ADURO BIOTECH, INC.
Form 10-K
March 08, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2015

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 001-37345

ADURO BIOTECH, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	94-3348934
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

626 Bancroft Way, 3C

Berkeley, California 94710

(Address of principal executive offices including zip code)

Registrant's telephone number, including area code: (510) 848-4400

Securities registered pursuant to Section 12(b) of the Act: Common Stock, Par Value $0.0001 Per Share; Common stock traded on the NASDAQ Stock 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 x

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 x

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definition of "large accelerated filer", "accelerated filer", and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer x (Do not check if a small reporting company)	Small reporting company ¨

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ¨ NO x

The aggregate market value of the Registrant's common stock held by non-affiliates as of June 30, 2015, based on the closing price of the shares of common stock on the NASDAQ Stock Market for such date, was $1,113,738,008.

The number of shares of Registrant's Common Stock outstanding as of March 2, 2016 was 64,517,822.

Portions of the Registrant's Definitive Proxy Statement relating to the Annual Meeting of Shareholders, which will be filed with the Securities and Exchange Commission within 120 days after the end of the Registrant's fiscal year ended December 31, 2015, are incorporated by reference into Part III of this Report.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. All statements, other than statements of historical facts contained in this Annual Report on Form 10-K, including statements regarding our future financial condition, business strategy and plans, and objectives of management for future operations, are forward-looking statements. In some cases you can identify these statements by forward-looking words such as “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “could,” “project,” “plan,” “expect” or the negative or plural of these words or similar expressions. These forward-looking statements include, but are not limited to, statements concerning the following:

- our history of net operating losses and uncertainty regarding our ability to achieve profitability;
- our ability to fund our working capital needs;
- our ability to develop and commercialize our product candidates;
- our ability to use and expand our technology platforms to build a pipeline of product candidates;
- our dependence on our lead product candidate, CRS-207, and GVAX Pancreas;
- our ability to obtain and maintain regulatory approval of our product candidates;
- our inability to operate in a competitive industry and compete successfully against competitors that have greater resources than we do;
- the potential benefits of our acquisition of BioNovion Holding B.V., our wholly-owned subsidiary known as Aduro Biotech Europe;
- our ability to retain and attract key personnel;
- our products may not gain market acceptance;
- our reliance on third parties;
- our ability to obtain and adequately protect intellectual property rights for our product candidates; and
- expected timing of our clinical results.

These statements are only current predictions and are subject to known and unknown risks, uncertainties and other factors that may cause our or our industry’s actual results, levels of activity, performance or achievements to be materially different from those anticipated by the forward-looking statements. We discuss many of these risks in greater detail under the heading “Risk Factors” and elsewhere in this Annual Report on Form 10-K. You should not rely upon forward-looking statements as predictions of future events. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risks and uncertainties.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Except as required by law, after the date of this report, we are under no duty to update or revise any of the forward-looking statements, whether as a result of new information, future events or otherwise.

We obtained industry, market and competitive position data in this report from our own internal estimates and research as well as from industry and general publications and research surveys and studies conducted by third parties. These data involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such information or estimates.

PART I

Item 1. Business.

Overview

References herein to “we,” “us,” “Company”, and “Aduro” refer to Aduro Biotech, Inc. and its consolidated subsidiaries unless the context specifically states otherwise.

We are a clinical-stage immunotherapy company focused on the discovery, development and commercialization of therapies that transform the treatment of challenging diseases. Our first-in-class technology platforms, which are designed to harness the body's natural immune system, are being investigated in cancer indications and have the potential to expand into autoimmune and infectious diseases. Our Live, Attenuated, Double-Deleted, or LADD, Listeria monocytogenes technology platform is engineered to express tumor-associated antigens to induce specific and targeted immune responses. Based on compelling clinical data in advanced cancers, this platform is being developed as a treatment for multiple indications, including pancreatic, ovarian, lung and prostate cancers, mesothelioma and glioblastoma. Our STING Pathway Activator platform is designed to activate the intracellular Stimulator of Interferon Genes, or STING receptor, resulting in a potent tumor-specific immune response. Our B-select monoclonal antibody platform includes a number of immune modulating assets in research and preclinical development. We are also collaborating with leading global pharmaceutical companies to expand our products and technology platforms.

Our lead LADD product candidate, CRS-207, is an immuno-oncology therapy (a class of therapies that leverage the patient’s immune system to slow the growth and spread of, or eliminate, tumor cells). Immuno-oncology is an emerging field of cancer therapy that aims to activate the immune system in the tumor microenvironment to create and enhance anti-tumor immune responses, as well as to overcome the immuno-suppressive mechanisms that cancer cells have developed against the immune system. Recent developments in the field of immuno-oncology, including checkpoint inhibitors—therapies that have mechanisms focused on unmasking hidden cancer cells—have shown the potential to provide dramatic efficacy and extended survival, even in cancers where conventional therapies, such as surgery, chemotherapy and radiotherapy, have failed. The immunotherapy field is rapidly advancing with new immuno-oncology combinations that focus on strengthening therapeutic efficacy in a wide range of cancers. We intend to pursue a broad strategy of combining our technology platforms with conventional and novel immuno-oncology therapies, based on their mechanisms of action, safety profiles and versatility.

CRS-207 is currently being developed in metastatic pancreatic cancer, unresectable malignant pleural mesothelioma and ovarian cancer. In a completed randomized controlled Phase 2a clinical trial in metastatic pancreatic cancer patients, CRS-207 demonstrated a statistically significant improvement in overall survival when combined with GVAX Pancreas, a cellular vaccine product candidate. The 93-patient two-arm Phase 2a clinical trial was designed to compare the combination of CRS-207 and GVAX Pancreas versus GVAX Pancreas alone. The trial met the primary efficacy endpoint of overall survival at an interim analysis and was stopped upon recommendation from the Data Monitoring Committee. Based on the data from this study, our lead immuno-oncology regimen of CRS-207 and GVAX Pancreas was granted Breakthrough Therapy designation by the U.S. Food and Drug Administration, or FDA. Breakthrough Therapy designation is intended to expedite the development and review of products that treat serious or life-threatening conditions. We have obtained orphan drug designation for CRS-207 and GVAX Pancreas for the treatment of pancreatic cancer and for CRS-207 for the treatment of mesothelioma in the United States and European Union from the FDA and European Medicines Agency, respectively. Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biologic intended to treat a rare disease or condition. Orphan drug designation entitles a party to certain financial incentives and can provide limited market exclusivity in certain circumstances.

We are developing a pipeline of proprietary product candidates on our own and through partnerships. We have developed two LADD product candidates in collaboration with Janssen Biotech, Inc., or Janssen, targeting prostate and lung cancers and STING Activator product candidates in oncology under our worldwide collaboration with Novartis Pharmaceuticals Corporation, or Novartis. In addition, we are developing monoclonal antibodies, or mAbs, with the potential to yield novel immunotherapy combinations as a result of our recent acquisition of BioNovion Holding B.V., our wholly-owned subsidiary known as Aduro Biotech Europe, based in the Netherlands. We have intellectual property protection on our LADD and STING Pathway Activator technology platforms and each of our product candidates, which we believe we will maintain into the 2030s.

Our Proprietary Technology Platforms and Pipeline

We have developed first-in-class technology platforms – LADD, STING Pathway Activator and B-select monoclonal antibodies. We believe our technology platforms represent innovative approaches in immuno-oncology. Since our product candidates act by leveraging the patient’s own immune system, we believe they have the potential to deliver enhanced efficacy and to be safer and more tolerable than existing therapies, such as chemotherapy and radiotherapy. Based on the mechanism of action and safety profile of our technology platforms, we intend to build a deep pipeline of product candidates that can be readily combinable and synergistic with both conventional and novel therapies, such as checkpoint inhibitors. Our vision is to leverage our scientific expertise

and understanding of the body's natural defense systems, including the interplay between the innate and adaptive immune responses, to develop safe and effective therapies for the benefit of patients.

Live, Attenuated, Double-Deleted Listeria Monocytogenes

Our proprietary LADD product candidates have been engineered for safety. In addition, we seek to optimize tumor-specific immune responses by engineering our LADD product candidates to express encoded tumor-specific antigens and deliver them to antigen-presenting cells. Antigen-presenting cells, which include dendritic cells, lead to efficient priming of a class of immune cells known as T cells. Once primed, these T cells seek out and eliminate the targeted tumor cells. Our LADD product candidates have been engineered for safety in humans through the deletion of two genes critical for virulence of unmodified Listeria: actA and inlB. The deletion of the actA gene prevents the spread of our LADD product candidates from cell to cell, which controls the spread of infection. The deletion of the inlB gene prevents the infection of hepatocytes, or liver cells, which can lead to toxicity. We believe key attributes of our LADD technology platform include:

- Early Evidence of Efficacy. Our randomized controlled Phase 2a clinical trial in patients with metastatic pancreatic cancer who had received or refused prior therapy demonstrated improved overall survival.
- Novel Mechanism. Our LADD product candidates are designed to initiate a powerful innate immune response and drive a targeted, durable adaptive immune response.
- Early Evidence of Safety in Preclinical Studies and Clinical Trials. Through our proprietary deletion of two genes that contribute to Listeria's virulence, we substantially reduce the natural disease-causing properties of Listeria, creating stable product candidates suitable for therapeutic use.
    - Versatility. Individual LADD product candidates can be engineered to target a wide range of cancers by promoting anti-tumor immune responses against antigens associated with specific tumors.
- Combinability. The mechanisms of action and safety profile of our LADD product candidates may give them the potential for combination with conventional and novel therapies, such as cellular vaccines, chemotherapy, radiotherapy and checkpoint inhibitors, among others.
- Repeatable Administration. Our LADD product candidates are not neutralized by the patient's immune system and are designed for repeat administration, thus allowing a chronic therapy for a sustained tumor antigen-specific response.
- Cost-effectiveness. Our LADD product candidates are not personalized for each patient and can be manufactured through a relatively simple and cost-effective fermentation process.

STING Pathway Activators

Our proprietary STING Activator product candidates are synthetic small molecule immune modulators that are designed to target and activate a receptor known as STING. Once activated, the STING receptor initiates a profound innate immune response by signaling through three distinct pathways, inducing the expression of a broad profile of cytokines that activate the development of an effective tumor antigen-specific T cell adaptive immune response. The STING receptor is generally expressed at high levels in the cytosol of immune cells, including dendritic cells. Recent advancements reported in numerous leading scientific journals have created interest in the potential for STING receptor-targeting drug candidates across diverse applications. We believe the STING receptor represents an attractive target for novel drug candidates because it is known to be critical for immune surveillance and control of cancer progression. We are developing STING Activator product candidates as therapies that are intended to prime and enhance the innate and adaptive immune responses. Our proprietary synthetic STING Activator product candidates are from a family of compounds known as cyclic dinucleotide, or CDN molecules, and are significantly more potent than naturally occurring CDNs, indicating high translational potential as a therapeutic approach to elicit an effective immune response. We believe key attributes of our STING Pathway Activator technology platform include:

- Early Evidence of Potency. Our STING Activator product candidates have demonstrated significant anti-tumor activity in pre-clinical studies.
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Novel Mechanism. Our STING Activator product candidates are designed to initiate broad and strong innate and adaptive immune responses through the activation of the STING receptor signaling pathway.

- Versatility of Delivery. We believe our STING pathway product candidates can be effectively delivered via intratumoral injection, systemic delivery via formulation and other novel modalities, such as conjugation with antibodies.
- Combinability. Based on their mechanism of action, we believe our STING Activator product candidates may have synergistic or additive benefits of immune-mediated tumor killing mechanisms when combined with conventional and novel therapies, such as cellular vaccines, chemotherapy, radiotherapy and checkpoint inhibitors, among others.

- Ease of Manufacture. Our STING Activator product candidates are small molecules manufactured through a relatively simple and cost-effective process.
- Broad Applicability. We believe our STING pathway product candidates will have broad application in oncology and the potential to expand into other therapeutic areas such as infectious and autoimmune diseases.

B-select Antibodies

Our B-select monoclonal antibody, or mAbs, platform technology is composed of agonist and antagonist mAbs. The unique approach to mAbs discovery through in vitro clonal expansion of B cells (antibody producing cells) has led to a number of immune modulating product candidates in research and preclinical development. The platform will allow us to further develop our portfolio of therapeutic antibodies to be used as monotherapies or in combination with existing or novel therapies, including our product candidates from the LADD and STING Pathway Activator platforms.

Pipeline

Our most advanced immuno-oncology regimen is currently in a randomized controlled Phase 2b clinical trial known as ECLIPSE to assess the combination of our lead LADD product candidate, CRS-207, with GVAX Pancreas to treat late-stage metastatic pancreatic cancer patients who have received at least one prior line of therapy. GVAX Pancreas, which has demonstrated a favorable safety profile in clinical trials to date, is an important combination candidate because it is designed to induce T cells against an array of pancreatic cancer antigens and enable a broad-based immune response. In a Phase 2b study called STELLAR, we are evaluating CRS-207 in combination with GVAX Pancreas and an anti-PD-1 checkpoint inhibitor in patients with metastatic pancreatic cancer. In addition, we are advancing into Phase 3 CRS-207 in combination with chemotherapy in patients with unresectable malignant pleural mesothelioma. We also have ongoing and planned clinical development programs evaluating LADD regimens for patients with glioblastoma multiforme and ovarian cancer, and for patients with lung and prostate cancers under collaborations with Janssen.

We envision multiple product opportunities for our STING Pathway Activator technology platform, including ADU-S100. Because STING receptors are known to be critical for immune surveillance and control of cancer progression, we believe that STING receptors represent an attractive target for novel drug candidates. We are developing our STING Activator product candidates as impactful therapies that are intended to prime and enhance innate and adaptive immune responses. Based on their mechanism of action, our STING Activator product candidates may also have synergistic or additive benefits when combined with other cancer therapies.

In addition, we are developing mAbs with the potential to yield novel immunotherapy combinations as a result of our recent acquisition of BioNovion Holding B.V., known as Aduro Biotech Europe.

Our pipeline of product candidates is depicted in the following chart:

Our Strategy

Our current focus is to discover, develop and commercialize best-in-class cancer therapies using our LADD, STING Activator and B-select technology platforms. Key elements of our strategy include:

- Rapidly advance CRS-207 through clinical development and regulatory approval. We are currently conducting two Phase 2b clinical trials known as ECLIPSE and STELLAR utilizing CRS-207 in combination with GVAX Pancreas in patients with metastatic pancreatic cancer. We are also using CRS-207 in combination with standard-of-care chemotherapy for treatment in the front line-setting of unresectable malignant pleural mesothelioma.
- Maximize the commercial value of our proprietary LADD, STING Pathway Activator and B-select technology platforms. We currently have global development, marketing and commercialization rights for our lead product candidate, CRS-207, as well as additional LADD product candidates. If we obtain regulatory approvals for CRS-207 in pancreatic cancer or other indications, we plan to build a commercial organization with a specialty sales force to market CRS-207. We also plan to retain commercial rights to additional LADD product candidates. In addition, we established a worldwide collaboration with Novartis for STING Activator product candidates in oncology. We also maintain worldwide rights to our STING pathway programs outside of oncology.
- Develop novel drug candidates by leveraging our proprietary technology platforms and our understanding of combination therapy in immuno-oncology. We have proprietary technology platforms that we believe can generate novel and combinable therapies to target a wide range of cancers with significant unmet medical need. We plan to invest in these technology platforms to develop additional product candidates. We intend to further explore combination opportunities with conventional and novel treatments, including cellular vaccines, checkpoint inhibitors (including product candidates from the B-select platform), chemotherapy and radiotherapy.
- Expand on the value of our product candidates through collaborations. We may decide to selectively partner large and complex oncology indications, in certain geographies and where we believe a partner could bring additional resources and expertise to maximize the value of our product candidates. We entered into two strategic collaborations with Janssen for the treatment of prostate, lung and certain other cancers. We also established a worldwide development and commercialization collaboration with Novartis for STING Activator product candidates in oncology. We believe these collaborations have the potential to drive significant value through the extensive capabilities of these organizations.

- Leverage the expertise of our scientific founders and key advisors to develop innovative technologies at the forefront of the immuno-oncology field. Our scientific founders and advisors are from some of the world's leading research institutions and have a history of seminal discoveries and significant experience in oncology, immuno-oncology and vaccines. As such, we plan to continue to leverage the collective talent of our scientists, clinicians and a network of highly influential advisors to inform our development strategy and enable our technology to be at the forefront of the immuno-oncology field. We strive to protect our commercially important discoveries and product candidates by applying for, maintaining and defending our patent rights. As of February 12, 2016, our owned U.S. patent portfolio consisted of 22 issued patents and 22 pending patent applications.

The Aduro Approach to Immuno-Oncology

We believe that our LADD and STING Pathway Activator technology platforms represent a new, significant advancement within the field of immuno-oncology that can both overcome the limitations of other "create and expand" approaches and potentially complement emerging "remove the brakes" approaches to immuno-oncology. Our "create and expand" approach is designed to prime and enhance innate and adaptive immune responses against cancer cells. In addition, our technology platforms have the potential for combination with conventional and novel therapies, including other immuno-oncology products that modulate the immune response, including checkpoint inhibitors that "remove the brakes," due to the mechanism of action and safety profile. Using our proprietary method of modifying Listeria, we engineer LADD product candidates that are designed to prime and enhance an innate and adaptive immune responses specific for several targets present on tumor cells. We have designed our LADD product candidates to directly address the safety concerns seen with other vector-based vaccines by deleting two genes critical for the virulence of unmodified Listeria. Our LADD product candidates are not neutralized by the patient's immune system, thereby allowing for repeat administration as a chronic therapy which has a sustained enhancing of tumor antigen-specific T cell immunity. Our STING Pathway Activator technology platform is designed to specifically activate the STING receptor. Once activated, the STING receptor initiates a profound innate immune response, causing the secretion of cytokines that enhance the adaptive immune response against tumor cells. Both our LADD and STING Pathway Activator technology platforms are intended to prime and enhance an innate and adaptive immune response specific for several targets present on tumor cells.

Our B-select technology platform further expands our immunotherapy capabilities to encompass mAbs, including preclinical assets that inhibit clinically validated immune checkpoint pathways. Such immune checkpoint inhibitors could potentially be used alone or in combination with our LADD and STING Pathway Activator platforms to increase immunotherapy potency and durability. In addition, we are developing novel preclinical mAbs which inhibit or activate unique immune response pathways that have a role in controlling the progression of diverse malignancies.

Our Immuno-Oncology Technology Platforms

LADD Technology Platform Overview

Listeria is a natural bacterium that has inherent characteristics to recruit and activate natural killer, or NK, cells, triggering a strong and immediate innate immune response. Our LADD technology platform modifies Listeria in two ways: (1) to exclude two harmful genes required for the virulence of the unmodified Listeria and (2) to express and secrete tumor antigens which prime and enhance an adaptive immune response in the form of a T cell attack specifically against tumor cells.

There are a number of desirable features of the natural biology of Listeria that make it an attractive platform for immuno-oncology drug development, in particular is its ability to induce strong innate and adaptive immune responses by effective stimulation of CD4+ and CD8+ T cell immunity. There are also practical features of Listeria-based vaccines, including that they are not neutralized by the patient's immune system, are designed for repeat administration and can be manufactured through a relatively simple and cost-effective fermentation process. We believe we have developed a LADD technology platform that is safe yet retains the potency of the natural, or

unmodified, bacteria.

We designed our LADD technology platform to enable the safe administration of Listeria by deleting two genes critical to the bacterium's natural virulence, actA and inlB, which are required for the spread from one cell to another and the infection of hepatocytes, respectively. Our method of attenuation results in the complete deletion of actA and inlB virulence genes, and as a result we believe there is no possibility for reversion to unmodified Listeria. The attenuated strain of bacteria is then modified with new genetic material to encode and express specific tumor antigens. Our method of antigen expression involves site-specific insertion of antigen expression cassettes in up to four locations on the chromosome of the attenuated platform strain.

Upon intravenous administration, our LADD product candidates initially target antigen presenting cells, or APCs, including dendritic cells, or DCs. DCs circulate in the blood stream and continuously monitor their environment for danger signals by sampling proteins known as antigens from dying tumor cells and pathogens such as Listeria. Activated DCs release cytokines and process the sampled antigens and present them on the cell surface to be recognized by T cells, thereby training the T cells to specifically target the

presented antigens. In this way, DCs are the primary initiators of both the innate and adaptive immune responses and serve as messengers between the innate and adaptive immune systems, as illustrated in the figure below. Our LADD product candidates are designed to leverage the combined effect of broad-based innate immune responses and antigen-specific T cell responses to initiate destruction of tumor cells while sparing normal tissue.

LADD-Based Pipeline

Our LADD product candidates are developed alone and in combination with complementary therapies to treat specific cancers. The current portfolio includes:

Program	Indication	Combination	Status
CRS-207 (Mesothelin)	Pancreatic	GVAX	Phase 2b / Ongoing
	Pancreatic	GVAX+ anti-PD-1	Phase 2b / Ongoing
	Mesothelioma	Chemo	Phase 3 / Planned
	Ovarian**	epacadostat	Phase 1b / Planned
ADU-623 (NYESO-1 + EGFRvIII)	Glioblastoma	None	Phase 1 / Ongoing
ADU-741* (Multiple)	Prostate	TBD	Phase 1 / Ongoing
ADU-214* (Mesothelin + EGFRvIII)	Lung	Multiple / TBD	Phase 1 / Ongoing

*Programs under collaboration with Janssen.
**Clinical trial under collaboration with Incyte.
We filed the investigational new drug application, or IND, for CRS-207 for use in combination with GVAX Pancreas for pancreatic cancer in April 2011. The IND for CRS-207 in combination with GVAX Pancreas and nivolumab for pancreatic cancer was filed by The Johns Hopkins University, or JHU, in September 2014. The IND for CRS-207 for use in mesothelioma was filed by Cerus Corporation in June 2007. We filed the IND for CRS-207 for use in combination with epacadostat for ovarian cancer in November 2015.

The IND for ADU-623 for use in glioblastoma was filed by Providence Health & Services in August 2013.

We have filed INDs for the two programs in collaboration with Janssen, ADU-741 for prostate cancer and ADU-214 for lung cancer. Both of these INDs have been transferred to Janssen.

CRS-207

CRS-207 is our lead LADD product candidate. CRS-207 is a monovalent LADD product candidate engineered to express the mesothelin antigen that is over-expressed in pancreatic and mesothelioma tumors. Some studies have shown that mesothelin is over-expressed in the following additional cancer types: ovarian, gastric, lung, triple negative breast, esophageal and colorectal.

CRS-207 in Pancreatic Cancer

Pancreatic Cancer Overview

Pancreatic cancer is the fourth leading cause of cancer deaths in the United States. In 2012, the estimated incidence according to Globocan was 43,000 in the United States and 338,000 worldwide. Pancreatic cancer is aggressive and often not diagnosed until it is too advanced for current treatments to be effective. Most patients are diagnosed after the age of 45, and 94% of patients die within five years from diagnosis. The majority of pancreatic cancer patients are treated with chemotherapy, but this cancer is highly resistant to chemotherapy. Approximately 20% of the pancreatic cancer patients are treated with surgery; however, even for those with successful surgical resection, the median survival is approximately two years. Radiotherapy may be used for locally advanced tumors, but it is not curative. There are currently no approved treatments for second and third-line patients.

CRS-207 with GVAX Pancreas in Pancreatic Cancer

CRS-207 combined with GVAX Pancreas is our lead LADD regimen. We are currently conducting two Phase 2b clinical trials, known as ECLIPSE and STELLAR, utilizing CRS-207 in combination with GVAX Pancreas in patients with metastatic pancreatic cancer. We have obtained orphan drug designation for CRS-207 and GVAX Pancreas for the treatment of pancreatic cancer in the United States and European Union from the FDA and European Medicines Agency, respectively.

About GVAX and GVAX Pancreas

GVAX product candidates are a family of vaccines derived from human cancer cell lines that have been engineered to recruit the immune system. In 2013, we acquired the rights, title and interest of ANI Pharmaceuticals Inc. to GVAX Pancreas product candidates. These irradiated tumor cell lines are modified to express GM-CSF, the most potent DC recruitment factor. GVAX induces T cells against a broad array of cancer antigens. Low-dose cyclophosphamide is administered one day prior to GVAX Pancreas to inhibit regulatory T cells. GVAX Pancreas is derived from human pancreatic cancer cell lines and is designed to activate specific T cell immunity to cancer antigens including mesothelin enabling, or priming, a broad-based immune response.

Preclinical studies have shown the concept of synergy between immune checkpoint inhibitors such as anti-CTLA-4 antibodies and cancer vaccines such as GVAX. For example, researchers at JHU conducted a Phase 1b, open-label, randomized study to build on these preclinical observations by evaluating ipilimumab (a checkpoint inhibitor, anti-CTLA-4 antibody) alone or in combination with GVAX Pancreas for the treatment of previously treated, locally advanced, or metastatic pancreatic cancer. The primary objective of the study was to determine the safety profile. Secondary objectives included estimation of overall survival. A total of 30 patients with previously treated advanced pancreatic cancer were randomized (1:1). The median overall survival was 3.6 months for patients receiving ipilimumab, Arm 1, compared with 5.7 months for patients receiving ipilimumab in combination with GVAX Pancreas, Arm 2 (hazard ratio for death, or HR, = 0.51, p-value = 0.072). The one-year survival probability for patients in Arm 1 was 7% compared to 27% for patients in Arm 2. The hazard ratio is a measure of the risk of a

particular event in one group compared to another group, over time. An HR lower than 1.00 indicates that the observed risk is lower in the treatment arm than in the control arm. A p-value is a measure of the statistical significance of the observed result. By convention, a p-value lower than 0.05 is considered statistically significant. Similar to prior ipilimumab studies, 20% of patients in each arm had grade 3/4 immune-related adverse events. Based on the results of the study, the investigators concluded that immune checkpoint blockade in combination with GVAX Pancreas has the potential for clinical benefit and should be evaluated further in a larger study.

Clinical Status

Preclinical and Phase 1 clinical studies conducted by Cerus Corporation in 2005-2006 and Anza Therapeutics in 2007-2009 demonstrated the potential of utilizing the heterologous priming and enhancing combination of CRS-207 and GVAX Pancreas. Based on these data, we initiated a randomized controlled Phase 2a clinical trial with this combination. The results of our randomized controlled Phase 2a clinical trial were first presented at the American Society of Clinical Oncology, or ASCO, in 2013 and published in the January 2015 issue of the Journal of Clinical Oncology and further supported this combination approach to treat metastatic pancreatic cancer.

In the randomized controlled Phase 2a clinical trial the combination of CRS-207 with GVAX Pancreas demonstrated a statistically significant improvement in overall survival compared to GVAX Pancreas alone in patients with metastatic pancreatic cancer who previously received or refused prior chemotherapy. Based on these data, the FDA granted Breakthrough Therapy designation for the combination of CRS-207 and GVAX Pancreas. We designed our Phase 2b ECLIPSE clinical trial based on the results we observed in the Phase 2a clinical trial. The ECLIPSE clinical trial is being conducted to compare the clinical outcomes of the combination of CRS-207 and GVAX Pancreas to currently used single agent chemotherapies or to CRS-207 alone. We completed enrollment in ECLIPSE in the third quarter of 2015.

Phase 2a (Completed)

We conducted a randomized controlled Phase 2a clinical trial of CRS-207 in combination with GVAX Pancreas in patients with metastatic pancreatic cancer who received or refused prior therapy. The 93-patient two-arm study was designed to compare the combination of CRS-207 and GVAX Pancreas versus GVAX Pancreas alone. The trial met the primary efficacy endpoint of overall survival at an interim analysis and was stopped upon recommendation from the Data Monitoring Committee.

The trial enrolled advanced-stage metastatic pancreatic cancer patients, with most patients having received two or more prior therapies in the metastatic setting. Patients were randomized in a two to one ratio in Arm A, which received GVAX Pancreas vaccine followed by four doses of CRS-207, or Arm B, which received six doses of GVAX Pancreas vaccine alone. In each arm, low dose cyclophosphamide was administered one day prior to GVAX Pancreas in order to enhance its immunogenicity and anti-tumor activity. Low dose cyclophosphamide inhibits T regulatory cells, and T regulatory cells may diminish a vaccine’s efficacy. Patients were allowed to receive additional treatment courses (a treatment course contains six vaccinations) if they were clinically stable and perceived by the investigator to benefit from treatment. In both arms, treatments are administered at three week intervals, with a four week interval between treatment courses. After a four-week rest, clinically stable patients were offered additional courses.

In January 2014, safety and efficacy data were presented at the ASCO Gastrointestinal Cancers Symposium. The study demonstrated a statistically significant survival benefit in patients receiving the combination of CRS-207 and GVAX Pancreas, Arm A, compared to GVAX Pancreas vaccine alone, Arm B. The median overall survival, or mOS, of the patients receiving the combination was 6.1 months compared to 3.9 months for those receiving GVAX Pancreas monotherapy (hazard ratio for death, or HR, = 0.59, one-sided p value = 0.0172). One-year survival probability for patients in Arm A was 24% compared with 12% for patients in Arm B. The Kaplan-Meier survival curve for the full analysis set, patients who received at least one treatment, as of October 2013 is shown below.

Phase 2a Overall Survival - Full Analysis Set

To better evaluate the effect of CRS-207, we performed a pre-defined subset analysis that included only patients who received at least three doses in either treatment group, GVAX Pancreas followed by at least one CRS-207 dose in Arm A or at least three doses of GVAX Pancreas in Arm B. In this subset of 45 Arm A patients and 21 Arm B patients, the mOS was 9.7 months in Arm A compared to 4.6 months in Arm B (HR = 0.53, one-sided p value = 0.0167). The Kaplan-Meier survival curve for the subset of patients who received at least three doses (per protocol subset) as of October 2013 is shown below.

Phase 2a Overall Survival - Per Protocol Analysis Set

In addition to the 45 Arm A patients in the per protocol subset who received the combination of CRS-207 and GVAX Pancreas, three Arm B patients were crossed over into combination therapy. Of these 48 patients, nine survived longer than 24 months from randomization. None of the patients who received only GVAX Pancreas survived longer than 21 months. We continue to monitor the long-term survival of patients treated in our Phase 2a clinical trial. As of February 2016, one patient continued to receive the combination treatment and is in the 38th month of treatment and four patients remained in follow up.

Carbohydrate antigen 19-9, or CA 19-9, is a serum biomarker used in the diagnosis of pancreatic cancer in symptomatic patients and is being studied further to determine if it could also be used as a biomarker for prognosis, overall survival, response to chemotherapy and recurrence. While not statistically significant, we observed a higher proportion of patients with stable or declining levels of CA 19-9 during treatment in Arm A than in Arm B. There was no difference in progression-free survival, or PFS.

Side effects are known as adverse events, or AEs, and are graded in level of severity from Grade 1 to Grade 4. Grade 1 and 2 AEs are generally characterized as mild. Grade 3 AEs are considered moderate and Grade 4 AEs are considered severe. In our Phase 2a clinical trial, the most frequent drug-related Grade 3 or 4 AE was lymphopenia (an abnormally low level of white blood cells), with three patients experiencing Grade 3 lymphopenia and two patients experiencing Grade 4 lymphopenia. Lymphopenia is expected based on prior nonclinical studies and CRS-207's mechanism of action. In addition, the AEs of lymphopenia were self-correcting or did not reveal an unexpected pattern of toxicity. We currently do not plan to alter our development plan for CRS-207 based on these observed AEs of lymphopenia. There were no other Grade 4 AEs, and there were no other Grade 3 AEs with frequencies higher than five percent in either arm. The most common Grade 3 AEs were transient lymphopenia, fevers, elevated liver enzymes and fatigue. One Grade 3 serious AE of listeriosis was reported. At the request of the patient and the investigator, this patient continues to receive study treatment.

Phase 2b ECLIPSE (Enrollment Completed)

We are conducting our Phase 2b ECLIPSE clinical trial of CRS-207 in combination with GVAX Pancreas to treat late-stage metastatic pancreatic cancer patients who have received at least one prior line of therapy. The study is designed to evaluate the efficacy and safety of CRS-207 in combination with GVAX Pancreas, Arm A, compared to single agent chemotherapies, Arm C, commonly used in this setting. The study also includes an arm in which patients receive CRS-207 as a monotherapy, Arm B, to

evaluate the contribution of GVAX Pancreas to the combination therapy. The three-arm trial enrolled 303 patients at over 20 clinical trial sites in the United States and Canada.

Patients were enrolled in two cohorts. The primary cohort includes 214 patients who have received at least two prior treatment regimens for metastatic pancreatic cancer, or third+ line. The exploratory cohort includes 89 patients who have received only one prior treatment regimen for metastatic pancreatic cancer, or second line. Patients were randomized in a one to one to one ratio across each arm of the trial. Patients in Arm A receive two doses of GVAX and four doses of CRS-207. Patients in Arm B receive six doses of CRS-207. Patients in Arm C receive a physician's choice of the following single-agent chemotherapies: gemcitabine, 5-Fluorouracil, capecitabine, irinotecan or erlotinib.

In Arms A and B, treatments are administered at three-week intervals. Low-dose cyclophosphamide is delivered intravenously one day before each GVAX Pancreas treatment. GVAX Pancreas is administered as six intradermal injections. CRS-207 is delivered by one-hour intravenous infusion followed by a four-hour observation period. Oral antibiotics are initiated seven days after the final CRS-207 vaccination of each treatment course. After a four-week rest, clinically stable patients are offered additional courses.

The primary objective is to compare overall survival, or OS, in the primary cohort between Arms A and C. Secondary/exploratory objectives include comparison of OS in both primary and exploratory cohorts between all treatment arms, assessment of safety and clinical responses through tumor assessments and CA19-9 levels, and correlation of Listeria- and mesothelin-specific T cell and other immunological responses with OS, PFS, best overall response and quality of life.

The study is 80% powered (one-sided overall alpha = 0.15) for OS in the primary cohort between Arms A and C.

CRS-207 with GVAX Pancreas and Anti-PD-1 in Pancreatic Cancer

We have initiated a clinical trial using CRS-207 in combination with GVAX Pancreas and nivolumab, an anti-PD-1 checkpoint inhibitor, in metastatic pancreatic cancer. Nivolumab is being developed by Bristol-Myers Squibb and is currently approved in the U.S. for treatment of melanoma, non-small cell lung cancer and renal cell carcinoma. We anticipate that combining CRS-207 and GVAX Pancreas with a checkpoint inhibitor may further improve clinical outcomes because of their complementary mechanisms of action.

About Anti-PD-1

Programmed cell death protein 1, or PD-1, is expressed on the surface of activated T cells, B cells, and DCs. PD-1 and associated ligands, PD-L1 and PD-L2, negatively regulate immune responses with the ligands expressed on many murine tumor cell lines. Anti-PD-1/PD-L1 monoclonal antibodies, a class of checkpoint inhibitors, target this novel immunosuppressive pathway with the goal of strengthening the anti-tumor T cell response by impairing the interaction of the inhibitory receptor PD-1 on T cells with PD-L1 expressed on tumor cells. While anti-PD-1 therapies have shown efficacy in subsets of patients in some tumor types, patients with certain cancers have not responded to treatment with anti-PD-1 in early clinical trials, including pancreatic cancer patients. Based on preclinical models and early clinical data, we believe that checkpoint inhibitors when combined with strong adaptive immune cell stimulators, such as cancer vaccines, can have an amplified anti-tumor effect against poorly immunogenic tumors. These results provide rationale for further testing of checkpoint inhibitors in combination with other immunotherapies.

Clinical Status

The investigator-sponsored randomized controlled Phase 2b clinical trial, or STELLAR, is supported by Aduro, Bristol-Myers Squibb, Stand Up to Cancer, PanCAN/AACR and the Lustgarten Foundation. STELLAR is designed to

explore the synergistic effects on our treatment regimen in combination with nivolumab. The first patient was dosed in the first quarter of 2015.

Phase 2b STELLAR (Ongoing)

Our STELLAR clinical trial is a randomized controlled Phase 2b clinical trial of CRS-207 in combination with GVAX Pancreas and nivolumab in patients with metastatic pancreatic cancer who have received only one prior line of therapy in the metastatic setting. The ongoing 102-patient randomized controlled two-arm Phase 2b clinical trial is being conducted by leading investigators at five U.S. clinical trial sites. Patients receive either the combination therapy with nivolumab or the combination therapy alone. The primary endpoint of the trial is overall survival and secondary endpoints include evaluation of clinical and immune response and safety.

CRS-207 in Mesothelioma

Mesothelioma Overview

Malignant mesothelioma is a tumor in the tissue lining, most commonly the tissue lining surrounding the lungs. Mesothelioma is a relatively rare disease; it is estimated that the incidence in the United States is approximately 3,000 cases per year.

Malignant mesothelioma carries a poor prognosis with a mOS of approximately 12 months from diagnosis. Mesothelioma is currently treated with surgery, chemotherapy and radiotherapy.

CRS-207 with Chemotherapy in Mesothelioma

We are using CRS-207 in combination with standard-of-care chemotherapy for treatment in the front line-setting of unresectable malignant pleural mesothelioma. We have obtained orphan drug designation for CRS-207 for the treatment of mesothelioma in the United States and European Union from the FDA and European Medicines Agency, respectively.

About Chemotherapy

Chemotherapy can be an effective treatment option to enhance immune responses, inhibit immunosuppression and modify the tumor microenvironment to be more susceptible to immune-mediated killing. This provides a strong rationale to use chemotherapies in combination with a LADD product candidate to trigger robust innate and adaptive immune responses in a more susceptible tumor environment.

Clinical Status

We have completed enrollment in our single-arm Phase 1b clinical trial of CRS-207 in combination with standard-of-care chemotherapy in patients with unresectable malignant pleural mesothelioma who have not received prior therapy. A total of 38 patients were treated under this regimen. Based on encouraging results, we have opened an exploratory cohort within the same population in which patients receive the addition of low-dose cyclophosphamide intravenously one day before each CRS-207 in combination with standard-of-care chemotherapy.

Phase 1b (Enrollment Completed, Exploratory Cohort Ongoing)

The study design is single-arm; patients receive two prime CRS-207 vaccinations followed by standard-of-care chemotherapy, consisting of pemetrexed and cisplatin, or PEM/CIS, and then followed with boost and maintenance vaccinations of CRS-207. The study was initially designed to enroll 16 patients. The primary endpoints of the study are safety and immune response to the CRS-207 therapy. Secondary endpoints include tumor response, time to progression, immune analyses and tumor marker kinetics.

