 square feet of manufacturing space, which was subsequently amended resulting in a total of approximately 30,000 square feet of manufacturing space being leased. The lease is expected to expire in June 2025.

In September 2018, we entered into a lease for office space in Durham, North Carolina for 5,099 square feet of office space. The lease is expected to expire in February 2024.

In November 2018, we entered into a lease for part of a floor of office space in London, United Kingdom. The lease is expected to expire in November 2023. As a part of the lease, we have a contractual requirement to remove the tenant improvements and restore the leased office space to a condition as specified in the lease agreement.

Financing Lease

In July 2016, we entered into a five-year capital lease agreement for certain equipment in our Florida manufacturing facility. The current portion of the capital lease obligation is included in Other Current Liabilities and the noncurrent portion is included in Other Liabilities.

Leases

The maturities of our operating and financing lease liabilities are as follows (in thousands):

Remaining Lease Payments at December 31, 2019	Operating	Financing	Total
2020	$ 3,772	$ 34	$ 3,806
2021	3,907	35	3,942
2022	3,961	9	3,970
2023	3,782	—	3,782
2024	1,857	—	1,857
Thereafter	227	—	227
Total lease payments	17,506	78	17,584
Less: Effects of discounting	(4,725)	(17)	(4,742)
Present value of lease liabilities	12,781	61	12,842
Less: current portion	(2,257)	(23)	(2,280)
Long-term lease liabilities	$ 10,524	$ 38	$ 10,562
Weighted-average remaining lease term	4.5 years	2.3 years	
Weighted-average incremental borrowing rate	11%	23%	

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

	Year Ended December 31,		
	2019	2018	2017
Operating lease cost	$ 3,753	$ 3,738	$ 2,320
Finance lease cost			
Amortization of leased assets	33	33	25
Interest on lease liabilities	16	19	16
Net lease cost	$ 3,802	$ 3,790	$ 2,361

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

Other Information	Year Ended December 31, 2019
Cash paid for amounts included in the measurement of lease liabilities	
Operating cash flows from operating leases	$ 3,753
Operating cash flows from finance leases	$ 49

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

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

Asset Retirement Obligation

We recognized the estimated fair value of our asset retirement obligation related to our office space in London, United Kingdom in long-term liabilities in November 2018. The fair value of the asset retirement obligation is also capitalized as construction in progress. The fair value of the asset retirement obligation was estimated by discounting projected cash flows over the estimated life of the related assets using our credit adjusted risk-free rate. Our asset retirement obligation consists of a contractual requirement to remove the tenant improvements at our office space in London, United Kingdom and restore the lease office space to a condition as specified in the lease agreement.

The following is the activity for our asset retirement obligation included in long-term liabilities (in thousands):

Balance as of December 31, 2018	$ 88
Liabilities incurred during the year	11
Balance as of December 31, 2019	$ 99

Purchase Commitments

We purchase food-grade peanut flour from Golden Peanut Company, or GPC, a wholly-owned subsidiary of Archer Daniels Midland, pursuant to a long-term exclusive commercial supply agreement, which was expanded and extended in January 2018. GPC is precluded from selling several peanut flour products to any third party worldwide for use in OIT for the treatment or cure of peanut allergy, provided that we are in compliance with our exclusive purchase obligation and meet specified annual purchase commitments. The restated agreement remains in effect until ten years after the first delivery to us of peanut flour for commercial use and includes an option for us to extend the term for an additional five years.

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

Pursuant with the restated agreement, our purchase obligation commences with the first delivery of peanut flour for commercial use, which we currently anticipate will occur in 2020. The aggregate purchase commitment under this agreement would be $5.6 million over a term of nine years.

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

In May 2019, we entered into a Commercial Supply Agreement, or the Commercial Supply Agreement, pursuant to which CoreRx, Inc. agreed to manufacture commercial supply of PALFORZIA, if approved. Under the Commercial Supply Agreement, we are required to purchase a minimum percentage of our PALFORZIA commercial supply requirements in each of the first six years of the Commercial Supply Agreement, subject to certain conditions and restrictions, ranging from 100% in 2019 and decreasing to a majority in 2024.We are also required to purchase a minimum percentage or our PALFORZIA supply requirements for release testing in each of the first six years of the Commercial Supply Agreement, ranging from 100% in 2019 and decreasing to a significant majority in 2024. As of December 31, 2019, the minimum aggregate purchase commitment under this agreement would be $43.8 million over the next five years. The initial term of the Commercial Supply Agreement began upon execution of the Commercial Supply Agreement and will continue until December 31, 2024. The Commercial Supply Agreement then automatically renews for successive two-year terms, unless earlier terminated pursuant to its terms, or upon either party's notice of termination to the other.

In November 2019, we entered into a commercial packaging agreement, or the Commercial Packaging Agreement, with AndersonCrecon Inc. doing business as PCI of Illinois, or PCI, pursuant to which PCI package bulk product in accordance with our specifications, applicable laws and the terms and conditions of the Commercial Packaging Agreement. The initial term of the Commercial Packaging Agreement is for four contract years following the effective date. Contract Year one means the period beginning on the effective date of the Commercial Packaging Agreement and ending on December 31, 2019. Each contract year thereafter is the 12-month period from January 1 to December 31. The Commercial Packaging Agreement will automatically be renewed for one-year terms after the end of the Initial Term unless and until one party gives the other party at least three (3) years prior written notice of its desire to terminate as of the end of the then-current term, or is otherwise terminated in accordance with the other terms of the Commercial Packaging Agreement. As of December 31, 2019, the minimum aggregate purchase commitment under this agreement would be $3.0 million over the next 4 years.

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 will pay Xencor an upfront payment of $5.0 million, and we issued to Xencor 156,238 shares of Common Stock, pursuant to a Securities Issuance Agreement with Xencor, dated February 4, 2020.

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 the 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.

7. Stockholders' Equity

Convertible Preferred Stock

As of December 31, 2019 and 2018, we had authorized 10,000,000 shares of convertible preferred stock, and no shares of convertible preferred stock were issued and outstanding.

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 proceeds of $200.0 million.

Common Stock

On November 23, 2016, we issued and sold 7,522,084 shares of our common stock, par value $0.0001 per share, for an aggregate cash purchase price of $145.0 million, pursuant to the Purchase Agreement, dated November 2, 2016, by and between us and Nestle Health Science. In connection with the closing of the Equity Investment, we and Nestle Health Science entered into a Registration Rights Agreement and a Standstill Agreement.

Under the terms of the Registration Rights Agreement, upon the written request of Nestle Health Science, we shall prepare and file with the Securities and Exchange Commission, or the Commission, a registration statement covering the resale of all the shares sold to Nestle Health Science that are not then registered on an existing and effective registration statement for an offering to be made on a continuous basis pursuant Commission Rule 415. Additionally, we shall use commercially reasonable efforts to cause such registration statement filed under the Registration Rights Agreement to be declared effective under the Securities Act of 1933, as amended, within certain defined time limits and to keep such registration statement continuously effective for a period of potentially three years from the original effect date of such registration statement.

Under the terms of the Standstill Agreement, Nestle Health Science is prohibited from entering into transactions with the shares purchased in the Equity Investment, as well as to enter into any transactions with any of our assets, without prior written consent of a majority of the members of our board of directors until the later of the end of the term of the Collaboration Agreement and November 23, 2018.

In January 2018, we issued Archer Daniels Midland Company 300,000 shares of restricted common stock, vesting in four tranches over a 3.5-year period. Refer to Note 6 for further information.

In February and March 2018, we issued and sold an aggregate of 6,325,000 shares of our common stock in an underwritten public offering at a price to the public of $32.00 per share, including the closing of the full exercise of the underwriters' option to purchase an additional 825,000 shares of common stock, for proceeds of $190.4 million, net of underwriting discounts and commissions and offering expenses.

In November 2018, we entered into an extension of the strategic collaboration on similar terms and issued and sold an additional 3,237,529 shares of our common stock in a private placement at a price of $30.27 per share for aggregate proceeds of $98.0 million, increasing Nestlé Health Science's ownership of Aimmune to approximately 19%. The transaction documents include the extension of

the registration rights, standstill rights and market standoff provisions. We are not subject to any partnership, collaboration, or negotiation restrictions under the extension agreements. In addition, we retain all rights to our current and future pipeline assets.