In August 2015, data from scheduled radiologic time points of 34 evaluable patients was renewed and disease control was observed in 94% (32/34), including 59% (20/34) with partial responses and 35% (12/34) experiencing stable disease following treatment with CRS-207 and chemotherapy. Median duration of response was 5.3 months (95% CI: 4.7-16.7 months) and median progression free survival was 8.5 months (95% CI: 6.9 – 10.8 months). No treatment-related serious adverse events or unexpected toxicities were observed. Treatment, follow-up and immune response evaluations are ongoing. Radiologic images were also read by an independent, central radiologist supporting our investigators' findings.

Phase 3 (Planned)

We have conducted meetings with the U.S. FDA and Paul-Ehrlich-Institut to discuss Phase 3 plans for our mesothelioma program. We expect to initiate a randomized controlled Phase 3 clinical trial in North America, Europe and Australia to evaluate OS, PFS, overall response rate, and safety of the combination therapy of CRS-207 and standard-of-care chemotherapy.

CRS-207 in Ovarian Cancer

Ovarian Cancer Overview

In the United States, ovarian cancer is the fifth leading cause of cancer-related death in women. It is estimated that the incidence in the United States is approximately 21,000 cases per year.

Epithelial ovarian cancer is the most common and lethal form of ovarian cancer. Prognosis for survival depends on the stage of the disease at diagnosis; however, most women are diagnosed with advanced stage ovarian cancer, with a 5-year survival of only 30%. For patients with advanced stage ovarian cancer, surgical removal of the tumor is generally performed. Standard of care for these patients is then platinum-based combination chemotherapy. However, of the 60% to 80% of patients who present with advanced disease and who respond to first-line chemotherapy, more than 75% will develop resistant or recurrent disease. Ultimately, almost all patients develop platinum chemotherapy resistance.

CRS-207 with epacadostat in Ovarian Cancer

We are using CRS-207 in combination with Incyte's investigational selective IDO1 inhibitor, epacadostat, for treatment in platinum resistant epithelial ovarian, fallopian, or primary peritoneal cancer patients that have progressed within 6 months after completing platinum-based chemotherapy. This study is being conducted by us in collaboration with Incyte.

About epacadostat

Epacadostat is an inhibitor of the enzyme indoleamine 2,3-dioxygenase, or IDO1. IDO1 is an immunosuppressive enzyme that has been shown to induce regulatory T cell generation and activation, and allow tumors to escape immune surveillance. Epacadostat is an orally bioavailable small molecule inhibitor of IDO1 that has nanomolar potency in both biochemical and cellular assays and has demonstrated potent activity in enhancing T lymphocyte, dendritic cell and natural killer cell responses in vitro, with a high degree of selectivity. Together, epacadostat, which has been shown to enhance activities of multiple types of immune cells by reducing the immune suppression characteristic of the tumor microenvironment, and CRS-207, which has shown to stimulate immune cell activity with particular targeting mechanisms that seek and attack tumor cells that express mesothelin like those found in ovarian cancer, provide a strong rationale to use in combination for ovarian cancer.

Clinical Status

Aduro entered into a clinical trial agreement with Incyte to evaluate the safety, tolerability and preliminary efficacy of CRS-207, in combination with epacadostat in patients with ovarian cancer. Under the terms of the agreement, we will collaborate with Incyte on a non-exclusive basis to evaluate the combination. We will be responsible for conducting the study and the results will be used to determine whether further clinical development of this combination is warranted. Costs for the trial will be shared on an equal basis.

Phase 1/2 (Planned)

The Phase 1/2 trial is designed to test combinations of CRS-207 with two dose levels of epacadostat in dose escalation and then will expand to a Phase 2 evaluating the combination at the optimal dose level compared to CRS-207 alone based on safety and tumor biomarkers. The study plans to enroll up to 42 patients in Phase 1 and up to 86 patients in Phase 2 with platinum-resistant ovarian, fallopian or peritoneal cancers.

ADU-623 in Glioblastoma Multiforme

ADU-623 is a bivalent LADD product candidate engineered to express EGFRvIII and NY-ESO-1, antigens expressed in glioblastoma multiforme, as well as other cancers.

Glioblastoma Multiforme Overview

Glioblastoma multiforme is a brain cancer with an incidence of approximately 11,000 people in the United States in 2013 according to Datamonitor Healthcare. These tumors are rapidly progressing, with a median time from diagnosis to the patient's death of approximately 15 months. In recurrent glioblastoma multiforme, treatment consists of both symptomatic and palliative therapies. However, with currently available therapies glioblastoma multiforme typically remains fatal within a very short period of time.

Clinical Status

ADU-623 is being evaluated in an ongoing Phase 1 clinical trial conducted by leading investigators at the Earle A. Chiles Research Institute at Providence Cancer Center in Portland, Oregon.

Phase 1 (Ongoing)

The Phase 1, dose escalation, safety and immunogenicity trial will enroll up to a total of 38 patients in the second-line. Second-line glioblastoma multiforme patients are those who have previously completed standard-of-care radiotherapy and temozolomide followed by adjuvant temozolomide or who have progressed following standard-of-care radiotherapy and chemotherapy. The study will evaluate three dose levels of ADU-623 with the primary endpoint of establishing the safety of the therapy and determining the optimal dose. The trial will also evaluate the patients' tumor responses and immune response to the ADU-623 therapy.

ADU-741 in Prostate Cancer

ADU-741 is a LADD product candidate engineered to express multiple antigens, and is under partnership with Janssen, which has exclusive rights to certain LADD-based product candidates specifically engineered for the treatment of prostate cancer.

Prostate Cancer Overview

According to the American Cancer Society, approximately one in seven men in the United States will be diagnosed with prostate cancer in his lifetime. According to Globocan, the incidence of prostate cancer was 233,000 cases in the United States and 1.1 million cases worldwide in 2012.

Clinical Status

In May 2014, we entered into an agreement whereby we granted Janssen an exclusive, worldwide license to certain product candidates specifically engineered for the treatment of prostate cancer, based on our novel LADD technology platform for any and all uses. We are eligible to receive up to a potential total of $365.0 million in upfront fees and development and commercialization milestones. Janssen will have exclusive rights to develop and commercialize LADD product candidates in prostate cancer and will assume responsibility for all research, development, manufacturing, regulatory and commercialization activities for the licensed products.

Phase 1 (Ongoing)

Janssen initiated the Phase 1 trial in prostate cancer in the fourth quarter of 2015. The Phase 1 study will evaluate intravenous administration of ADU-741 in patients with metastatic castration resistant prostate cancer.

ADU-214 in Lung Cancer

ADU-214 is a bivalent LADD product candidate expressing EGFRvIII and mesothelin, and is licensed to Janssen, which has exclusive rights for LADD product candidates for lung cancer indications and exclusive rights to develop and commercialize LADD product candidates expressing these antigens for any and all uses.

Lung Cancer Overview

Lung cancer causes more deaths than the next three leading causes of cancer deaths—colon, breast and prostate cancers—combined. According to Globocan, there were an estimated 214,000 new cases of lung cancer diagnosed in the United States in 2012 and 1.8 million new cases of lung cancer diagnosed worldwide in 2012.

Clinical Status

In November 2014, an additional agreement with Janssen became effective, granting Janssen an exclusive, worldwide license to certain product candidates engineered for the treatment of lung cancer and certain other cancers based on our novel LADD technology platform for any and all uses. Under the agreement we are eligible to receive significant development, regulatory and commercialization milestone payments up to a potential total of $817.0 million. Janssen will have exclusive rights to develop and commercialize LADD product candidates in lung cancer and will assume responsibility for all research, development, manufacturing, regulatory and commercialization activities for the licensed products.

Phase 1 (Ongoing)

Janssen initiated the Phase 1 trial in lung cancer in the fourth quarter of 2015. The Phase 1 study will evaluate intravenous administration of ADU-214 in patients with advanced or metastatic non-small cell lung cancer.

STING Pathway Activator Technology Platform Overview

Recent advancements reported in numerous leading scientific journals have generated significant interest and rationale for targeting the STING receptor as a novel therapeutic approach to immuno-oncology. We are developing a portfolio

of STING Activator product candidates, synthetic proprietary small molecule immune modulators that target and activate the STING receptor with applications across diverse diseases. The STING receptor is generally expressed at high levels in the cytosol of immune cells, including DCs. Once activated, the STING receptor initiates a profound innate immune response by signaling through three distinct pathways, inducing the expression of a broad profile of cytokines, including interferons and chemokines. This cytokine profile subsequently leads to the development of an effective tumor antigen-specific T cell adaptive immune response.

Naturally occurring cyclic dinucleotides, or CDNs, that target the STING receptor are produced by bacteria that secrete CDNs into the host cell or by mammalian cells through cyclic GMP-AMP synthetase, or cGAS. cGAS is a recently discovered receptor that senses double-stranded, or ds, DNA in the cytosol of APCs, and in response synthesizes a CDN that is structurally distinct from the CDNs produced by bacteria. While both bacterial- and cGAS-produced CDNs target and activate the STING receptor, CDNs

produced by cGAS bind more tightly to STING than CDNs produced by bacteria. This stronger binding triggers a larger and more stable change in shape of the STING receptor, leading to the development of a more effective tumor antigen-specific immune response. Additionally, while some of the five unique STING receptors in humans respond poorly to CDNs produced by bacteria, all respond to CDNs produced by cGAS. We are advancing through development novel synthetic STING Activator product candidates that contain a structure based on the cGAS-produced CDNs, thus stimulating potent innate immune responses to all of the known human STING receptors.

We have developed proprietary STING Activator derivative compounds that are significantly more potent than the natural cGAS-produced molecules, which can be demonstrated by comparing the expression levels the cytokines produced from signaling through three distinct pathways. The NF-kB pathway induces the expression of numerous pro-inflammatory cytokines, including IL-6 and TNFa that stimulate a variety of immune cells. The IRF-3 pathway leads to the induction of IFN-b and co-regulated genes which orchestrate diverse innate immune responses. The STAT6 pathway leads to expression of chemokines, including CCL2 and CCL20 that are involved in immune cell recruitment. The unique profile of cytokines induced through activating the STING receptor results in strong efficacy in numerous aggressive preclinical mouse models of cancer.

In healthy individuals, DCs and other APCs constantly sample nearby tumor and non-tumor cells, however, in cancer patients, tumors can produce immune-inhibitory molecules which can make the DCs non-functional. The activation of the STING receptor in the tumor microenvironment by IT injection of our proprietary STING Activator product candidates stimulate the maturation of the DCs, leading to the presentation of antigens found on the individual's unique tumor. The activated tumor-specific T cells induce tumor cell death both locally and systemically, resulting in significant and durable therapeutic efficacy in preclinical tumor models.

STING Activator Product Candidates

We envision multiple immuno-oncology STING Activator product opportunities as a monotherapy or in combination with other cancer treatments. In preclinical animal models, our data have shown that our proprietary STING Activator product candidates can be combined with designated recombinant proteins to induce potent antigen-specific CD4+, which recognize foreign antigens and assist in the immune response, and CD8+, which recognize and destroy cells expressing foreign antigens, T cell immunity. We believe our STING Activator product candidates can also be combined with conventional cancer treatments such as chemotherapy and radiotherapy to enhance our STING Activator product candidates' immune-mediated tumor killing mechanisms. We also believe that our STING Activator product candidates could alter the nature of the tumor microenvironment, thus allowing for improved responses to checkpoint inhibitors.

ADU-S100

Our lead STING Activator product candidate is ADU-S100, with proprietary modifications to the mammalian CDN structure designed to optimize stability, STING receptor binding affinity and potency, without significant toxicity. In March 2015, we entered into a worldwide collaboration with Novartis to further advance the research and development of STING agonist candidates in oncology.

ADU-S100 Preclinical Studies

In preclinical mouse tumor models, IT injection of ADU-S100 induced tumor shrinkage and generated substantial immune responses that may be capable of providing long-lasting systemic antigen-specific T cell immunity to prevent further growth of distal, untreated tumor metastases, a response known as an abscopal effect. Further preclinical studies demonstrated that the abscopal effect is entirely STING receptor-dependent. These data provide the rationale for advancing this novel molecule for the treatment of locally advanced or metastatic cancers.

Further rationale for the approach of IT injection of ADU-S100 is the recent discovery by Dr. Thomas Gajewski of the University of Chicago that the STING-dependent innate immune sensing in the tumor microenvironment is a critical step in promoting spontaneous tumor-initiated T cell priming, subsequent infiltration of tumor lymphocytes and tumor regression. Analyses conducted

with tumors isolated from melanoma patients have also revealed that tumors containing infiltrating activated T cells are characterized by an IFN-ß transcriptional signature. Studies in mice have demonstrated that IFN-ß signaling plays a critical role in tumor-initiated T cell priming. We believe that treatment strategies to induce IFN-ß signaling and DC activation in the tumor microenvironment to bridge the innate and adaptive immune responses have significant therapeutic potential. IT delivery of our synthetic STING Activator product candidates activate a tumor-specific T cell response that is unique to the individual's tumor; conceptually, a small molecule approach to patient-specific immuno-oncology treatments.

Single Agent ADU-S100 (B16 Melanoma Therapeutic Model)

Proprietary ADU-S100 versus Naturally Occurring cGAS CDN

In the preclinical study depicted above, mice were injected with melanoma tumor cells. Once the tumor grew to be 100 mm^3, groups of mice were given three 50 µg IT doses of ML cGAMP, a naturally occurring cGAS CDN, or ADU-S100. In addition, one group was treated with Hank's Balanced Salt Solution, or HBSS, as a control. All three doses of the compounds were given over the same one-week period. In this study we demonstrated that ADU-S100 in mice had superior anti-tumor activity as compared to a naturally occurring cGAS CDN.

ADU-S100 Versus TLR Ligands (B16 Melanoma Therapeutic Model)

Proprietary ADU-S100 versus TLR Ligands

In this experiment, similar in design to the prior experiment, mice were injected with melanoma tumor cells and received three IT doses of select compounds over the same one-week period once the tumors grew to be 100 mm^3. ADU-S100 was compared to TLR ligand product candidates in order to compare against other innate immune activators which are currently in clinical development by other companies. The doses of the IT injections for the TLR ligands and ADU-S100 were kept constant at 50 µg. While it is appreciated that the doses may not be optimized for each TLR ligand, the same dosing was used for consistency. In addition, one group was treated with HBSS, as a control. The results from this study supported the selection of ADU-S100 for tumor regression and control.

IT STING Activator Therapy with ADU-S100 Induces a Potent Abscopal Effect (B16 Melanoma Therapeutic Model)

In the preclinical study designed to examine the abscopal effect, mice were injected with melanoma cells on their right flank to create the primary tumor, and also given additional melanoma cells one week later by intravenous injection to create lung metastases, distal tumor lesions. The primary tumor was treated three times over a one-week period with 50 μg of ADU-S100, or HBSS, as a control. On day 28, the lungs were examined to determine the number of lung metastases. Mice treated with ADU-S100 in the primary tumor showed significant inhibition of the treated tumor and additionally demonstrated a significant inhibition of distant lung metastases. The photographs of the lungs are representative of the two treatment groups and show the contrast in the number of lung metastases (black nodules) between the control group, where numerous metastases are visible, and the treatment group, where only a few metastases are visible. Thus, these results show that IT injection with ADU-S100 primes an effective systemic CD8+ T cell immune response that significantly inhibits the growth of distal untreated lesions.

Clinical Status

In March 2015, we established a worldwide collaboration with Novartis to further advance the research and development of STING Activator product candidates in oncology. We filed the IND for ADU-S100, our first STING Activator product candidate, in the fourth quarter of 2015.

Phase 1 (Planned)

We expect to initiate a Phase 1 trial with our lead STING Activator product candidate, ADU-S100, in collaboration with Novartis. The Phase 1 study will evaluate safety and tolerability of ADU-S100 in patients with cutaneously accessible, treatment-refractory primary or metastatic solid tumors or lymphomas.

STING Pathway Opportunities

We envision multiple product opportunities for the STING Pathway Activator technology platform. We believe that our STING Activator product candidates can be used as a monotherapy to directly activate the tumor microenvironment, enhancing recognition of the tumor by the immune system and leading to tumor destruction. In preclinical animal models, we have shown that our proprietary STING Activator product candidates can be co-formulated with designated recombinant proteins to induce potent antigen-specific CD4+ and CD8+ T cell immunity. We believe that due to our STING Activator product candidates' immune-mediated tumor killing mechanisms and ability to alter the nature of the tumor microenvironment our proprietary STING Activator product candidates could be combined with conventional and novel therapies, such as cellular vaccines, chemotherapy, radiotherapy and checkpoint inhibitors, among others.

In addition, our STING Activator product candidates directly activate natural killer cells and could enhance Antibody-Dependent Cellular Cytotoxicity, or ADCC, tumor cell killing mechanisms, which are a significant mechanism of action of several established monoclonal antibody therapies. Another possible opportunity would be to directly conjugate our STING Activator product candidates to enhance ADCC.

We also believe that our STING pathway product candidates have the potential to be used in treatments for infectious and autoimmune diseases as an adjuvant to enhance existing vaccines or in formulations for new products. We are also developing other STING Inhibitors that, in contrast to our current STING Activator product candidate that activates the STING receptor, would block the STING receptor, thus preventing or controlling the immune response which is key in the treatment of autoimmune diseases.

Manufacturing

Overview

We rely on third-party contract manufacturing organizations, or CMOs, to produce our product candidates for clinical use and currently do not own or operate manufacturing facilities. We have established manufacturing processes and supply and quality agreements for all of the investigational agents used in our ongoing clinical trials. We require that our CMOs produce bulk drug substances and finished drug products in accordance with current Good Manufacturing Practices, or cGMPs, and all other applicable laws and regulations. We may continue to rely on CMOs to manufacture our products for commercial sale. We maintain agreements with potential and existing manufacturers that include confidentiality and intellectual property provisions to protect our proprietary rights.

LADD Product Candidates

LADD product candidates are produced through a fermentation process and then concentrated and purified. The drug substance is diluted into a cryopreservative and filled into vials that are inspected, labeled and frozen as final drug product. We have contracts with IDT Biologika GmbH, or IDT, and Waisman Clinical BioManufacturing to produce and release LADD product candidates. We

recently transitioned manufacturing of our lead LADD product candidate, CRS-207, to IDT, which can support commercial manufacturing.

Under our process development and manufacturing agreement with IDT, which we entered into in December 2013, IDT provides manufacturing services for CRS-207. We pay for manufacturing services performed by IDT under the agreement pursuant to a work plan described in the agreement.

We may unilaterally terminate the agreement in the event of a material breach of the agreement by IDT if such breach remains uncured after 45 days of receiving written notice of such breach. In addition, either party may terminate the agreement in the event of the other party's insolvency. Either party may also terminate the agreement by providing 30 days' written notice to the other party if we decide to end our CRS-207 program, solely for reasons of clinical inefficacy or safety, or an action by the FDA, EMA or other regulatory authority not granting approval despite commercially reasonable efforts to gain such approval.

GVAX Pancreas Product Candidates

GVAX Pancreas product candidates are engineered cell lines that express GM-CSF and have been lethally irradiated to prevent replication. GVAX Pancreas is composed of two allogeneic pancreatic cancer cell lines that are expanded in cell factories. The cells are harvested, concentrated, purified and then lethally gamma irradiated. GVAX Pancreas is frozen, stored and transported in vapor-phase liquid nitrogen. We have contracts with Lonza Walkersville, Inc., or Lonza, and JHU to produce and release GVAX Pancreas product candidates. We recently began transferring the manufacturing process to Lonza, which can support commercial production of GVAX Pancreas product candidates.

Under our manufacturing services agreement with Lonza, which we entered into in August 2012, Lonza provides manufacturing services to produce cell lines for our GVAX Pancreas product candidates. We pay for manufacturing services performed by Lonza under the agreement pursuant to statements of work entered into from time to time.

We may unilaterally terminate the agreement upon 45 days' written notice to Lonza. Lonza may terminate the agreement upon 12 months' written notice to us. Either party may terminate the agreement in the event of the other party's insolvency or for the other party's material breach of the agreement if such breach remains uncured after 30 days of receiving written notice of such breach or after 90 days of receiving written notice of such breach if such breach is not capable of being cured within 30 days and the breaching party is making diligent efforts to cure such breach. Absent early termination, the agreement will continue until the fifth anniversary of the effective date of the original agreement.

STING Activator Product Candidates

Manufacturing of our STING Activator product candidates generally encompasses both the chemical synthesis of the active pharmaceutical ingredient, or API, and its formulation and fill/finish of the final product. The synthetic process for the manufacture of our STING Activator product candidates is a trade secret and we retain control and ownership of the process. We have contracted with a CMO to produce, release and stability test the ADU-S100 API. We have also entered into a drug product manufacturing and clinical supply agreement with a CMO for the formulation and fill/finish and release and stability testing of the drug product candidate.

Intellectual Property

Intellectual property is of vital importance in our field and in biotechnology generally. We seek to protect and enhance proprietary technology, inventions, and improvements that are commercially important to the development of our business by seeking, maintaining, and defending patent rights, whether developed internally or licensed from third parties. We will also seek to rely on regulatory protection afforded through orphan drug designations, data exclusivity, market exclusivity and patent term extensions where available.

We have obtained orphan drug designations for GVAX Pancreas and CRS-207 for the treatment of pancreatic cancer and for CRS-207 for the treatment of mesothelioma, which makes them eligible for a period of orphan drug exclusivity, if approved, under certain conditions. We believe that each of our different biological products approved under a biologics license application, or BLA, will be eligible for 12 years of market exclusivity in the United States, 10 years of market exclusivity in Europe and significant durations in other markets, which would be complementary to any relevant patent exclusivity.

Through licensing and through developing our own portfolio, we have rights to more than 100 issued patents and more than 200 pending applications in the United States and foreign countries. Families within the portfolio are directed to our LADD and STING Pathway Activator technology platforms, and to GVAX.

LADD Technology Platform

We own twelve issued U.S. patents, ten pending U.S. patent applications, and corresponding foreign issued patents and patent applications, and additionally we are the exclusive licensee to families of patents and patent applications, all relating to our LADD technology platform. The issued U.S. patents that we own expire between 2024 and 2031, not including any patent term extensions that may be available under U.S. laws. The patents and patent applications, if issued, cover attenuated Listeria strains that have deleted or disrupted genomic actA and inlB virulence genes in conjunction with the expression of non-Listeria polypeptides, as well as to Listeria strains that are engineered to express non-Listeria polypeptides, including cancer antigens or fragments thereof. There are also patents and patent applications, if issued, that cover proprietary antigen expression cassettes and methods which are applicable to Listeria generally and not limited to any particular strain or method of attenuation.

Antigen Expression

Within this portfolio are issued U.S. patents and pending U.S. applications, and corresponding foreign issued patents and patent applications, directed to Listeria strains that are engineered to express particular cancer antigens or fragments thereof, including mesothelin and NY-ESO-1. This portfolio includes U.S. patents covering CRS-207, which expire in 2024 and 2026, not giving effect to any potential patent term adjustment or extension that may be available on a jurisdictional basis and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. We have also filed U.S. and international patent applications

directed to a modified actA fusion protein, which, if issued, would cover ADU-623, ADU-214 and our future LADD product candidates. If patents with such claims are issued, they could extend the technology platform patent protection for such products until 2033.

EGFRvIII Family

Within this portfolio are an issued U.S. patent and pending U.S. and corresponding foreign patent applications that we co-own with Providence Health & Services–Oregon, a family of patent applications that are directed to Listeria strains that express EGFRvIII antigen. This technology is included in our ADU-623, ADU-214 and other product candidates. The issued U.S. patent expires in 2031, not including any patent term extensions that may be available under U.S. laws and assuming continued payment of any applicable fees.

Combination Therapy with LADD

Additionally, within this portfolio are U.S. patents and pending applications directed to compositions that can be used in conjunction with or as an adjuvant to the LADD technology platform. For example, we have an issued U.S. patent directed to a method of enhancing an immune response to mesothelin by administering a boost dose of an attenuated Listeria that encodes an active mesothelin antigen after administration of an effective amount of an inactivated tumor cell that encodes GM-CSF. These claims could cover the use of CRS-207 in combination with GVAX. This patent expires in 2027, not including any patent term extensions that may be available under U.S. laws and assuming continued payment of any applicable fees. In addition, we have an issued U.S. patent and corresponding foreign applications directed to a method of treating cancer by administering an attenuated Listeria that encodes an active portion of a cancer antigen after administration of an effective amount of radiotherapy as a primary therapy, and also after administration of an effective amount of an inactivated tumor cell that encodes GM-CSF and the cancer antigen. These claims could cover the use of CRS-207 in combination with GVAX. This patent expires in 2031, not including any patent term extensions that may be available under U.S. laws.

STING Activator Family

We own and license families of patent applications directed to our STING Activator product candidates, which target the STING receptor, which, if issued, would expire between 2025 and 2036. In particular, we own three pending U.S. patent applications and corresponding pending foreign patent applications directed to stereochemically pure cyclic purine dinucleotides and certain other substituted cyclic purine dinucleotides, which if issued would expire in 2033 and 2034, and four provisional patent applications directed to certain substituted cyclic purine dinucleotides, which if issued would expire in 2036. Within this portfolio are U.S. and international patent applications directed to systems and methods for activating STING utilizing our STING Activator product candidates that are jointly owned with the Regents of the University of California, and which, if issued, would expire in 2034. Also within this portfolio are U.S. and international patent applications directed to the use of our STING Activator product candidates in conjunction with cytokine expressing cells, for instance CSF-expressing cells, that are owned jointly with JHU, and which, if issued, would expire in 2033 and 2034. We also license a family of patents from Karagen Pharmaceuticals directed to certain STING Activator molecules and their use in modulating immune response in a patient, which expire in 2025, a family of patents from the Regents of the University of California also directed to certain STING Activator molecules and their uses that, if issued, would expire in 2034, and a family of patents from a consortium of universities led by Memorial Sloan Kettering also directed to certain STING Activator molecules and their uses that, if issued, would expire in 2034.

GVAX Technology

We own ten issued U.S. patents and four pending U.S. patent applications and exclusively license multiple families of patents and patent applications that cover cell lines that express GM-CSF. This technology is referred to as GVAX. We license a family of patents from JHU that covers the first generation GVAX platform, including a U.S. patent specifically covering GVAX Pancreas. The patents in this family are expected to expire between 2016 and 2022; however, we have a license with JHU for continued exclusive use of the cell lines produced by JHU after the patents expire. Additionally, in 2013, we entered into another license agreement with JHU relating to GVAX technology that includes toll-like receptor ligands. This GVAX technology includes two international patent applications, which, if issued, would expire in 2031 to 2032.

Other Technology

In addition to the technologies described in detail above, we license or own other intellectual property directed to compositions and methods that could be used in conjunction with our Listeria technology platform. The intellectual property is directed to, for example, methods of administering our Listeria products in conjunction with other therapeutics. Additionally, we have licensed technology from UC Berkeley that enables us to integrate expression sequences more easily into Listeria and allows us to develop multivalent vaccines more quickly and efficiently. We have an exclusive license to this technology, which expires in 2022, subject to any extensions or disclaimers of the licensed patents.

General Considerations

As with other biopharmaceutical companies, our ability to maintain and solidify a proprietary position for our lead product candidates will depend upon our success in obtaining effective patent claims that cover such product candidates and their intended methods of use, and enforcing those claims once granted.

The term of a patent that covers an FDA-approved drug or biologic may be eligible for patent term extension, which provides patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug or biologic is under regulatory review. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug or biologic may be extended. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug or biologic. In the future, if and when our biopharmaceutical products receive FDA approval, we expect to apply for patent term extensions on patents covering those products.

Many biopharmaceutical companies, biotechnology companies and academic institutions are competing with us in the field of oncology and filing patent applications potentially relevant to our business. Even when a third-party patent is identified, we may conclude upon a thorough analysis, that we do not infringe upon the patent or that the patent is invalid. If the third-party patent owner disagrees with our conclusion and we continue with the business activity in question, we may be subject to patent litigation. Alternatively, we might decide to initiate litigation in an attempt to have a court declare the third-party patent invalid or non-infringed by our activity. In either scenario, patent litigation typically is costly and time-consuming, and the outcome can be favorable or unfavorable.

In addition to patents, we rely upon unpatented trade secrets, know-how and continuing technological innovation to develop and maintain a competitive position. We seek to protect our proprietary information, in part, through confidentiality agreements with our employees, collaborators, contractors and consultants, and invention assignment agreements with our employees. We also have agreements with some of our consultants that require them to assign to us any inventions created as a result of their working with us. The confidentiality agreements are designed to protect

our proprietary information and, in the case of agreements or clauses requiring invention assignment, to grant us ownership of technologies that are developed through a relationship with a third party.

Our commercial success will depend in part upon not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us or our licensee(s) to alter our development or commercial strategies, obtain licenses, or cease certain activities. The biopharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. If a third party commences a patent infringement action against us, or our licensee(s), it could consume significant financial and management resources, regardless of the merit of the claims or the outcome of the litigation.

We may rely, in some circumstances, on trade secrets to protect our technology. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology

systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Collaborations

Janssen ADU-741 Agreement

In May 2014, we entered into a research and license agreement with Janssen Biotech, Inc., or Janssen, pursuant to which we granted Janssen an exclusive, worldwide license under intellectual property rights controlled by us to research, develop, manufacture, use, sell and otherwise exploit products containing ADU-741 for any and all uses. Under this Agreement, or the Janssen ADU-741 Agreement, we also granted Janssen the right, subject to availability, to develop specified derivatives of the Listeria strain. Janssen will have exclusive rights to develop LADD product candidates in prostate cancer and to develop and commercialize the licensed products and will assume responsibility for all research, development, manufacturing, regulatory and commercialization activities for the licensed products.

In partial consideration for the grant of this license, Janssen paid us $12.0 million as an upfront license fee. Additionally, under the Janssen ADU-741 Agreement we are eligible to receive from Janssen up to an aggregate of $10.0 million upon our achievement and performance of specified technology transfers and development and regulatory milestones pursuant to an agreed upon plan, an aggregate of $103.5 million upon Janssen's achievement of specified development and regulatory milestones, and an aggregate of $242.0 million upon Janssen's achievement of specified commercial milestones. Janssen is also obligated to pay us royalties on net sales of licensed products by Janssen, its affiliates and sublicensees at a rate ranging from the mid-single digits to the low teens based on the aggregate annual net sales of licensed products worldwide and based on the country of sale. Janssen's royalty obligation continues on a licensed product-by-licensed product and country-by-country basis until the later of (i) 12 years from the date of first commercial sale of such licensed product in such country, (ii) expiration of the last valid claim in the licensed patents covering the composition of matter or the approved method of use of such licensed product or (iii) the expiration of data exclusivity with respect to such licensed product in such country.

The Janssen ADU-741 Agreement will continue in effect until the later of expiration of all of the licensed patents and on a product-by-licensed product and country-by-country basis, the expiration of Janssen's royalty obligations with respect to such licensed product in such country. Either party may terminate the Janssen ADU-741 Agreement upon the other party's uncured material breach that is not cured within 60 days after the breaching party receives notice of such breach, provided, that Janssen may elect to make specified modifications to the agreement in lieu of terminating the agreement in the event we fail to timely cure any material breach of this agreement. Additionally, either party may terminate the Janssen ADU-741 Agreement for the other party's insolvency and Janssen may terminate this agreement at will after the first anniversary of the effective date upon 90 days' written notice. If the Janssen ADU-741 Agreement is terminated early for reasons other than our uncured material breach, Janssen is obligated to grant us a license to specified patents and know-how to exploit the terminated licensed products in the terminated countries.

Janssen ADU-214 Agreement

In November 2014, a research and license agreement with Janssen became effective, pursuant to which we granted Janssen an exclusive worldwide license under intellectual property rights controlled by us to research, develop, manufacture, use, sell and otherwise exploit products containing ADU-214 for any and all uses. Under this Agreement, or the Janssen ADU-214 Agreement, we also granted Janssen the right, subject to availability, to develop specified derivatives of the Listeria strain. Janssen will have exclusive rights to develop LADD product candidates in lung cancer and to develop and commercialize the licensed products and will assume responsibility for all research, development, manufacturing, regulatory and commercialization activities for the licensed products.

In partial consideration for the grant of this license, Janssen paid us $30.0 million as an upfront license fee. Additionally, under the Janssen ADU-214 Agreement we are eligible to receive from Janssen up to an aggregate of $11.0 million upon our achievement and performance of specified technology transfers and development and regulatory milestones pursuant to an agreed upon plan, an aggregate of $184.5 million upon Janssen's achievement of specified development and regulatory milestones, and an aggregate of $591.5 million upon Janssen's achievement of specified commercial milestones. Janssen is also obligated to pay us royalties on net sales of licensed products by Janssen, its affiliates and sublicensees at a rate ranging from the high-single digits to the low teens based on the aggregate annual net sales of licensed products worldwide and based on the country of sale. Janssen's royalty obligation continues on a licensed product-by-licensed product and country-by-country basis until the later of (i) 12 years from the date of first commercial sale of such licensed product in such country, (ii) expiration of the last valid claim in the licensed patents covering the composition of matter or the approved method of use of such licensed product or (iii) the expiration of data exclusivity with respect to such licensed product in such country.

The Janssen ADU-214 Agreement will continue in effect until the later of expiration of all of the licensed patents and on a product-by-licensed product and country-by-country basis, the expiration of Janssen's royalty obligations with respect to such licensed product in such country. Either party may terminate the Janssen ADU-214 Agreement upon the other party's uncured material breach that is not cured within 60 days after the breaching party receives notice of such breach, provided, that Janssen may elect to make specified modifications to the agreement in lieu of terminating the agreement in the event we fail to timely cure any material breach of this agreement. Additionally, either party may terminate the Janssen ADU-214 Agreement for the other party's insolvency and Janssen may terminate this agreement at will after the first anniversary of the closing date of the Janssen ADU-214 Agreement upon 90 days' written notice. If the Janssen ADU-214 Agreement is terminated early for reasons other than our uncured material breach, Janssen is obligated to grant us a license to specified patents and know-how to exploit the terminated licensed products in the terminated countries.

Janssen GVAX Prostate Agreement

In May 2014, we also entered into a license agreement with Janssen, or the Janssen GVAX Prostate Agreement, pursuant to which we granted Janssen an exclusive worldwide license under intellectual property rights controlled by us to research develop, manufacture, use, sell and otherwise exploit products containing GVAX Prostate for any and all uses. Janssen will have exclusive rights to develop and commercialize the licensed products and will assume responsibility for all research, development, manufacturing, regulatory and commercialization activities for the licensed products.

In partial consideration for the grant of this license, Janssen paid us $500,000 as an upfront license fee. Additionally, under the Janssen GVAX Prostate Agreement we are eligible to receive from Janssen up to $2.0 million upon Janssen's achievement of a specified commercial milestone. Janssen is also obligated to pay us royalties on net sales of licensed products by Janssen and its affiliates and sublicensees at a rate in the mid- to high-single digits. Janssen's royalty obligation continues on a licensed product-by-licensed product and country-by-country basis until 12 years from the date of first commercial sale of such licensed product in such country.

The Janssen GVAX Prostate Agreement will continue in effect until the later of expiration of all of the licensed patents and on a licensed product-by-licensed product and country-by-country basis, the expiration of Janssen's royalty obligations with respect to such licensed product in such country. Either party may terminate the Janssen GVAX Prostate Agreement upon the other party's uncured material breach that is not cured within 60 days after the breaching party receives notice of such breach, provided, that Janssen may elect to make specified modifications to the agreement in lieu of terminating the agreement in the event we fail to timely cure any material breach of this agreement. Additionally, either party may terminate the Janssen GVAX Prostate Agreement for the other party's insolvency and Janssen may terminate this agreement at will after the first anniversary of the effective date upon 90 days' written notice. If the Janssen GVAX Prostate Agreement is terminated early for reasons other than our uncured material breach, Janssen is obligated to grant us a license to specified patents and know-how to exploit the terminated licensed products in the terminated countries.

Novartis Agreement

In March 2015, we entered into a collaboration and license agreement with Novartis pursuant to which we are collaborating worldwide with Novartis regarding the development and commercialization of products containing an agonist of the molecular target known as STING in the field of oncology, including immuno-oncology and cancer vaccines. Under this agreement, or the Novartis Agreement, we granted Novartis a co-exclusive license to develop such products worldwide, an exclusive license to commercialize such products outside the United States and a non-exclusive license to support us in commercializing such products in the United States if we request such support. The collaboration is guided by a joint steering committee with each party having final decision making authority regarding specified areas of development or commercialization.

Pursuant to the Novartis Agreement, each party is obligated to use commercially reasonable efforts to perform specified development activities in accordance with a development plan. Novartis is obligated to use commercially reasonable efforts to commercialize products developed under the collaboration outside the United States and we are obligated to use commercially reasonable efforts to commercialize the products in the United States.

Under the Novartis Agreement, we received an upfront payment of $200 million from Novartis. We are also eligible to receive up to an additional $250 million in development milestones and up to an additional $250 million in regulatory approval milestones.

We are responsible for 38% of the joint development costs worldwide and Novartis is responsible for the remaining 62% of the joint development costs worldwide. We will also receive 50% of all profits for any products commercialized pursuant to this collaboration in the United States and 45% of all profits for specified European countries and Japan. For each of these profit share countries, each party will be responsible for its respective commercial sharing percentage of all joint commercialization costs incurred in that country. For all other countries where we are not sharing profits, Novartis will be responsible for all commercialization costs

and will pay us a royalty in the mid-teens on all net sales of product sold by Novartis, its affiliates and sublicensees, with such percentage subject to reduction post patent and data exclusivity expiration and subject to reduction, capped at a specified percentage, for royalties payable to third party licensors. Novartis' royalty obligation will run on a country-by-country basis until the later of expiration of the last valid claim covering the product, expiration of data exclusivity for the product and 12 years after first commercial sale of the product in such country.

With respect to the United States, specified European countries and/or Japan, we may elect for such region to either reduce by 50% or to eliminate in full our development cost sharing obligation. If we elect to reduce our cost sharing percentage by 50% in any such region, then our profit share in such region will also be reduced by 50%. If we elect to eliminate our development cost sharing obligation, then such region will be removed from the profit share, and instead Novartis will owe us royalties on net sales of product for such region, as described above.

The Novartis Agreement will continue in effect until the later of (i) the date on which the parties mutually agree to cease the commercialization of products in the profit share region and (ii) the date on which Novartis' royalty obligations cease. Either party may terminate the Novartis Agreement upon the other party's uncured material breach, for the other party's bankruptcy or insolvency, or for safety reasons. Additionally, Novartis may terminate the Novartis Agreement for convenience at any time after March 19, 2018 upon 180 days' notice. Certain termination events are subject to a continuing license and a technology transfer.