In February 2020, we announced a $200.0 million equity investment by Nestle Health Science S.A. and the extension of their existing strategic collaboration designed to enable the development and commercialization of innovative food allergy therapies, which will terminate in November 2021.

8. 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 December 31, 2019 and 2018 there were 4,599,005 shares and 4,364,963 shares available for future grant, respectively.

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

In August 2015, we adopted the 2015 ESPP, which commenced on January 1, 2018. Under the 2015 ESPP our employees may purchase common stock through payroll deductions at a price equal to 85% of the lower of the fair market value of the stock at the beginning of the offering period or at the end of each applicable purchase period. The 2015 ESPP generally provides for offering periods of six months in duration with purchase periods ending on either May 15 or November 15. Contributions under the 2015 ESPP are limited to a maximum of 15% of an employee's eligible compensation. ESPP purchases are settled with common stock from the ESPP's previously authorized and available pool of shares. As of December 31, 2019, we had issued 101,989 shares under the ESPP at a weighted average price of $17.67 per share and 2,303,797 shares under the ESPP remain available for purchase. We issued 41,030 shares at a weighted average price of $25.28 per share during the year ended December 31, 2018.

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, 2018	7,133,113	$ 20.08	7.6	$ 27,413
Options granted	3,156,942	$ 23.00		
Options exercised and shares vested	(1,442,889)	$ 12.89		
Options cancelled	(1,217,343)	$ 27.15		
Balance, December 31, 2019	7,629,823	$ 21.52	8.0	$ 91,745
Options vested and expected to vest as of December 31, 2019	6,972,545	$ 21.23	7.9	$ 85,878
Options exercisable as of December 31, 2019	3,460,494	$ 18.09	6.9	$ 53,479

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 December 31, 2019. The 2013 Plan provided for early exercise, therefore, all of the outstanding stock options issued under that plan are exercisable. The total intrinsic value of options exercised during the year ended December 31, 2019 was $18.2 million.

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

	Shares	Weighted Average Grant Date Fair Value
Unvested Balance, December 31, 2018	309,847	$ 33.37
Awarded	485,027	22.98
Released	(91,354)	33.28
Forfeited	(172,725)	27.97
Unvested Balance, December 31, 2019	530,795	$ 25.79

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

In connection with the expansion and extension of our long-term exclusive commercial supply agreement with GPC, we issued 300,000 shares of restricted common stock in January 2018. The restricted common stock vests in four tranches over a 3.5-year period and is measured based on the fair market value of our common stock on December 31, 2018. As of December 31, 2019, 150,000 shares had vested, and the remaining shares were restricted. As of December 31, 2019, total estimated unrecognized expense related to these restricted shares was $2.7 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 1.5 years as general and administrative expense. Stock-based compensation expense recognized during the years ended December 31, 2019 and 2018 related to these shares was $1.8 million and $3.0 million, respectively.

As of December 31, 2019, 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. As the vesting for 46,000 RSUs was contingent upon specific performance conditions that were not met, they were cancelled with no stock-based compensation expense recognized.

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:

	Year Ended December 31,		
	2019	2018	2017
Expected term (in years)	6.0	6.0	6.0
Expected volatility	62.4%	67.8%	73.1%
Risk free interest rate	2.3%	2.5%	2.0%
Dividend yield	—	—	—
Weighted average estimated fair value	$ 13.47	$ 19.53	$ 13.70

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

	Year Ended December 31,		
	2019	2018	2017
Expected term (in years)	0.5	0.8	—
Expected volatility	51.0%	50.2%	—
Risk free interest rate	1.1%	2.0%	—
Dividend yield	—	—	—
Weighted average estimated fair value	$ 7.32	$ 11.06	—

Stock-Based Compensation Expense

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

	Year Ended December 31,		
	2019	2018	2017
Research and development	$ 11,245	$ 9,945	$ 5,077
General and administrative	21,684	22,787	11,642
Total stock-based compensation expense	$ 32,929	$ 32,732	$ 16,719

The fair value of options granted is expensed over the vesting period of the options, which is either four years or two years, on a straight-line basis as the services are being provided. No tax benefits were realized from options during the periods.

During the years ended December 31, 2019, 2018 and 2017, we recorded approximately $2.5 million, $3.3 million and $0.4 million, respectively, of stock-based compensation expense related to the acceleration of certain former executives' stock options.

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

	As of December 31, 2019
Stock-options	
Unrecognized stock compensation expense	$ 48,246
Weighted-average remaining vesting period (years)	2.7
RSU	
Unrecognized stock compensation expense	$ 7,887
Weighted-average remaining vesting period (years)	2.4
ESPP	
Unrecognized stock compensation expense	$ 472
Weighted-average remaining vesting period (years)	0.4

9. Income Taxes

The following table presents loss before provision for income taxes (in thousands)**:**

	Year Ended December 31,		
	2019	2018	2017
Income/(loss) before income taxes			
Domestic	$ (218,920)	$ (176,085)	$ (100,107)
Foreign	(28,861)	(34,606)	(31,162)
Total loss before provision for income taxes	$ (247,781)	$ (210,691)	$ (131,269)

The federal, state and foreign income tax provisions for the years ended December 31, 2019, 2018 and 2017 are summarized as follows (in thousands):

	Year Ended December 31,		
	2019	2018	2017
Current			
Federal	$ —	$ —	$ —
State	—	—	—
Foreign	716	61	56
Total Current	716	61	56
Deferred			
Federal	—	—	—
State	—	—	—
Foreign	—	—	—
Total Deferred	—	—	—
Total provision for income taxes	$ 716	$ 61	$ 56

Income tax expense for the years ended December 31, 2019, 2018 and 2017 differed from the amount expected by applying the statutory federal tax rate to the loss before taxes as summarized below (in thousands):

	Year Ended December 31,		
	2019	2018	2017
Federal tax benefit at statutory rate	21.00%	21.00%	34.00%
State tax benefit, net of federal benefit	1.16%	0.82%	0.54%
Stock compensation	(0.85)%	(0.30)%	1.72%
Change in valuation allowance	(19.29)%	(19.29)%	(9.31)%
Research and development credits	1.26%	1.65%	1.70%
Foreign income taxed at different rates	(2.74)%	(3.48)%	(8.11)%
Impact related to 2017 Tax Act	0.00%	0.00%	(20.46)%
Other	(0.83)%	(0.43)%	(0.12)%
Income tax expense	(0.29)%	(0.03)%	(0.04)%

The significant components of our deferred taxes are as follows (in thousands):

	Year Ended December 31,	
	2019	2018
Deferred tax assets (liabilities):		
Net operating loss carryforwards	$ 113,179	$ 70,831
Intangible asset	31,500	—
Start-up costs	625	683
Stock-based compensation	6,277	6,387
Tax credit carryforwards	17,264	11,693
Operating lease liability	2,734	—
Accruals	2,403	1,765
Other	828	482
Subtotal deferred tax assets	174,810	91,841
Less: valuation allowance	(170,839)	(91,520)
Total deferred tax assets	3,971	321
Basis differences in fixed assets	(1,492)	(321)
Operating lease right-of-use asset	(2,479)	—
Net deferred income taxes	$ —	$ —

We recognize deferred income taxes for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes. We periodically evaluate the positive and negative evidence bearing upon realizability of our deferred tax assets. Based upon the weight of available evidence, which includes our historical operating performance, reported cumulative net losses since inception and difficulty in accurately forecasting our future results, we maintained a full valuation allowance on the net deferred tax assets as of December 31, 2019 and 2018. We intend to maintain a full valuation allowance on the federal, foreign and state deferred tax assets until sufficient positive evidence exists to support reversal of the valuation allowance. The net change in the valuation allowance for the years ended December 31, 2019 and December 31, 2018 was an increase of $79.3 million and $41.6 million, respectively.

As of December 31, 2019, we had net operating loss, or NOL, carryforwards for Federal, California and other state income tax purposes of $522.3 million, $12.0 million, and $63.9 million, respectively. As of December 31, 2018, we had NOL carryforwards for Federal, California and other state income tax purposes of $326.4 million, $12.0 million, and $30.2 million, respectively, which will begin to expire in 2031, 2031, and 2030, respectively, if not utilized.