Novartis Stock Purchase

Concurrent with the entry into the Novartis Agreement, we and Novartis Institutes for BioMedical Research, Inc., or NIBR, entered into a stock purchase agreement under which NIBR purchased 2,361,029 shares of our Series E Preferred Stock (or 1,699,940 shares of common stock on an as-converted basis), representing 2.7% of our then-outstanding equity and convertible securities, for $25.0 million. Under the stock purchase agreement, NIBR committed to purchase an additional $25.0 million of our common stock in a separate private placement transaction that closed concurrently with the IPO and at the IPO price.

Acquisition of BioNovion Holding B.V.

In September 2015, we entered into a Share Sale Agreement with Aduro Netherlands Coöperatief U.A., a cooperative organized under the laws of the Netherlands and our wholly-owned indirect subsidiary or Aduro Netherlands, BioNovion and the shareholders of BioNovion, or the Sellers. Pursuant to the Share Sale Agreement, Aduro Netherlands acquired all of the issued and outstanding shares of BioNovion from the Sellers for an aggregate purchase price of (i) EUR 14.5 million in cash and (ii) 697,306 shares of our common stock of the Company, subject to a post-closing adjustments based on working capital, net cash and borrowings of BioNovion and its subsidiary as of the closing date. The transaction closed on October 30, 2015.

The Sellers have the opportunity to receive additional contingent payments from Aduro as follows: (i) EUR 6.0 million upon acceptance by the FDA of an investigational new drug application for a specified BioNovion antibody product candidate; and (ii) EUR 20.0 million upon receipt by BioNovion of a $40.0 million milestone payment by the licensee under a pre-existing antibody discovery and license agreement, triggered by marketing authorization for the first indication in the United States for a specified BioNovion antibody product candidate.

Our Research and Development and License Agreements

Listeria-Based Agreements

JHU Listeria Agreement

In March 2011, we entered into a license agreement with JHU pursuant to which we received an exclusive, worldwide, sublicensable license to certain patent rights covering the tumor-associated antigen mesothelin to make, use, import and commercialize products and to provide services for all bacteria-based therapeutic and/or prophylactic uses for cancer treatment and/or prevention and as a companion diagnostic. Under the agreement, or the JHU Listeria Agreement, we are obligated to use commercially reasonable efforts to develop and market licensed products and services, which can be demonstrated by achieving specified development milestones by specified dates.

Under the JHU Listeria Agreement, we paid an upfront fee of $25,000 in 2011 and a milestone payment of $25,000 in 2012 and are required to make future milestone payments totaling up to $375,000 upon achievement of certain regulatory milestones. Under the JHU Listeria Agreement, we are obligated to pay JHU royalties based on net sales of licensed products and services by us, our affiliates and our sublicensees at a rate in the low-single digits, subject to minimum annual royalties, and a percentage of consideration received from any sublicensing arrangements ranging from the low-single digits to the low twenties depending on the field of use and the stage of development of the product candidate at the time the sublicense is granted.

The JHU Listeria Agreement will continue in effect on a country-by-country basis until the expiration of the last patent within the licensed patent rights or if no patents issue then for 20 years from the effective date of the agreement. Either party may terminate the JHU Listeria Agreement for the other party's uncured breach of the agreement upon 30 days' prior notice or for the other party's insolvency. Additionally, we may terminate the JHU Listeria Agreement at will upon 90 days' prior written notice to JHU.

UCB Listeria Agreement

In March 2012, we entered into a license agreement with the Regents of the University of California on behalf of its Berkeley campus, or UCB, granting us an exclusive, worldwide, sublicensable license to certain patent rights covering the use of the Listeria monocytogenes phage integration vector which accelerates the genetic engineering of Listeria to express more than one antigen to make, use, import and commercialize products and to provide services for all fields of use. Under this agreement, or the UCB Listeria Agreement, we are obligated to use commercially reasonable efforts to develop, manufacture and sell licensed products and services and we are obligated to achieve specified development and regulatory milestones by specified dates.

Under the UCB Listeria Agreement, we paid UCB an upfront fee of $25,000 in 2012 and a milestone payment of $25,000 in 2013 and are required to make future milestone payments totaling up to $350,000 upon achievement of certain development and regulatory milestones. We are required to pay an annual license maintenance fee until our first sale of a product covered by the licensed patent rights. Under the UCB Listeria Agreement, we are obligated to pay UCB royalties based on net sales of licensed products and services sold by us and our sublicensees at a rate in the low single digits, subject to minimum annual royalties and customary reductions, and a percentage of certain of our sublicensing revenues ranging from the low-single digits to the low thirties depending on how the product covered by the licensed patent rights is used.

The UCB Listeria Agreement will last until the expiration of the last patent within the licensed patent rights. UCB may terminate the agreement for our uncured material breach upon 90 days' prior written notice and we may terminate the agreement at will upon 90 days' prior written notice to UCB.

GVAX-Based Agreements

ANI Agreement

In January 2013, we entered into an asset purchase agreement with BioSante Pharmaceuticals, Inc., which subsequently merged with and into ANI Pharmaceuticals, Inc., or ANI, in June 2013. Under the agreement, or the ANI Agreement, we purchased all the rights, title and interest of ANI in and to all of the assets related to or comprising GVAX product candidates and any assets necessary or reasonably useful to make, have made, use, have used, sell, offer for sale, have sold, import, have imported, develop, have developed, commercialize and have commercialized GVAX products.

Under the ANI Agreement, we paid ANI cash consideration of $1.0 million and will be required to make royalty payments on net sales of GVAX products sold by us, our affiliates and our sublicensees for the treatment of certain cancers, which are covered by purchased intellectual property rights or developed using purchased technology, at rates in the low-single digits. We are also required to pay milestone payments of up to $4.0 million for GVAX pancreas or prostate products in combination with Listeria or up to $12.0 million per product for other GVAX products upon the achievement of certain sales milestones. We are obligated to make royalty payments on a product-by-product and country-by-country basis until the later of (i) the expiration of the last to expire of the purchased patent rights covering the GVAX product or the regulatory exclusivity period and (ii) up to seven years from the first commercial sale of the product in such country depending on the level of net sales in such country after the expiration of the patent or regulatory exclusivity period. The royalties and milestone payments for GVAX products for the treatment of pancreas and prostate cancer, as well as the royalties and milestone payments for other cancer products, are each capped at

specified maximum amounts. To the extent we enter into a sublicensing agreement relating to the GVAX pancreas or prostate cancer products in combination with Listeria, we are required to pay ANI a percentage of our sublicensing income, ranging from the low teens to the low thirties based on the indication, the stage of development of the GVAX products at the time the sublicense is granted and the amount of development costs expended by us at the time the sublicense is granted. The sublicensing payments owed under this ANI Agreement for pancreas and prostate cancer in combination with Listeria are each capped at specified maximum amounts.

JHU GVAX Agreement

In January 2013, we entered into a license agreement with JHU granting us an exclusive, worldwide, sublicensable license under certain GVAX-related patent rights and cell lines, and a non-exclusive, worldwide, sublicensable license to related know-how, in each case to make, have made, use, have used, sell, offer for sale, have sold, import, have imported, develop and commercialize products and services using or incorporating licensed patent rights, cell lines or know-how for any use. Under the agreement, or the New License Agreement, we are obligated to use commercially reasonable efforts to develop and market licensed products and services, including using commercially reasonable efforts to achieve specified development milestones by specified dates.

Under the New License Agreement, we paid upfront fees of $125,000 in February 2013 and $125,000 in February 2014. Under the New License Agreement, we are also required to pay JHU development and regulatory milestone payments totaling up to approximately $1.1 million for STINGVAX, a GVAX product with STING Activators, approximately $1.2 million for TEGVAX, a GVAX product with TLRs, and approximately $1.2 million for other licensed products. We are also required to pay JHU royalties based on net sales of licensed products and services by us, our affiliates and our sublicensees at a rate in the low single digits, subject to minimum annual royalties and standard reductions upon expiration of patent coverage and for licenses to third-party intellectual property rights, as well as a percentage of certain consideration received in consideration of the grant of sublicenses under this agreement ranging from the low tens to the mid-twenties depending on the stage of development of the product candidate at the time the sublicense is granted and the number of sublicenses granted.

The New License Agreement will continue in effect on a product-by-product basis and service-by-service basis until 30 years after the first commercial sale of such product or service, provided that the term may be extended for additional 10-year periods upon mutual agreement of the parties. Either party may terminate the New License Agreement for the other party's uncured material breach of the agreement upon 60 days' prior notice to the breaching party, or 30 days' notice if such breach relates to a payment obligation, or for the other party's insolvency. Additionally, we may terminate the New License Agreement at will upon 90 days' prior written notice to JHU.

GVAX RALA

In January 2013, as a result of entering into the ANI Agreement, we were assigned the March 2011 Restated and Amended License Agreement, or the RALA, by and between JHU and BioSante Pharmaceuticals, Inc. Under the RALA, we were granted a worldwide license, sublicensable under certain conditions, under certain patent rights to make, have made, use, import and sell licensed products and to provide licensed services for any use. Such licensed patents include patents covering the cell lines used in the GVAX Pancreas product candidate. Pursuant to the agreement, we must use reasonable commercial efforts to develop and commercialize licensed products and meet certain specified milestones.

Under the RALA, we are required to pay JHU an annual license fee as well as milestone payments totaling up to $300,000 upon the occurrence of certain development, regulatory, and patent-related milestones. We are also required to pay JHU royalties based on net sales of licensed products and services by us, our affiliates and our sublicensees at a rate in the low single digits, as well as a percentage of amounts received in consideration for sublicenses under the agreement in the mid-teens.

The RALA will expire on a country-by-country basis upon the expiration of the last to expire patent within the licensed patent rights or if no patent issues, then 20 years from the effective date of the agreement. Either party may terminate the agreement for the other party's uncured breach of the agreement upon 60 days' prior written notice. We may terminate the agreement upon 60 days' prior written notice.

STING Activator-Based Agreements

Karagen Agreement

In June 2012, we entered into a license agreement with Karagen Pharmaceuticals, Inc., or Karagen, pursuant to which Karagen granted us an exclusive, worldwide, sublicenseable license under certain patents and know-how related to STING Activators to make, develop, use and commercialize products for use in the therapeutic and/or prophylactic treatment of cancer or precancerous conditions and a non-exclusive license to such patents and know-how to make, develop, use and commercialize products for all other uses. Under the agreement, or the Karagen Agreement, we were also granted an option to designate a particular disease or condition to be added to the field of use under our exclusive license. Under the Karagen Agreement, we are obligated to use commercially reasonable efforts to develop and commercialize licensed products in the United States and the European Union.

Under the Karagen Agreement, we are required to make milestone payments totaling up to $900,000, in aggregate, for the achievement of specified development and regulatory milestones as well as royalties based on net sales of products by us, our affiliates and sublicensees at rates ranging in the low single-digit percentages, determined by whether the disease field is an exclusive or non-exclusive disease field, subject to minimum annual royalties and standard reductions. In addition, we are required to pay Karagen a percentage of consideration received from any sublicensing arrangements ranging from the mid-single digits to the mid-teen digits determined by the current stage of development of the relevant licensed product at the time of the sublicense grant, or by whether we have exercised our option to add a designated field of use to its exclusive license, as applicable.

The Karagen Agreement will expire, on a country-by-country basis, upon the expiration of the last-to-expire valid claim within the licensed patent rights. Either party may terminate the Karagen Agreement upon 90 days' advance written notice in the event of the other party's material breach that is not cured within such 90-day period, and immediately upon notice in the event of the other party's

bankruptcy or insolvency. Additionally, we may terminate the Karagen Agreement at will upon 90 days' advance written notice to Karagen.

UCB Vance Agreement

In September 2014, we entered into a license agreement with UCB, granting us an exclusive, worldwide sublicenseable license under certain patent rights covering the use of the STING Activator molecules that activate the STING receptor to make, develop, use and commercialize products, to practice methods and to offer services, in each case that are covered by the licensed patent rights, in all fields of use. Under this agreement, or the UCB Vance Agreement, we are obligated to use commercially reasonable efforts to develop, manufacture and sell licensed products and services and are obligated to achieve specified development and regulatory milestones by specified dates.

Under the UCB Vance Agreement, we paid UCB an upfront fee of $50,000 in 2014 and are required to make future milestone payments totaling up to $1.5 million, in the aggregate, upon our achievement of certain specified development and regulatory milestones for the first indication and up to $250,000 upon our achievement of a specified development and regulatory milestone for each additional indication developed. Under the UCB Vance Agreement, we are obligated to pay UCB royalties based on net sales of licensed products and services sold by us and our sublicensees at a rate in the low single-digit percentages, subject to minimum annual royalties and customary reductions, and a percentage of consideration received from any sublicensing arrangements at rates ranging from the low-single digits to the low thirties, determined by the current stage of development of the relevant licensed product at the time the sublicense is granted.

The UCB Vance Agreement will continue in effect until the expiration of the last-to-expire valid claim within the licensed patent rights. UCB may terminate the agreement upon 90 days' advance written notice in the event of our material breach that is not cured within such 90-day period. We may terminate the agreement at will upon 90 days' advance written notice. UCB may the terminate agreement upon 90 days' advance written notice in the event we challenge the validity or unenforceability of any licensed patent.

MSK Agreement

In December 2014, we entered into a license agreement with Memorial Sloan Kettering Cancer Center, or MSK, The Rockefeller University, Rutgers, The State University of New Jersey, and University of Bonn, collectively the Licensors, pursuant to which we received an exclusive, worldwide, sublicensable license under certain patents related to STING Activators and a non-exclusive, worldwide, sublicensable license under specified know-how, in each case to develop, make, have made, use, have used, import, sell, and otherwise commercialize certain licensed products for use in therapeutic and/or prophylactic treatments in humans. Under the agreement, or the MSK Agreement, we are obligated to use commercially reasonable efforts to develop and commercialize a licensed product, including achieving specified development and regulatory milestones by specified dates.

Under the MSK Agreement, we paid MSK upfront fees of $50,000 in January 2015. We are required to pay MSK development and regulatory milestone payments totaling up to $375,000 for each licensed product and commercialization milestone payments totaling up to $2,950,000 for each licensed product. We are also required to pay MSK royalties based on net sales of licensed products by us and our sublicensees at a rate ranging in the low single digits depending on whether the licensed product is covered by a valid claim of the licensed patents, subject to minimum annual royalties. Our royalty obligation to MSK continues on a country-by-country basis until the later of the expiration of the last patent right covering the licensed product in such country or 10 years from the first commercial sale in such country. We are also obligated to pay MSK a percentage of certain consideration received for the grant of sublicenses, ranging from ten to the mid-twenties.

The MSK Agreement will continue in effect until the expiration of our royalty obligations. Either party may terminate the MSK Agreement upon the other party's uncured material breach that is not cured within 90 days after the breaching party receives notice of such breach. Additionally, the Licensors may terminate the MSK Agreement for our bankruptcy or insolvency or if we fail to pay any undisputed amounts owed under the agreement and do not cure such failure within 30 days after receiving notice of such failure.

Competition

The biotechnology and pharmaceutical industries, and the immuno-oncology subsector, are characterized by rapid evolution of technologies, fierce competition and strong defense of intellectual property. A wide variety of institutions, including large pharmaceutical companies, specialty biotechnology companies, academic research departments and public and private research institutions, are actively developing potentially competitive products and technologies. We face substantial competition from biotechnology and pharmaceutical companies developing products in immuno-oncology and in our lead indications. They generally fall within the following categories:

- diversified immuno-oncology: AstraZeneca PLC, Bristol-Myers Squibb Company, Celgene Corporation, GlaxoSmithKline plc, Merck & Co., Inc., Novartis AG, Pfizer Inc., Roche Holding Ltd and Sanofi SA, Bayer Healthcare;
- immuno-oncology aimed at stimulating immune response: AdaptImmune LLC, Idera Pharmaceuticals, Inc., Immune Design Corp. and NewLink Genetic Corporation;
- Listeria-based technology: Advaxis, Inc.;
- pancreatic cancer: Incyte Corporation and Merrimack Pharmaceuticals, Inc.; and
- mesothelioma: Boeringer Ingelheim and Morphotek/Eisai.

While we believe that our product candidates, technology, knowledge and experience provide us with competitive advantages, we face competition from established and emerging pharmaceutical and biotechnology companies, among others. Any product candidates that we successfully develop and commercialize will compete with existing and new therapies that may become available in the future. The availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of our products.

Many of our competitors, either alone or with strategic partners, have substantially greater financial, technical and human resources than we do. Accordingly, our competitors may be more successful than us in obtaining approval for treatments and achieving widespread market acceptance, rendering our treatments obsolete or non-competitive. Accelerated mergers and acquisitions activity in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. These companies also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical study sites and patient registration for clinical studies and acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our commercial opportunity could be substantially limited in the event that our competitors develop and commercialize products that are more effective, safer, less toxic, more convenient or cheaper than our comparable products. In geographies that are critical to our commercial success, competitors may also obtain regulatory approvals before us, resulting in our competitors building a strong market position in advance of our product’s entry. We believe the factors determining the success of our programs will be the efficacy, safety and convenience of our product candidates.

Government Regulation and Product Approval

As a biopharmaceutical company that operates in the United States, we are subject to extensive regulation. Federal, state and local government authorities in the United States and in other countries extensively regulate, among other things, the research, development, testing, manufacturing, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of biological and pharmaceutical products such as those we are developing. Our product candidates must be approved by the FDA before they may be legally marketed in the United States and by the appropriate foreign regulatory agency before they may be legally marketed in foreign countries. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the United States, although there can be important differences. Additionally, some significant aspects of regulation in Europe are addressed in a centralized

way, but country-specific regulation remains essential in many respects. The process for obtaining regulatory marketing approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

U.S. Product Development Process

In the United States, the FDA regulates pharmaceutical and biological products under the Federal Food, Drug, and Cosmetic Act, or FDCA, and the Public Health Service Act, or PHSA, and the FDA's implementing regulations. Products are also subject to other federal, state and local statutes and regulations. 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. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. FDA sanctions could include, among other actions, refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us. The FDA has limited experience with commercial development of combination immuno-oncology products. The process required by the FDA before a drug or biological product may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests and animal studies according to good laboratory practices, or GLPs, and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an IND which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as good clinical practices, or GCPs, and any additional requirements for the protection of human research patients and their health information, to establish the safety and efficacy of the product candidate for its intended use;
- submission to the FDA of a BLA for any biologic or an NDA for any drug we seek to market that includes substantive evidence of safety, purity, and potency, or safety and effectiveness from results of nonclinical testing and clinical trials;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the product is produced, to assess compliance with cGMP, to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity, and, if applicable, the FDA's current good tissue practices, or GTPs, for the use of human cellular and tissue products;
- potential FDA audit of the nonclinical study and clinical trial sites that generated the data in support of the BLA or NDA; and
- FDA review and approval, or licensure, of the NDA or BLA.

Before testing any product candidate in humans, the product candidate enters the preclinical testing stage. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs. The clinical trial sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such trials.

Where a recombinant nucleic acid trial is conducted at, or sponsored by, institutions receiving funding for recombinant DNA research from the U.S. National Institutes of Health, or NIH, prior to the submission of an IND to the FDA, a protocol and related documentation is submitted to and the study is registered with the NIH Office of Biotechnology Activities, or OBA, pursuant to the NIH Guidelines for Research Involving Recombinant DNA Molecules, or NIH Guidelines. Compliance with the NIH Guidelines is mandatory for investigators at institutions receiving NIH funds for research involving recombinant DNA, however many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them. The NIH is responsible for convening the Recombinant DNA Advisory Committee, or RAC, a federal advisory committee, which discusses protocols that raise novel or particularly important scientific, safety or ethical considerations at one of its quarterly public meetings. The

OBA will notify the FDA of the RAC's decision regarding the necessity for full public review of a protocol. RAC proceedings and reports are posted to the OBA web site and may be accessed by the public.

Clinical trials involve the administration of the product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control (except in the cases of Sponsor-Investigator studies). Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted and monitored in accordance with the

FDA’s regulations composing the GCP requirements, including the requirement that all research patients provide informed consent. Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Clinical trials of certain biologics also must be reviewed by an institutional biosafety committee, or IBC, a local institutional committee that reviews and oversees basic and clinical research conducted at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1. The biological product is initially introduced into healthy human patients and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- Phase 2. The biological product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.
- Phase 3. Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk to benefit ratio of the product and provide an adequate basis for product labeling.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gather additional information about a product's safety, efficacy, or optimal use. Some of the studies may be required under statue or regulation; others may be trials a sponsor has committed to conduct.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Quarterly safety reporting is required for marketed products for the first three years after approval. Annual progress reports detailing the results of the clinical trials (for INDs) and changes to the application (for marketed products) must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA, the NIH and the investigators for serious and unexpected adverse events that are considered related to study drug, any findings from other studies, tests in laboratory animals or in vitro testing that suggest a significant risk for human patients, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening adverse reaction that is considered related to study drug within seven calendar days after the sponsor’s initial receipt of the information. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research patients are being exposed to an unacceptable health risk, including risks inferred from other unrelated immuno-oncology trials. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB’s requirements or if the biological product has been associated with unexpected serious harm to patients.

Human immuno-oncology products are a new category of therapeutics. Because this is a relatively new and expanding area of novel therapeutic interventions, there can be no assurance as to the length of the trial period, the number of patients the FDA will require to be enrolled in the trials in order to establish the safety, efficacy, purity and potency of immuno-oncology products, or that the data generated in these trials will be acceptable to the FDA to support marketing approval.

Concurrently with clinical trials, companies usually complete additional studies and must also develop additional information about the physical characteristics of the product candidate as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHSA emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other criteria, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Processes

After the completion of clinical trials of a product candidate, FDA approval of a BLA or NDA must be obtained before commercial marketing of the product. The BLA or NDA must include results of product development, laboratory and animal studies, human trials, information on the manufacture and composition of the product, proposed labeling and other relevant information. The FDA may grant deferrals for submission of data, or full or partial waivers. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the BLA or NDA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each BLA or NDA must be accompanied by a significant user fee. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual product fee for products and an annual establishment fee on facilities used to manufacture prescription biological or drug products. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs or NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

Within 60 days following submission of the application, the FDA reviews a BLA or NDA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA or NDA that it deems incomplete or not properly reviewable at the time of submission, and may request additional information. In this event, the BLA or NDA may be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA or NDA. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe, potent, and/or effective for its intended use, and has an acceptable purity profile, and in the case of an NDA, whether the product is safe and effective for its intended use, and in each case, whether the product is being manufactured in accordance with cGMP. The FDA may refer applications for novel biological or drug products or biological or drug products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and 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. During the product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the BLA or NDA must submit a proposed REMS. The FDA will not approve a BLA or NDA without a REMS, if required.

Before approving a BLA or NDA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product 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. For human tissue-based products, the FDA also will not approve the product if the manufacturer is not in compliance with the FDA's current good tissue practices, or GTPs, to the extent applicable. These are FDA regulations and guidance documents that govern the methods used in, and the facilities and controls used for, the manufacture of human cells, tissues, and cellular and tissue based products, or HCT/Ps, which are human cells or tissue intended for implantation, transplant, infusion, or transfer into a human recipient. The primary intent of the GTP requirements is to ensure that cell and tissue based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable disease. FDA regulations also require tissue establishments to register and list their HCT/Ps with the FDA and, when applicable, to evaluate donors through screening and testing. Additionally, before approving a BLA or NDA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND trial requirements and GCP requirements. To assure cGMP, GTP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production and quality control.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA or NDA does not satisfy its regulatory criteria for approval and deny approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. If the agency decides not to approve the BLA or NDA in its present form, the FDA will issue a complete response letter that describes all of the specific deficiencies in the BLA or NDA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the BLA or NDA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be significantly limited to specific indications and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product.

Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk management plan,

or otherwise limit the scope of any approval. In addition, the FDA may require post marketing clinical trials, sometimes referred to as Phase 4 clinical trials, designed to further assess a biological product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

In addition, under the Pediatric Research Equity Act, or PREA, a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any product for an indication for which orphan designation has been granted. However, if only one indication for a product has orphan designation, a pediatric assessment may still be required for any applications to market that same product for the non-orphan indication(s).

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA application user fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

In the European Union, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and 10 years of market exclusivity is granted following drug or biological product approval. This period may be reduced to 6 years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

We have received orphan drug designation for CRS-207 and GVAX Pancreas for the treatment of pancreatic cancer and CRS-207 for the treatment of mesothelioma. There can be no assurance that we will receive orphan drug designation for additional indications or for any additional product candidates.

Expedited Development and Review Programs

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new products that meet certain criteria. Specifically, new 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 the

disease or condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. Unique to a Fast Track product, the FDA may consider for review sections of the BLA or NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA or NDA, the FDA agrees to accept sections of the BLA or NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA or NDA.

Any product, submitted to the FDA for approval, including a product with a Fast Track designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new product designated for priority review in an effort to facilitate the review. Additionally, a product may be eligible for accelerated approval. Products studied for their safety and

effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has an effect on 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. As a condition of approval, the FDA may require that a sponsor of a drug or biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical studies. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Fast Track designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

In 2012 the FDA established a Breakthrough Therapy designation which is intended to expedite the development and review of products that treat serious or life-threatening conditions. The designation is available for product candidates that are intended, alone or in combination with one or more other products, to treat serious or life-threatening diseases or conditions and for which preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently available therapy on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The 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 Fast Track designation and priority review, which can also be granted to the same product if relevant criteria are met. If a product is designated as Breakthrough Therapy, FDA will expedite the development and review of such product.

We received Breakthrough Therapy designation for the combination of CRS-207 and GVAX Pancreas. Where applicable, we plan to request Fast Track and Breakthrough Therapy designation for other product candidates and regimens. Even if we receive one or both of these designations for our product candidates, the FDA may later decide that our product candidates no longer meets the conditions for qualification. In addition, these designations may not provide us with a material commercial advantage.

Post-Approval Requirements

Any products for which we receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, and complying with FDA promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product’s approved uses, known as off-label use, limitations on industry-sponsored scientific and educational activities and requirements for promotional activities involving the internet. Although physicians may prescribe legally available products for off-label uses, if the physicians deem to be appropriate in their professional medical judgment, manufacturers may not market or promote such off-label uses.

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval to ensure the long-term stability of the product. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA or NDA, including, among other things, recall or

withdrawal of the product from the market. In addition, changes to the manufacturing process are strictly regulated, and depending on the significance of the change, may require prior FDA approval before being implemented.

Other types of changes to the approved product, such as adding new indications and claims, are also subject to further FDA review and approval.

The FDA also may require post-marketing testing, known as Phase 4 testing, and surveillance to monitor the effects of an approved product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

U.S. Patent Term Restoration and Marketing Exclusivity

The Biologics Price Competition and Innovation Act, or BPCIA, amended the PHSA to authorize the FDA to approve similar versions of innovative biologics, commonly known as biosimilars. A competitor seeking approval of a biosimilar must file an application to establish its product as highly similar to an approved innovator biologic, among other requirements. The BPCIA, however, bars the FDA from approving biosimilar applications for 12 years after an innovator biological product receives initial marketing approval.

Depending upon the timing, duration and specifics of the FDA approval of the use of our product candidates, some of our U.S. patents, if granted, may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years, as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA or NDA plus the time between the submission date of a BLA or NDA and the approval of that application. Only one patent applicable to an approved product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may intend to apply for restoration of patent term for one of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA or NDA.

Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent terms, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial.

Other U.S. Healthcare Laws and Compliance Requirements

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare and Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services, for instance the Office of Inspector General, the U.S. Department of Justice, or DOJ, and individual U.S. Attorney offices within the DOJ, and state and local governments. For example, sales, marketing and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, the physician payment transparency laws, the privacy and security provisions of the Health Insurance Portability and Accountability Act, or HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and similar state laws, each as amended.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor, however, does not make the conduct per se illegal

under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances.

Additionally, the intent standard under the Anti-Kickback Statute was amended by the Affordable Care Act to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act codified case law 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, as discussed below.

The civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

The federal False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, and thus non-reimbursable, uses.

HIPAA created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, 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 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.

Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

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

Additionally, the federal Physician Payments Sunshine Act under the Affordable Care Act, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with certain exceptions, to report information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members and payments or other "transfers of value" made to such physician owners. Failure to submit timely, accurately, and completely the required information may result in civil monetary penalties of up to an aggregate of $150,000 per year and up to an aggregate of $1 million per year for "knowing failures"). Manufacturers were required to begin collecting data on August 1, 2013 and submit reports on aggregate payment data to the government for the first reporting period of August 1, 2013 to December 31, 2013, by March 31, 2014, and to report detailed payment data for the first reporting period and submit legal attestation to the accuracy of such data by June 30, 2014. Thereafter, manufacturers must submit reports by the 90th day of each subsequent calendar year. CMS made all reported data publicly available on September 30, 2014. Certain states also mandate implementation of compliance programs, impose restrictions on pharmaceutical manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to healthcare providers and entities.

In order to distribute products commercially, we must also comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including without limitation, civil, criminal and/or

administrative penalties, damages, fines, disgorgement, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Coverage, Pricing and Reimbursement

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

Different pricing and reimbursement schemes exist in other countries. In the EU, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care 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 product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs 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.

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on healthcare pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare Reform

In March 2010, President Obama enacted 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 is substantially changing healthcare financing and delivery by both governmental and private insurers, and significantly impact the pharmaceutical and biotechnology industry.

Among the Affordable Care Act's provisions of importance to the pharmaceutical and biotechnology industries, in addition to those otherwise described above, are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively and a cap on the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price, or AMP;

- addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics, including our product candidates, that are inhaled, infused, instilled, implanted or injected;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013, and will remain in effect through 2024 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers. Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs.

We anticipate that the Affordable Care Act and other legislative reforms will result in additional downward pressure on the price that we receive for any approved product, if covered, and could seriously harm our business, though we are still unsure what its full impact will be. There have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect such challenges and amendments to continue in the future. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

Further, in January 2016, CMS issued a final rule regarding the Medicaid drug rebate program. The final rule, effective April 1, 2016, among other things, revises the manner in which the "average manufacturer price" is to be calculated by manufacturers participating in the program and implement certain amendments to the Medicaid rebate statute created under the Affordable Care Act. In addition, it is possible that there will be further legislation or regulation that could harm our business, financial condition and results of operations.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Additional Regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with

applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

Europe and Rest of World Government Regulation

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. Whether or not we obtain FDA approval of a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In the EU, for example, a clinical trial application must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the clinical trial application is approved in accordance with a country's requirements, clinical trial development may proceed. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of an investigational drug or biological product under EU regulatory systems, we must submit a marketing authorization application. The application used to file the BLA in the United States is similar to that required in the EU, with the exception of, among other things, country-specific document requirements.

For other countries outside of the EU, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we or our potential collaborators fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Employees

As of December 31, 2015 we had 111 full-time employees, 35 of whom hold Ph.D. degrees, 82 of whom were engaged in research and development activities and 29 of whom were engaged in finance, business development, facilities, human resources and administrative support. None of our employees are subject to a collective bargaining agreement. We consider our relationship with our employees to be good.

Corporate Information

We were incorporated in California as Oncologic, Inc. in 2000. In 2008, we merged with Triton BioSystems, Inc. and subsequently changed our name to Aduro Biotech, Inc. in 2009. In June 2011, we reincorporated as a Delaware corporation. Our principal executive offices are located at 626 Bancroft Way, 3C, Berkeley, California 94710 and our telephone number is (510) 848-4400. Our website address is www.aduro.com. Information contained on or accessible through our website is not a part of this Annual Report on Form 10-K.

Aduro, Aduro Biotech, the Aduro logo and other trade names, trademarks or service marks of Aduro appearing in this Annual Report on Form 10-K are the property of Aduro. Trade names, trademarks and service marks of other companies appearing in this report are the property of their respective holders.

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Item 1A. Risk Factors.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the following risks and all of the other information contained in this Annual Report on Form 10-K, including our financial statements and related notes and the section "Management's Discussion and Analysis of Financial Condition and Results of Operations," before investing in our common stock. While we believe that the risks and uncertainties described below are the material risks currently facing us, additional risks that we do not yet know of or that we currently think are immaterial may also arise and materially affect our business. If any of the following risks materialize, our business, financial condition and results of operations could be materially and adversely affected. In that case, the trading price of our common stock could decline, and you may lose some or all of your investment.

Risks Related to Our Business

We have incurred net losses in every year since our inception and anticipate that we will continue to incur substantial and increasing net losses in the foreseeable future.

We are a clinical-stage biopharmaceutical company with a limited operating history. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We have financed our operations primarily through the sale of equity securities and convertible debt securities. Since our inception, most of our resources have been dedicated to the preclinical and clinical development of our product candidates. The size of our future net losses will depend, in part, on our future expenses and our ability to generate revenue. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception. For the years ended December 31, 2015, 2014 and 2013, we reported a net loss of $39.2 million, $17.0 million and $16.1 million, respectively. At December 31, 2015, we had an accumulated deficit of $100.9 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates.

Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

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

Our operations have consumed substantial amounts of cash since inception. At December 31, 2015, our cash and cash equivalents and marketable securities were $431.0 million. We expect to continue to spend substantial amounts to continue the clinical development of our product candidates. If we are able to gain regulatory approval for any of our product candidates, we will require significant additional amounts of cash in order to launch and commercialize any such product candidates. In addition, other unanticipated costs may arise. Because the design and outcome of our planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates.

Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical studies and clinical trials;
- the timing of, and costs associated with, obtaining regulatory approvals for our product candidates if clinical trials are successful;
- the cost of commercialization activities for our product candidates, if any of our product candidates is approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing our product candidates for clinical trials in preparation for regulatory approval and in preparation for commercialization and product launch;
- our ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements;

- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the timing, receipt and amount of sales of, or royalties on, our future products, if any; and
- the emergence of competing cancer therapies and other adverse market developments.

We do not have any committed external source of funds or other support for our development efforts other than our license agreements, including our license agreements with Janssen, which may be terminated by Janssen upon delivery of notice, and our collaboration and license agreement with Novartis, which may be terminated by Novartis at any time after March 19, 2018 upon 180 days' notice. Until we can generate sufficient product and royalty revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. Additional financing may not be available to us when we need it or it may not be available on favorable terms.

If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of or suspend one or more of our clinical trials or research and development programs or our commercialization efforts.

Risks Related to the Development and Commercialization of Our Current and Future Product Candidates

Our technology platforms and product candidates are based on novel technologies, and the development and regulatory approval pathway for such product candidates is unproven and may never lead to marketable products.

We are developing our pipeline of immuno-oncology product candidates via our technology platforms. Immuno-oncology encompasses a class of therapies that leverage the patient's immune system to slow the growth and spread of, or eliminate, tumor cells. Any products we develop may not effectively modulate the immune response to slow the spread of or eliminate cancer cells. The scientific evidence to support the feasibility of developing product candidates based on impacting the anti-tumor immune response is preliminary and limited. Advancing these novel immuno-oncology therapies creates significant challenges for us, including, among others:

- obtaining approval from regulatory authorities to conduct clinical trials with our product candidates;
- successful completion of preclinical studies and successful enrollment of clinical trials with favorable results;
- obtaining approvals from regulatory authorities to manufacture and market our product candidates;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- making arrangements with third-party manufacturers for, or establishing, commercial manufacturing capabilities;
- manufacturing our product candidates at an acceptable cost;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with Janssen, Novartis or other partners;
- acceptance of our product candidates, if and when approved, by patients, the medical community and third-party payors; and
- effectively competing with other cancer therapies.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully develop and commercialize our product candidates, which could materially harm our business, financial condition and results of operations.

We may not be successful in our efforts to use and expand our technology platforms to build a pipeline of product candidates.

A key element of our strategy is to use and expand our technology platforms to build a pipeline of product candidates, combine our product candidates with existing and novel therapies, and progress these product candidates and combinations through clinical

development for the treatment of various diseases. Although our research and development efforts to date have resulted in a pipeline of product candidates directed at various cancers, we may not be able to develop product candidates that are safe and effective. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. If we do not continue to successfully develop and begin to commercialize product candidates, we will face difficulty in obtaining product revenues in future periods.

Our business is highly dependent on the success of our lead product candidate, CRS-207, and GVAX Pancreas. CRS-207, GVAX Pancreas and our other product candidates will require significant additional clinical testing before we can seek regulatory approval and potentially launch commercial sales.

We do not have any products that have gained regulatory approval. Our business and future success depend on our ability to obtain regulatory approval of and then successfully commercialize our lead product candidate, CRS-207, and GVAX Pancreas. CRS-207, GVAX Pancreas and our other product candidates are in the early stages of development. CRS-207 in combination with GVAX Pancreas is currently being tested in two Phase 2b clinical trials known as ECLIPSE and STELLAR in metastatic pancreatic cancer, and we expect to advance CRS-207 in combination with standard-of-care chemotherapy into Phase 3 clinical development for mesothelioma. Our ability to develop, obtain regulatory approval for, and successfully commercialize CRS-207 and GVAX Pancreas effectively will depend on several factors, including the following:

- successful completion of our Phase 2b ECLIPSE clinical trial or other clinical trials, which will depend substantially upon the satisfactory performance of third-party contractors;
- successful achievement of the objectives of our Phase 2b ECLIPSE clinical trial, including the demonstration of a survival benefit and a favorable risk-benefit outcome;
- receipt of marketing approvals for CRS-207 and GVAX Pancreas from the U.S. Food and Drug Administration, or FDA, and similar regulatory authorities outside the United States;
- establishing commercial manufacturing and supply arrangements;
- establishing a commercial infrastructure;
- acceptance of the product by patients, the medical community and third-party payors;
- establishing market share while competing with other therapies;
- successfully executing our pricing and reimbursement strategy;
- a continued acceptable safety and adverse event profile of the product following regulatory approval; and
- qualifying for, identifying, registering, maintaining, enforcing and defending intellectual property rights and claims covering the product.

All of our product candidates, including CRS-207 and GVAX Pancreas, will require additional clinical and non-clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. If we are unable to develop or receive marketing approval for CRS-207 or GVAX Pancreas in a timely manner or at all, we could experience significant delays or an inability to commercialize CRS-207 and GVAX Pancreas, which would materially and adversely affect our business, financial condition and results of operations.

Clinical development involves a lengthy and expensive process with uncertain outcomes, and results of earlier studies and trials may not be predictive of future clinical trial results. Our clinical trials may fail to demonstrate adequately the safety and efficacy of one or more of our product candidates, which would prevent or delay regulatory approval and commercialization.

Before obtaining regulatory approvals for the commercial sale of our product candidates, including CRS-207, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication. 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 preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. For example, the positive results generated to date in preclinical studies and in our Phase 2a metastatic pancreatic cancer study of CRS-207 and GVAX Pancreas do not ensure that future studies will demonstrate similar results. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in

the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. We cannot be certain that we will not face similar setbacks. Most product candidates that commence clinical trials are never approved as commercial products.