As of December 31, 2019, we had Federal and California research credit carryforwards of $17.1 million and $5.7 million, respectively. As of December 31, 2018, we had Federal and California research credit carryforward of $12.1 million and $3.1 million, respectively. The Federal research credits will begin to expire in 2031, while the California research credits have no expiration date.

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.

Following the equity investment by Nestle Health Science in November 2016, we performed a Section 382 analysis and determined that we experienced multiple ownership changes under Section 382 of the Code prior to July 31, 2017. Utilization of the NOL and tax credit carryforwards are subject to a substantial annual limitation due to the ownership change limitations set forth in Internal Revenue Code Section 382 and similar state provisions. Such annual limitations could impact 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 if we have experienced an ownership change.

Tax benefits from uncertain tax positions are recognized when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on technical merits. The amount recognized is measured as the largest amount of tax benefit that is greater than 50% likely of being realized upon effective settlement.

The following table summarizes the activity related to our unrecognized benefits (in thousands**):**

	Year Ended December 31,	
	2019	2018
Beginning balance - unrecognized tax benefit, gross	$ 3,055	$ 1,657
Increases related to tax positions taken during a prior year	—	—
Decreases related to a tax position taken during a prior year	—	—
Increases related to tax positions taken during the current year	4,750	1,398
Decreases related to settlements with taxing authorities	—	—
Decreases related to expiration of statute of limitations	—	—
Ending balance - unrecognized tax benefits, gross	$ 7,805	$ 3,055

At December 31, 2019, the unrecognized tax benefits for uncertain tax positions were offset against the deferred tax assets and would not affect the income tax rate if recognized due to our being in a valuation allowance position. Our policy is to include interest and penalties related to unrecognized tax benefits, if any, within the provision for taxes in the consolidated statements of operations. We did not accrue any interest or penalties for the years ended December 31, 2019 and 2018. We do not have any tax positions for which it is reasonably possible that the total amount of gross unrecognized tax benefits will significantly change within 12 months of December 31, 2019.

We file federal, state and foreign income tax returns in jurisdictions with varying statutes of limitations. Due to our NOL carryforwards, our income tax returns remain subject to examination by federal and most state taxing authorities for all tax years.

10. Defined Contribution Plan

We sponsor a 401(k) Plan, or the 401(k) Plan, which stipulates that eligible employees may contribute to the 401(k) Plan subject to certain limitations. We may match employee contributions in amounts to be determined at our sole discretion. Commencing in 2018, we began a discretionary matching of employee contributions up to a maximum match of $2,000 in any calendar year. We incurred total expenses of $0.4 million and $0.2 million for the years ended December 31, 2019 and 2018, respectively.

11. Related Party Transactions

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 years ended December 31, 2019, 2018 and 2017, there were payments of $0.1 million, $0.1 million and $0.2 million, respectively, to MyHealthTeams pursuant to such agreement. At December 31, 2019 and 2018, there was no and $0.1 million accrued liabilities due under the MyHealthTeams agreement.

12. Selected Quarterly Results of Operations (Unaudited)

The following table presents our unaudited quarterly financial data. Our quarterly results of operations for these periods are not necessarily indicative of our future results of operations.

	Quarter Ended			
	March 31	June 30	September 30	December 31
2019	(In thousands, except per share data)			
Operating expenses:				
Research and development	$ 31,316	$ 31,988	$ 30,558	$ 30,125
General and administrative	23,712	31,200	34,044	36,861
Total operating expenses	55,028	63,188	64,602	66,986
Loss from operations	(55,028)	(63,188)	(64,602)	(66,986)
Interest income	1,901	1,710	1,315	925
Interest expense	(1,144)	(1,262)	(1,260)	(1,250)
Other income (expense), net	34	(90)	(12)	1,156
Loss before provision (benefit) for income taxes	(54,237)	(62,830)	(64,559)	(66,155)
Provision (benefit) for income taxes	29	48	(104)	743
Net loss	$ (54,266)	$ (62,878)	$ (64,455)	$ (66,898)
Net loss per common share, basic and diluted	$ (0.87)	$ (1.01)	$ (1.03)	$ (1.06)

	Quarter Ended			
	March 31	June 30	September 30	December 31
2018	(In thousands, except per share data)			
Operating expenses:				
Research and development	$ 33,446	$ 35,254	$ 31,691	$ 33,029
General and administrative	16,673	18,559	21,285	25,404
Total operating expenses	50,119	53,813	52,976	58,433
Loss from operations	(50,119)	(53,813)	(52,976)	(58,433)
Interest income	708	1,400	1,394	1,482
Interest expense	(29)	(28)	(28)	(28)
Other expense, net	(43)	(78)	(63)	(37)
Loss before provision (benefit) for income taxes	(49,483)	(52,519)	(51,673)	(57,016)
Provision (benefit) for income taxes	17	33	29	(18)
Net loss	$ (49,500)	$ (52,552)	$ (51,702)	$ (56,998)
Net loss per common share, basic and diluted	$ (0.92)	$ (0.91)	$ (0.89)	$ (0.95)

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. 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, or 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 December 31, 2019. Based on the evaluation of our disclosure controls and procedures, our Chief Executive Officer and Chief Financial Officer have concluded that, as of December 31, 2019, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) of the Exchange Act). Internal control over financial reporting is a process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, and effected by our Board of Directors, management and other personnel, 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 and includes those policies and procedures that:

- Pertain to the maintenance of records that accurately and fairly reflect in reasonable detail the transactions and dispositions of the assets of our company;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- Provide reasonable assurances regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material adverse effect on our financial statements.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2019 based on the criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO 2013. Based on our evaluation under the criteria set forth in Internal Control - Integrated Framework issued by the COSO, our management concluded our internal control over financial reporting was effective as of December 31, 2019.

The effectiveness of our internal control over financial reporting as of December 31, 2019 has been audited by KPMG LLP, an independent registered public accounting firm, as stated in its attestation report included in this Annual Report on Form 10-K.

Changes in Internal Control over Financial Reporting.

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2019 identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act 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.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information required by this Item is incorporated herein by reference to the sections titled "Executive Officers," "Election of Directors," "Corporate Governance" and "Section 16(a) Beneficial Ownership and Reporting Compliance" in our Definitive Proxy Statement with respect to our 2020 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 11. Executive Compensation.

Information required by this Item is incorporated herein by reference to the section titled "Executive Compensation," "Director Compensation" and "Corporate Governance" in our Definitive Proxy Statement with respect to our 2020 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Information required by this Item is incorporated herein by reference to the section titled "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" in our Definitive Proxy Statement with respect to our 2020 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Information required by this Item is incorporated herein by reference to the section titled "Certain Relationships and Related Party Transactions" and "Corporate Governance" in our Definitive Proxy Statement with respect to our 2020 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 14. Principal Accountant Fees and Services.

Information required by this Item is incorporated herein by reference to the section titled "Ratification of Selection of Independent Registered Public Accounting Firm" in our Definitive Proxy Statement with respect to our 2020 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The following documents are filed as part of this Annual Report on Form 10-K:

1. Financial Statements

   See Index to Financial Statements at Item 8 herein.

2. Financial Statement Schedules

   All schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

3. Exhibits

Exhibit Index

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	2/4/2020	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	2/4/2020	4.2	
4.6	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock.	8-K	2/4/2020	3.1	
4.7	Description of Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.				X
10.1†	Amended and Restated Supply Agreement, dated as of January 10, 2018, by and between the Company and Golden Peanut Company, L.L.C.	10-K	2/20/18	10.1	
10.2(a)	Office Lease, dated February 23, 2015, by and between, the Company, Diamond Marina LLC and Diamond Marina II LLC.	S-1	7/6/2015	10.3	
10.2(b)	First Amendment to Office Lease, dated August 26, 2015, by and between, the Company, Diamond Marina LLC and Diamond Marina II LLC.	10-Q	8/31/2015	10.2	
10.2(c)	Second Amendment to Office Lease, dated June 27, 2017, by and between, the Company, Diamond Marina LLC and Diamond Marina II LLC.	10-Q	8/8/2017	10.2	
10.2(d)	Assignment of Office Lease June 11, 2019.	10-Q	8/8/2019	10.7	
10.2(e)	Third Amendment to Office Lease, dated December 20, 2019, by and between the Company and HCP Life Science REIT, Inc.				X
10.3††	License Agreement, dated February 4, 2020, by and among, the Company and Xencor, Inc.	8-K	2/4/2020	10.3	
10.4(a)†	Manufacturing Facility Lease, dated June 8, 2015, by and between, the Company and MIDA Group, LLC.	S-1	7/6/2015	10.4	
10.4(b)	Amendment to Manufacturing Facility Lease, dated June 8, 2015, by and between the Company and Myerlake, LLC.	10-Q	8/10/2016	10.2	
10.5(a)††	Amended and Restated Strategic Collaboration Agreement, dated February 4, 2020, by and between the Company and Société des Produits Nestlé S.A.	8-K	2/4/2020	10.1	
10.5(b)	Securities Purchase Agreement, dated February 4, 2020, by and between the Company and Nestle Health Science US Holdings, Inc.	8-K	2/4/2020	10.2	
10.6 ††	Commercial Supply Agreement, dated May 10, 2019, by and between CoreRx, Inc. and Aimmune Therapeutics, Inc.	10-Q	8/8/2019	10.5	