We may experience delays in our ongoing clinical trials and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- obtaining regulatory approval to commence a trial;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining institutional review board, or IRB, approval at each site;
- recruiting suitable patients to participate in a trial;
- having patients complete a trial or return for post-treatment follow-up;
    - clinical sites deviating from trial protocol or dropping out of a trial;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of product candidate for use in clinical trials.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions, lack of adequate funding to continue the clinical trial or safety concerns raised by other clinical trials of therapies with similar mechanisms of action.

Furthermore, we rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance. 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 will 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 may harm our business, financial condition and prospects significantly. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive cash compensation in connection with such services. We also give grants to investigators' institutions from time to time. If certain of these relationships exceed specific financial thresholds, they must be reported to the FDA. If these relationships and any related compensation paid results in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected interpretation of the study, 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 in approval, or rejection, of our marketing applications by the FDA. 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 addition, even if the trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and we may need to conduct additional trials before we submit applications seeking regulatory approval of our product candidates.

To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, approval of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

Our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential, if approved, or result in significant negative consequences.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable

foreign regulatory authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics.

To date, patients treated with CRS-207 have experienced drug-related side effects including Grade 3 adverse events, or AEs, which are considered moderate, and Grade 4 AEs which are considered severe. In our Phase 2a clinical trial of CRS-207 and GVAX Pancreas, the most frequent drug-related Grade 3 or 4 AE was lymphopenia (an abnormally low level of white blood cells), with three patients experiencing Grade 3 lymphopenia and two patients experiencing Grade 4 lymphopenia. Lymphopenia is expected based on prior nonclinical studies and CRS-207's mechanism of action, and the AEs of lymphopenia were self-correcting or did not reveal an unexpected pattern of toxicity. We currently do not plan to alter our development plan for CRS-207 based on these observed AEs of lymphopenia. There were no other Grade 4 AEs, and there were no other Grade 3 AEs with frequencies higher than five percent in either arm. The most common Grade 3 AEs were transient lymphopenia, fevers, elevated liver enzymes and fatigue. One Grade 3 serious AE of listeriosis was reported. At the request of the patient and the investigator, this patient continues to receive study treatment.

If unacceptable side effects arise in the development of our product candidates, we could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. In addition, if side effects are observed in competing product candidates that are perceived to have similarities to ours, such as competing listeria-based vaccines or other more general approaches to immuno-oncology, regulators or patients may infer that our product candidates could cause similar side effects. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- FDA could require a Risk and Evaluation Medication Strategy or REMS which could require the creation and management of a medication guide, communication plan or other elements to ensure safe use;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;

- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to study sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;

- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site. Moreover, because our product candidates represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy and hematopoietic cell transplantation, rather than enroll patients in any future clinical trial.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

Clinical trials are expensive, time-consuming and difficult to design and implement.

Human clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Because our product candidates are based on new technologies, we expect that they will require extensive research and development and have substantial manufacturing and processing costs. In addition, costs to treat patients with relapsed/refractory cancer and to treat potential side effects that may result from our product candidates may be significant. Accordingly, our clinical trial costs are likely to be significantly higher than for more conventional therapeutic technologies or drug products.

The market opportunities for our product candidates may be limited to those patients who are ineligible for established therapies or for whom prior therapies have failed, and may be small.

Cancer therapies are sometimes characterized as first line, second line or third line, and the FDA often approves new therapies initially only for third line use. When cancer is detected early enough, first-line therapy, usually chemotherapy, hormone therapy, surgery, radiotherapy or a combination of these, is sometimes adequate to cure the cancer or prolong life without a cure. Second- and third-line therapies are administered to patients when prior therapy is not effective. We expect to initially seek approval of our product candidates as a therapy for patients who have received one or more prior treatments. Subsequently, for those products that prove to be sufficiently beneficial, if any, we would expect to seek approval potentially as a first-line therapy, but there is no guarantee that our product candidates, even if approved, would be approved for first-line therapy, and, prior to any such approvals, we may have to conduct additional clinical trials.

Our projections of both the number of people who have the cancers we are targeting, as well as the subset of people with these cancers who have received one or more prior treatments, and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these cancers. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. Even if we obtain significant market share for our product candidates, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications, including to be used as first or second line therapy.

We have obtained orphan drug designations from the FDA and European Medicines Agency for CRS-207 and GVAX Pancreas for the treatment of pancreatic cancer and for CRS-207 for the treatment of mesothelioma. We may be

unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biologic intended to treat a rare disease or condition, which is defined as one occurring in a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug or biologic will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a full Biologics License Application, or BLA, to market the same biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity.

In the European Union, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and 10 years of market exclusivity is granted following drug or biological product approval. This period may be reduced to 6 years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Even though we have received orphan drug designation for both CRS-207 and GVAX Pancreas for the treatment of pancreatic cancer and for CRS-207 for the treatment of mesothelioma, we may not be the first to obtain marketing approval of either product candidate for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Even after an orphan product is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is safer, more effective, or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. In addition, while we intend to seek orphan drug designation for other product candidates, we may never receive such designations.

We have obtained Breakthrough Therapy designation from the FDA for the combination of CRS-207 and GVAX Pancreas in pancreatic cancer, but we may be unable to maintain the benefits associated with this designation.

In 2012, the FDA established a new Breakthrough Therapy designation, which is intended to expedite the development and review of products that treat serious or life-threatening conditions where “preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development.” The designation of a product candidate as a Breakthrough Therapy provides potential benefits that include but are not limited to more frequent meetings with the FDA to discuss the development plan for the product candidate and ensure collection of appropriate data needed to support approval; more frequent written correspondence from FDA about such things as the design of the proposed clinical trials and use of biomarkers; intensive guidance on an efficient drug development program; organizational commitment involving senior managers; and eligibility for rolling review and priority review. Breakthrough Therapy designation does not change the standards for product approval. The FDA can also rescind Breakthrough Therapy designation in the event that the program no longer meets the criteria for eligibility. This could occur if a new therapy is approved and the existing data no longer show a substantial improvement over the new therapy. We have obtained Breakthrough Therapy designation for our CRS-207 and GVAX Pancreas combination. Despite the potential advantages of Breakthrough Therapy designation, we may fail to maintain the designation or ultimately obtain regulatory approval of CRS-207 and GVAX Pancreas, and if we do obtain approval, we may fail to do so on an accelerated basis. In addition, while we intend to seek Breakthrough Therapy designation for other product candidates, we may never receive such designation.

If we fail to develop additional product candidates, our commercial opportunity will be limited.

We expect to initially develop our lead product candidate, CRS-207. However, one of our strategies is to pursue clinical development of additional product candidates. Developing, obtaining regulatory approval for and commercializing additional product candidates will require substantial additional funding and are prone to the risks of failure inherent in medical product development. We cannot assure you that we will be able to successfully advance any of these additional product candidates through the development process.

Even if we obtain FDA approval to market additional product candidates for the treatment of cancer, we cannot assure you that any such product candidates will be successfully commercialized, widely accepted in the marketplace or

more effective than other commercially available alternatives. If we are unable to successfully develop and commercialize additional product candidates, our commercial opportunity will be limited. Moreover, a failure in obtaining regulatory approval of additional product candidates may have a negative effect on the approval process of any other, or result in losing approval of any approved, product candidate.

We are subject to a multitude of manufacturing and supply chain risks, any of which could substantially increase our costs and limit the supply of our product candidates.

The process of manufacturing our product candidates is complex, highly regulated and subject to several risks, including:

- The manufacturing of drug products is susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment or vendor or operator error. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If foreign microbial,

viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our products are made, these manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination;

- The manufacturing facilities in which our product candidates are made could be adversely affected by equipment failures, labor shortages, natural disasters, power failures and numerous other factors;
- We and our contract manufacturers must comply with the FDA's current good manufacturing practices, or cGMP, regulations and guidelines. Any failure to follow cGMP or other regulatory requirements or any delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our products as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our products, including leading to significant delays in the availability of products for our clinical studies or the termination or hold on a clinical study, or the delay or prevention of a filing or approval of marketing applications for our product candidates. Significant noncompliance could also result in the imposition of sanctions, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation. If we are not able to maintain regulatory compliance, we may not be permitted to market our products and/or may be subject to product recalls, seizures, injunctions, or criminal prosecution; and
- Our LADD product candidates, GVAX Pancreas, ADU-S100 and antibody product candidates are temperature sensitive and must be frozen during storage and transportation, which adds complexity and expense. We rely on third parties to provide controlled temperature storage and shipping. If any third-party provider fails to maintain proper temperature control or if a shipment is delayed in transit for a prolonged period of time, the product could become unsuitable for use.

Any adverse developments affecting manufacturing operations for our product candidates and/or damage that occurs during shipping may result in delays, inventory shortages, lot failures, withdrawals or recalls or other interruptions in the supply of our drug substance and drug product. We may also have to write off inventory, incur other charges and expenses for supply of drug product that fails to meet specifications, undertake costly remediation efforts, or seek more costly manufacturing alternatives. Inability to meet the demand for any of our product candidates, if approved, could damage our reputation and the reputation of our products among physicians, healthcare payors, patients or the medical community, which could adversely affect our ability to operate our business and our results of operations.

We currently have no marketing and sales organization and have no experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to generate product revenue.

We currently have no sales, marketing or distribution capabilities and have no experience in marketing products. We intend to develop an in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we will pursue collaborative arrangements regarding the sales and marketing of our products; however, we cannot assure you that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

We cannot assure you that we will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in the United States or elsewhere.

A variety of risks associated with marketing our product candidates internationally could materially adversely affect our business.

We plan to seek regulatory approval of our product candidates outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;

- 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 revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;
- challenges protecting our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biopharmaceutical industry is characterized by intense competition and rapid innovation. Our competitors may be able to develop other compounds or drugs that are able to achieve similar or better results. Many major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and universities and other research institutions continue to invest time and resources in developing novel approaches to immuno-oncology. Promising results have spurred significant competition from major pharmaceutical and biotechnology companies alike. Our competitors in the field of immuno-oncology and cancer vaccines include AdaptImmune Therapeutics, PLC, Advaxis, Inc., AstraZeneca PLC, Bristol Myers-Squibb Company, Celgene Corporation, GlaxoSmithKline plc, Idera Pharmaceuticals, Inc., Immune Design Corp., Incyte Corporation, Merck & Co., Inc., Merrimack Pharmaceuticals, Inc., NewLink Genetic Corporation, Novartis AG, Pfizer Inc., Roche Holding AG, Sanofi SA, and Bayer Healthcare, among others. Many of our competitors have substantially greater financial, technical and other resources than we do, such as larger research and development staff and experienced marketing, market access and manufacturing organizations and well-established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products. We believe the key competitive factors that will affect the development and commercial success of our product candidates are efficacy, safety, tolerability, reliability, convenience of use, price and reimbursement.

Even if we obtain regulatory approval of our product candidates, the availability and price of our competitors' products could limit the demand and the price we are able to charge for our product candidates. We may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances.

We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel, including our President and Chief Executive Officer, our Chief Scientific Officer and our Chief Operating Officer. The loss of the services of any of our executive officers, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements could result in delays in product development and harm our business.

We conduct our operations at our facility in Northern California. This region is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain “key man” insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel.

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

At December 31, 2015, we had 111 full-time employees, including 82 employees engaged in research and development. As our development and commercialization plans and strategies develop, and as we transition into operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including substantially all aspects of regulatory approval, clinical management, and manufacturing. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Our internal computer systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. While we have not to our knowledge experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our CROs and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce and process our product candidates on a patient by patient basis. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption. Our corporate headquarters is in Northern California near major earthquake faults and fire zones. The ultimate impact on us, our significant suppliers and our general infrastructure of being located near major earthquake faults and fire zones and being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake, fire or other natural disaster.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, commercial partners and vendors may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (1) the laws of the FDA and other similar foreign regulatory bodies, including those laws requiring the reporting of true, complete and accurate information to such regulators; (2) manufacturing standards; (3) healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or (4) laws that require the true, complete and accurate reporting of financial information or data. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commissions, certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials.

We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent these activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment of operations, any of which could adversely affect our ability to operate our business and our results of operations. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations.

Even if we obtain regulatory approval of our product candidates, the products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers and others in the medical community.

The use of LADD, STING Activator or B-select product candidates as potential cancer treatments, even if approved, may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers and others in the medical community. For example, certain of the product candidates that we are developing target a cell surface marker that may be present on non-cancerous cells as well as cancer cells. It is possible that our product candidates may kill these non-cancerous cells, which may result in unacceptable side effects, including death. Additional factors will influence whether our product candidates are accepted in the market, including:

- the clinical indications for which our product candidates are approved;
- physicians, hospitals, cancer treatment centers and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the prevalence and severity of any side effects;

- side effects or results reported for competing products or product candidates that are perceived to have similarities to ours, such as competing listeria-based vaccines or other more general approaches to immuno-oncology;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA;
- the timing of market introduction of our product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate coverage, reimbursement and pricing by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

In addition, we are utilizing replication competent vectors, and adverse publicity due to the ethical and social controversies surrounding the therapeutic use of such technologies, and reported side effects from any clinical trials using these technologies or the failure of such trials to demonstrate that these therapies are safe and effective may limit market acceptance our product candidates. If our product candidates are approved but fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers or others in the medical community, we will not be able to generate significant revenue.

Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

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 our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. 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 or 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 our product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management’s time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate; and
- a decline in our share price.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with corporate collaborators.

We currently hold $5.0 million in product liability insurance in the aggregate, which we believe is customary for similarly situated companies and adequate to provide us with insurance coverage for foreseeable risks, but which may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain insurance at a reasonable cost or in an amount adequate to satisfy any liability that may arise, if at all. Our insurance policy contains various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may 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. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

Risks Related to Our Reliance on Third Parties

We have entered into licensing agreements with third parties for certain product candidates and as a result have placed restrictions on our development of certain product candidates for particular indications. We may elect to enter into additional licensing or collaboration agreements to partner our product candidates in territories we currently retain. Our dependence on such relationships may adversely affect our business.

Because we have limited resources, we may seek to enter into collaboration agreements with other pharmaceutical or biotechnology companies. Any failure by our partners to perform their obligations or any decision by our partners to terminate these agreements could negatively impact our ability to successfully develop, obtain regulatory approvals for and commercialize our product candidates. In the event we grant exclusive rights to such partners, we would be precluded from potential commercialization of our product candidates within the territories in which we have a partner. For example, we have entered into exclusive research and license agreements with Janssen for the development and commercialization of ADU-741, GVAX for prostate cancer and ADU-214. Under these agreements, we have granted Janssen exclusive rights to develop and commercialize LADD product candidates for prostate and lung cancers. In addition, we have granted Janssen exclusive rights to develop and commercialize LADD product candidates with certain antigens and antigen combinations implicated in lung and other cancers for all fields of use. We have also entered into a collaboration and license agreement with Novartis for the development and commercialization of STING Activator product candidates in oncology. Under this agreement, we have granted Novartis a co-exclusive license to develop such products worldwide and an exclusive license to commercialize such products outside of the United States. In addition, any termination of our collaboration agreements will terminate the funding we may receive under the relevant collaboration agreement and may impair our ability to fund further development efforts and our progress in our development programs.

Our commercialization strategy for our product candidates may depend on our ability to enter into agreements with collaborators to obtain assistance and funding for the development and potential commercialization of our product candidates in the territories in which we seek to partner. Despite our efforts, we may be unable to secure additional collaborative licensing or other arrangements that are necessary for us to further develop and commercialize our product candidates. Supporting diligence activities conducted by potential collaborators and negotiating the financial and other terms of a collaboration agreement are long and complex processes with uncertain results. Even if we are successful in entering into one or more collaboration agreements, collaborations may involve greater uncertainty for us, as we have less control over certain aspects of our collaborative programs than we do over our proprietary development and commercialization programs. For example, under our collaboration and license agreement with Novartis, we are responsible for a share of the worldwide joint development costs, which may be significant. If we elect to reduce our share of development funding as provided for under the agreement, our share in profits would decrease or convert to a royalty. We may determine that continuing a collaboration under the terms provided is not in our best interest, and we may terminate the collaboration. Our potential future collaborators could delay or terminate

their agreements, and as a result our product candidates may never be successfully commercialized.

Further, our potential future collaborators may develop alternative products or pursue alternative technologies either on their own or in collaboration with others, including our competitors, and the priorities or focus of our collaborators may shift such that our product candidates receive less attention or resources than we would like, or they may be terminated altogether. We may also enter into agreements with collaborators to share in the burden of conducting clinical trials, manufacturing and marketing our product candidates. Any such actions by our potential future collaborators may adversely affect our business prospects and ability to earn revenues. In addition, we could have disputes with our potential future collaborators, such as the interpretation of terms in our agreements. Any such disagreements could lead to delays in the development or commercialization of our product candidates or could result in time-consuming and expensive litigation or arbitration, which may not be resolved in our favor.

We rely and will 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 not be able to obtain regulatory approval of or commercialize our product candidates.

We depend and plan to continue to depend upon independent investigators, other third parties and collaborators, such as universities, medical institutions, CROs and strategic partners, to conduct our preclinical and clinical trials under agreements with us. We expect to have to negotiate budgets and contracts with CROs and study sites, which may result in delays to our development timelines and increased costs. We rely and plan to continue relying heavily on these third parties over the course of our clinical trials, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with good clinical practices, or GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP regulations. In addition, our clinical trials must be conducted with biologic product produced under cGMPs regulations and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our clinical trials are not our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical, clinical and nonclinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies or other drug development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they 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 protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Switching or adding third parties to conduct our clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with third parties conducting our clinical trials, we cannot assure you that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We rely and expect to continue to rely on third parties to manufacture our clinical product supplies, and we intend to rely on third parties to produce and process our product candidates, if approved, and our commercialization of any of our product candidates could be stopped, delayed or made less profitable if those third parties fail to obtain approval of government regulators, fail to provide us with sufficient quantities of drug product or fail to do so at acceptable quality levels or prices.

We do not currently have nor do we plan to acquire the infrastructure or capability internally to manufacture our clinical supplies for use in the conduct of our clinical trials, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. We currently rely on outside vendors to manufacture our clinical supplies of our product candidates and plan to continue relying on third parties to manufacture our product candidates on a commercial scale, if approved.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our marketing applications to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements, known as cGMPs, for manufacture of our product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

We do not yet have sufficient information to reliably estimate the cost of the commercial manufacturing of our product candidates, and the actual cost to manufacture our product candidates could materially and adversely affect the commercial viability of our product candidates. As a result, we may never be able to develop a commercially viable product.

In addition, our reliance on third-party manufacturers exposes us to the following additional risks:

- We may be unable to identify manufacturers on acceptable terms or at all.
- Our third-party manufacturers might be unable to timely formulate and manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any.
- Contract manufacturers may not be able to execute our manufacturing procedures appropriately.
- Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products.
- Manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.
- We may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our products.
- Our third-party manufacturers could breach or terminate their agreement with us.

Each of these risks could delay our clinical trials, the approval, if any of our product candidates by the FDA or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenue. In addition, we rely on third parties to perform release testing on our product candidates prior to delivery to patients. If these tests are not appropriately conducted and test data are not reliable, patients could be put at risk of serious harm and could result in product liability suits.

The manufacture of medical products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of biologic products often encounter difficulties in production, particularly in scaling up and validating initial production and absence of contamination. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if contaminants are discovered in our supply of our product candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any stability or other issues relating to the manufacture of our product candidates will not occur in the future. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide our product candidates to patients in clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely.

We may form or seek strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.

We may form or seek strategic alliances, create joint ventures or collaborations or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face

significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

We may not realize the benefits of acquisitions, including our acquisition of BioNovion Holding B.V., our wholly-owned subsidiary known as Aduro Biotech Europe, or other strategic transactions.

We acquired BioNovion Holding B.V. in October 2015, and may acquire other businesses, products or technologies, as well as pursue joint ventures or investments in complimentary businesses. The success of acquisitions, including our acquisition of Aduro Biotech Europe, and any future strategic transactions, depends on a number of risks and uncertainties, including:

- unanticipated liabilities related to acquired companies;
- difficulties integrating acquired personnel, technologies and operations into our existing business;
- retention of key employees;
- diversion of management time and focus from operating our business to management of strategic alliances or joint ventures or acquisition integration challenges;
- increases in expenses and reductions in our cash available for operations and other uses;
- disruption in our relationships with collaborators or suppliers as a result of such a transaction; and
- possible write-offs or impairment charges relating to acquired businesses.

If any of these risks or uncertainties occur, we may not realize the anticipated benefit of any acquisition or strategic transaction. For example, Aduro Biotech Europe's B-select antibody platform may fail to identify product candidates that are safe and effective, or at all. Additionally, foreign acquisitions, including our acquisition of BioNovion Holding B.V., a Dutch company, are subject to additional risks, including those related to integration of operations across different cultures and languages, currency risks, potentially adverse tax consequences of overseas operations and the particular economic, political and regulatory risks associated with specific countries.

If our third-party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by our third-party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

Risks Related to Government Regulation

The FDA regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our product candidates.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not previously submitted a BLA or NDA to the FDA, or similar marketing applications filings to comparable foreign authorities. A BLA or NDA must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety, purity and potency, or safety

and effectiveness for each desired indication. The BLA or NDA must also include significant information regarding the chemistry, manufacturing and controls for the product. We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. For example, the FDA has limited experience with commercial development of immunotherapies for cancer. We also intend to obtain regulatory approval of future product candidates regardless of cancer type or origin, which the FDA may have difficulty accepting if our clinical trials only involved cancers of certain origins. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and approval may not be obtained.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; or
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Even if we receive regulatory approval of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or the conditions of approval, or contain requirements for potentially costly post-market testing and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a risk evaluation and

mitigation strategy, or REMS, as a condition of approval of our product candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

In addition, if we were able to obtain accelerated approval of our pancreatic cancer combination of CRS-207 and GVAX Pancreas, the FDA would require us to conduct a confirmatory study to verify the predicted clinical benefit and additional safety studies. The results from the confirmatory study may not support the clinical benefit, which would result in the approval being withdrawn.

Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our product candidates profitably.

Successful sales of our product candidates, if approved, depend, in part, on the availability of adequate coverage and reimbursement from third-party payors. In addition, because our product candidates represent new approaches to the treatment of cancer, we cannot accurately estimate the potential revenue from our product candidates.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and

· neither experimental nor investigational.

Obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our products. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Further, we plan to develop our product candidates for use in combination with other products, which may make them cost prohibitive or less likely to be covered by

third-party payors. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific, clinical and cost-effectiveness data and support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained. We intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the EU, the pricing of biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. In particular, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the Affordable Care Act, was enacted. The Affordable Care Act and its implementing regulations, among other things, subjected biologic products to potential competition by lower-cost biosimilars, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics, including our product candidates, that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, provided incentives to programs that increase the federal government’s comparative effectiveness research and established a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D.

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

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

Our current and future relationships with customers and third-party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, which may constrain the business or financial arrangements and relationships through which we sell, market and distribute any drugs for which we obtain marketing approval. In addition, we may be subject to transparency laws and patient privacy regulation by the U.S. federal and state governments and by governments in foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. 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;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other third-party payors that are false or fraudulent or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating these statutes without actual knowledge of the statutes or specific intent to violate them;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization;
- the federal Physician Payment Sunshine Act, created under the Affordable Care Act, and its implementing regulations, which require manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services, or HHS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members and payments or other "transfers of value" made to such physician owners;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our business activities could be subject to challenge under one or more of such laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time-and resource-consuming and can divert management's attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in federal and state healthcare programs and the curtailment or restricting of our operations, any of which could harm our ability to operate our business and our financial results. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

Risks Related to Our Intellectual Property

If we are unable to protect our intellectual property rights or if our intellectual property rights are inadequate for our technology and product candidates, our competitive position could be harmed.

Our commercial success will depend in part on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our proprietary technology and products. We rely on trade secret, patent, copyright and trademark laws, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. We seek to protect our proprietary position by filing and prosecuting patent applications in the United States and abroad related to our novel technologies and products that are important to our business.

The patent positions of biotechnology and pharmaceutical companies generally are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patents, including those patent rights licensed to us by third parties, are highly uncertain. The steps we or our licensors have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights, both inside and outside of the United States. Further, the examination process may require us or our licensors to narrow the claims for our pending patent applications, which may limit the scope of patent protection that may be obtained if these applications issue. The rights already granted under any of our currently issued patents or those licensed to us and those that may be granted under future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. If we or our licensors are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize technology and products similar or superior to ours, and our ability to successfully commercialize our technology and products may be adversely affected. It is also possible that we or our licensors will fail to identify patentable aspects of inventions made in the course of our development and commercialization activities before it is too late to obtain patent protection on them.

With respect to patent rights, we do not know whether any of the pending patent applications for any of our compounds or biologic products will result in the issuance of patents that effectively protect our technology or products, or if any of our issued patents or if any of our or our licensors' issued patents will effectively prevent others from commercializing competitive technologies and products. Publications of discoveries in the scientific literature

often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or in some cases not at all, until they are issued as a patent. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions.

Our pending applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, issued patents that we own or have licensed from third parties may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in the loss of patent protection, the narrowing of claims in such patents or the invalidity or unenforceability of such patents, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection for our technology and products. Protecting against the unauthorized use of our or our licensor’s patented technology, trademarks and other intellectual property rights is expensive, difficult and may in some cases not be possible. In some cases, it may be difficult or impossible to detect third-party

infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult. For example, two of our patents, U.S. Patent Nos. 7,842,289 and 7,935,804, have previously been subject to reexamination proceedings in the U.S. Patent and Trademark office at the request of a third party.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could harm our business.

Our commercial success depends upon our ability to develop, manufacture, market and sell our product candidates, and to use our related proprietary technologies without infringing the intellectual property rights of third parties. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates, including interference or derivation proceedings before the U.S. Patent and Trademark Office, or USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue commercializing our product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Under certain circumstances, we could be forced, including by court order, to cease commercializing our product candidates. In addition, in any such proceeding or litigation, we could be found liable for monetary damages. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar negative impact on our business.

While our product candidates are in preclinical studies and clinical trials, we believe that their use in these preclinical studies and clinical trials falls within the scope of the exemptions provided by 35 U.S.C. Section 271(e) in the United States, which exempts from patent infringement liability activities reasonably related to the development and submission of information to the FDA. As our product candidates progress toward commercialization, the possibility of a patent infringement claim against us increases. We attempt to ensure that our product candidates and the methods we employ to manufacture them, as well as the methods for their use that we intend to promote, do not infringe other parties' patents and other proprietary rights. We cannot assure you they do not, however, and competitors or other parties may assert that we infringe their proprietary rights in any event.

In addition, we are testing our product candidates administered with other product candidates or products that are covered by patents held by other companies or institutions. In the event that a labeling instruction is required in product packaging recommending that combination, we could be accused of, or held liable for, infringement of the third-party patents covering the product candidate or product recommended for administration with our product candidates. In such a case, we could be required to obtain a license from the other company or institution to use the required or desired package labeling, which may not be available on commercially reasonable terms, or at all.

We are aware of certain U.S. and foreign patents owned by a certain third party with claims that are broadly directed to a Listeria vaccine strain that contains certain proteins, some of these patents expire as late as 2021. These patents could be construed to cover CRS-207. In addition, we are aware of certain U.S. and foreign patents owned by a certain third party with claims that are broadly directed methods of using Listeria-based vaccines to treat certain cancers, which patents expire in 2017. The patents expiring in 2017 may be construed to cover our LADD product candidate, CRS-207, as well as the product candidates licensed to Janssen, ADU-214 and ADU-741. Notwithstanding, we do not currently expect a product launch prior to 2017 and, therefore, the patents expiring in 2017 would not appear relevant to our commercialization plans unless our approval was accelerated or they somehow were extended.

If we breach any of our license agreements, it could have a material adverse effect on our commercialization efforts for our product candidates.

Our commercial success depends on our ability, and the ability of our licensors and collaborators, to develop, manufacture, market and sell our product candidates and use our licensors' or collaborators' proprietary technologies without infringing the property rights of third parties. For example, we have entered into license agreements with the Johns Hopkins University and the Regents of the University of California related to our LADD product candidates, and license agreements with Karagen Pharmaceuticals, Inc. and the Regents of the University of California related to our STING Activator product candidates, and we expect to enter into additional licenses in the future. If we fail to comply with the obligations under these agreements, including payment and diligence terms, our licensors may have the right to terminate these agreements, in which event we may not be able to develop, manufacture, market or sell any product that is covered by these agreements or may face other penalties under the agreements. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements, which may not be available to us on equally favorable terms, or at all, or cause us to lose our rights under these agreements, including our rights to intellectual property or technology important to our development programs.

We have granted Janssen certain rights to file, prosecute, maintain and enforce specific patents that relate to ADU-214, ADU-741 and GVAX Prostate. Our inability to control the filing, prosecution, maintenance and enforcement of such patents could materially harm our business.

As part of the agreements with Janssen related to ADU-214, ADU-741 and GVAX Prostate, we have granted Janssen the initial right and responsibility to file, prosecute, maintain and enforce any patents and patent applications that contain pending or issued claims that are specifically directed to the antigens contained in ADU-214, ADU-741 and GVAX Prostate. For example, if a third party is infringing one of the antigen-specific patents by marketing a product that is identical or similar to ADU-214 for the treatment of lung cancer (such as a biosimilar of ADU-214), Janssen would have the initial right to enforce the antigen-specific patents against the third party. If we do not have the ability to control the enforcement of the antigen-specific patents against a third party that is marketing a product that is identical or similar to ADU-214, ADV-741 or GVAX Prostate, our business may be materially harmed.

We have granted Janssen the right to determine patent term extension strategy for specific patents that relate to ADU-214, ADU-741 and GVAX Prostate. Our inability to control the patent term extension strategy could materially harm our business.

As part of the license agreements with Janssen related to ADU-214, ADU-741 and GVAX Prostate, we have granted Janssen the right and responsibility to determine the strategy to apply for the extension of the term of any licensed patents that are specifically directed to the antigen contained in ADU-214 or the antigens contained in ADU-741. Janssen may decide not to apply for extension of any term of a licensed patent that may otherwise be eligible for extension, which could decrease the royalties received from Janssen for the sale of ADU-214, ADU-741 and/or GVAX Prostate. If we allow Janssen to also apply for extension of a licensed patent for ADU-214, ADU-714 and/or GVAX Prostate that may also be relevant to another product candidates that we may be developing and commercializing, we could be prevented from seeking extension of the same patent for our product. If we do not have the ability to control the strategy for patent term extension of any of our licensed patents, our business may be materially harmed.

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

Filing, prosecuting and defending patents on all of our product candidates throughout the world would be prohibitively expensive, and our or our licensors' intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws and practices of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we and our licensors may not be able to prevent third parties from practicing our and our licensors' inventions in all countries outside the United States, or from selling or importing products made using our and our licensors' inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products, and may export otherwise infringing products to territories where we or our licensors have patent protection, but where enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our or our licensor's patents or marketing of competing products in violation of our proprietary rights generally in those countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business, could put our and our licensors' patents at risk of being invalidated or interpreted narrowly and our and our licensors' patent applications at risk of not issuing and could provoke third parties to assert

claims against us or our licensors. We or our licensors may not prevail in any lawsuits that we or our licensors initiate and the damages or other remedies awarded, if any, may not be commercially meaningful.

The laws of certain foreign countries may not protect our rights to the same extent as the laws of the United States, and these foreign laws may also be subject to change. For example, methods of treatment and manufacturing processes may not be patentable in certain jurisdictions, and the requirements for patentability may differ in certain countries, particularly developing countries. Furthermore, generic and/or biosimilar product manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' patents, requiring us or our licensors to engage in complex, lengthy and costly litigation or other proceedings.

Generic or biosimilar product manufacturers may develop, seek approval for, and launch biosimilar versions or generic versions, respectively, of our products. The FDA has published four draft guidance documents on biosimilar product development. 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, the biosimilar 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. However, complexities associated with the larger, and often more complex, structures of biological products, as well as the process by which such products are manufactured, pose significant

hurdles to implementation, which are still being worked out by the FDA. To date, no biosimilar or interchangeable biologic has been licensed under the Biologics Price Competition and Innovation Act of 2009, or BPCIA, framework, although such approvals have occurred in Europe, and it is anticipated that the FDA will approve a biosimilar in the relatively near future. If any of our product candidates are approved by the FDA, the approval of a biologic product biosimilar to one of our products could have a material impact on our business. In particular, a biosimilar could be significantly less costly to bring to market and priced significantly lower than our products, if approved by the FDA.

Some jurisdictions may require us to grant licenses to third parties. Such compulsory licenses could be extended to include some of our product candidates, which may limit our potential revenue opportunities.

Many countries, including European Union countries, have compulsory licensing laws under which a patent owner may be compelled under certain circumstances to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our and our licensors' efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time, and our product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

Given the amount of time required for the development, testing and regulatory review of new product candidates, such as our product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Currently, we own or license patent families that cover our LADD technology platform, which expire between 2022 and 2027, subject to any extensions, and we own or license patent families that cover Listeria strains engineered to express particular antigens, which expire between 2031 and 2033. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, which is limited to the approved indication (or any additional indications approved during the period of extension). However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

The BPCIA established 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. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. The law 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 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 products.

We anticipate being awarded market exclusivity for each of our biological product candidates that is subject to its own BLA for 12 years in the United States, 10 years in Europe and significant durations in other markets. However, the term of the patents that cover such product candidates may not extend beyond the applicable market exclusivity awarded by a particular country. For example, in the United States, if all of the patents that cover our particular biologic product expire before the 12-year market exclusivity expires, a third party could submit a marketing application for a biosimilar product four years after approval of our biologic product, and the FDA could immediately review the application and approve the biosimilar product for marketing 12 years after approval of our biologic.

Alternatively, a third party could submit a BLA for a similar or identical product any time after approval of our biologic product, and the FDA could immediately review and approve the similar or identical product for marketing and the third party could begin marketing the similar or identical product upon expiry of all of the patents that cover our particular biologic product.

Additionally, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. 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, and will depend on a number of marketplace and regulatory factors that are still developing.

Changes in patent law, including recent patent reform legislation, could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involve technological and legal complexity, and obtaining and enforcing pharmaceutical patents is costly, time-consuming, and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. For example, the U.S. 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 and our licensors' 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 decisions by Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our and our licensors' ability to obtain new patents or to enforce existing patents and patents we and our licensors may obtain in the future. Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our and our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents.

In September 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a "first to file" system in which the first inventor to file a patent application will be entitled to the patent. Third parties are allowed to submit prior art before the issuance of a patent by the USPTO and may become involved in opposition, derivation, reexamination, inter-partes review or interference proceedings challenging our patent rights or the patent rights of our licensors. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our or our licensors' patent rights, which could adversely affect our competitive position.

The USPTO is currently developing regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, did not become effective until March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents and those licensed to us.

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

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent 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. Noncompliance 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 or our licensors fail to maintain the patents and patent applications covering our product candidates, our competitive position would be adversely affected.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming and unsuccessful and have a material adverse effect on the success of our business.

Competitors may infringe our patents or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. Also, third parties may initiate legal proceedings against us or our licensors to challenge the validity or scope of intellectual property rights we own or control. These proceedings can be expensive and time consuming. Many of our current and potential competitors have the ability to dedicate substantially greater resources to defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, in an infringement proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly. 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. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments in any such proceedings. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock.

We may be subject to claims by third parties asserting that our licensors, employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees and our licensors' employees, including our senior management, were previously employed at universities or at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, including each member of our senior management, executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such third party. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- Others may be able to make compounds or biologics that are the same as or similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed.
- We or our licensors or any strategic partners might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or have exclusively licensed.
- We or our licensors might not have been the first to file patent applications covering certain of our inventions.
- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights.
- It is possible that our pending patent applications will not lead to issued patents.
- Issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges.
- Our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as 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.
- We may not develop additional proprietary technologies that are patentable.
- The patents of others may have an adverse effect on our business.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, know-how and confidential and proprietary information. To maintain the confidentiality of trade secrets and proprietary information, we will enter into confidentiality agreements with our employees, consultants and

collaborators upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. Our agreements with employees also provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential

information. To the extent that our employees, consultants or contractors use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions.

Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information. The disclosure of our trade secrets would impair our competitive position and may materially harm our business, financial condition and results of operations.

Risks Related to our Financial Results

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 in the future, which makes it difficult for us to predict our future operating results. From time to time, in addition to existing agreements with Janssen and Novartis, we may enter into license or collaboration agreements with other companies that include development funding and significant upfront and milestone payments and/or royalties, which may become an important source of our revenue. Accordingly, our revenue may depend on development funding and the achievement of development and clinical milestones under current and any potential future license and collaboration agreements and sales of our products, if approved. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next.

In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award as approved by the compensation committee and sub-committees, and recognize the cost as an expense over the employee’s requisite service period. As the variables that we use as a basis for valuing these awards change over time, including our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly.

Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and cost of, and level of investment in, research and development activities relating to our current and any future product candidates, which will change from time to time;
- our ability to enroll patients in clinical trials and the timing of enrollment;
- the cost of manufacturing our current and any future product candidates, which may vary depending on FDA guidelines and requirements, the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we will or may incur to acquire or develop additional product candidates and technologies;
- the timing and outcomes of clinical studies for our product candidates or competing product candidates;
- competition from existing and potential future drugs that compete with our product candidates, and changes in the competitive landscape of our industry, including consolidation among our competitors or partners;
- any delays in regulatory review or approval of CRS-207 or any of our other product candidates;
- the level of demand for our product candidates, if approved, which may fluctuate significantly and be difficult to predict;
- the risk/benefit profile, cost and reimbursement policies with respect to our products candidates, if approved, and existing and potential future drugs that compete with our product candidates;
- our ability to commercialize our product candidates, if approved, inside and outside of the United States, either independently or working with third parties;
- our ability to establish and maintain collaborations, licensing or other arrangements;
- our ability to adequately support future growth;
- potential unforeseen business disruptions that increase our costs or expenses;
- future accounting pronouncements or changes in our accounting policies; and
- the changing and volatile global economic environment.

The cumulative effect 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.

Our ability to use our net operating loss carryforwards to offset future taxable income, and our ability to use our tax credit carryforwards, may be subject to certain limitations.

Our ability to use our federal and state net operating losses to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income before the expiration dates of the net operating losses, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our net operating losses. In addition, a corporation that undergoes an "ownership change" under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, is subject to limitations on its ability to utilize its pre-change net operating loss carryforwards, or NOLs, to offset future taxable income and its ability to utilize tax credit carryforwards. As of December 31, 2015, we reported U.S. federal and state NOLs of approximately $66.8 million and $7.7 million, respectively.

Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, our ability to utilize NOL carryforwards or other tax attributes, such as research tax credits, in any taxable year may be limited if we have experienced an "ownership change." Generally, a Section 382 ownership change occurs if one or more stockholders or groups of stockholders who owns at least 5% of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a specified testing period. Similar rules may apply under state tax laws. We have experienced an ownership change that we believe under Section 382 of the Code will result in limitations in our ability to utilize net operating losses and credits. In addition, we may experience future ownership changes as a result of future offerings or other changes in ownership of our stock. As a result, the amount of the NOLs and research and credit carryforwards presented in our financial statements could be limited and may expire unutilized.

Risks Related to Ownership of our Common Stock

The price of our stock may be volatile, and you could lose all or part of your investment.

The trading price of our common stock has been, and is likely to continue to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Annual Report on Form 10-K, these factors include:

- the commencement, enrollment or results of the planned clinical trials of our product candidates or any future clinical trials we may conduct, or changes in the development status of our product candidates;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- adverse results or delays in clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning our manufacturers;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- our inability to establish collaborations if needed;
- our failure to commercialize our product candidates;

- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates;
- side effects or results reported for competing products or product candidates, such as competing listeria based vaccines or other more general approaches to immuno-oncology, that are perceived to have similarities to ours;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;

- our ability to effectively manage our growth;
- the size and growth of our initial cancer target markets;
- our ability to successfully treat additional types of cancers or at different stages;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or immuno-oncology in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the NASDAQ Global Select Market and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results or financial condition.

An active trading market for our common stock may not be maintained.

Our common stock is currently traded on the NASDAQ Global Select Market, but we can provide no assurance that we will be able to maintain an active trading market for our shares on the NASDAQ Global Select Market or any other exchange in the future. If there is no active market for our common stock, it may be difficult for our stockholders to sell shares without depressing the market price for the shares or at all.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

As widely reported, global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. We cannot assure you that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

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At December 31, 2015, we had $431.0 million of cash and cash equivalents and marketable securities. While we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents and marketable securities since December 31, 2015, we cannot assure you that further deterioration of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or our ability to meet our financing objectives. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock.

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

Our executive officers, directors, and 5% stockholders together beneficially own a significant percentage of our voting stock. These stockholders may be able to determine the outcome of matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

We are an emerging growth company and are taking advantage of reduced disclosure and governance applicable to emerging growth companies, which could make our common stock less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act, and we are taking advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We will remain an emerging growth company until the earliest of (1) December 31, 2020, (2) the last day of the fiscal year (a) in which we have total annual gross revenue of at least $1.0 billion or (b) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed $700.0 million as of the prior June 30th, and (3) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Even after we no longer qualify as an emerging growth company, we may still qualify as a “smaller reporting company” which would allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the

application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

Complying with the laws and regulations affecting public companies has increased and will increase our costs and the demands on management and could harm our operating results.

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses. We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, which requires, among other things, that we file with the Securities and Exchange Commission, or the SEC, annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and the NASDAQ Global Select Market to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the SEC has adopted and will adopt additional rules and regulations, such as mandatory “say on pay” voting requirements, that will apply to us when we cease to be an emerging growth company. Stockholder activism, the current political environment and the current high level of government

intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. To the extent these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

If, in the future, we are no longer an emerging growth company, we may not be exempt from various reporting requirements. For example, the Sarbanes-Oxley Act requires us, among other things, to assess the effectiveness of our internal control over financial reporting annually and to assess the effectiveness of our disclosure controls and procedures quarterly. Section 404 of the Sarbanes-Oxley Act ("Section 404") would require us to perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on, and our independent registered public accounting firm potentially to attest to, the effectiveness of our internal control over financial reporting. Our compliance with applicable provisions of Section 404 will require that we incur substantial accounting expense and expend significant management time on compliance-related issues as we implement additional corporate governance practices and comply with reporting requirements. Moreover, if we are not able to comply with the requirements of Section 404 applicable to us in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources. Furthermore, investor perceptions of our company may suffer if deficiencies are found, and this could cause a decline in the market price of our stock. Irrespective of compliance with Section 404, any failure of our internal control over financial reporting could have a material adverse effect on our stated operating results and harm our reputation. If we are unable to implement these requirements effectively or efficiently, it could harm our operations, financial reporting, or financial results and could result in an adverse opinion on our internal control over financial reporting from our independent registered public accounting firm.

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Moreover, holders of certain shares of our common stock have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have registered all currently reserved shares of common stock that we may issue under our equity compensation plans and intend to register in the future any additional reserved or issued shares of common stock. These registered shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our 2015 Plan, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our common stock.

Pursuant to our equity incentive plans, our compensation committee is authorized to grant equity-based incentive awards to our employees, non-employee directors and consultants. Future grants of restricted stock units, options and other equity awards and issuances of common stock under our equity incentive plans will result in dilution and may have an adverse effect on the market price of our common stock.

Additionally, the number of shares of our common stock reserved for issuance under our 2015 Plan will automatically increase on January 1 of each year, beginning on January 1, 2016 and continuing through and including January 1, 2025, by 4% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors. Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer, or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

Our 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 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 certificate of incorporation or our 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.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no securities or industry analysts commence coverage of our company, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

We lease an approximately 25,000 square foot facility in Berkeley, California for research and development and administrative activities. The current lease agreement commenced on June 1, 2014 and has an initial term expiring on August 31, 2016. In February 2015, we entered into an addendum to the lease, which extends the term of the lease through December 31, 2018, with an option to extend until December 31, 2020.

In September 2015, we entered into an Office/Laboratory Lease with Seventh Street Properties VII, LLC relating to the lease of approximately 56,000 square feet of office and laboratory space at a facility located in Berkeley, California. The term of the lease commences when the Landlord delivers possession of the property to us, which is currently estimated to be on June 1, 2016. Upon commencement of the lease, the lease has an initial term of twelve years. We have the option to extend the lease beyond the initial term for up to two renewal terms of five years each.

We also lease a research and development facility in the Netherlands for employees of Aduro Biotech Europe. We believe that our existing facilities are adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms.

Item 3. Legal Proceedings.

We are not currently subject to any material legal proceedings.

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 Price of Common Stock

Our common stock has been listed on the NASDAQ Global Select Market under the symbol "ADRO" since April 15, 2015. Prior to that date, there was no public trading market for our common stock. The following table sets forth for the period indicated the high and low sales prices per share of our common stock as reported on the NASDAQ Stock Market:

	High	Low
Year Ended December 31, 2015:		
Second Quarter (from April 15, 2015)	$49.25	$24.68
Third Quarter	$32.19	$16.28
Fourth Quarter	$34.95	$18.40

On March 2, 2016, the last reported sale price of our common stock on the NASDAQ Global Select Market was $16.64 per share.

Holders of Record

As of March 2, 2016, we had 184 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

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

Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans is incorporated by reference herein to Item 12 of Part III of this Annual Report on Form 10-K.

Stock Performance Graph

This performance graph shall not be deemed “soliciting material” or to be “filed” with the SEC for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (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 of 1933, as amended, or the Exchange Act.

The graph below shows the cumulative total stockholder return assuming the investment of $100.00 on the date specified in each of our common stock, The NASDAQ Global Market Index, and the NASDAQ Biotechnology Index for the period commencing on April 15, 2015 (the first day of trading of our common stock) and ending on December 31, 2015. The comparisons in the table are required by the Securities and Exchange Commission and are not intended to forecast or be indicative of future performance of our common stock. All amounts are shown are based on the closing price with the exception of April 15, 2015 which is the opening price based on initial trading of Aduro stock.

Recent Sales of Unregistered Securities

(1) In October 2015, we issued 697,306 shares of our common stock as partial consideration to acquire of all of the issued and outstanding shares of BioNovion Holding B.V., our wholly-owned subsidiary known as Aduro Biotech Europe.
(2) From October 1, 2015 to December 31, 2015, we issued 17,280 shares of common stock pursuant to the cash exercise of warrants to purchase our common stock at an exercise price of $0.6944 per share. We received cash proceeds of approximately $12,000 from the exercise of such warrants. These warrants were issued to one accredited investor.

The offer, sale, and issuance of the securities described above was deemed to be exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act and/or Regulation S or Regulation D promulgated thereunder as a transaction by an issuer not involving a public offering. The recipients of securities in these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in this transaction. The recipients of securities in these transactions were accredited investors and had adequate access, through employment, business or other relationships, to information about us.

Item 5(b). Use of Proceeds from our Public Offering of Common Stock

On April 14, 2015, our registration statement on Form S-1 (File No. 333-202667) relating to our initial public offering, or the IPO, of common stock became effective. The IPO closed on April 20, 2015 at which time we issued 8,050,000 shares of our common stock at an initial offering price of $17.00 per share. We received net proceeds from the IPO of $124.2 million, after deducting the underwriting discount of $9.6 million and offering related expenses paid by us of $3.0 million. None of the expenses associated with the IPO were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to their associates, or to our affiliates. Merrill, Lynch, Pierce, Fenner & Smith Incorporated and Leerink Partners LLC acted as joint book-running managers and William Blair & Company, L.L.C. and Canaccord Genuity Inc. acted as co-managers for the offering.

Shares of our common stock began trading on the NASDAQ Global Select Market on April 15, 2015. The shares were registered under the Securities Act on registration statement on Form S-1 (Registration No. 333-202667).

There has been no material change in the planned use of proceeds from the IPO from that described in the prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on April 15, 2015. As of December 31, 2015, we had used approximately $69.0 million of the proceeds from our IPO.

Item 5(c). Repurchases of Shares or of Company Equity Securities

None.

Item 6. Selected Financial Data.

The selected consolidated financial data included in this section are not intended to replace the consolidated financial statements included elsewhere in this Annual Report on Form 10-K. We derived the selected consolidated statements of operations data for the years ended December 31, 2015, 2014 and 2013 and the selected consolidated balance sheet data at December 31, 2015 and 2014 from our audited consolidated financial statements included elsewhere in this report. We derived the selected balance sheet data at December 31, 2013 from our audited financial statements which are 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. You should read the selected historical consolidated financial data below in conjunction with the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and the audited consolidated financial statements included elsewhere in this report.

	Year Ended December 31,		
	2015	2014	2013
	(in thousands, except share and per share data)		
Consolidated Statements of Operations Data:			
Revenue:			
Collaboration and license revenue	$71,689	$13,038	$—
Grant revenue	1,290	351	828
Total revenue	72,979	13,389	828
Operating expenses:			
Research and development[1]	58,649	23,513	10,687
General and administrative[1]	27,805	8,994	4,677
Amortization of intangibles	89	—	—
Total operating expenses	86,543	32,507	15,364
Loss from operations	(13,564)	(19,118)	(14,536)
Loss from remeasurement of fair value of warrants	(26,077)[4]	(566)	(162)
Gain on extinguishment of convertible promissory notes	—	3,553[3]	—
Interest income (expense), net	494	(2,395)[2]	(1,371)
Other (expense) income, net	(161)	1,512	15
Loss before income tax	(39,308)	(17,014)	(16,054)
Income tax benefit	99	—	—
Net loss	$(39,209)	$(17,014)	$(16,054)
Net loss per common share, basic and diluted	$(0.88)	$(53.06)	$(55.80)
Shares used in computing net loss per common share, basic and diluted	44,706,393	320,686	287,711

(1) Includes stock-based compensation as follows:

	Year Ended December 31,		
	2015	2014	2013
	(in thousands)		
Research and development	$2,493	$202	$194
General and administrative	5,937	368	215
Total stock-based compensation	$8,430	$570	$409

(2) Includes amortization of debt discount associated with convertible promissory notes due to the issuance of warrants and beneficial conversion feature associated with such convertible promissory notes. See Note 7 to our audited consolidated financial statements included elsewhere in this report.

(3) Upon the conversion of convertible promissory notes to related parties into Series C convertible preferred stock in May 2014, a gain on extinguishment was recorded because the amount allocated to reacquire the convertible notes was less than the carrying value of the notes. See Note 7 to our audited consolidated financial statements included elsewhere in this report.

(4) In 2015, the Company remeasured warrants to their fair value of $27.1 million and recognized a loss from remeasurement of $26.1 million. The carrying value of the warrants of $27.1 million was reclassified to additional paid-in capital. See Note 14 to our audited consolidated financial statements included elsewhere in this report.

	As of December 31,		
	2015	2014	2013
	(in thousands)		
Consolidated Balance Sheet Data:			
Cash, cash equivalents and marketable securities	$431,045	$119,456	$8,532
Working capital	393,438	81,006	(5,075)
Total assets	481,825	126,462	9,880
Note payable to related party	—	—	200
Convertible promissory notes payable to related parties, net	—	—	12,789
Convertible preferred stock warrant liability	—	100	72
Common stock warrant liability	—	889	505
Convertible preferred stock	—	139,963	32,224
Accumulated deficit	(100,852)	(61,643)	(44,629)
Total stockholders' equity (deficit)	261,622	(61,297)	(38,758)

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 together with the section of this Annual Report on Form 10-K titled "Selected Financial Data" and our consolidated financial statements included elsewhere in this report. This discussion and other parts of this report contain forward-looking statements that involve risk and uncertainties, such as statements of our plans, objectives, expectations and intentions. As a result of many factors, including those factors set forth in the "Risk Factors" section of this report, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage immunotherapy company focused on the discovery, development and commercialization of therapies that transform the treatment of challenging diseases. Our first-in-class technology platforms, which are designed to harness the body's natural immune system, are being investigated in cancer indications and have the potential to expand into autoimmune and infectious diseases. Our Live, Attenuated, Double-Deleted, or LADD, Listeria monocytogenes technology platform is engineered to express tumor-associated antigens to induce specific and targeted immune responses. Based on compelling clinical data in advanced cancers, this platform is being developed as a treatment for multiple indications, including pancreatic, ovarian, lung and prostate cancers, mesothelioma and glioblastoma. Our STING Pathway Activator platform is designed to activate the intracellular Stimulator of Interferon Genes, or STING receptor, resulting in a potent tumor-specific immune response. Our B-select monoclonal antibody platform includes a number of immune modulating assets in research and preclinical development. We are also collaborating with leading global pharmaceutical companies to expand our products and technology platforms.

Our lead LADD product candidate, CRS-207, is an immuno-oncology therapy (a class of therapies that leverage the patient's immune system to slow the growth and spread of, or eliminate, tumor cells). Immuno-oncology is an emerging field of cancer therapy that aims to activate the immune system in the tumor microenvironment to create and enhance anti-tumor immune responses, as well as to overcome the immuno-suppressive mechanisms that cancer cells have developed against the immune system. Recent developments in the field of immuno-oncology, including checkpoint inhibitors—therapies that have mechanisms focused on unmasking hidden cancer cells—have shown the potential to provide dramatic efficacy and extended survival, even in cancers where conventional therapies, such as surgery, chemotherapy and radiotherapy, have failed. The immunotherapy field is rapidly advancing with new immuno-oncology combinations that focus on strengthening therapeutic efficacy in a wide range of cancers. We intend to pursue a broad strategy of combining our technology platforms with conventional and novel immuno-oncology therapies, based on their mechanisms of action, safety profiles and versatility.

CRS-207 is currently being developed in metastatic pancreatic cancer, unresectable malignant pleural mesothelioma and ovarian cancer. In a completed randomized controlled Phase 2a clinical trial in metastatic pancreatic cancer patients, CRS-207 demonstrated a statistically significant improvement in overall survival when combined with GVAX Pancreas, a cellular vaccine product candidate. The 93-patient two-arm Phase 2a clinical trial was designed to compare the combination of CRS-207 and GVAX Pancreas versus GVAX Pancreas alone. The trial met the primary efficacy endpoint of overall survival at an interim analysis and was stopped upon recommendation from the Data Monitoring Committee. Based on the data from this study, our lead immuno-oncology regimen of CRS-207 and GVAX Pancreas was granted Breakthrough Therapy designation by the U.S. Food and Drug Administration, or FDA. Breakthrough Therapy designation is intended to expedite the development and review of products that treat serious or life-threatening conditions. We have obtained orphan drug designation for CRS-207 and GVAX Pancreas for the treatment of pancreatic cancer and for CRS-207 for the treatment of mesothelioma in the United States and European Union from the FDA and European Medicines Agency, respectively. Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biologic intended to treat a rare disease or condition. Orphan drug designation entitles a party to certain financial incentives and can provide limited market exclusivity in certain circumstances.

We are developing a pipeline of proprietary product candidates on our own and through partnerships. We have developed two LADD product candidates in collaboration with Janssen Biotech, Inc., or Janssen, targeting prostate and lung cancers and STING Activator product candidates in oncology under our worldwide collaboration with Novartis Pharmaceuticals Corporation, or Novartis. In addition, we are developing monoclonal antibodies, or mAbs, with the potential to yield novel immunotherapy combinations as a result of our recent acquisition of BioNovion Holding B.V., our wholly-owned subsidiary known as Aduro Biotech Europe, based in the Netherlands. We have intellectual property protection on our LADD and STING Pathway Activator technology platforms and each of our product candidates, which we believe we will maintain into the 2030s.

Since commencing our operations, our efforts have been focused on research, development and the advancement of our product candidates into clinical trials. As a result we have incurred significant losses. We have funded our operations primarily through the sale of common stock and convertible preferred stock, the issuance of convertible promissory notes, licensing agreements with pharmaceutical partners and revenue from government grants. We incurred a net loss of $39.2 million, $17.0 million, and $16.1

million for the years ended December 31, 2015, 2014 and 2013, respectively. At December 31, 2015, our accumulated deficit was $100.9 million.

Financial Operations Overview

Revenue

We have not generated any revenue from product sales. Our revenue to date has been primarily derived from two research and license agreements we entered into with Janssen, a collaboration and license agreement we entered into with Novartis in March 2015, as well as research and development grants from the U.S. government. We recognize revenue related to research and development grants when the related research expenses are incurred and our specific performance obligations under the terms of the respective contracts are satisfied. We recognize revenue from upfront payments under our Janssen and Novartis agreements ratably over the term of our estimated period of performance under the agreement. In addition to receiving upfront payments, we may also be entitled to milestone and other contingent payments upon achieving predefined objectives. Revenue from milestones, if they are nonrefundable and deemed substantive, are recognized upon successful accomplishment of the milestones. To the extent that non-substantive milestones are achieved and we have remaining performance obligations, milestones are deferred and recognized as revenue over the estimated remaining period of performance.

We expect that any revenue we generate from our research and license agreements with Janssen and Novartis, government research and development grants, and any future collaboration partners will fluctuate from year to year as a result of the timing and amount of milestones and other payments.

Research and Development Expenses

The largest component of our total operating expenses has historically been our investment in research and development activities, including the clinical development of our product candidates. Research and development expenses represent costs incurred to conduct research, such as the discovery and development of our product candidates, as well as the development of product candidates pursuant to our research and license agreement with Janssen. We recognize all research and development costs as they are incurred. Clinical trial costs, contract manufacturing and other development costs incurred by third parties are expensed as the contracted work is performed.

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

General and Administrative Expenses

General and administrative expenses include personnel costs, expenses for outside professional services and other allocated expenses. Personnel costs consist of salaries, bonuses, benefits and stock-based compensation. Outside professional services consist of legal, accounting and audit services and other consulting fees. Allocated expenses consist of rent expense related to our office and research and development facility. We have incurred additional expenses as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the Securities and Exchange Commission, and those of any national securities exchange on which our

securities are traded, additional insurance expenses, investor relations activities and other administrative and professional services.

Loss from remeasurement of fair value of warrants

Loss from remeasurement of fair value of warrants consists of losses from the remeasurement of the fair value of our liabilities related to our convertible preferred stock warrants and common stock warrants.

Prior to the IPO, our convertible preferred stock warrants were exercisable into shares that were contingently redeemable. Our common stock warrants were subject to performance conditions that could have resulted in the issuance of a variable number of shares. As such, these warrants were classified as liabilities in the consolidated balance sheets at their estimated fair values, and we recorded the change in the estimated fair values each reporting period as loss from remeasurement of fair value of warrants during the years ended December 31, 2015, 2014 and 2013. We continued to record adjustments to the estimated fair values of the convertible

preferred stock warrants until they converted into common stock warrants upon the closing of the IPO. We also continued to record adjustments to the estimated fair value of our common stock warrants until the performance conditions lapsed in April 2015, at which time they were reclassified to additional paid-in capital.

Gain on Extinguishment of Convertible Promissory Notes

During 2014 and 2013, we issued convertible promissory notes to related parties, which were subsequently converted in May 2014 to Series C convertible preferred stock. The conversion of convertible promissory notes was determined to be an extinguishment of debt and a portion of the reacquisition price was allocated to the reacquisition of the embedded beneficial conversion feature. We recorded a gain on extinguishment, as the amount allocated to reacquire the notes was less than the carrying value of the notes.

Interest Income (Expense), Net

Interest income (expense), net consists of interest income from our cash equivalents and marketable securities. Interest expense consists of amortization of debt discount associated with convertible promissory note warrants, issuance of the equity component of a convertible promissory note and beneficial conversion features associated with certain convertible promissory notes, as well as stated interest costs associated with our borrowings.

Other Income (Expense), Net

Other income (expense), net, consists of the change in the fair value of the preferred stock derivative liability associated with our obligation to issue additional shares of Series C convertible preferred stock and foreign currency transaction gains and losses.In May 2014, we entered into a Series C convertible preferred stock purchase agreement. Under the agreement, we agreed to issue to the purchasers, and the purchasers agreed to purchase, additional shares of our Series C convertible preferred stock in tranches within a specified timeframe after the initial closing. We determined that the obligation to issue additional Series C convertible preferred stock at future dates was a freestanding financial instrument that should be accounted for as a liability. Accordingly, we recorded a preferred stock derivative liability related to this instrument at the time of the initial close in May 2014, and we remeasured the liability at fair value at each reporting period with the corresponding gain or loss from the adjustment recorded as other income (expense), net until the tranche obligation either expired or was fulfilled. In December 2014, the final tranche of the Series C convertible preferred stock was issued and the corresponding preferred stock derivative liability was remeasured and then reclassified as equity.

Results of Operations

Comparison of the Years Ended December 31, 2015 and 2014

	Year Ended December 31, 2015	2014	Change $
	(in thousands)		
Revenue:			
Collaboration and license revenue	$71,689	$13,038	$58,651
Grant revenue	1,290	351	939
Total revenue	72,979	13,389	59,590
Operating expenses:			
Research and development	58,649	23,513	35,136
General and administrative	27,805	8,994	18,811
Amortization of intangibles	89	—	89
Total operating expenses	86,543	32,507	54,036
Loss from operations	(13,564)	(19,118)	5,554
Loss from remeasurement of fair value of warrants	(26,077)	(566)	(25,511)
Gain on extinguishment of convertible promissory notes	—	3,553	(3,553)
Interest income (expense), net	494	(2,395)	2,889
Other income (expense), net	(161)	1,512	(1,673)
Loss before income tax	(39,308)	(17,014)	(22,294)
Income tax benefit	99	—	99
Net loss	$(39,209)	$(17,014)	$(22,195)

Revenue

Collaboration and license revenue was $71.7 million for the year ended December 31, 2015, an increase of $58.7 million compared to the year ended December 31, 2014. The increase was primarily due to an increase of $31.3 million recognized as a portion of the upfront fees under the Novartis and Janssen agreements, an increase of $23.4 million recognized from development-related milestones that were achieved under the Janssen agreements and $3.7 million recognized from reimbursement of research and development costs.

Grant revenue was $1.3 million for the year ended December 31, 2015, an increase of $0.9 million compared to the year ended December 31, 2014, primarily due to significantly higher spending in research and development activities.

Research and Development Expenses

The following table summarizes our research and development expenses incurred during the years ended December 31, 2015 and 2014:

	Year Ended December 31, 2015	2014	Change $
	(in thousands)		

Contract manufacturing	$14,652	$5,246	$9,406
Licensing fees	9,839	1,617	8,222
Clinical development	13,594	7,547	6,047
Compensation and related personnel costs	10,959	5,010	5,949
Other research and development costs	6,611	3,611	3,000
Stock-based compensation expense	2,493	202	2,291
Facility costs	501	280	221
Total research and development	$58,649	$23,513	$35,136

Research and development expenses were $58.6 million for the year ended December 31, 2015, an increase of $35.1 million compared to the year ended December 31, 2014. The increase was primarily attributed to a $9.4 million increase in contract manufacturing expense related to higher manufacturing and process development costs for GVAX pancreas and development programs in collaboration with Janssen and Novartis; an $8.2 million increase in licensing fees primarily related to our STING Activator technology; a $6.0 million increase in clinical development expenses mainly associated with ongoing trials for our lead indication in pancreatic cancer; a $5.9 million increase in compensation expense primarily related to additional research and

development staff; a $3.0 million increase for other research and development costs principally related to contract research and higher utilization of consultants to support collaborations; and a $2.3 million increase in stock-based compensation expense.

General and Administrative Expenses

The following table summarizes our general and administrative expenses incurred during the years ended December 31, 2015 and 2014:

	Year Ended December 31,		Change
	2015	2014	$
	(in thousands)		
Stock-based compensation expense	$5,937	$368	$5,569
Compensation and related personnel costs	8,171	2,658	5,513
Outside professional services	9,852	4,784	5,068
Other general and administrative	2,368	536	1,832
Facility costs	1,477	648	829
Total general and administrative	$27,805	$8,994	$18,811

General and administrative expenses were $27.8 million for the year ended December 31, 2015, an increase of $18.8 million, compared to the year ended December 31, 2014. The increase was primarily related to a $5.6 million increase in stock-based compensation expense and a $5.5 million increase in compensation expense due to additional administrative personnel; a $5.1 million increase in professional, consulting and recruiting fees mainly related to operating as a public company as well as fees incurred for the acquisition of BioNovion Holding B.V., known as Aduro Biotech Europe; a $1.8 million increase in other general and administrative expenses including higher insurance; and an increase in facility costs of $0.8 million.

Loss from Remeasurement of Fair Value of Warrants

Loss from remeasurement of fair value of warrants was $26.1 million for the year ended December 31, 2015, an increase of $25.5 million, compared to the year ended December 31, 2014. As of April 2015, all of the convertible preferred stock warrants and common stock warrants were no longer subject to remeasurement due to the IPO or expiration of the performance condition and the total fair value was expensed on the statement of operations.

Gain on Extinguishment of Convertible Promissory Notes

During 2014 and 2013, we issued convertible promissory notes to related parties, which were subsequently converted in May 2014 to Series C convertible preferred stock. The conversion of convertible promissory notes was determined to be an extinguishment of debt and a portion of the reacquisition price was allocated to the reacquisition of the embedded beneficial conversion feature. We recorded a gain on extinguishment of $3.6 million during the year ended December 31, 2014, as the amount allocated to reacquire the notes was less than the carrying value of the notes.

Interest Income (Expense), Net

Interest income (expense), net was income of $0.5 million for the year ended December 31, 2015, an increase of $2.9 million, compared to the year ended December 31, 2014. The interest expense incurred in 2014 was primarily attributed to the amortization of debt discount associated with the warrants and beneficial conversion feature

associated with our convertible promissory notes payable to related parties. The interest income earned in 2015 relates to interest earned from cash equivalents and marketable securities.

Other Income (Expense), Net

Other income (expense), net was an expense of $0.2 million for the year ended December 31, 2015, a decrease of $1.7 million compared to the year ended December 31, 2014. The decrease was primarily due to the remeasurement of the fair value of the preferred stock derivative liability associated with the future issuance of our Series C convertible preferred stock. At December 31, 2014, there was no obligation remaining related to the future issuance of our Series C convertible preferred stock and therefore no preferred stock derivative liability on the consolidated balance sheets.

Comparison of the Years Ended December 31, 2014 and 2013

	Year Ended December 31,		Change
	2014	2013	$
	(in thousands)		
Revenue:			
Collaboration and license revenue	$13,038	$—	$13,038
Grant revenue	351	828	(477)
Total revenue	13,389	828	12,561
Operating expenses:			
Research and development	23,513	10,687	12,826
General and administrative	8,994	4,677	4,317
Total operating expenses	32,507	15,364	17,143
Loss from operations	(19,118)	(14,536)	(4,582)
Loss from remeasurement of fair value of warrants	(566)	(162)	(404)
Interest expense	(2,395)	(1,371)	(1,024)
Gain on extinguishment of convertible promissory notes	3,553	—	3,553
Other income (expense), net	1,512	15	1,497
Net loss	$(17,014)	$(16,054)	$(960)

Revenue

Collaboration and license revenue was $13.0 million for the year ended December 31, 2014, a $13.0 million increase compared to the year ended December 31, 2013, due to recognition of a portion of the upfront fees and substantive and non-substantive development-related milestones achieved under the Janssen agreements.

Grant revenue was $0.4 million for the year ended December 31, 2014, a decrease of $0.5 million compared to the year ended December 31, 2013, primarily due to our focus on other research and development activities which resulted in a decrease in grant-related research and development in 2014.

Research and Development Expenses

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

	Year Ended December 31,		Change
	2014	2013	$
	(in thousands)		
Clinical development	$7,547	$3,196	$4,351
Contract manufacturing	5,246	1,323	3,923
Other research and development costs	3,611	1,244	2,367
Compensation and related personnel costs	5,212	3,245	1,967
Licensing fees	1,617	461	1,156
Facility costs	280	218	62

Acquired GVAX technology	—	1,000	(1,000)
Total research and development	$23,513	$10,687	$12,826

Research and development expenses were $23.5 million for the year ended December 31, 2014, an increase of $12.8 million, compared to the year ended December 31, 2013. The increase was primarily attributed to a $4.4 million increase in clinical development expenses mainly associated with ongoing trials for our lead indication in pancreatic cancer; a $3.9 million increase in contract manufacturing costs of our clinical product candidates; a $2.4 million increase in other research and development costs; a $2.0 million increase in compensation expenses primarily related to additional research and development staff; and a $1.2 million increase in licensing fees primarily due to payment of sublicense fees in connection with the research and license agreement with Janssen. The increase was partially offset by the $1.0 million expense recognized in 2013 related to the acquisition of GVAX technology from BioSante Pharmaceuticals, Inc. (which later merged into ANI Pharmaceuticals, Inc.).

General and Administrative Expenses

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

	Year Ended December 31,		Change
	2014	2013	$
	(in thousands)		
Outside professional services	$4,784	$2,117	$2,667
Compensation and related personnel costs	3,026	1,895	1,131
Facility costs	648	375	273
Other general and administrative	536	290	246
Total general and administrative	$8,994	$4,677	$4,317

General and administrative expenses were $9.0 million for the year ended December 31, 2014, an increase of $4.3 million, compared to the year ended December 31, 2013. The increase was primarily due to a $2.7 million increase in legal fees related to licensing and general corporate matters and other professional services fees, including accounting fees, as well as a $1.1 million increase in compensation expenses primarily related to our additional administrative personnel.

Loss from Remeasurement of Fair Value of Warrants

Loss from remeasurement of fair value of warrants was $0.6 million for the year ended December 31, 2014, an increase of $0.4 million, compared to the year ended December 31, 2013. The increase was primarily due to the higher stock prices used in the remeasurement of the fair value of liability classified preferred and common stock warrants.

Interest Income (Expense), Net

Interest income (expense), net was an expense of $2.4 million for the year ended December 31, 2014, an increase of $1.0 million compared to the year ended December 31, 2013. The increase was primarily due to the amortization of debt discount associated with the warrants and beneficial conversion feature associated with our convertible promissory notes payable to related parties.

Gain on Extinguishment of Convertible Promissory Notes

During 2014 and 2013, we issued convertible promissory notes to related parties, which were subsequently converted in May 2014 to Series C convertible preferred stock. The conversion of convertible promissory notes was determined to be an extinguishment of debt and a portion of the reacquisition price was allocated to the reacquisition of the embedded beneficial conversion feature. We recorded a gain on extinguishment of $3.6 million during the year ended December 31, 2014, as the amount allocated to reacquire the notes was less than the carrying value of the notes.

Other Income (Expense), Net

Other income (expense), net was income of $1.5 million for the year ended December 31, 2014, an increase of $1.5 million compared to the year ended December 31, 2013. The increase was primarily due to the remeasurement of the fair value of the preferred stock derivative liability associated with the future issuance of our Series C convertible preferred stock. At December 31, 2014, there was no obligation remaining related to the future issuance of our Series

C convertible preferred stock and therefore no preferred stock derivative liability on the consolidated balance sheets.

Liquidity and Capital Resources

To date, our operations have been financed primarily by net proceeds from the IPO, sale of convertible preferred stock, proceeds from our collaboration and license agreements and revenue from government grants. At December 31, 2015, we had cash and cash equivalents and marketable securities of $431.0 million. We believe that our available cash and cash equivalents and marketable securities and anticipated funding from our collaboration agreements will be sufficient to fund our planned operations through 2018. We have based our cash sufficiency estimate on assumptions that may prove to be incorrect. If our assumptions prove to be incorrect, we could consume our available capital resources sooner than we currently expect or in excess of amounts that we currently expect, which could adversely affect our development activities.

In March 2015, we established a worldwide collaboration with Novartis for the development and commercialization of products containing an agonist of the molecular target known as STING in the field of oncology, including immuno-oncology and cancer vaccines. Under the Novartis Agreement, we received an upfront payment of $200.0 million in April 2015. We are also eligible to

receive up to an additional $250.0 million in development milestones and up to an additional $250.0 million in regulatory approval milestones. Concurrent with the entry into the Novartis Agreement, we and Novartis Institutes of BioMedical Research, Inc., or NIBR, entered into a stock purchase agreement under which NIBR purchased 2,361,029 shares of our Series E Preferred Stock (which converted into 1,699,940 shares of common stock at the completion of the IPO), for $25.0 million.

On April 20, 2015, we closed the IPO and sold 8,050,000 shares of our common stock (inclusive of 1,050,000 shares of common stock pursuant to the full exercise of the underwriters' option to purchase additional shares) at a price to the public of $17.00 per share. We received aggregate net proceeds of $124.2 million, net of underwriting discounts and offering expenses. We also sold to NIBR in a concurrent private placement 1,470,588 shares of common stock at a price of $17.00 per share for proceeds of $25.0 million. Upon the closing of the IPO, all then-outstanding shares of convertible preferred stock converted by their terms into 51,822,659 shares of common stock. Additionally, we amended and restated our certificate of incorporation effective April 14, 2015 to, among other things, change the authorized number of shares of common stock to 300,000,000 shares and the authorized number of shares of preferred stock to 10,000,000 shares.

Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, third-party clinical, manufacturing, and other research and development services, laboratory and related supplies and legal and other professional services. Cash used to fund operating expenses is impacted by the timing of when we pay expenses, as reflected in the change in our outstanding accounts payable and accrued expenses. We expect to incur substantial expenditures in the foreseeable future for the development and potential commercialization of our product candidates, specifically in connection with our Phase 2b ECLIPSE clinical trial in metastatic pancreatic cancer, manufacturing of our product candidates, and advancement of CRS-207 in combination with standard-of-care chemotherapy into Phase 3 clinical development for mesothelioma.

We plan to continue to fund our operations and capital funding needs through equity and/or debt financing. We may also consider entering into additional collaboration arrangements or selectively partnering for clinical development and commercialization. In addition, we expect to continue to opportunistically seek access to the equity capital markets to support our development efforts and operations. The sale of additional equity would result in additional dilution to our stockholders. The incurrence of debt financing would result in debt service obligations and the instruments governing such debt could provide for operating and financing covenants that would restrict our operations. To the extent that we raise additional funds through collaboration or partnering arrangements, we may be required to relinquish some of our rights to our technologies or rights to market and sell our products in certain geographies, grant licenses on terms that are not favorable to us, or issue equity that may be substantially dilutive to our stockholders. If we are not able to secure adequate additional funding, we may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible and/or suspend or curtail planned programs. Any of these actions could harm our business, results of operations, financial condition and future prospects.

Cash Flows

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

	Year Ended December 31,		
	2015	2014	2013
	(in thousands)		
Net cash provided by (used in):			
Operating activities	$154,810	$19,365	$(14,232)
Investing activities	(297,988)	(782)	(170)

Financing activities	174,178	92,341	19,239
Net change in cash and cash equivalents	$31,000	$110,924	$4,837

Operating Activities

Net cash provided by operating activities was $154.8 million for the year ended December 31, 2015, compared to $19.4 million for the year ended December 31, 2014. The increase in net cash provided by operating activities was primarily due to the upfront and milestone payments totaling approximately $224.4 million received from the research and license agreements with Novartis and Janssen during 2015, partially offset by increased operating expenses due to additional headcount, increased clinical trial activities and other research and development.

Net cash provided by operating activities was $19.4 million for the year ended December 31, 2014, compared to net cash used of $14.2 million for the year ended December 31, 2013. The increase in net cash provided was primarily due to the upfront and milestone payments totaling $46.0 million received from the research and license agreements with Janssen during 2014, partially

offset by increased operating expenses due to additional headcount, increased clinical trial activities and other research and development.

Investing Activities

Net cash used in investing activities was $298.0 million for the year ended December 31, 2015, compared to $0.8 million for the year ended December 31, 2014. The increase in net cash used was primarily due to the purchase of marketable securities, as well as payments made to acquire BioNovion Holding B.V., known as Aduro Biotech Europe, partially offset by proceeds from maturities of marketable securities.

Net cash used in investing activities was $0.8 million for the year ended December 31, 2014, compared to $0.2 million for the year ended December 31, 2013. The increase in net cash used was the result of purchases of laboratory and office equipment, furniture and leasehold improvements.

Financing Activities

Net cash provided by financing activities was $174.2 million for the year ended December 31, 2015, compared to $92.3 million for the year ended December 31, 2014. The increase was primarily related to $150.3 million in net proceeds from the IPO and private placement and $22.5 million in net proceeds from sale of convertible preferred stock.

Net cash provided by financing activities was $92.3 million for the year ended December 31, 2014, compared to $19.2 million for the year ended December 31, 2013. The increase was primarily related to $51.4 million in gross proceeds from the issuance of Series D convertible preferred stock, $41.9 million in net proceeds from the issuance of Series C convertible preferred stock and $0.3 million in proceeds from the issuance of convertible promissory notes, which were converted into Series C convertible preferred stock in May 2014, partially offset by $1.1 million of payments made related to preparing to become a public company.

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 in the United States, or GAAP. 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 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.

Revenue Recognition

We have historically generated revenue through government grants and, beginning in 2014, from funds received under research and license arrangements. Government grants provide funding for certain types of expenditures in connection with research and development activities over a contractually-defined period. Revenue related to government grants is recognized in the period during which the related costs are incurred and the related services are rendered, provided that the applicable performance obligations under the government grants have been met. We intend to continue to evaluate pursuing additional government grant opportunities on a case-by-case basis.