10.7 †	Credit Agreement, dated January 3, 2019, by and among the Company, KKR Peanut Aggregator L.P. and Cortland Capital Markets Services LLC. By and between the Company and Nestle Health Science US Holdings Inc.	10-K	2/28/2019	10.6	
10.8 ††	Commercial Packaging Agreement, dated November 11, 2019, by and between AndersonBrecon Inc. and Aimmune Therapeutics, Inc.				X
10.9(a)#	2013 Stock Plan.	S-1	7/6/2015	10.5(a)	
10.9(b)#	Amendment to the 2013 Stock Plan, dated January 20, 2015.	S-1	7/6/2015	10.5(b)	
10.9(c)#	Form of Stock Option Grant Notice and Stock Option Agreement under the 2013 Stock Plan.	S-1	7/6/2015	10.5(c)	
10.9(d)#	Form of Restricted Stock Purchase Grant Notice and Restricted Stock Purchase Agreement under the 2013 Stock Plan.	S-1	7/6/2015	10.5(d)	
10.10(a)#	2015 Equity Incentive Annual Plan.	S-8	8/11/2015	99.2(a)	
10.10(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)	
10.10(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)	
10.11#	Form of Indemnification Agreement for directors and officers.	S-1/A	7/27/2015	10.7	
10.12(a)#	Transition and Separation Agreement, dated November 5, 2017, by and between the Company and Stephen G. Dilly, M.B.B.S., Ph.D.	10-Q	11/6/2017	10.1	
10.12(b)#	Amendment Letter, dated December 27, 2018, by and between the Company and Stephen G. Dilly, M.B.B.S., Ph.D.	10-K	2/28/2019	10.10(b)	
10.12(c)#	Letter Agreement, dated June 13, 2019, between the Company and Stephen G. Dilly, M.B.B.S., Ph.D.	10-Q	8/8/2019	10.6#	
10.12(d)#	Letter Agreement, dated December 19, 2019, between the Company and Stephen G. Dilly, M.B.B.S., Ph.D.	8-K	12/20/2019	10.1	
10.13#	Executive Employment Agreement, dated June 4, 2018, by and between the Company and Jayson Dallas M.D.	10-Q	8/8/2018	10.1	
10.14#	Executive Employment Agreement, dated April 4, 2016, by and between the Company and Douglas T. Sheehy.	10-Q	5/16/2016	10.3	
10.15#	Executive Employment Agreement, dated June 16, 2016, by and between the Company and Daniel Adelman.	10-Q	8/10/2016	10.3	
10.16#	Executive Employment Agreement, dated April 28, 2017, by and between the Company and Eric H. Bjerkholt.	10-Q	5/8/2017	10.1	
10.17#	Executive Employment Agreement, dated January 22, 2019, by and between the Company and Andrew Oxtoby.	10-K	2/28/2019	10.16	
10.18#	Aimmune Therapeutics, Inc. Employee Stock Purchase Plan.	S-8	8/11/2015	99.3	
10.19#	Non-Employee Director Compensation Program.	10-K	2/28/2019	10.18	
10.20#	Aimmune Therapeutics, Inc. Corporate Bonus Plan.	8-K	2/25/2016	10.1	
21.1	List of subsidiaries				X
23.1	Consent of independent registered public accounting firm.				X

24.1	Power of Attorney. Reference is made to the signature page to this Annual Report on Form 10-K.	X
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
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X
101.INS	Inline XBRL Instance Document-the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document	X
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
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

† Confidential treatment has been granted for certain information contained in this exhibit. Such information has been omitted and filed separately with the Securities and Exchange Commission.