Revenues from research activities made under collaboration arrangements are recognized when there is persuasive evidence that an arrangement exists, services have been rendered, the price is fixed or determinable and collectability is reasonably assured. Revenue generated from our collaboration arrangements is not subject to repayment and typically includes upfront fees, milestone payments and royalties on future licensee's product sales. Our obligations under collaboration agreements may include the transfer of intellectual property rights in the form of licenses, obligations to provide research and development services and obligations to participate on certain development committees with the collaboration party. We make judgments that affect the period over which we recognize revenue. On a quarterly basis, we review our estimated period of performance for our collaboration and license revenue based on the progress under the arrangement and account for the impact of any changes in estimated periods of performance on a prospective basis. We record amounts received prior to satisfying the above revenue recognition criteria as deferred revenue until all applicable revenue recognition criteria are met. Deferred revenue represents the portion of research or license payments received that have not been earned.

For revenue agreements with multiple-element arrangements, such as license and development agreements, we allocate revenue to each non-contingent element based on the relative selling price of each element. When applying the relative selling price method, we determine the selling price for each deliverable using vendor-specific objective evidence or third-party evidence. If neither exists, we use the best estimate of selling price for that deliverable. Revenue allocated is then recognized when the four basic revenue recognition criteria are met for each element. Our obligations under the agreements may include the transfer of intellectual property rights in the form of licenses, obligations to provide research and development services and obligations to participate on certain development committees.

Milestones are considered substantive if all of the following conditions are met: (1) the milestone is nonrefundable; (2) achievement of the milestone was not reasonably assured at the inception of the arrangement; (3) substantive effort is involved to achieve the milestone; and (4) the amount of the milestone appears reasonable in relation to the effort expended, and the other milestones in the arrangement and the related risk associated with the achievement of the milestone and any ongoing research and development or other services are priced at fair value. Such payments that are contingent upon the achievement of a substantive milestone are recognized entirely as revenue in the period in which the milestone is achieved. To the extent that non- substantive milestones are achieved and we have remaining performance obligations, milestones are deferred and recognized as revenue over the estimated remaining period of performance. If there were no remaining performance obligations, we recognize the revenue in the period it is earned.

Business Combinations

We account for acquisitions using the acquisition method of accounting which requires the recognition of tangible and identifiable intangible assets acquired and liabilities assumed at their estimated fair values as of the business combination date. We allocate any excess purchase price over the estimated fair value assigned to the net tangible and identifiable intangible assets acquired and liabilities assumed to goodwill. Contingent consideration is included within the acquisition cost and is recognized at its fair value on the acquisition date. A liability resulting from contingent consideration is remeasured to fair value at each reporting date until the contingency is resolved and changes in fair value are recognized in earnings. Transaction costs are expensed as incurred in general and administrative expenses. Results of operations and cash flows of acquired companies are included in our operating results from the date of acquisition.

Goodwill and Intangible Assets

Goodwill represents the excess of the consideration transferred over the estimated fair value of assets acquired and liabilities assumed in a business combination. Intangible assets with indefinite useful lives are related to acquired in-process research and development, or IPR&D, projects and are measured at their respective fair values as of the acquisition date. Goodwill and intangible assets with indefinite useful lives are not amortized but are tested for impairment on an annual basis or more frequently if we become aware of any events or changes that would indicate the fair values of the assets are below their carrying amounts. Intangible assets related to IPR&D projects are considered to be indefinite-lived until the completion or abandonment of the associated R&D efforts. If and when development is complete, which generally occurs if and when regulatory approval to market a product is obtained, the associated assets are deemed finite-lived and are amortized based on their respective estimated useful lives at that point in time. We have not recorded an impairment of goodwill or IPR&D since inception.

Intangible assets with finite useful lives are amortized over their estimated useful lives, primarily on a straight-line basis.

Impairment of Long-Lived Assets

We review our long-lived assets for impairment whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. Recoverability of assets held and used is measured by comparison of the

carrying amount of an asset to the future undiscounted cash flows expected to be generated from the use of the asset and its eventual disposition. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount exceeds the fair value of the impaired assets. Assets to be disposed of are reported at the lower of their carrying amount or fair value less cost to sell.

Accrued Research and Development Costs

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

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

Stock-Based Compensation

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

We recorded stock-based compensation expense related to options granted of $8.4 million, $0.6 million and $0.4 million in each of the years ended December 31, 2015, 2014 and 2013, respectively.

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

Fair Value of Common Stock. Prior to the IPO in April 2015, our board of directors, determined the fair value of our common stock by taking into consideration, among other things, contemporaneous valuations of our common stock prepared by an unrelated third-party valuation firm. Given the previous absence of a public trading market for our common stock, our board of directors exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of our common stock, including our stage of development; progress of our research and development efforts; the rights, preferences and privileges of our preferred stock relative to those of our common stock; equity market conditions affecting comparable public companies and the lack of marketability of our common stock.

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

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

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

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

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.

Historically, for all periods prior to the IPO, the fair value of the shares of common stock underlying our share-based awards were estimated on each grant date by our board of directors. In order to determine the fair value of our common stock underlying option grants, our board of directors considered, among other things, contemporaneous valuations of our common stock prepared by an unrelated third-party valuation firm at February 28, 2013, March 31, 2014, June 30, 2014, September 30, 2014, December 31, 2014 and March 6, 2015 in accordance with the guidance provide by the American Institute of Certified Public Accountants Practice Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. Given the absence of a public trading market for our common stock, our board of directors exercised reasonable judgment and considered a number of objective and subjective factors to

determine the best estimate of the fair value of our common stock, including our stage of development; progress of our research and development efforts; the rights, preferences and privileges of our preferred stock relative to those of our common stock; equity market conditions affecting comparable public companies and the lack of marketability of our common stock.

The unrelated third-party valuations were prepared using the discounted cash flow approach to estimate our aggregate enterprise value at each valuation date. To arrive at the estimated fair value of our common stock, the enterprise value was allocated across our classes and series of capital stock using the Probability Weighted Expected Return Method, or PWERM, or Option Pricing Method, or OPM. The PWERM is a scenario-based analysis that estimates the value per share of common stock based on the probability-weighted present value of expected future equity values for the common stock, under various possible future liquidity event scenarios, including initial public offering, sale of the company, dissolution and staying private. The OPM values each equity class by creating a series of call options on the equity value, with exercise prices based on the liquidation preferences, participation rights and strike prices of derivatives.

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

Income Taxes

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

At December 31, 2015, we generated net operating loss, or NOL, carryforwards (before tax effects) for federal and state income tax purposes of $66.8 million and $7.7 million, respectively. Of this amount, $12.9 million and $1.5 million represent federal and state deductions from stock-based compensation which will be recorded as an adjustment to additional paid-in capital when they reduce tax payable. These federal and state NOL carryforwards will begin to expire in 2027 and 2033, respectively, if not utilized. In addition, we generated federal and state research and development tax credit carryforwards of $1.5 million and $2.5 million, respectively, to offset future income tax liabilities. The federal research and development tax credits can be carried forward for 20 years and will start to expire in 2034, if not utilized, while the state research and development tax credits can be carried forward indefinitely. Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, our ability to utilize NOL carryforwards or other tax attributes, such as research tax credits, in any taxable year may be limited if we have experienced an “ownership change.” We have experienced an ownership change that we believe under Section 382 of the Code will result in limitations in our ability to utilize net operating losses and credits

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

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

Contractual Obligations and Other Commitments

The following table summarizes our contractual obligations at December 31, 2015:

	Payments due by period				
	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years	Total
	(in thousands)				
Operating leases	$2,653	$9,229	$9,850	$45,397	$67,129
Total contractual obligations	$2,653	$9,229	$9,850	$45,397	$67,129

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

We are obligated to make future payments to third parties under in-license agreements, including sublicense fees, royalties and payments that become due and payable on the achievement of certain development and commercialization milestones. As the amount and timing of sublicense fees and the achievement and timing of these milestones are not probable and estimable, such commitments have not been included on our consolidated balance sheets or in the contractual obligations table above.

JOBS Act

We are an “emerging growth company” as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, and therefore we may take advantage of certain exemptions from various public company reporting requirements, including not being required to have our internal control over financial reporting audited by our independent registered public accounting firm pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments. We may take advantage of these exemptions until we are no longer an “emerging growth company.” We may remain an “emerging growth company” for up to five years. We will cease to be an “emerging growth company” upon the earliest of: (1) December 31, 2020, (2) the last day of the first fiscal year in which our annual gross revenues are $1.0 billion or more, (3) the date on which we have, during the previous rolling three-year period, issued more than $1.0 billion in non-convertible debt securities, and (4) the date on which we are deemed to be a “large accelerated filer” as defined in the Securities Exchange Act of 1934, as amended, or the Exchange Act. We have chosen to irrevocably opt out of the extended transition periods available under the JOBS Act for complying with new or revised accounting standards.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, or FASB, issued Auditing Standards Update, or ASU, No. 2014-09, Revenue from Contracts with Customers (Topic 606). This ASU affects any entity that either enters into contracts with customers to transfer goods and services or enters into contracts for the transfer of nonfinancial assets. ASU 2014-09 will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. The standard’s core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which it expects to be entitled in exchange for those goods or services. In doing so, companies will need to use more judgment and make more estimates than under the currently effective guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. In July 2015, the FASB voted to defer the effective date of the ASU by one year to December 15, 2017 for fiscal years, and interim periods within those periods, beginning after that date. Entities are permitted to adopt in accordance with the original effective date of December 15, 2016 if they choose. We are currently evaluating the impact of this guidance on our consolidated financial statements

In November 2015, the FASB issued ASU No. 2015-17, Balance Sheet Classification of Deferred Taxes, which requires that deferred tax assets and liabilities be classified as noncurrent in a classified statement of financial position. The accounting standard is effective, either prospectively to all deferred tax assets and liabilities or retrospectively to all periods presented, for annual periods beginning after December 15, 2016, and interim periods therein. Early adoption is permitted as of the beginning of an interim or annual reporting period. We early adopted this standard as of December 31, 2015 on a prospective basis which did not have a material impact on our financial statements because in the prior year we did not have material deferred tax balances.

In January 2016, the FASB issued ASU No. 2016-01, Financial Instruments--Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities, which amends the guidance in U.S. GAAP on the classification and measurement of financial instruments. Changes to the current guidance primarily affects the accounting for equity investments, financial liabilities under the fair value option, and the presentation and disclosure requirements for financial instruments. In addition, the ASU clarifies guidance related to the valuation allowance assessment when recognizing deferred tax assets resulting from unrealized losses on available-for-sale debt securities. The new standard is effective for fiscal years and interim periods beginning after December 15, 2017, and upon adoption, an entity should apply the amendments by means of a cumulative-effect adjustment to the balance sheet at the beginning of the first reporting period in which the guidance is effective. Early adoption is not permitted except for the provision to record fair value changes for financial liabilities under the fair value option resulting from instrument-specific credit risk in other comprehensive income. We are currently evaluating the impact of adopting this guidance.

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

At December 31, 2015, we had cash and cash equivalents and marketable securities of $431.0 million, which consisted of bank deposits, money market funds, commercial paper, U.S. government and agency securities and corporate debt securities. Such interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations of interest income have not been significant. The cash and cash equivalents are held for working capital purposes. The marketable securities are held for capital preservation purposes.

We have not been exposed nor do we anticipate being exposed to material risks due to changes in interest rates. A hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our consolidated financial statements.

Item 8. Financial Statements and Supplementary Data.

ADURO BIOTECH, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of

Aduro Biotech, Inc.

Berkeley, California

We have audited the accompanying consolidated balance sheets of Aduro Biotech, Inc. and its subsidiaries (the "Company") as of December 31, 2015 and 2014, and the related consolidated statements of operations, comprehensive loss, convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2015. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of Aduro Biotech, Inc. and its subsidiaries as of December 31, 2015 and 2014, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2015 in conformity with accounting principles generally accepted in the United States of America.

/s/ Deloitte & Touche LLP

San Francisco, California
March 8, 2016

ADURO BIOTECH, INC.

Consolidated Balance Sheets

(In thousands, except share and per share amounts)

	December 31, 2015	2014
Assets		
Current assets:		
Cash and cash equivalents	$150,456	$119,456
Short-term marketable securities	265,198	—
Accounts receivable	4,846	3,153
Prepaid expenses and other current assets	4,004	2,612
Total current assets	424,504	125,221
Long-term marketable securities	15,391	—
Property and equipment, net	3,986	1,053
Goodwill	8,469	—
Intangible assets, net	29,400	—
Other assets	75	188
Total assets	$481,825	$126,462
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$5,086	$5,030
Accrued clinical trial and manufacturing expenses	5,522	3,350
Accrued expenses and other liabilities	5,412	2,408
Deferred revenue	15,046	33,427
Total current liabilities	31,066	44,215
Contingent consideration	3,750	—
Deferred revenue	178,037	2,592
Deferred tax liabilities	7,350	—
Convertible preferred stock warrant liability	—	100
Common stock warrant liability	—	889
Total liabilities	220,203	47,796
Commitments and contingencies (Note 11)		
Convertible preferred stock; $0.0001 par value, zero and 69,716,345 shares authorized at December 31, 2015 and 2014; zero and 69,608,339 shares issued and outstanding at December 31, 2015 and 2014	—	139,963
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; 10,000,000 and zero shares authorized at December 31, 2015 and 2014; and zero shares issued and outstanding at December 31, 2015 and 2014	—	—
Common stock, $0.0001 par value; 300,000,000 and 85,000,000 shares authorized at December 31, 2015 and 2014; and 63,587,833 and 361,997 shares issued and	6	—

outstanding at December 31, 2015 and 2014		
Additional paid-in capital	362,807	346
Accumulated other comprehensive loss	(339)	—
Accumulated deficit	(100,852)	(61,643)
Total stockholders' equity (deficit)	261,622	(61,297)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$481,825	$126,462

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

ADURO BIOTECH, INC.

Consolidated Statements of Operations

(In thousands, except share and per share amounts)

	Year Ended December 31,		
	2015	2014	2013
Revenue:			
Collaboration and license revenue	$71,689	$13,038	$—
Grant revenue	1,290	351	828
Total revenue	72,979	13,389	828
Operating expenses:			
Research and development	58,649	23,513	10,687
General and administrative	27,805	8,994	4,677
Amortization of intangible assets	89	—	—
Total operating expenses	86,543	32,507	15,364
Loss from operations	(13,564)	(19,118)	(14,536)
Loss from remeasurement of fair value of warrants	(26,077)	(566)	(162)
Gain on extinguishment of convertible promissory notes	—	3,553	—
Interest income (expense), net	494	(2,395)	(1,371)
Other (expense) income, net	(161)	1,512	15
Loss before income tax	(39,308)	(17,014)	(16,054)
Income tax benefit	99	—	—
Net loss	$(39,209)	$(17,014)	$(16,054)
Net loss per common share, basic and diluted	$(0.88)	$(53.06)	$(55.80)
Shares used in computing net loss per common share, basic and diluted	44,706,393	320,686	287,711

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

ADURO BIOTECH, INC.

Consolidated Statements of Comprehensive Loss

	Year Ended December 31,		
	2015	2014	2013
Net loss	$(39,209)	$(17,014)	$(16,054)
Other comprehensive loss:			
Unrealized loss on marketable securities, net of tax of $0	(181)	—	—
Foreign currency translation adjustments, net of tax of $0	(158)	—	—
Comprehensive loss	$(39,548)	$(17,014)	$(16,054)

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

ADURO BIOTECH, INC.

Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)

(In thousands, except share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Loss	Deficit	Equity (Deficit)
Balance at January 1, 2013	14,839,965	$23,693	262,827	$ —	$866	$ —	$(28,575)	$ (27,709)
Issuance of Series B convertible preferred stock for cash, net of $65 of issuance costs	2,593,639	3,031	—	—	—	—	—	—
Issuance of Series B convertible preferred stock upon conversion of convertible promissory notes	4,607,399	5,500	—	—	—	—	—	—
Convertible promissory notes beneficial conversion feature (Note 7)	—	—	—	—	2,339	—	—	2,339
Recognition of equity component of Series B convertible promissory note (Note 7)	—	—	—	—	2,241	—	—	2,241
Issuance of common stock upon exercise	—	—	32,671	—	16	—	—	16

of stock options								
Stock-based compensation expense	—	—	—	—	409	—	—	409
Net loss	—	—	—	—	—	—	(16,054)	(16,054)
Balance at December 31, 2013	22,041,003	32,224	295,498	—	5,871	—	(44,629)	(38,758)
Issuance of Series C convertible preferred								
stock for cash, net of $262 of issuance								
costs (Note 12)	19,423,965	41,888	—	—	—	—	—	—
Issuance of Series C convertible preferred								
stock upon conversion of convertible								
promissory notes (Note 7)	6,199,217	13,452	—	—	—	—	—	—
Effects of Series C convertible preferred								
stock tranche (Note 12)	—	(1,475)	—	—	—	—	—	—
Issuance of Series B convertible preferred								
stock upon conversion of Series B								
convertible promissory notes (Note 7)	2,931,981	4,956	—	—	—	—	—	—
Issuance of Series D convertible preferred	19,012,173	48,918	—	—	—	—	—	—
stock for cash, net of $2,470 of								

issuance costs (Note 12)								
Reclassification of common stock warrants (Note 14)	—	—	—	—	784	—	—	784
Convertible promissory notes beneficial conversion feature	—	—	—	—	57	—	—	57
Reacquisition of equity component of Series B convertible promissory note	—	—	—	—	(3,432)	—	—	(3,432)
Reacquisition of convertible promissory notes beneficial conversion feature	—	—	—	—	(3,553)	—	—	(3,553)
Issuance of common stock upon exercise of stock options	—	—	66,499	—	49	—	—	49
Stock-based compensation	—	—	—	—	570	—	—	570
Net loss	—	—	—	—	—	—	(17,014)	(17,014)
Balance at December 31, 2014	69,608,339	139,963	361,997	—	346	—	(61,643)	(61,297)
Issuance of Series E convertible preferred stock for cash, net of $8 of issuance costs (Note 12)	2,361,029	24,992	—	—	—	—	—	—
Issuance of convertible preferred stock upon exercise of preferred stock	6,668	9	—	—	—	—	—	—

warrants								
Conversion of convertible preferred stock to common stock	(71,976,036)	(164,964)	51,822,659	5	164,959	—	—	164,964
Issuance of common stock in initial public offering (Note 1)	—	—	8,050,000	1	124,192	—	—	124,193
Issuance of common stock in private placement (Note 1)			1,470,588	—	25,000	—		25,000
Reclassification of convertible preferred stock and common stock warrant liability to additional paid-in capital (Note 12)			—	—	27,066	—		27,066
Issuance of common stock upon exercise of stock options and grants	—	—	843,441	—	673	—	—	673
Issuance of common stock upon exercise of warrants	—	—	302,269	—	117	—	—	117
Issuance of common stock in business acquisition (Note 5)	—	—	697,306	—	11,452	—	—	11,452
Issuance of common stock under Employee Stock Purchase Plan	—	—	39,573	—	572	—	—	572

Stock-based compensation	—	—	—	—	8,430	—	—	8,430
Other comprehensive loss	—	—	—	—	—	(339)	—	(339)
Net loss	—	—	—	—	—	—	(39,209)	(39,209)
Balance at December 31, 2015	—	$—	63,587,833	$ 6	$362,807	$ (339)	$(100,852)	$ 261,622

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

ADURO BIOTECH, INC.

Consolidated Statement of Cash Flows

(In thousands)

	Year Ended December 31,		
	2015	2014	2013
Cash Flows from Operating Activities			
Net loss	$(39,209)	$(17,014)	$(16,054)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation and amortization	634	240	129
Amortization of intangibles	89	—	—
Accretion of discounts and amortization of premiums on marketable securities	725	—	—
Stock-based compensation	8,430	570	409
Loss from remeasurement of fair value of warrants	26,077	566	162
Gain from changes in the fair value of preferred stock derivative liability	—	(1,475)	—
Gain on extinguishment of convertible promissory notes	—	(3,553)	—
Non-cash interest expense related to convertible promissory notes payable	—	2,380	1,367
Changes in operating assets and liabilities:			
Accounts receivable	(1,693)	(2,796)	(315)
Prepaid expenses and other assets	(2,654)	(1,117)	(382)
Accounts payable	1,537	1,681	(670)
Deferred revenue	157,064	35,962	—
Accrued clinical trial and manufacturing expenses	2,172	2,460	711
Accrued expenses and other liabilities	1,638	1,461	411
Net cash provided by (used in) operating activities	154,810	19,365	(14,232)
Cash Flows from Investing Activities			
Purchase of marketable securities	(359,378)	—	—
Proceeds from maturities of marketable securities	77,885	—	—
Purchase of property and equipment	(2,174)	(782)	(170)
Acquisition, net of cash acquired	(14,321)	—	—
Net cash used in investing activities	(297,988)	(782)	(170)
Cash Flows from Financing Activities			
Proceeds from issuance of common stock, net of offering costs	150,283	—	—
Deferred offering costs	—	(1,092)	—
Proceeds from issuance of convertible promissory note payable to related parties	—	308	16,192
Repayment of note payable to related party	—	(200)	—
Proceeds from issuance of convertible preferred stock, net of issuance costs	22,522	93,276	3,031
Proceeds from exercise of stock options and warrants	801	49	16
Proceeds from employee stock purchase plan	572	—	—
Net cash provided by financing activities	174,178	92,341	19,239
Net increase in cash and cash equivalents	31,000	110,924	4,837
Cash and cash equivalents at beginning of period	119,456	8,532	3,695
Cash and cash equivalents at end of period	$150,456	$119,456	$8,532
Supplemental Disclosure			
Cash paid for interest	$—	$18	$32

Supplemental Disclosure of Non-Cash Investing and Financing Activities			
Stock issued in connection with business acquisition	$11,452	$—	$—
Conversion of convertible preferred stock to common stock	$164,964	$—	$—
Reclassification of warrant liabilities to additional paid-in capital	$27,066	$—	$—
Purchase of property and equipment in accounts payable and accrued liabilities	$692	$—	$—
Issuance of Series C convertible preferred stock to a related party and other investors in connection with conversion of convertible promissory notes and accrued interest	$—	$13,452	$—
Issuance of Series B convertible preferred stock to a related party in connection with conversion of convertible promissory notes	$—	$4,956	$5,500

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

ADURO BIOTECH, INC.

Notes to Consolidated Financial Statements

1. Organization and Nature of Business

Aduro Biotech, Inc., or the Company, is a clinical-stage immunotherapy company located in Berkeley, California focused on the discovery, development and commercialization of therapies that transform the treatment of challenging diseases. The Company's technology platforms, which are designed to harness the body's natural immune system, are being investigated in cancer indications and have the potential to expand into autoimmune and infectious diseases. The Company operates in one business segment.

The Company has developed three technology platforms, LADD, STING Pathway Activator and B-select monoclonal antibodies. The Company's Live, Attenuated, Double-Deleted, or LADD, technology platform is engineered to express tumor-associated antigens to induce specific and targeted immune responses. Based on compelling clinical data in advanced cancers, this platform is being developed as a treatment for multiple indications, including pancreatic, ovarian, lung and prostate cancers, mesothelioma and glioblastoma. The Company's STING Pathway Activator platform is designed to activate the intracellular Stimulator of Interferon Genes, or STING, receptor, resulting in a potent tumor-specific immune response. The Company's B-select monoclonal antibody platform has the potential to yield novel immunotherapy combinations as a result of our recent acquisition of BioNovion Holding B.V., a wholly-owned subsidiary known as Aduro Biotech Europe, based in the Netherlands. The Company is also collaborating with leading global pharmaceutical companies to expand its products and technology platforms.

Initial Public Offering and Concurrent Private Placement

On April 20, 2015, the Company closed its initial public offering, or IPO, and sold 8,050,000 shares of its common stock (inclusive of 1,050,000 shares of common stock pursuant to the full exercise of the underwriters' option to purchase additional shares) at a price to the public of $17.00 per share. The Company received aggregate net proceeds of $124.2 million, net of underwriting discounts and offering expenses. The Company also sold to Novartis Institutes for BioMedical Research, Inc., or NIBR, in a concurrent private placement 1,470,588 shares of common stock at a price of $17.00 per share for proceeds of $25.0 million (See Note 8). Upon the closing of the IPO, all then-outstanding shares of convertible preferred stock converted by their terms into 51,822,659 shares of common stock. Additionally, the Company amended and restated its certificate of incorporation effective April 20, 2015 to, among other things, change the authorized number of shares of common stock to 300,000,000 shares and the authorized number of shares of preferred stock to 10,000,000 shares.

2. Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP, and include the accounts of Aduro Biotech, Inc. and its wholly owned subsidiaries. All intercompany transactions and balances have been eliminated. A reclassification was made on the

statement of operations in order to confirm with current period presentation. Specifically, expense of $566,000 and $162,000 for the years ended December 31, 2014 and 2013, respectively, has been reclassified from other income (expense), net to loss from remeasurement of fair value of warrants.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities and reported amounts of revenue and expenses in the financial statements and accompanying notes. On an ongoing basis, management evaluates its estimates, including those related to revenue recognition, clinical trial accruals, convertible preferred stock and related warrants, common stock and related warrants, income taxes and stock-based compensation. Management bases its estimates on historical experience and on various other market-specific and relevant assumptions that management believes to be reasonable under the circumstances. Actual results could differ from these estimates.

Reverse Stock Split

On April 1, 2015, the Company effected a 0.72-for-1 reverse split of its common stock. Upon the effectiveness of the reverse stock split, (i) every 1 share of outstanding common stock was combined into 0.72 of a share of common stock, (ii) the number of shares of common stock for which each outstanding option or warrant to purchase common stock is exercisable was proportionally decreased on a 0.72-for-1 basis, (iii) the exercise price of each outstanding option or warrant to purchase common stock was proportionately increased on a 0.72-for-1 basis, and (iv) the conversion ratio for each share of preferred stock which was convertible into the Company’s common stock was proportionately reduced on a 0.72-for-1 basis. All of the outstanding common stock share numbers,

warrants to purchase common stock, common stock share prices, common stock exercise prices and per share amounts have been adjusted, on a retroactive basis, to reflect this 0.72-for-1 reverse stock split for all periods presented. The par value per share, authorized number of shares of common stock, preferred stock and preferred stock warrants were not adjusted as a result of the reverse stock split.

Offering Costs

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

Revenue Recognition

The Company recognizes revenues from collaboration, license or research arrangements and development grants when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable and collectability is reasonably assured.

For revenue agreements with multiple-element arrangements, such as license and research and development agreements, the Company allocates revenue to each non-contingent element based on the relative selling price of each element. When applying the relative selling price method, the Company determines the selling price for each deliverable by first using vendor-specific objective evidence, if available, and then third-party evidence. If neither exists, the Company uses its best estimate of selling price for that deliverable. Revenue allocated to an element is then recognized when the four basic revenue recognition criteria are met.

Revenue associated with nonrefundable upfront license fees under arrangements where the license fees and research and development activities cannot be accounted for as separate units of accounting is deferred and recognized as revenue on a straight-line basis over the expected period of performance. Revenues from the achievement of research and development milestones, if deemed substantive, are recognized as revenue when the milestones are achieved and the milestone payments are due and collectible. If not deemed substantive, the Company recognizes such milestones as revenue on a straight-line basis over the remaining expected performance period under the arrangement. The Company will account for sales-based royalties as revenue upon achievement of certain sales milestones.

Milestones are considered substantive if all of the following conditions are met: (1) the milestone is nonrefundable; (2) achievement of the milestone was not reasonably assured at the inception of the arrangement; (3) substantive effort is involved to achieve the milestone; and (4) the amount of the milestone appears reasonable in relation to the effort expended, and the other milestones in the arrangement and the related risk associated with the achievement of the milestone and any ongoing research and development or other services are priced at fair value. Revenue related to research and development grants is recognized when the related research expenses are incurred and the Company's specific performance obligations under the terms of the respective contracts are satisfied. Revenue recognized in the consolidated statement of operations is not subject to repayment.

Deferred revenue at December 31, 2015 and 2014 represents the portion of payments received for which the earnings process has not been completed. Deferred revenue expected to be recognized within the next 12 months is classified as a current liability.

Cash and Cash Equivalents

Cash and cash equivalents include all cash balances and highly liquid investments with original maturities of three months or less from the date of purchase. At December 31, 2015 and 2014, cash and cash equivalents consisted of cash in bank deposits, money market funds held at financial institutions, commercial paper and U.S. government and agency securities. The recorded carrying amount of cash equivalents approximates their fair value.

Preferred Stock Derivative Liability

In May 2014, the Company recorded a preferred stock derivative liability for a related party's right to purchase from the Company, on the same terms as the Series C Preferred Stock Purchase Agreement, additional shares of Series C preferred stock in a second and third tranche. At initial recognition, the Company recorded this derivative as a liability on the balance sheets at its estimated fair value. The derivative was subject to remeasurement at each balance sheet date, with changes in fair value recognized as a component of other income (expense), net. At the time of each tranche funding, the Company remeasured the derivative liability, with the change in fair value recognized as a component of other income (expense), net and then reclassified the remaining value associated with the preferred stock derivative liability to the Series C convertible preferred stock.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist of cash and cash equivalents and accounts receivable. Cash and cash equivalents are held at financial institutions in the United States and in the Netherlands. The Company is exposed to credit risk in the event of default by the financial institution to the extent that cash and cash equivalent balances recorded in the balance sheets are in excess of the amounts that are insured by the Federal Deposit Insurance Corporation, or FDIC. The Company has not experienced any losses on its deposits since inception, and management believes that minimal credit risk exists with respect to these financial institutions.

Accounts receivable consist of amounts due from various collaboration agreements and grant proceeds for services under an agreement with the United States government. The Company’s management believes these receivables are fully collectible.

Property and Equipment

Property and equipment is carried at cost less accumulated depreciation and amortization. Depreciation and amortization of property and equipment is calculated using the straight-line method. When assets are retired or otherwise disposed of, the cost and accumulated depreciation are removed from the balance sheet and any resulting gain or loss is reflected in operations in the period realized.

The useful lives of the property and equipment are as follows:

Lab equipment	5 years
Furniture and fixtures	5 years
Computer and office equipment	3 – 5 years
Leasehold improvements	Shorter of remaining lease term or estimated useful life

Expenditures for repairs and maintenance, which do not improve or extend the life of the assets, are expensed as incurred.

Business Combinations

The Company accounts for acquisitions using the acquisition method of accounting which requires the recognition of tangible and identifiable intangible assets acquired and liabilities assumed at their estimated fair values as of the business combination date. The Company allocates any excess purchase price over the estimated fair value assigned to the net tangible and identifiable intangible assets acquired and liabilities assumed to goodwill. Contingent consideration is included within the acquisition cost and is recognized at its fair value on the acquisition date. A liability resulting from contingent consideration is remeasured to fair value at each reporting date until the contingency is resolved and changes in fair value are recognized in earnings. Transaction costs are expensed as incurred in general and administrative expenses. Results of operations and cash flows of acquired companies are included in the Company's operating results from the date of acquisition.

Goodwill and Intangible Assets

Goodwill represents the excess of the consideration transferred over the estimated fair value of assets acquired and liabilities assumed in a business combination. Intangible assets with indefinite useful lives are related to acquired in-process research and development, or IPR&D, projects and are measured at their respective fair values as of the

acquisition date. Goodwill and intangible assets with indefinite useful lives are not amortized but are tested for impairment on an annual basis or more frequently if the Company becomes aware of any events or changes that would indicate the fair values of the assets are below their carrying amounts. Intangible assets related to IPR&D projects are considered to be indefinite-lived until the completion or abandonment of the associated R&D efforts. If and when development is complete, which generally occurs if and when regulatory approval to market a product is obtained, the associated assets are deemed finite-lived and are amortized based on their respective estimated useful lives at that point in time. The Company has not recorded an impairment of goodwill or IPR&D since inception.

Intangible assets with finite useful lives are amortized over their estimated useful lives, primarily on a straight-line basis.

Impairment of Long-Lived Assets

The Company reviews its long-lived assets, including property and equipment and definite-lived intangible assets, for impairment whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. Recoverability of assets held and used is measured by comparison of the carrying amount of an asset to the future undiscounted cash flows expected to be generated from the use of the asset and its eventual disposition. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount exceeds the fair value of the impaired assets. Assets to be

disposed of are reported at the lower of their carrying amount or fair value less cost to sell. The Company has not recorded an impairment of long-lived assets since inception.

Accrued Research and Development Costs

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

Convertible Preferred Stock

The Company's convertible preferred stock was classified as temporary equity in the balance sheets prior to the IPO due to certain change in control events that were outside the Company's control, including liquidation, sale or transfer of the Company, as holders of the convertible preferred stock had the ability to cause redemption of the shares. The carrying values of the convertible preferred stock were not adjusted to the liquidation preferences of such shares because it was uncertain whether or when an event would occur that would obligate the Company to pay the liquidation preferences to holders of shares of convertible preferred stock. The outstanding shares of convertible preferred stock were automatically converted into shares of the Company's common stock upon the consummation of the IPO as described in Note 1.

Convertible Preferred Stock and Common Stock Warrant Liability

Warrants for shares that were contingently redeemable were classified as liabilities in the December 31, 2014 balance sheet. Certain common stock warrants were subject to performance conditions which could have resulted in the issuance of a variable number of shares. At initial recognition, the Company classified these warrants as liabilities on the balance sheet at their estimated fair value. The warrants were subject to remeasurement at each balance sheet date, with changes in fair value recognized on the statement of operations under loss from remeasurement of fair value of warrants. Upon consummation of the IPO, the common stock warrants did not meet the performance conditions and the number of shares became fixed. They were remeasured at the IPO date and reclassified to additional paid-in capital with a loss recognized on the statement of operations. In addition, upon consummation of the IPO, the convertible preferred stock warrants automatically converted into common stock warrants. The related liability was remeasured at the IPO date and the resulting increase in the fair value was recognized as a loss on the statement of operations. The carrying value was then reclassified to additional paid-in capital.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development costs consist of salaries and benefits, lab supplies, contract and grant research costs, fees paid to consultants and third parties that conduct certain research and development activities on the Company's behalf and allocations of facilities-related costs. Nonrefundable advance payments for goods or services to be rendered in the future for use in research and development activities are deferred and capitalized as prepaid expenses until the related goods are delivered or the services are performed.

Stock-Based Compensation

The Company measures its stock-based awards made to employees based on the estimated fair values of the awards as of the grant date using the Black-Scholes option-pricing model. Stock-based compensation expense is recognized over the requisite service period using the straight-line method and is based on the value of the portion of stock-based payment awards that is ultimately expected to vest. As such, the Company's stock-based compensation is reduced for the estimated forfeitures and revised, if necessary, in subsequent periods if actual forfeitures differ from the original estimates.

Stock-based compensation expense for options granted to non-employees as consideration for services received is measured on the date of performance at the fair value of the consideration received or the fair value of the equity instruments issued, using the Black-Scholes option-pricing model, whichever can be more reliably measured. Stock-based compensation expense for options granted to non-employees is remeasured each period as the underlying options vest.

Income Taxes

The Company accounts for income taxes using the asset and liability method. Under this method, deferred income tax assets and liabilities are recorded based on the estimated future tax effects of differences between the financial reporting and the tax bases of 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. Deferred income taxes are classified as noncurrent in connection with Company's early adoption of ASU 2015-17. 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.

The tax effects of the Company's income tax positions are recognized only if determined "more likely than not" to be sustained based solely on the technical merits as of the reporting date. The Company considers many factors when evaluating and estimating its tax positions and tax benefits, which may require periodic adjustments and which may not accurately anticipate actual outcomes.

Foreign Currency Translation

The impact of changes in foreign currency exchange rates resulting from the translation of foreign currency financial statements into U.S. dollars for financial reporting purposes is included in other comprehensive loss. Assets and liabilities are translated into U.S. dollars at exchange rates in effect at the balance sheet date. Income and expense items are translated at average rates for the period.

Foreign currency transaction gains and losses are recorded as they are realized, and such amounts have historically been insignificant.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, or FASB, issued Auditing Standards Update, or ASU, No. 2014-09, Revenue from Contracts with Customers (Topic 606). This ASU affects any entity that either enters into contracts with customers to transfer goods and services or enters into contracts for the transfer of nonfinancial assets. ASU 2014-09 will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. The standard's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In doing so, companies will need to use more judgment and make more estimates than under the currently effective guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. In July 2015, the FASB voted to defer the effective date of the ASU by one year to December 15, 2017 for fiscal years, and interim periods within those periods, beginning after that date. Entities are permitted to adopt in accordance with the original effective date of December 15, 2016 if they choose. The Company is currently evaluating the impact of this guidance on its consolidated financial statements.

In November 2015, the FASB issued ASU No. 2015-17, Balance Sheet Classification of Deferred Taxes, which requires that deferred tax assets and liabilities be classified as noncurrent in a classified statement of financial position. The accounting standard is effective, either prospectively to all deferred tax assets and liabilities or retrospectively to all periods presented, for annual periods beginning after December 15, 2016, and interim periods therein. Early adoption is permitted as of the beginning of an interim or annual reporting period. The Company early adopted this standard as of December 31, 2015 on a prospective basis which did not have a material impact on its financial statements because in the prior year the Company did not have material deferred tax balances.

In January 2016, the FASB issued ASU No. 2016-01, Financial Instruments--Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities, which amends the guidance in U.S. GAAP on the classification and measurement of financial instruments. Changes to the current guidance primarily affects the accounting for equity investments, financial liabilities under the fair value option, and the presentation and disclosure requirements for financial instruments. In addition, the ASU clarifies guidance related to the valuation allowance assessment when recognizing deferred tax assets resulting from unrealized losses on available-for-sale debt securities. The new standard is effective for fiscal years and interim periods beginning after December 15, 2017, and upon adoption, an entity should apply the amendments by means of a cumulative-effect adjustment to the balance sheet at the beginning of the first reporting period in which the guidance is effective. Early adoption is not permitted except for the provision to record fair value changes for financial liabilities under the fair value option resulting from instrument-specific credit risk in other comprehensive income. The Company is currently evaluating the impact of adopting this guidance.

3. Fair Value Measurements

The carrying amounts of certain of the Company’s financial instruments, including cash equivalents, accounts receivable and accounts payable approximate their fair values due to their short maturities. Assets and liabilities recorded at fair value on a recurring basis in the balance sheets, as well as assets and liabilities measured at fair value on a non-recurring basis or disclosed at fair value, are categorized based upon the level of judgment associated with inputs used to measure their fair values. The accounting guidance for fair value provides a framework for measuring fair value, and requires certain disclosures about how fair value is determined. Fair

value is defined as the price that would be received upon the sale of an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The accounting guidance also establishes a three-level valuation hierarchy that prioritizes the inputs to valuation techniques used to measure fair value based upon whether such inputs are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions made by the reporting entity. The three-level hierarchy for the inputs to valuation techniques is briefly summarized as follows:

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

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

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

The Company’s cash equivalents, which include money market funds, are classified as Level 1 because they are valued using quoted market prices. The Company’s marketable securities consist of available-for-sale securities and are generally classified as Level 2 because their value is based on valuations using significant inputs derived from or corroborated by observable market data.