†† Portions of this exhibit have been omitted in accordance with Item 601(b)(10) of Regulation S-K.

# Indicates management contract or compensatory plan.

** The certifications attached as Exhibit 32.1 and Exhibit 32.2 that accompany this Annual Report on Form 10-K are not deemed filed with the Securities and Exchange Commission and are 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 Annual Report on Form 10-K, irrespective of any general incorporation language contained in such filing.

Item 16. Form 10-K Summary.

Registrants may voluntarily include a summary of information required by Form 10-K under Item 16. We have elected not to include such summary.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

Aimmune Therapeutics, Inc.

Date: February 27, 2020

By: /s/ Jayson Dallas
Jayson Dallas
President, Chief Executive Officer and Director

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints each of Eric H. Bjerkholt and Douglas T. Sheehy his or her true and lawful attorney-in-fact and agent, with full power of substitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

IN WITNESS WHEREOF, each of the undersigned has executed this Power of Attorney as of the date indicated opposite his/her name.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Jayson Dallas **Jayson Dallas**	President, Chief Executive Officer and Director (Principal Executive Officer)	February 27, 2020
/s/ Eric H. Bjerkholt **Eric H. Bjerkholt**	Chief Financial Officer (Principal Financial and Accounting Officer)	February 27, 2020
/s/ Gregory Behar **Gregory Behar**	Director	February 27, 2020
/s/ Patrick G. Enright **Patrick G. Enright**	Director	February 27, 2020
/s/ Kathryn E. Falberg **Kathryn E. Falberg**	Director	February 27, 2020
/s/ Brett K. Haumann **Brett K. Haumann**	Director	February 27, 2020
/s/ Mark T. Iwicki **Mark T. Iwicki**	Director	February 27, 2020
/s/ Mark D. McDade **Mark D. McDade**	Director	February 27, 2020
/s/ Stacey D. Seltzer **Stacey D. Seltzer**	Director	February 27, 2020

Executive Officers

Jayson D.A. Dallas, M.D.
President, Chief Executive Officer and Director

Eric H. Bjerkholt
Chief Financial Officer

Daniel C. Adelman, M.D.
Chief Medical Officer

Andrew Oxtoby
Chief Commercial Officer

Douglas T. Sheehy
General Counsel and Secretary

Board of Directors

Jayson D.A. Dallas, M.D.
President and Chief Executive Officer
Aimmune Therapeutics, Inc.

Mark D. McDade
Chairman, Aimmune Therapeutics, Inc. and
Managing Partner, Qiming US Healthcare Fund, LP

Gregory Behar
Chief Executive Officer
Nestlé Health Science S.A.

Patrick G. Enright
Managing Director, Longitude Capital

Kathryn E. Falberg
Former Executive Vice President and
Chief Financial Officer, Jazz Pharmaceuticals plc.

Brett K. Haumann
Chief Medical Officer and Senior Vice President,
Clinical Development, Theravance Biopharma

Mark T. Iwicki
Chairman and Chief Executive Officer
Kala Pharmaceuticals, Inc.

Stacey D. Seltzer
Partner, Aisling Capital

Corporate Information

CORPORATE HEADQUARTERS
Aimmune Therapeutics, Inc.
8000 Marina Boulevard, Suite 300
Brisbane, CA 94005
TEL 650.614.5220
FAX 650.616.0075

Stockholder Information

ANNUAL MEETING OF STOCKHOLDERS
May 27, 2020
3:00 p.m., Pacific Time
www.virtualshareholdermeeting.com/AIMT2020

Transfer Agent

EQ Shareowner Services
1110 Centre Pointe, Suite 101
Mendota Heights, MN 55120

Stockholder Information

Symbol: AIMT
Exchange: Nasdaq

Legal Counsel

Latham & Watkins LLP
Menlo Park, CA

Independent Registered Public Accounting Firm

KPMG LLP
San Francisco, CA

Aimmune Therapeutics, Inc.

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