In certain cases where there is limited activity or less transparency around the inputs to valuation, securities are classified as Level 3. Level 3 liabilities consist of common and preferred stock warrant liabilities and contingent consideration liability. The determination of the contingent consideration and fair value of the warrants is discussed in Note 5 and Note 14, respectively.

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

	December 31, 2015			
	Level 1	Level 2	Level 3	Total
Financial Assets:				
Money market funds	$104,602	$—	$—	$104,602
U.S. government and agency securities	—	194,055	—	194,055
Corporate debt securities	—	74,918	—	74,918
Commercial paper	—	42,295	—	42,295
Total	$104,602	$311,268	$—	$415,870
Financial Liabilities:				
Contingent consideration related to acquisition	$—	$—	$3,750	$3,750
Total	$—	$—	$3,750	$3,750

	December 31, 2014			
	Level 1	Level 2	Level 3	Total
Financial Assets:				
Money market funds	$110,001	$ —	$—	$110,001

Total	$110,001	$ —	$—	$110,001
Financial Liabilities:				
Convertible preferred stock warrant liability	$—	$ —	$100	$100
Common stock warrant liability	—	—	889	$889
Total	$—	$ —	$989	$989

The acquisition-date fair value of the contingent consideration liability represents the future consideration that is contingent upon the achievement of specified development milestones for a product candidate. The fair value of the contingent consideration is based on the Company's probability-weighted discounted cash flow assessment that considers probability and timing of future payments. The fair value measurement is based on significant Level 3 inputs such as anticipated timelines and probability of achieving development milestones. Change in the fair value of the liability for contingent consideration, except for the impact of foreign currency, will be recognized in the statement of operations until settlement.

The Company did not have any financial assets and liabilities measured at fair value on a non-recurring basis as of December 31, 2015 and 2014. During the years ended December 31, 2015 and 2014, there were no transfers between the fair value measurement category levels.

The following table sets forth a summary of the changes in the fair value of the Company's Level 3 financial liabilities (in thousands):

	Contingent Consideration	Preferred Stock Warrant Liability	Common Stock Warrant Liability	Preferred Stock Derivative Liability	Convertible Promissory Note Warrants
Balance at December 31, 2013	$ —	$ 72	$ 505	$ —	$ 617
Issuance of convertible promissory note warrants	—	—	—	—	15
Initial recognition of preferred stock derivative liability	—	—	—	3,018	—
Issuance of preferred stock	—	—	—	(1,543)	—
Net increase (decrease) in fair value upon revaluation	—	28	384	(1,475)	152
Reclassification to additional paid-in capital	—	—	—	—	(784)
Balance at December 31, 2014	—	100	889	—	—
Net increase in fair value upon revaluation	—	1,108	24,969	—	—
Reclassification to additional paid-in capital	—	(1,208)	(25,858)	—	—
Contingent consideration recognized from acquisition	3,775	—	—	—	—
Foreign currency impact on contingent consideration	(25)	—	—	—	—
Balance at December 31, 2015	$ 3,750	$ —	$ —	$ —	$ —

The following tables summarize the estimated value of the Company's cash equivalents and marketable securities and the gross unrealized holding gains and losses (in thousands):

	December 31, 2015			
	Amortized cost	Unrealized gains	Unrealized losses	Estimated Fair Value
Cash and cash equivalents:				
Cash	$ 15,175	$ —	$ —	$ 15,175
Money market funds	104,602	—	—	104,602
Commercial paper	7,899	—	—	7,899
U.S. government and agency securities	22,780	—	—	22,780
Total cash and cash equivalents	$ 150,456	$ —	$ —	$ 150,456
Marketable securities:				
U.S. government and agency securities	$ 171,416	$ 3	$ (144)	$ 171,275
Corporate debt securities	74,958	38	(78)	74,918
Commercial paper	34,396	—	—	34,396
Total marketable securities	$ 280,770	$ 41	$ (222)	$ 280,589

4. Balance Sheet Components

Property and Equipment, Net

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

	December 31,	
	2015	2014
Lab equipment	$3,011	$1,165
Computer and office equipment	959	520
Furniture and fixtures	306	87
Leasehold improvements	1,367	304
Total property and equipment	5,643	2,076
Less: accumulated depreciation and amortization	(1,657)	(1,023)
Property and equipment, net	$3,986	$1,053

Depreciation and amortization expense for the years ended December 31, 2015, 2014 and 2013 was $634,000, $240,000, and $129,000, respectively.

Accrued Expenses and Other Liabilities

Accrued expenses and other liabilities consisted of the following (in thousands):

	December 31,	
	2015	2014
Compensation and related benefits	$2,765	$1,276
Professional and consulting services	1,650	961
Other	997	171
Total accrued expenses and other liabilities	$5,412	$2,408

5. Acquisition of BioNovion Holding B.V.

On October 30, 2015, the Company acquired the outstanding shares of BioNovion Holding B.V., or BioNovion, a privately held company in the Netherlands that specializes in immune oncology antibody discovery, in exchange for cash and 697,306 shares of the Company’s common stock for an aggregate purchase price of $34.2 million. BioNovion was subsequently renamed Aduro Biotech Holding, Europe B.V., or Aduro Biotech Europe. As of the date of acquisition, the purchase price was preliminarily allocated to the assets acquired and liabilities assumed based upon their estimated fair value, and is subject to change as the Company finalizes its estimates.

The Company believes that the acquisition of BioNovion, known as Aduro Biotech Europe will create synergies that will provide future value. These factors, among others, contributed to a purchase price in excess of the estimated fair value of the acquired company's net identifiable assets acquired and resulted in the recognition of goodwill. The goodwill related to the acquisition is not deductible for tax purposes.

A summary of the total purchase consideration on October 30, 2015 is as follows:

Cash consideration	$19,006
Fair value of Aduro common stock issued	11,452
Fair value of Contingent Purchase Price	3,775
Total purchase consideration	$34,233

The results of operations and the provisional fair values of the acquired assets and liabilities assumed have been included in the accompanying consolidated financial statements since the acquisition date. Revenue and net loss from Aduro Biotech Europe were $288,000 and $(595,000), respectively, for the period ended December 31, 2015.

The Company will pay additional consideration, or the Contingent Purchase Price, upon the achievement of certain development milestones associated with specified Aduro Biotech Europe antibody product candidates. The Contingent Purchase Price was initially recorded at fair value on the acquisition date in long-term liabilities on the consolidated balance sheet. The fair value of the Contingent Purchase Price of $3.8 million was estimated based on the risk-adjusted present value of the amount payable. Subsequent changes in the fair value of the Contingent Purchase Price will be recognized as adjustments to contingent consideration and reflected in the consolidated statements of operations. For additional information related to the fair value of this obligation, please read Note 3 to these

consolidated financial statements. The Contingent Purchase Price has not been released as of the issuance date of these consolidated financial statements because the development milestones have not yet been achieved.

The Company incurred $572,000 in acquisition-related costs which were recorded within operating expenses for the year ended December 31, 2015.

The following table summarizes the fair value of assets acquired and liabilities assumed on October 30, 2015:

Assets acquired and liabilities assumed:	
Cash and cash equivalents	$4,684
Accounts receivable	180
Prepaid expenses and other current assets	57
Property and equipment	814
Accounts payable	(1,460)
Accrued expenses and other liabilities	(780)
Net tangible assets acquired	3,495
Intangible assets:	
License agreement	10,857
In-process research and development	18,827
Goodwill	8,475
Net intangible assets acquired	38,159
Deferred tax liabilities	(7,421)
Total	$34,233

Aduro Biotech Europe has a license and research agreement with a third-party for the development of clinical candidates. The license and research agreement intangible asset has an estimated life of 20 years and will be amortized on a straight line basis. IPR&D represents incomplete research and development projects at Aduro Biotech Europe. The fair value of the license agreement and IPR&D were determined using the income approach, which was prepared based on forecasts by management.

Pro Forma Financial Information

The following unaudited pro forma financial information presents the combined results of operations for the years ended December 31, 2015 and 2014 as if the acquisition of BioNovion, known as Aduro Biotech Europe had been completed on January 1, 2014. Adjustments have been made to give effect to pro forma events that are directly attributable to the acquisition such as amortization expense from acquired intangible assets, stock-based compensation expense related to the acquisition and acquisition-related transaction costs. The unaudited pro forma results do not reflect any operating efficiencies or potential cost savings which may result from the consolidation of the operations of the Company and Aduro Biotech Europe. Accordingly, these unaudited pro forma results are not necessarily indicative of what the actual results of operations of the combined company would have been if the acquisition had occurred at the beginning of the period presented, nor are they indicative of future results of operations:

	Year Ended December 31,	
	2015	2014
	(Unaudited)	
Revenue	$78,272	$19,944
Net loss	(39,520)	(19,390)
Basic and diluted net loss per share	(0.76)	(24.31)

The unaudited pro forma combined financial information includes non-recurring pro forma adjustments including acquisition-related transaction costs of $2.3 million for the year ended December 31, 2015, stock-based compensation expense as a direct result of the acquisition of $2.1 million and $5.3 million for the years ended December 31, 2015 and 2014, respectively, and intangible asset amortization of $0.5 million and $0.6 million for the years ended December 31, 2015 and 2014, respectively.

6. Goodwill and Intangible Assets

Goodwill

The gross carrying amount of goodwill was as follows (in thousands):

Balance at December 31, 2014	$—
Goodwill arising from BioNovion acquisition	8,475
Foreign currency translation adjustment	(6)
Balance at December 31, 2015	$8,469

Intangible assets

The gross carrying amounts and net book value of our intangible assets were as follows (in thousands):

	December 31, 2015		
	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Intangible assets with finite lives:			
License agreement	$10,786	$ 89	$10,697
Total intangible assets with finite lives	10,786	89	10,697
Acquired IPR&D assets	18,703	—	18,703
Total intangible assets	$29,489	$ 89	$29,400

Intangible assets are carried at cost less accumulated amortization. Amortization is over a period of 20 years and the amortization expense is recorded in operating expenses. The increase in the gross carrying amount of intangible assets as of December 31, 2015 compared to the acquisition date of October 30, 2015 reflected a negative impact of foreign currency exchange which was primarily due to the strengthening of the U.S. dollar against the Euro.

Amortization expense was $89,000 for the year ended December 31, 2015 and $0 for the years ended December 31, 2014 and 2013. Based on finite-lived intangible assets recorded as of December 31, 2015, the estimated future amortization expense is as follows (in thousands):

Year Ending December 31,	Estimated Amortization Expense
2016	$ 539
2017	539
2018	539
2019	539
2020	539

7. Related Party Convertible Promissory Notes

Convertible Promissory Notes Payable to Related Parties, Short-Term

In August 2013, the Company entered into a note and warrant purchase agreement with related parties to raise up to $13.0 million via the issuance of convertible promissory notes, or the Notes, and warrants to purchase common stock. The Notes bear interest at 5% per annum and automatically convert into equity shares upon the earlier of the closing of a convertible preferred stock financing with proceeds of at least $35.0 million, or Next Financing Event, or the merger or sale of the Company, or Sale Event, or the maturity of the notes on May 30, 2014. If the Notes are

converted due to a Next Financing Event, the conversion price shall be equal to the issue price of the equity financing, with investors receiving a variable number of shares. The Company determined that the automatic conversion feature upon occurrence of the Next Financing Event represented a redemption feature embedded within the Notes. The Company also determined that the provisions whereby the Notes automatically convert upon a Sale Event or on the original maturity date of the Notes of May 30, 2014 were considered to be conversion options within the Notes.

During 2013, the Company issued $12.7 million in Notes and in January 2014 issued an additional $0.3 million in Notes. At the time the Notes were issued, the Company determined that a beneficial conversion feature existed as the fair value of the securities into which the Notes were convertible was greater than the effective conversion price on the borrowing date. Accordingly, the Company recorded a beneficial conversion feature of $0.1 million and $2.3 million during 2014 and 2013, respectively. The beneficial conversion feature was recorded as an increase to additional paid-in capital with the offset recorded as a discount on the Notes.

Each Note was also issued with warrants to purchase common stock with the number of warrants being equal to 10% of the outstanding principal balance of the Notes (or $1.3 million) divided by the issuance price per share of the shares into which the Notes convert. The warrants can be exercised at any time into a variable number of shares of common stock at an exercise price of $0.02 per share for a period of 10 years from the date of issuance. See Note 14. In May 2014, a total of 431,316 warrant shares were issued when the Notes and accrued interest were converted into Series C convertible preferred stock. At the time the warrants were issued, the Company recognized the fair value of the warrants of $0.6 million as a discount on the related Notes. Prior to the Series C convertible preferred stock financing in May of 2014, such warrants were determined to be embedded derivatives and classified together with the Notes on the consolidated balance sheet.

The discounts associated with both the beneficial conversion feature and warrants were amortized to interest expense using the effective interest method through May 30, 2014, the contractual maturity date of the Notes. During the years ended December 31, 2015, 2014 and 2013, the Company recognized interest expense of $0, $2.0 million and $1.0 million, respectively.

At the time of the Series C convertible preferred stock offering in May 2014, the Notes were redeemed under the Next Financing Event redemption feature whereby the aggregate of the outstanding principal and accrued interest balance of the Notes of $13.5 million was converted into 6,199,217 shares of Series C convertible preferred stock based on the Series C convertible preferred stock fair value. The redemption of the Notes was accounted for as a debt extinguishment. Additionally, the Notes contained a beneficial conversion feature which was reacquired and a portion of the reacquisition price allocated to the beneficial conversion feature. The amount allocated to reacquire the beneficial conversion feature was measured using the intrinsic value of the conversion option at the extinguishment date and reflected as a reduction to equity of $3.6 million. As a result, the amount allocated to reacquire the Notes was less than the carrying value of the Notes which resulted in a gain on extinguishment of $3.6 million.

Additionally, on the date of the Series C convertible preferred stock offering in May 2014, the warrants issued together with the Notes were no longer classified as embedded derivatives and accordingly the fair value of such warrants was reclassified to equity in the amount of $0.8 million.

Convertible Promissory Notes Payable to Related Party, Long-Term

As part of the Series B convertible preferred stock financing, the Company entered into various unsecured convertible promissory notes and warrants with an investor. The notes are noninterest-bearing, convertible into Series B preferred stock at a price of $1.1937322 per share upon the closing of a convertible preferred stock financing with proceeds of at least $2.0 million and mature on April 15, 2021. Convertible promissory notes in the amounts of $2.5 million, $3.0 million and $3.5 million were issued in October 2011, August 2012 and January 2013, respectively. In January 2013, the $2.5 million and $3.0 million notes were converted into 4,607,399 shares of Series B convertible preferred stock. In May and November 2014 $1.6 million and $1.9 million of the convertible promissory notes, respectively, were converted into 1,373,843 and 1,558,138 shares of Series B convertible preferred stock, respectively. See Note 12.

As part of the Series B preferred stock financing, the Company also issued warrants to the investor as follows: (a) in April 2011, warrants to purchase 61,410 shares of Series B convertible preferred stock and 60,315 shares of common stock; (b) in June 2011, warrants to purchase 241,260 shares of common stock; and (c) in October 2011, warrants to purchase 150,787 shares of common stock. See Note 14 for information regarding the terms of the warrants.

The notes issued in January 2013 were determined to contain a feature allowing for cash settlement. In accordance with the applicable accounting standards for certain convertible debt instruments that may be settled in cash or other assets, or partially in cash, upon conversion, the Company recorded the long-term debt and equity components of the convertible promissory note separately. At initial recognition, the Company allocated $1.3 million and $2.2 million to the debt and equity components, respectively. The Company recorded the equity component as a discount on the related debt. The discount, which represents non-cash interest expense, is being amortized to interest expense through maturity date of April 15, 2021 using the effective interest method. The Company recognized $0.1 million in interest expense for each of the years ended December 31, 2014 and 2013. In May 2014 and November 2014, the Company converted $1.6 million and $1.9 million, respectively, of the $3.5 million Series B convertible promissory notes prior to their maturity date. Upon conversion, the Company reacquired the equity component of the related convertible promissory notes, recording a reduction to additional paid in capital of $3.4 million, the elimination of the related unamortized debt discount of $2.0 million and the issuance of Series B preferred stock of $5.0 million.

There was no balance outstanding at December 31, 2015 and 2014.

8. Note Payable to Related Party

In December 2008, the Company issued an unsecured note payable to an existing minority stockholder for $200,000. The note bears interest at the U.S. Federal Reserve prime rate, or prime, per annum, compounded quarterly, and beginning in 2014, the interest rate increases to prime plus 4%, compounded quarterly. Accrued interest from the date of issuance of the note until December 31, 2013 in the amount of $32,000 was paid in 2013, according to the terms of the note agreement. The outstanding principal balance of $200,000 along with $15,000 of accrued interest was paid in December 2014.

9. Collaboration Agreements

Pharma License Agreement

In connection with the Aduro Biotech Europe acquisition in October 2015, the Company became party to an agreement with a third-party pharmaceutical company, or Pharma. The agreement sets forth the parties' respective obligations for development, commercialization, regulatory and manufacturing and supply activities for antibody product candidates.

In exchange for the licenses and research and development services under the agreement, Pharma paid Aduro Biotech Europe an upfront non-refundable cash payment of $15.0 million in April 2014. No amounts of this upfront payment were recognized in post-acquisition revenue. The Company is eligible to receive future contingent payments, including a $2.0 million research milestone, up to $312.0 million in potential development milestone payments for each of two product candidates, and up to $135.0 million in commercial and net sales milestones for each of two products. In addition, the Company is eligible to receive royalties in the mid-single digits to low teens based on net sales of the product.

The Company identified the following performance deliverables under the agreement: 1) the license, 2) the obligation to provide research activities and 3) the obligation to participate on a Joint Research Committee.

The Company considered the provisions of the multiple-element arrangement guidance in determining how to recognize the total consideration of the agreement. The Company determined that none of the deliverables have standalone value; all of these obligations will be delivered throughout the estimated period of performance and therefore are accounted for as a single unit of accounting.

The Company determined that all of the future contingent payments meet the definition of a milestone. Accordingly, revenue for the achievement of these milestones will be recognized in the period when the milestone is achieved and collectability is reasonably assured. No amounts had been recognized as revenue for any of these milestones for the year ended December 31, 2015.

Novartis Agreement

In March 2015, the Company entered into a collaboration and license agreement with Novartis Pharmaceuticals Corporation, or Novartis, pursuant to which the Company is collaborating worldwide with Novartis regarding the development and potential commercialization of product candidates containing an agonist of the molecular target known as STING in the field of oncology, including immuno-oncology and cancer vaccines. Under this agreement, or the Novartis Agreement, the Company granted Novartis a co-exclusive license to develop such products worldwide, an exclusive license to commercialize such products outside the United States and a non-exclusive license to support the Company in commercializing such products in the United States if it requests such support. The collaboration is guided by a joint steering committee with each party having final decision making authority regarding specified areas of development or commercialization.

Under the Novartis Agreement, the Company received an upfront payment of $200.0 million in April 2015. The Company is also eligible to receive up to an additional $250.0 million in development milestones and up to an additional $250.0 million in regulatory approval milestones.

The Company is responsible for 38% of the joint development costs worldwide and Novartis is responsible for the remaining 62% of the joint development costs worldwide.

The Company will also receive 50% of gross profits on sales of any products commercialized pursuant to this collaboration in the United States and 45% of gross profits for specified European countries and Japan. For each of

these profit share countries, each party will be responsible for its respective commercial sharing percentage of all joint commercialization costs incurred in that country.

For all other countries where the Company is not sharing profits, Novartis will be responsible for all commercialization costs and will pay the Company a royalty in the mid-teens on all net sales of product sold by Novartis, its affiliates and sublicensees, with such percentage subject to reduction post patent and data exclusivity expiration and subject to reduction, capped at a specified percentage, for royalties payable to third party licensors. Novartis' royalty obligation will run on a country-by-country basis until the later of expiration of the last valid claim covering the product, expiration of data exclusivity for the product or 12 years after first commercial sale of the product in such country.

With respect to the United States, specified European countries and/or Japan, the Company may elect for such region to either reduce by 50% or to eliminate in full the Company's development and commercialization cost sharing obligation. If the Company elects to reduce its cost sharing percentage by 50% in any such region, then its profit share in such region will also be reduced by 50%. If the Company elects to eliminate its development cost sharing obligation, then such region will be removed from the profit share, and instead Novartis will owe the Company royalties on any net sales of product for such region, as described above.

The Company recognizes revenue from collaboration, license or research arrangements when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable and collection is reasonably assured. The Company has determined that the license does not have stand-alone value separable from the co-development services to be performed under the agreement, with the Company participating in the research and development services. As a result, the Company recognizes revenue from the $200.0 million upfront fee received on a straight-line basis over its estimated performance period of 13.5 years, commencing in July 2015, the date of the Joint Steering Committee's approval of the research and development plan. Changes in the estimated period of performance will be accounted for prospectively as a change in estimate. The Company will recognize substantive milestone payments in their entirety in the period in which the milestone is achieved. Non-substantive milestone payments will be recognized on a straight-line basis over the remaining performance period. Costs associated with co-development activities performed under the agreement are included in research and development expenses in the accompanying consolidated statements of operations. Reimbursement of research and development costs by Novartis is included in collaboration and license revenue. The Company will recognize revenue from the sale of any products commercialized pursuant to this collaboration in the United States, will retain 50% of the gross profits from such sales, and will pay the remaining 50% of the gross profits to Novartis. The Company will receive from Novartis 45% of gross profits for specified European countries and Japan. Profit sharing payments made to or received from Novartis are aggregated by product by territory and are reported as expenses or revenues, as applicable.

For the year ended December 31, 2015, the Company recognized revenue from its collaboration with Novartis totaling $7.4 million related to amortization of the upfront fee. The remaining balance of the upfront fees of $192.6 million is included in deferred revenue at December 31, 2015. In addition, for the year ended December 31, 2015, there was $1.2 million recognized in revenue related to research and development costs incurred by the Company that were subsequently reimbursed by Novartis.

Janssen ADU-214 Agreement

In November 2014, the Company entered into a Research and License Agreement with Janssen, or Janssen ADU-214 Agreement, to develop a drug for the treatment of lung cancer. Under the terms of the Janssen ADU-214 Agreement, the Company granted Janssen an exclusive, worldwide license to research, develop, manufacture, use, sell and otherwise exploit products containing ADU-214 for any and all uses. Janssen has agreed not to administer or cause to be administered ADU-214 in humans in clinical trials for the treatment of pancreatic cancer or mesothelioma. The Company is responsible for certain research and development activities from the effective date of the agreement until investigational new drug application, or IND, approval. Since the inception of the Janssen ADU-214 Agreement, the Company received an upfront license fee of $30.0 million and a substantive milestone payment of $0.5 million upon submission of an IND. Under the terms of the Janssen ADU-214 Agreement, the Company may receive future nonrefundable milestone payments up to a total of $10.5 million after completion of various stages of the research and development activities, and the Company is eligible to receive future contingent payments up to a total of $776.0 million composed of development milestones through completion of all Phase 3 clinical trials, as well as regulatory and commercial milestones. The contingent payments are triggered upon the activities expected to be undertaken by Janssen. The Company is eligible to receive royalties on any net sales of licensed products by Janssen, its affiliates and sublicensees at a rate ranging from high-single digits to low teens based on the aggregate annual net sales of licensed products worldwide and based on the country of sale.

The upfront license fee of $30.0 million was being recognized on a straight-line basis from the effective date of the agreement through October 2015, the Company's estimated performance period which was accelerated based on progress in the development program during the third quarter of 2015.

For the year ended December 31, 2015, the Company recognized revenue from the Janssen ADU-214 Agreement totaling $47.2 million, including $26.2 million related to amortization of the upfront fees and $21.0 million for development-related milestones. As of December 31, 2015 all payments have been received and fully amortized.

Janssen ADU-741 and GVAX Prostate Agreements

In May 2014, the Company entered into a Research and License Agreement, or Janssen ADU-741 Agreement, and a GVAX Prostate License Agreement, or Janssen GVAX Prostate Agreement, with Janssen Biotech, Inc., or Janssen, a wholly-owned subsidiary of Johnson & Johnson Development Corporation, to collaborate on the development of a drug for the treatment of prostate cancer. Under the terms of the Janssen ADU-741 Agreement, the Company granted Janssen an exclusive, worldwide license to research, develop, manufacture, use, sell and otherwise exploit products containing ADU-741 for any and all uses. The Company is responsible for certain research and development activities from the effective date of the agreement until approval of an investigational new drug application, or IND.

Since the inception of the Janssen ADU-741 Agreement, the Company received an upfront payment of $12.0 million and non-substantive and substantive milestone payments of $10.0 million upon completion of certain development activities. Under the terms of the Janssen ADU-741 Agreement, the Company is eligible to receive future contingent payments up to a total of $345.5 million composed of development milestones through completion of all Phase 3 clinical trials, as well as launch, commercialization and sales

milestones. The contingent payments are triggered upon the activities expected to be undertaken by Janssen. The Company is eligible to receive royalties on net sales of licensed products by Janssen, its affiliates and sublicensees at a rate ranging from mid-single digits to low teens based on aggregate annual net sales and based on the country of sale.

Under the Janssen GVAX Prostate Agreement, the Company granted Janssen an exclusive worldwide license to research, develop, manufacture, use, sell and otherwise exploit products containing GVAX Prostate for any and all uses. The Company received an upfront payment of $500,000 in May 2014 and is eligible to receive an additional $2.0 million on the achievement of a specified commercial milestone. In addition, the Company is eligible to receive royalties in the high single digits based on net sales of the product.

The development activities being conducted by the Company are based on a combination of the technology licensed under both agreements. Accordingly, the Company has accounted for the Janssen ADU-741 Agreement and Janssen GVAX Prostate Agreement as one arrangement and has identified the deliverables within the arrangement as a license to the technology and research and development activities through IND approval. The Company has determined that the licenses and development services under the license and research agreements represent a single unit of accounting. The licenses do not have stand-alone value to Janssen, separable from the development services to be performed under the agreement, as Janssen is unable to use the licenses for their intended purpose without the Company's performance of the research and development services. As a result, the Company recognizes revenue from the upfront payments ratably over the term of its estimated period of performance under the agreement. Changes in the estimated period of performance will be accounted for prospectively as a change in estimate. The upfront fees received totaling $12.5 million were recognized on a straight-line basis from the effective date of the agreements through October 2015, the Company's estimated performance period. The Company recognized non-substantive milestone payments on a straight-line basis through October 2015, the Company's estimated performance period.

For the year ended December 31, 2015, the Company recognized revenue from its Janssen ADU-741 and GVAX Prostate Agreements totaling $13.2 million related to amortization of the upfront fees and development-related milestones. In addition, for the year ended December 31, 2015, there was $2.2 million recognized in revenue related to cost incurred by the Company that were subsequently reimbursed by Janssen.

10. Research and Development and License Agreements

Listeria-Based Agreements

JHU Listeria Agreement

In March 2011, the Company entered into a license agreement with The Johns Hopkins University, or JHU, pursuant to which the Company received an exclusive, worldwide, sublicensable license to certain patent rights covering the tumor-associated antigen mesothelin to make, use, import and commercialize products and to provide services for all bacteria-based therapeutic and/or prophylactic uses for cancer treatment and/or prevention and as a companion diagnostic.

Under the JHU Listeria Agreement, the Company is required to make future milestone payments totaling up to $375,000 upon achievement of certain regulatory milestones. Under the JHU Listeria Agreement, the Company is obligated to pay JHU royalties based on net sales of licensed products and services by the Company, its affiliates and its sublicensees at a rate in the low-single digits, subject to minimum annual royalties, and a percentage of consideration received from any sublicensing arrangements ranging from the low-single digits to the low twenties depending on the field of use and the stage of development of the product candidate at the time the sublicense is

granted.

The JHU Listeria Agreement will continue in effect on a country-by-country basis until the expiration of the last patent within the licensed patent rights, or if no patents issue then for 20 years from the effective date of the agreement. Either party may terminate the JHU Listeria Agreement for the other party's uncured breach of the agreement upon 30 days' prior notice or for the other party's insolvency. Additionally, the Company may terminate the JHU Listeria Agreement at will upon 90 days' prior written notice to JHU.

The Company made milestone payments of $15,000, $10,000 and $5,000 related to this agreement during the years ended December 31, 2015, 2014 and 2013, respectively.

UCB Listeria Agreement

In March 2012, the Company entered into a license agreement with the Regents of the University of California on behalf of its Berkeley campus, or UCB, granting the Company an exclusive, worldwide, sublicensable license to certain patent rights covering the use of the Listeria monocytogenes phage integration vector which accelerates the genetic engineering of Listeria to express more than one antigen to make, use, import, and commercialize products and to provide services for all fields of use.

Under the UCB Listeria Agreement, the Company is required to make future milestone payments totaling up to $350,000 upon achievement of certain development and regulatory milestones. The Company is required to pay an annual license maintenance fee until its first sale of a product covered by the licensed patent rights. Under the UCB Listeria Agreement, the Company is obligated to pay UCB royalties based on net sales of licensed products and services sold by the Company and its sublicensees at a rate in the low single digits, subject to minimum annual royalties and customary reductions, and a percentage of certain of the Company's sublicensing revenues in the low-single digits to low thirties depending on how the product covered by the licensed patent rights is used.

The UCB Listeria Agreement will last until the expiration of the last patent within the licensed patent rights. UCB may terminate the agreement for the Company's uncured material breach upon 90 days' prior written notice and the Company may terminate the agreement at will upon 90 days' prior written notice to UCB.

The Company made payments of $5,000, $845,000 and $30,000 in milestone, annual maintenance fees and sublicensing fees related to this agreement during the years ended December 31, 2015, 2014 and 2013, respectively, which were recorded in research and development expenses.

Cerus Corporation Agreement

On November 3, 2009, the Company entered into a license agreement with Cerus Corporation, or Cerus. Under the terms of this license agreement, Cerus granted the Company a worldwide exclusive license under certain of Cerus' patents and technology to make, have made, use, import, offer for sale and sell therapeutics for the treatment or prevention of any human or animal diseases involving a vaccine or immunotherapy.

The Company is required to pay Cerus royalties based on a percentage of net sales in the low single digits, including net sales by sublicensees, of products incorporating the licensed technology and from the provision of any services based upon the licensed technology. If the products or services are bundled with any other products or services, the portion of the net sales allocated to the licensed technology would be used in determining the royalty payments.

GVAX-Based Agreements

ANI Agreement

In January 2013, the Company entered into an asset purchase agreement with BioSante Pharmaceuticals, Inc., which subsequently merged with and into ANI Pharmaceuticals, Inc., or ANI, in June 2013. Under the agreement, or the ANI Agreement, the Company purchased all the rights, title and interest of ANI in and to all of the assets related to or comprising GVAX product candidates and any assets necessary or reasonably useful to make, have made, use, have used, sell, offer for sale, have sold, import, have imported, develop, have developed, commercialize and have commercialized GVAX products.

Under the ANI Agreement, the Company paid ANI cash consideration of $1.0 million and will be required to make royalty payments on net sales of GVAX products sold by the Company, its affiliates and its sublicensees for the treatment of certain cancers, which are covered by purchased intellectual property rights or developed using purchased technology, at rates in the low single digits. The Company is also required to pay milestone payments up to $4.0 million for GVAX pancreas or prostate products in combination with Listeria or up to $12.0 million per product for other GVAX products upon the achievement of certain sales milestones. The Company is obligated to make royalty payments on a product-by-product and country-by-country basis until the later of (i) the expiration of the last to expire of the purchased patent rights covering the GVAX product or the regulatory exclusivity period and (ii) up to seven years from the first commercial sale of the product in such country depending on the level of net sales in such country after the expiration of the patent or regulatory exclusivity period. The royalties and milestone payments for GVAX products for the treatment of pancreas and prostate cancer, as well as the royalties and milestone payments for other cancer products, are each capped at specified maximum amounts. To the extent the Company enters into a

sublicensing agreement relating to the GVAX pancreas or prostate cancer products in combination with Listeria, the Company is required to pay ANI a percentage of the Company's sublicensing income, ranging from the low teens to the low thirties based on the indication, the stage of development of the GVAX products at the time the sublicense is granted and the amount of development costs expended by the Company at the time the sublicense is granted. The sublicensing payments owed under this ANI Agreement for pancreas and prostate cancer products in combination with Listeria are each capped at specified maximum amounts.

The Company paid $0 and $99,000 for the years ended December 31, 2015 and 2014, respectively, for sublicensing fees, which were recorded in research and development expenses. For the year ended December 31, 2013, the Company recorded the $1.0 million payment for the purchase of the assets as research and development expenses because the Company determined that there was no alternative future use.

JHU GVAX Agreement

In January 2013, the Company entered into a license agreement with JHU granting the Company an exclusive, worldwide, sublicensable license under certain GVAX-related patent rights and cell lines, and a non-exclusive, worldwide, sublicensable license to related know-how, in each case to make, have made, use, have used, sell, offer for sale, have sold, import, have imported, develop and commercialize products and services using or incorporating licensed patent rights, cell lines, or know-how for any use.

Under the New License Agreement, the Company is required to pay JHU development and regulatory milestone payments totaling up to approximately $1.1 million for STINGVAX, a GVAX product with STING Activators, approximately $1.2 million for TEGVAX, a GVAX product with TLRs, and approximately $1.2 million for other licensed products. The Company is also required to pay JHU royalties based on net sales of licensed products and services by the Company, its affiliates and its sublicensees at a rate in the low single digits, subject to minimum annual royalties and standard reductions upon expiration of patent coverage and for licenses to third-party intellectual property rights, as well as a percentage of certain consideration received in consideration of the grant of sublicenses under this agreement ranging from the low tens to the mid-twenties depending on the stage of development of the product candidate at the time the sublicense is granted and the number of sublicenses granted.

The New License Agreement will continue in effect on a product-by-product basis and service-by- service basis until 30 years after the first commercial sale of such product or service, provided that the term may be extended for additional ten-year periods upon mutual agreement of the parties. Either party may terminate the New License Agreement for the other party’s uncured material breach of the agreement upon 60 days’ prior notice to the breaching party, or 30 days’ notice if such breach relates to a payment obligation, or for the other party’s insolvency. Additionally, the Company may terminate the New License Agreement at will upon 90 days’ prior written notice to JHU.

Under the New License Agreement, the Company paid licensing fees of $5,000, $125,000 and $125,000 for the years ended December 31, 2015, 2014 and 2013, respectively, which were recorded in research and development expenses.

STING Activator-Based Agreements

Karagen Agreement

In June 2012, the Company entered into a license agreement with Karagen Pharmaceuticals, Inc., or Karagen, pursuant to which Karagen granted the Company an exclusive, worldwide, sublicenseable license under certain patents and know-how related to STING Activators to make, develop, use and commercialize products for use in the therapeutic and/or prophylactic treatment of cancer or precancerous conditions and a non-exclusive license to such patents and know-how to make, develop, use, and commercialize products in all other fields of use. Under the agreement, or the Karagen Agreement, the Company was also granted an option to designate a particular disease or condition to be added to the field of use under its exclusive license. Under the Karagen Agreement, the Company is obligated to use commercially reasonable efforts to develop and commercialize licensed products in the United States and the European Union.

Under the Karagen Agreement, the Company is required to make milestone payments up to $900,000, in aggregate, upon its achievement of specified development and regulatory milestones as well as royalty payments based on net sales of products by the Company and by its affiliates and sublicensees at rates ranging in the low single-digit percentages, determined by whether the disease field is an exclusive or non-exclusive disease field, subject to minimum annual royalties and standard reductions. In addition, the Company is required to pay Karagen a percentage of consideration received from any sublicensing arrangements ranging from the mid-single digits to the mid-teen digits, determined by the current stage of development of the relevant licensed product at the time of the sublicense grant, or by whether the Company has exercised its option to add a designated field of use to its exclusive license, as applicable.

The Karagen Agreement will expire, on a country-by-country basis, upon the expiration of the last-to- expire valid claim within the licensed patent rights. Either party may terminate the Karagen Agreement upon 90 days' advance written notice in the event of the other party's material breach that is not cured within such 90-day period, and immediately upon notice in the event of the other party's bankruptcy or insolvency. Additionally, the Company may terminate the Karagen Agreement at will upon 90 days' advance written notice to Karagen.

The Company paid licensing fees of $3.3 million, $15,000 and $15,000 for the years ended December 31, 2015, 2014 and 2013, respectively, which were recorded in research and development expenses.

UCB Vance Agreement

In September 2014, the Company entered into a license agreement with UCB, granting the Company an exclusive, worldwide, sublicenseable license under certain patent rights covering the use of the STING Activator molecules that activate the STING receptor

to make, develop, use and commercialize products, to practice methods and to offer services, in each case that are covered by the licensed patent rights, in all fields of use. Under this agreement, or the UCB Vance Agreement, the Company is obligated to use commercially reasonable efforts to develop, manufacture and sell licensed products and services and are obligated to achieve specified development and regulatory milestones by specified dates.

Under the UCB Vance Agreement, the Company is required to make future milestone payments totaling up to $1.8 million upon achievement of certain development and regulatory milestones. Under the UCB Vance Agreement, the Company is also obligated to pay UCB royalties based on net sales of licensed products by the Company and its sublicensees at a rate in the low single-digit percentages, subject to minimum annual royalties and a percentage of certain of the Company's sublicensing revenues ranging from the low-single digits to the low thirties, determined by the current stage of development of the relevant licensed product at the time the sublicense is granted.

The UCB Vance Agreement will continue in effect until the expiration of the last-to-expire valid claim within the licensed patent rights. UCB may terminate the agreement upon 90 days' advance written notice in the event of the Company's material breach that is not cured within such 90 day period. The Company may terminate the agreement at will upon 90 days' advance written notice.

The Company paid $20,000 and $50,000 for the years ended December 31, 2015 and 2014, respectively, in upfront, milestone and sublicensing fees, which were recorded in research and development expenses.

Memorial Sloan Kettering Cancer Center Agreement

In December 2014, the Company entered into a license agreement with Memorial Sloan Kettering Cancer Center, or MSK, The Rockefeller University, Rutgers, The University of New Jersey, and University of Bonn, collectively the Licensors, granting the Company an exclusive, worldwide, sublicensable license to certain patent rights related to STING Activators and a non-exclusive, worldwide, sublicensable license under specified know-how, in each case to develop, make, have made, use, have used, import, sell, and otherwise commercialize licensed products for use in therapeutic and/or prophylactic treatments in humans. Under this agreement, or the MSK Agreement, the Company is obligated to use commercially reasonable efforts to develop and commercialize a licensed product, including achieving specified development and regulatory milestones by specified dates.

Under the MSK Agreement, the Company is required to make future milestone payments totaling up to $3.3 million upon achievement of certain development, regulatory and commercialization milestones. Under the MSK Agreement, the Company is also obligated to pay MSK royalties based on net sales of licensed products by the Company and its sublicensees at a rate in the low single digits, subject to minimum annual royalties and a percentage of certain of the Company's sublicensing revenues ranging from ten to mid-twenties.

The MSK Agreement will continue in effect until the expiration of the Company's royalty obligations. The Company or the Licensors may terminate the agreement for uncured material breach upon 90 days' prior written notice and the Company may terminate the agreement at will upon 30 days' prior written notice to the Licensors.

For the years ended December 31, 2015 and 2014, respectively, the Company recorded $25,000 and $50,000 in upfront and milestone payments in research and development expenses.

11. Commitments and Contingencies

Leases

The Company leases its office and research and development facility in Berkeley, California, under a non-cancelable operating lease. In February 2015, the Company amended its office lease agreement to increase the total square footage to approximately 25,000 square feet and extended the term of the lease to expire on December 31, 2018. The lease also contains an option to extend the lease for an additional two years.

In September 2015, the Company entered into an Office/Laboratory Lease for approximately 56,000 square feet of office and laboratory space at a new facility located in Berkeley, California. The term of the lease commences when the landlord delivers possession of the facility to the Company, which is expected to be June 1, 2016. The lease has an initial term of twelve years.

The Company has the option to extend the lease beyond the initial term for up to two renewal terms of five years each, provided that the rental rate would be subject to market adjustment at the beginning of each renewal term. The Company also has a one-time option that may be exercised any time prior to July 1, 2016 to lease additional space within the facility of approximately 26,000 square feet commencing on January 1, 2017 and approximately 29,000 square feet commencing on January 1, 2018.

The Company also has office and laboratory space in Oss, the Netherlands, for employees of Aduro Biotech Europe. The term of the lease is through December 2017, with a one-year renewal option.

Rent expense was $784,000, $344,000 and $281,000 for the years ended December 31, 2015, 2014 and 2013, respectively. Under the terms of the lease agreements, the Company is also responsible for certain insurance, property tax and maintenance expenses. Future minimum payments under the lease at December 31, 2015 are as follows (in thousands):

Year ending December 31,	Amounts
2016	$ 2,653
2017	3,741
2018	5,488
2019	4,925
2020	4,925
Thereafter	45,397
Total	$ 67,129

Indemnifications

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. Pursuant to such agreements, the Company may indemnify, hold harmless and defend an indemnified party for losses suffered or incurred by the indemnified party. Some of the provisions will limit losses to those arising from third party actions. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments the Company could be required to make under these provisions is not determinable. The Company has never incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. The Company has also entered into indemnification agreements with its directors and officers that may require the Company to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers to the fullest extent permitted by Delaware corporate law. The Company currently has directors' and officers' insurance.

Legal

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

Other Commitments

The Company has various manufacturing, clinical, research and other contracts with vendors in the conduct of the normal course of its business. All contracts are terminable, with varying provisions regarding termination. If a contract with a specific vendor were to be terminated, the Company would only be obligated for the products or services that the Company had received at the time the termination became effective as well as non-cancelable and non-refundable payment obligations incurred by the vendor for products or services before the termination became effective. In the case of terminating a clinical trial agreement at a particular site, the Company would also be obligated to provide continued support for appropriate medical procedures at that site until completion or termination.

12. Convertible Preferred Stock

In January 2013, the Company issued 2,593,639 shares of Series B convertible preferred stock to related parties for net cash proceeds of $3.0 million and 4,607,399 shares as settlement of outstanding convertible promissory notes issued in October 2011 and August 2012, in the amount of $5.5 million. In May and November 2014, the Company issued 1,373,843 and 1,558,138 shares, respectively, of Series B convertible preferred stock to the related party as settlement of a convertible promissory note issued in January 2013. See Note 7.

On May 30, 2014, the Company entered into the Series C Preferred Stock Purchase Agreement with existing as well as new investors for the issuance of up to 31,544,844 shares of Series C convertible preferred stock at a purchase price of $2.17 per share. Upon the execution of the agreement, the Company issued 17,119,818 shares of Series C convertible preferred stock for net cash proceeds of $36.9 million and 6,199,217 shares as settlement of outstanding convertible promissory notes, including accrued interest, in the amount of $13.5 million. On December 15, 2014, the Company issued 2,304,148 additional shares of Series C convertible preferred stock to the related party for cash proceeds of $5.0 million.

In May 2014, the Company recorded a preferred stock derivative liability in the amount of $3.0 million, as a related party received the right to purchase from the Company, on the same terms, additional shares of Series C convertible preferred stock, in a second and third tranche. As the related party holds a majority of the board seats, the decision to complete these tranches was deemed to be outside the control of the Company. During the year ended December 31, 2014, the Company recognized a $1.5 million gain related to changes in fair value of the preferred stock derivative liability. At the time of the second and third tranche funding, the Company remeasured the preferred stock derivative liability, with the change in fair value recognized as a component of other income (expense), net. At the date of derecognition of the preferred stock derivative liability, the Company reclassified the remaining value associated with the liability of $1.5 million to Series C convertible preferred stock.

The key assumptions used in the valuation of the preferred stock derivative liability were as follows:

	Year Ended December 31, 2014
Expected term (in years)	0 – 0.55
Fair value of underlying shares	$2.17 – $2.46
Volatility	80.0%
Risk-free interest rate	0.02% –0.07%
Dividend yield	— %

Concurrent with the March 2015 entry into the Novartis Agreement (See Note 9), the Company and NIBR, entered into a stock purchase agreement under which NIBR purchased 2,361,029 shares of the Company's Series E Convertible Preferred Stock (or 1,699,940 shares of common stock on an as-converted basis) for $25.0 million. Upon the closing of the IPO, these preferred shares converted into common stock. Under the stock purchase agreement, NIBR purchased an additional $25.0 million of the Company's common stock concurrent with the completion of the IPO at the initial price per share offered to the public.

There were no outstanding shares of convertible preferred stock as of December 31, 2015 as they had all converted to common stock as part of the IPO. At December 31, 2014, convertible preferred stock consisted of the following (in thousands, except share data):

	Shares Authorized	Shares Outstanding	Net Carrying Value	Liquidation Preference
Series A	161,843	161,843	$ 8,092	$ 8,092
Series A-1	3,393,666	3,369,431	4,582	4,582
Series B	21,525,480	21,441,709	24,505	25,596
Series C	25,623,183	25,623,183	53,866	55,603
Series D	19,012,173	19,012,173	48,918	51,388

Total	69,716,345	69,608,339	$ 139,963	$ 145,261

13. Common Stock

The Company had reserved shares of common stock, on an as-converted basis, for future issuance as follows:

	December 31,	
	2015	2014
Convertible preferred stock outstanding	—	50,117,919
Options issued and outstanding	9,931,229	5,970,382
Shares available for future stock option grants	4,810,271	3,154,755
Series A-1 convertible preferred stock warrants	—	17,447
Series B convertible preferred stock warrants	—	60,308
Common stock warrants	929,437	1,154,270
Total	15,670,937	60,475,081

14. Warrants

The Company had issued and outstanding warrants as follows:

	Warrants Outstanding			Exercise Price	Terms
	December 31, 2015	December 31, 2014	Issuance Date	per Share	(Years)
Type of Security:					
Common	1,152	1,152	November 2008	$ 34.73	10.0
Common	720	720	January 2009	$ 34.73	10.8
Common	288	288	February 2009	$ 34.73	10.0
Common	360	360	March 2009	$ 34.73	10.0
Common	144	144	April 2009	$ 34.73	10.0
Common	13,235	66,176	July 2009	$ 1.89	10.0
Common	21,176	21,176	September 2009	$ 1.89	10.0
Common	—	17,280	April 2011	$ 0.70	10.0
Common	2,400	10,002	[1] April 2011	$ 1.88	10.0
Common	—	14,233	[1] April 2011	$ 1.71	10.0
Common	50,455	83,771	[1] April 2011	$ 1.66	5.0
Common	116,443	197,638	April 2011	$ 0.01	10.0
Common	241,260	241,260	June 2011	$ 0.01	9.8
Common	161,381	176,760	October 2011	$ 0.01	9.5
Common	232,258	232,258	[2] August 2013	$ 0.02	10.0
Common	42,246	132,715	[2] September 2013	$ 0.02	10.0
Common	45,919	56,131	[2] December 2013	$ 0.02	10.0
Common	—	10,212	[2] January 2014	$ 0.02	10.0
Total	929,437	1,262,276			

[1] As of December 31, 2014 these warrants were convertible preferred stock warrants and converted into common stock warrants upon the consummation of the IPO in April 2015. The number of outstanding warrants were converted on a 0.72-to-1 basis and the exercise price was increased proportionally.

[2] In connection with the issuance of convertible promissory notes to related parties, warrants to purchase common stock were issued in August 2013, September 2013, December 2013 and January 2014. These warrants were classified together with convertible promissory notes payable at issuance. At December 31, 2013, the number of warrants issued was subject to adjustment pending the occurrence of the next round of financing. On May 30, 2014, outstanding principal and accrued interest of the convertible promissory notes in the amount of $13.5 million was converted into Series C convertible preferred stock and issued 431,316 common stock warrants. See Note 7. At the conversion date, warrants at the then fair value were reclassified into additional paid-in capital in the amount of $0.8 million.

In April 2011, the Company issued warrants to purchase 24,235 shares of Series A-1 convertible preferred stock, or Series A-1 warrants, and 83,771 warrants to purchase shares of Series B convertible preferred stock, or Series B warrants. The Series A-1 warrants and Series B warrants were immediately exercisable and expire, if not exercised, in April 2021 and April 2016, respectively. As the shares into which the warrants were exercisable were contingently redeemable, the Company recognized a liability for the fair value of the warrants on the condensed consolidated balance sheet. At the date of the IPO, the Series A-1 warrants and Series B warrants became exercisable for common stock and were no longer contingently redeemable. At the IPO, the warrants were remeasured to their fair value of

$1.2 million and the Company recognized a loss from remeasurement of $1.1 million in the consolidated statement of operations for the year ended December 31, 2015. The carrying value of the warrants of $1.2 million was reclassified to additional paid-in capital.

In April, June, and October 2011, the Company issued warrants to purchase 615,658 shares of common stock. The common stock warrants were exercisable beginning in April 2015 and would have terminated in whole or part, if the Company had obtained certain levels of government grant funds by April 15, 2015. The warrants expire, if not exercised, in April 2021. As the warrants were subject to performance conditions which may result in the issuance of a variable number of shares, the Company recognized a liability for the fair value of the common stock warrants on the consolidated balance sheet. On April 15, 2015, the Company did not obtain the specified levels of government grant funds and the performance conditions expired. As a result, the number of common shares issuable was fixed and the warrants no longer met the requirements for classification as a liability. The warrants were remeasured to their fair value of $25.9 million and the Company recognized a loss from remeasurement of $25.0 million in the consolidated statement of operations for the year ended December 31, 2015. The carrying value of the warrants of $25.9 million was reclassified to additional paid-in capital.

15. Equity Incentive Plans

2015 Plan

In March 2015, the Company's board of directors adopted and in April 2015 the Company's stockholders approved the 2015 Equity Incentive Plan, or the 2015 Plan, which became effective upon the IPO and provides for the granting of incentive stock options, nonstatutory stock options, and other forms of stock awards to its employees, directors and consultants.

The 2015 Plan is administered by the board of directors or a committee appointed by the board of directors, which determines the types of awards to be granted, including the number of shares subject to the awards, the exercise price and the vesting schedule. The exercise price of incentive stock options and nonqualified stock options will be no less than 100% of the fair value per share of the Company's common stock on the date of grant. If an individual owns capital stock representing more than 10% of the voting shares, the price of each share will be at least 110% of the fair value on the date of grant. Options expire after 10 years (five years for stockholders owning greater than 10% of the voting stock). The number of shares of common stock initially reserved for issuance under the 2015 Plan was 6,134,292 shares with an automatic annual increase to the shares issuable under the 2015 Plan to the lower of (i) 4% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, or (ii) a lower number determined by the board of directors.

2009 Plan

The Company's 2009 Stock Incentive Plan, or the 2009 Plan, terminated on the date the 2015 Plan was adopted. Options granted or shares issued under the 2009 Plan that were outstanding on the date the 2015 Plan became effective will remain subject to the terms of the 2009 Plan. Prior to the 2009 Plan termination, the number of options available for grant was increased by 360,000 shares. At December 31, 2015, 8,217,296 options under the 2009 Plan remained outstanding.

Stock option activity under the Company's stock option plan was as follows:

	Shares Available for Grant	Options Outstanding Number of Options	Weighted-Average Exercise Price	Aggregate Intrinsic Value (In thousands)
Balance—December 31, 2012	582,610	3,105,901	$ 0.74	
Authorized	468,000	—		
Granted	(964,888)	964,888	$ 0.82	
Exercised	—	(32,671)	$ 0.48	
Canceled	6,556 [1]	(8,787)	$ 17.15	
Balance—December 31, 2013	92,278	4,029,331	$ 0.72	$ 985
Authorized	5,071,079	—		

Granted	(2,019,598)	2,019,598	$ 1.00	
Exercised	—	(66,499)	$ 0.74	
Canceled	10,996 [1]	(12,048)	$ 9.33	
Balance—December 31, 2014	3,154,755	5,970,382	$ 0.80	$ 4,335
Authorized	6,494,292	—		
Granted	(4,893,562)	4,893,562	$ 9.94	
Exercised	—	(836,241)	$ 0.82	
Canceled	54,786	(96,474)	$ 1.74	
Balance—December 31, 2015	4,810,271	9,931,229	$ 5.29	$ 229,591
Options exercisable—December 31, 2015		4,462,121	$ 1.47	$ 119,080
Options vested and expected to vest—December 31, 2015		9,886,497	$ 5.18	$ 229,587

[1] The amount excludes 41,688, 1,052 and 2,231 canceled options for the years ended December 31, 2015, 2014 and 2013, respectively, initially granted from the legacy stock option plans. As these plans have been terminated, any options canceled are not added back to the existing option plan pool.

The aggregate intrinsic value represents the difference between the exercise price of the options and the estimated fair value of the Company's common stock, as determined by the Board of Directors, for each of the respective periods.

The aggregate intrinsic value of options exercised was $19.4 million, $17,000 and $0 for the years ended December 31, 2015, 2014 and 2013, respectively.

The weighted-average grant date fair value of employee options granted during the years ended December 31, 2015, 2014 and 2013 were $6.54, $0.67 and $0.55 per share, respectively.

At December 31, 2015, the weighted-average remaining contractual life was 6.8 years and 8.0 years for exercisable options and vested and expected to vest options, respectively. The weighted-average remaining contractual life of options outstanding was 8.0 years, 7.9 years and 8.0 years at December 31, 2015, 2014 and 2013 respectively.

Stock-based Compensation Expense

Total stock-based compensation expense recognized was as follows (in thousands):

	Year Ended December 31,		
	2015	2014	2013
Research and development	$2,493	$202	$194
General and administrative	5,937	368	215
Total stock-based compensation expense	$8,430	$570	$409

At December 31, 2015, the total unrecognized compensation expense related to unvested options, net of estimated forfeitures, was $27.3 million, which the Company expects to recognize over an estimated weighted-average period of 2.8 years.

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

Fair Value of Common Stock. Prior to the IPO in April 2015, the board of directors, determined the fair value of the Company’s common stock by taking into consideration, among other things, contemporaneous valuations of the common stock prepared by an unrelated third-party valuation firm. Given the previous absence of a public trading market for the common stock, the board of directors exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of the common stock, including the Company’s stage of development; progress of its research and development efforts; the rights, preferences and privileges of its preferred stock relative to those of its common stock; equity market conditions affecting comparable public companies and the lack of marketability of the common stock.

Expected Term—The Company’s expected term represents the period that the Company’s stock-based awards are expected to be outstanding and is determined using the simplified method (based on the mid-point between the vesting date and the end of the contractual term).

Expected Volatility—Since the Company does not have a long trading history for its common stock, the expected volatility was estimated based on the average volatility for comparable publicly traded biopharmaceutical companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on their similar size, stage in the life cycle or area of specialty.

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

Expected Dividend—The Company has never paid dividends on its common stock and has no plans to pay dividends on its common stock. Therefore, the Company used an expected dividend yield of zero.

The fair value of stock option awards granted to employees was estimated at the date of grant using a Black-Scholes option-pricing model with the following assumptions:

	Year Ended December 31,		
	2015	2014	2013
Expected term (in years)	5.3 – 6.1	5.3 – 6.1	5.0 – 6.0
Volatility	70.2 – 82.3%	70.2 – 77.3%	75.7 – 78.6%
Risk-free interest rate	1.46 – 1.92%	1.85 – 2.0%	1.36 – 1.73%
Dividend yield	—%	—%	—%

For the years ended December 31, 2015, 2014 and 2013, the Company recognized $6.2 million, $0.5 million and $0.4 million, respectively, of stock-based compensation related to options granted to employees. The compensation expense is allocated on a departmental basis, based on the classification of the option holder. No income tax benefits have been recognized in the statements of

operations for stock-based compensation arrangements and no stock-based compensation costs have been capitalized as property and equipment as of December 31, 2015.

The Company uses the fair value method to value options granted to non-employees. In 2015, 2014 and 2013, the Company recognized stock-based compensation of $2.2 million, $85,000 and $50,000, respectively, related to options granted to non-employees.

The fair value of stock option awards granted to non-employees was estimated at the date of grant using a Black-Scholes option-pricing model with the following assumptions:

	Years Ended December 31,		
	2015	2014	2013
Expected term (in years)	9.1 – 9.9	9.3 – 9.7	10
Volatility	72.1 – 83.8%	78.0 – 78.1%	78.4%
Risk-free interest rate	2.06 – 2.36%	2.19 – 2.39%	2.72%
Dividend yield	—%	—%	—%

16. Income Taxes

The components of loss before income tax benefit were as follows (in thousands):

	December 31,		
	2015	2014	2014
Domestic	(38,702)	(17,014)	(16,054)
Foreign	(606)	—	—
Total	$(39,308)	$(17,014)	$(16,054)

The income tax benefit consists of the following (in thousands):

	December 31,		
	2015	2014	2013
Current income tax benefit:			
Total current income tax benefit	$—	$ —	$ —
Deferred income tax benefit:			
Foreign	99	—	—
Total deferred income tax benefit	99	—	—
Total income tax benefit	$99	$ —	$ —

A reconciliation of the statutory U.S. federal rate to the Company’s effective tax rate is as follows:

	Year Ended December 31,		
	2015	2014	2013
U.S. federal taxes at statutory rate	(34.0%)	(34.0%)	(34.0%)
State taxes, net of federal benefits	—	—	—
U.S. research credits	(3.4)	(1.0)	(1.3)
Warrants	23.0	2.1	3.8
Incentive stock option compensation	1.8	0.8	—
Other	—	0.2	0.2
Foreign income tax rate differential	0.4	—	—
Change in valuation allowance	11.9	31.9	31.3
Total	(0.3%)	—%	—%

The tax effects of temporary differences and carryforwards that give rise to significant portions of the deferred tax assets and liabilities are as follows (in thousands):

	December 31,	
	2015	2014
Current provision		
Net operating loss carryforwards	$18,668	$17,746
Research and development credits	2,223	870
Stock-based compensation	2,177	124
Accruals and reserves	1,318	488
Gross deferred tax assets	24,386	19,228
Valuation allowance	(24,072)	(19,212)
Total deferred tax assets	314	16
Deferred tax liabilities:		
Tangible assets	(314)	(16)
Intangible assets	(7,350)	—
Total deferred tax liabilities	(7,664)	(16)
Net deferred tax liabilities	$(7,350)	$—

The Company is required to reduce its deferred tax assets by a valuation allowance if it is more likely than not that some or all of its deferred tax assets will not be realized. Management must use judgment in assessing the potential need for a valuation allowance, which requires an evaluation of both negative and positive evidence. The weight given to the potential effect of negative and positive evidence should be commensurate with the extent to which it can be objectively verified. In determining the need for and amount of the valuation allowance, if any, the Company assesses the likelihood that it will be able to recover its deferred tax assets using historical levels of income, estimates of future income and tax planning strategies. As a result of historical cumulative losses, the Company determined that, based on all available evidence, there was substantial uncertainty as to whether it will recover recorded net deferred taxes in future periods. Accordingly, the Company recorded a valuation allowance against all of its net deferred tax assets at December 31, 2015 and 2014. The net valuation allowance increased by $4.9 million and $0.6 million in 2015 and 2014, respectively.

At December 31, 2015, the Company generated net operating loss, or NOL, carryforwards (before tax effects) for federal and state income tax purposes of $66.8 million and $7.7 million, respectively. Of this amount, $12.9 million and $1.5 million represent federal and state deductions from stock-based compensation, which will be recorded as an adjustment to additional paid-in capital when they reduce tax payable. These federal and state NOL carryforwards will begin to expire in 2027 and 2033, respectively, if not utilized. In addition, the Company generated federal and state research and development tax credit carryforwards of $1.5 million and $2.5 million, respectively, to offset future income tax liabilities. The federal research and development tax credits can be carried forward for 20 years and will start to expire in 2034, if not utilized, while the state research and development tax credit can be carried forward indefinitely.

Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, the Company’s ability to utilize NOL carryforwards or other tax attributes, such as research tax credits, in any taxable year may be limited if the Company has experienced an “ownership change.” Generally, a Section 382 ownership change occurs if one or more stockholders or groups of stockholders who owns at least 5% of a corporation’s stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a specified testing period. Similar rules may apply under state tax laws. We have experienced an ownership change that we believe under Section 382 of the Code will result in limitations in our ability to utilize net operating losses and credits. In addition, the Company may

experience future ownership changes as a result of future offerings or other changes in ownership of its stock. As a result, the amount of the NOLs and research and credit carryforwards presented in the financial statements could be limited and may expire unutilized.

Uncertain Tax Positions

A reconciliation of the Company's unrecognized tax benefits for the years ended December 31, 2015 and 2014 is as follows (in thousands):

	December 31,	
	2015	2014
Balance at beginning of year	$508	$695
Additions (reductions) based on tax positions related to prior year	11	(412)
Additions based on tax positions related to current year	685	225
Balance at end of year	$1,204	$508

There were no unrecognized tax benefits included in the balance sheet that would, if recognized, affect the effective tax rate.

The Company does not foresee material changes to its gross uncertain income tax position liability within the next 12 months.

The Company files income tax returns in the United States and the Netherlands. The federal and state income tax returns are open under the statute of limitations subject to tax examinations for the tax years ended December 31, 2011 through December 31, 2014. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the IRS or state tax authorities to the extent utilized in a future period. For the Netherlands, the tax administration can impose an additional assessment within five years from the year in which the tax debt originated.

The Company will recognize accrued interest and penalties related to unrecognized tax benefits as income tax expense in its statements of operations. At December 31, 2015, the amount of interest and penalties the Company has recorded was zero.

17. Employee Benefit Plan

The Company sponsors a 401(k) plan. All employees are eligible to participate in the 401(k) plan after meeting certain eligibility requirements. Participants may elect to have a portion of their salary deferred and contributed to the 401(k) plan up to the limit allowed under the Internal Revenue Code. The Company has made no contributions to the 401(k) plan since inception.

18. Net Loss per Common Share

Net Loss per Common Share

Since the Company was in a loss position for all periods presented, basic net loss per common share is the same as diluted net loss per common share for all periods presented as the inclusion of all potential common shares outstanding would have been anti-dilutive. Potentially dilutive securities that were not included in the diluted per common share calculations because they would be anti-dilutive were as follows:

	December 31,		
	2015	2014	2013
Convertible preferred stock	—	69,608,339	22,041,003
Options to purchase common stock	9,931,229	5,970,382	4,029,331
Convertible preferred stock warrants	—	108,006	108,006
Common stock warrants	929,437	1,154,270	722,954
Convertible notes	—	—	9,766,261
Total	10,860,666	76,840,997	36,667,555

19. Selected Quarterly Financial Data (Unaudited)

The following interim financial information presents the Company's 2015 and 2014 results of operations on a quarterly basis (in thousands, except per share amounts):

	Quarter Ended			
	March 31, 2015	June 30, 2015	September 30, 2015	December 31, 2015
Total revenue	$9,574	$9,883	$ 19,146	$ 34,376
Net (loss) income	(16,616)	(26,260)	567	3,100
Net (loss) income per common share, basic	(39.97)	(0.50)	0.01	0.05
Net (loss) income per common share, diluted	(39.97)	(0.50)	0.01	0.04

	Quarter Ended			
	March 31, 2014	June 30, 2014	September 30, 2014	December 31, 2014
Total revenue	$25	$985	$ 2,486	$ 9,893
Net loss	(7,784)	(3,626)	(4,684)	(920)
Net loss income per common share, basic and diluted	(26.34)	(12.27)	(14.24)	(2.54)

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.

Our management, with the participation of our President and Chief Executive Officer and our Chief Operating Officer, our principal financial officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of December 31, 2015. Based on that evaluation, our President and Chief Executive Officer and our Chief Operating Officer have concluded that, as of December 31, 2015, our disclosure controls and procedures were, in design and operation, effective.

Exemption from management's report on internal control over financial reporting for the fiscal year ended December 31, 2015

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting on an attestation report of our independent registered public accounting firm due to a transition period established by the rules of the SEC for newly public companies.

Changes in internal control over financial reporting.

There were no changes in our internal control over financial reporting during the three months ended December 31, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent limitation on the effectiveness of internal control.

The effectiveness of any system of internal control over financial reporting, including ours, is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating, and evaluating the controls and procedures, and the inability to eliminate misconduct completely. Accordingly, any system of internal control over financial reporting, including ours, no matter how well designed and operated, can only provide reasonable, not absolute assurances. In addition, 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. We intend to continue to monitor and upgrade our internal controls as necessary or appropriate for our business, but cannot assure you that such improvements will be sufficient to provide us with effective internal control over financial reporting.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information required by this item will be contained in our definitive proxy statement to be filed with the Securities and Exchange Commission on Schedule 14A in connection with our 2016 Annual Meeting of Stockholders, or the Proxy Statement, which will be filed not later than 120 days after the end of our fiscal year ended December 31, 2015, under the headings “Executive Officers,” “Election of Directors,” “Corporate Governance,” and “ Section 16(a) Beneficial Ownership Reporting Compliance,” and is incorporated herein by reference.

We have adopted a Code of Business Conduct and Ethics that applies to our officers, directors and employees which is available on our website at www.aduro.com. The Code of Business Conduct and Ethics is intended to qualify as a “code of ethics” within the meaning of Section 406 of the Sarbanes-Oxley Act of 2002 and Item 406 of Regulation S-K. In addition, we intend to promptly disclose (1) the nature of any amendment to our Code of Business Conduct and Ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions and (2) the nature of any waiver, including an implicit waiver, from a provision of our code of ethics that is granted to one of these specified officers, the name of such person who is granted the waiver and the date of the waiver on our website in the future.

Item 11. Executive Compensation.

The information required by this item regarding executive compensation will be incorporated by reference to the information set forth in the sections titled “Executive Compensation” and “Director Compensation” in our Proxy Statement.

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

The information required by this item regarding security ownership of certain beneficial owners and management will be incorporated by reference to the information set forth in the sections titled “Security Ownership of Certain Beneficial Owners and Management” and “Equity Compensation Plan Information” in our Proxy Statement.

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

The information required by this item regarding certain relationships and related transactions and director independence will be incorporated by reference to the information set forth in the sections titled “Certain Relationships

and Related Party Transactions” and “Election of Directors”, respectively, in our Proxy Statement.

Item 14. Principal Accounting Fees and Services.

The information required by this item regarding principal accountant fees and services will be incorporated by reference to the information set forth in the section titled “Principal Accountant Fees and Services” in our Proxy Statement.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The following documents are filed as part of this report:

1. Financial Statements

Information in response to this Item is included in Part II, Item 8 of this Annual Report on Form 10-K.

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

See Item 15(b) below.

(b) We have filed, or incorporated into this Annual Report on Form 10-K by reference, the exhibits listed on the Exhibit Index immediately following the Signatures page of this Annual Report on Form 10-K.

(c) See Item 15(a)2 above.

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 Report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Berkeley, State of California, on the 8th day of March, 2016.

ADURO BIOTECH, INC.

By: /s/ Stephen T. Isaacs
Stephen T. Isaacs

Chairman, President and Chief Executive Officer

(principal executive officer)

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Stephen T. Isaacs and Gregory W. Schafer, and each of them, as his or her true and lawful attorneys-in-fact and agents, each with the full power of substitution, for him or her and in his or her name, place or 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 attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their, his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Stephen T. Isaacs Stephen T. Isaacs	Chairman, President and Chief Executive Officer (principal executive officer)	March 8, 2016
/s/ Gregory W. Schafer Gregory W. Schafer	Chief Operating Officer (principal financial officer)	March 8, 2016
/s/ Jennifer Lew Jennifer Lew	Senior Vice President of Finance (principal accounting officer)	March 8, 2016
/s/ Gerald Chan, DSc Gerald Chan, DSc	Director	March 8, 2016
/s/ William M. Greenman William M. Greenman	Director	March 8, 2016
Ross Haghighat	Director	
/s/ Frank McCormick Frank McCormick	Director	March 8, 2016
/s/ Stephanie O’Brien Stephanie Monaghan O’Brien	Director	March 8, 2016
/s/ Stephen A. Sherwin Stephen A. Sherwin	Director	March 8, 2016

EXHIBIT INDEX

		Incorporated by Reference				Filed
Exhibit No.	Description of Exhibit	Form	File No.	Exhibit	Filing Date	Herewith
2.1†	Share Sale Agreement between BioNovion Holding B.V., Brabant Life Sciences Seed Fonds B.V., Spin Off Fonds Brabant B.V., BFF B.V., Aduro Biotech, Inc. and Aduro Netherlands Cöoperatief U.A., dated September 25, 2015.	10-Q	001-37345	2.1	11/23/2015	
3.1	Restated Certificate of Incorporation of Aduro Biotech, Inc.	8-K	001-37345	3.1	04/20/2015	
3.2	Amended and Restated Bylaws of Aduro Biotech, Inc.	S-1/A	333-202667	3.5	04/06/2015	
4.1	Form of common stock certificate.	S-1/A	333-202667	4.1	04/06/2015	
4.2	Amended and Restated Investor Rights Agreement, by and among Aduro Biotech, Inc. and the stockholders named therein, dated December 19, 2014.	S-1	333-202667	4.2	03/11/2015	
10.1+	2000 Oncologic Equity Incentive Plan.	S-1	333-202667	10.1	03/11/2015	
10.2+	Forms of Stock Option Agreement and Notice of Grant of Stock Option under the 2000 Oncologic Equity Incentive Plan.	S-1	333-202667	10.2	03/11/2015	
10.3+	2001 Triton BioSystems Equity Incentive Plan.	S-1	333-202667	10.3	03/11/2015	
10.4+	Forms of Stock Option Agreement and Notice of Grant of Stock Option under the 2001 Triton BioSystems Equity Incentive Plan.	S-1	333-202667	10.4	03/11/2015	
10.5+	Aduro Biotech 2009 Stock Incentive Plan.	S-1	333-202667	10.5	03/11/2015	
10.6+	Forms of Stock Option Agreement and Notice of Grant of Stock Option under the 2009 Stock Plan.	S-1	333-202667	10.6	03/11/2015	
10.7+	2015 Equity Incentive Plan.	S-1/A	333-202667	10.7	04/06/2015	
10.8+	Forms of Stock Option Agreement and Notice of Grant of Stock Option under the 2015 Equity Incentive Plan.	S-1/A	333-202667	10.8	04/06/2015	
10.9+	2015 Employee Stock Purchase Plan.	S-1/A	333-202667	10.9	04/06/2015	

10.10+	Form of Indemnification Agreement made by and between Aduro Biotech, Inc. and each of its directors and executive officers.	S-1	333-202667	10.11	03/11/2015
10.11+	Executive Employment Agreement between Aduro Biotech, Inc. and Stephen T. Isaacs, dated February 26, 2010.	S-1	333-202667	10.12	03/11/2015
10.12+	Amendment to Executive Employment Agreement between Aduro Biotech, Inc. and Stephen T. Isaacs, dated July 31, 2014.	S-1	333-202667	10.13	03/11/2015
10.13+	Offer of Employment Letter between Aduro Biotech, Inc. and Gregory W. Schafer, dated April 28, 2013.	S-1	333-202667	10.14	03/11/2015

		Incorporated by Reference				Filed
Exhibit No.	Description of Exhibit	Form	File No.	Exhibit	Filing Date	Herewith
10.14+	Severance Agreement between Aduro Biotech, Inc. and Gregory W. Schafer, dated July 31, 2014.	S-1	333-202667	10.15	03/11/2015	
10.15+	Offer of Employment Letter between Aduro Biotech, Inc. and Thomas Dubensky, dated September 7, 2011.	S-1	333-202667	10.16	03/11/2015	
10.16+	Severance Agreement between Aduro Biotech, Inc. and Thomas Dubensky, dated July 31, 2014.	S-1	333-202667	10.17	03/11/2015	
10.17†	Research and License Agreement between Aduro Biotech, Inc. and Janssen Biotech, Inc., dated as of May 27, 2014.	S-1	333-202667	10.18	03/11/2015	
10.18†	GVAX Prostate License Agreement between Aduro Biotech, Inc. and Janssen Biotech, Inc., dated as of May 27, 2014.	S-1	333-202667	10.19	03/11/2015	
10.19†	Research and License Agreement between Aduro Biotech, Inc. and Janssen Biotech, Inc., dated as of October 13, 2014.	S-1	333-202667	10.20	03/11/2015	
10.20†	Exclusive License Agreement between Aduro Biotech, Inc. and The Johns Hopkins University, dated March 24, 2011.	S-1	333-202667	10.21	03/11/2015	
10.21†	Exclusive License Agreement between Aduro Biotech, Inc. and the Regents of the University of California, dated March 15, 2012.	S-1	333-202667	10.22	03/11/2015	
10.22†	Asset Purchase Agreement between Aduro GVAX Inc. and BioSante Pharmaceuticals, Inc., dated January 31, 2013.	S-1	333-202667	10.23	03/11/2015	
10.23†	Patent and Technology License and Materials Transfer Agreement between Aduro Biotech, Inc. and The Johns Hopkins University, dated January 31, 2013.	S-1	333-202667	10.24	03/11/2015	
10.24†	Restated and Amended License Agreement between The Johns Hopkins University and BioSante Pharmaceuticals, Inc., dated March 3, 2011.	S-1	333-202667	10.25	03/11/2015	
10.25†	License Agreement between Karagen Pharmaceuticals, Inc. and Aduro Biotech, Inc., dated June 20, 2012.	S-1	333-202667	10.26	03/11/2015	
10.26†	Exclusive License between Aduro Biotech, Inc. and the Regents of the University of California, dated	S-1	333-202667	10.27	03/11/2015	

	September 25, 2014.				
10.27†	Exclusive License Agreement among Aduro Biotech, Inc., Memorial Sloan Kettering Cancer Center, The Rockefeller University, Rutgers, the State University of New Jersey and University of Bonn, dated December 18, 2014.	S-1	333-202667	10.28	03/11/2015

		Incorporated by Reference				Filed
Exhibit No.	Description of Exhibit	Form	File No.	Exhibit	Filing Date	Herewith
10.28†	Manufacturing Services Agreement between Lonza Walkersville, Inc. and Aduro Biotech, Inc., dated August 6, 2013.	S-1	333-202667	10.29	03/11/2015	
10.29†	Process Development and Manufacturing Services Agreement between IDT Biologika GmbH and Aduro Biotech, Inc., dated December 12, 2013.	S-1	333-202667	10.30	03/11/2015	
10.30	Fourth Addendum to Office Lease, dated February 20, 2015, by and between the Company and Bancroft Way, LLC.	S-1	333-202667	10.31	03/11/2015	
10.31†	Amendment No. 1 to Exclusive License between Aduro Biotech, Inc. and the Regents of the University of California, dated March 6, 2015.	S-1	333-202667	10.32	03/11/2015	
10.32+	Aduro Biotech, Inc. Severance Plan and Summary Plan Description.	S-1	333-202667	10.33	03/11/2015	
10.33+	Aduro Biotech, Inc. Non-Employee Director Compensation Policy.	S-1/A	333-202667	10.33	04/06/2015	
10.34†	Collaboration and License Agreement between Aduro Biotech, Inc. and Novartis Pharmaceuticals Corporation, dated March 12, 2015; and the related letter agreement dated March 19, 2015.	S-1/A	333-202667	10.34	04/06/2015	
10.35	Series E Preferred Stock Purchase Agreement between Aduro Biotech, Inc. and Novartis Institutes for BioMedical Research, Inc., dated March 12, 2015.	S-1/A	333-202667	10.35	04/06/2015	
10.36	Common Stock Purchase Agreement between Aduro Biotech, Inc. and Novartis Institutes for BioMedical Research, Inc., dated March 12, 2015.	S-1/A	333-202667	10.36	04/06/2015	
10.37+	Form of Severance Agreement	S-1/A	333-202667	10.37	04/14/2015	
10.38	Letter Agreement between Aduro Biotech, Inc. and Karagen Pharmaceuticals, Inc. dated June 5, 2015.	10-Q	001-37345	10.38	08/11/2015	
10.39†	Office/Laboratory Lease between Seventh Street Properties VII, LLC and Aduro Biotech, Inc., dated September 11, 2015.	10-Q	001-37345	10.1	11/23/2015	
10.40+	Offer of Employment between Blaine Templeman and Aduro Biotech, Inc., dated September 18, 2015.	10-Q	001-373345	10.2	11/23/2015	

10.41†	Amendment to Research and License Agreements between Aduro Biotech, Inc. and Janssen Biotech, Inc., dated November 11, 2015.	X
21.1	Subsidiaries of Registrant	X
23.1	Consent of Deloitte & Touche LLP, independent registered public accounting firm.	X

Exhibit No.	Description of Exhibit	Incorporated by Reference Form	File No.	Exhibit	Filing Date	Filed Herewith
24.1	Power of Attorney (included in the signature page hereto).					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 amended.					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 amended.					X
32.1*	Certification of Principal Executive Officer and Principal Financial Officer, as required by rules 13a-14(a) and 15d-14(a) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).					X
101.INS	XBRL Instance Document					X
101.SCH	XBRL Taxonomy Extension Schema Document					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					X

+Indicates management contract or compensatory plan, contract or agreement.

†Confidential treatment has been granted for a portion of this exhibit.

* The certifications attached as Exhibit 32.1 accompany this Annual Report on Form 10-K pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed “filed” by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.