UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2019

OR

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

Commission File Number 001-37345

ADURO BIOTECH, INC.

(Exact name of Registrant as specified in its Charter)

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

740 Heinz Avenue
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:

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the Registrant's common stock held by non-affiliates as of June 30, 2019, based on the closing price of the shares of common stock on the Nasdaq Stock Market for such date, was $100,194,037.

The number of shares of Registrant's Common Stock outstanding as of March 4, 2020 was 80,754,155.

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, 2019, 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,” “would,” “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:

- the potential of our technologies and our ability to execute on our corporate strategy;
- our ability to fund our working capital needs into 2023;
- our ability to develop and commercialize our product candidates;
- our ability to use and expand our technologies to build a pipeline of product candidates;
- our ability to obtain and maintain regulatory approval of our product candidates;
- the strength and breadth of our patent portfolio;
- the potential for receipt of additional milestone payments;
- our ability to obtain and adequately protect intellectual property rights for our product candidates;
- our continued reliance on third parties for manufacturing our product candidates, conducting our clinical trials and certain research activities;
- our ability to in-license, acquire or invest in complementary businesses, technologies, products or assets to further expand or complement our portfolio of product candidates;
- expected timing of our clinical trials;
- the timing and availability of results of our clinical trials and those of our collaborators; and
- our ability to extend our operating capital.

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 an immunotherapy company focused on the discovery, development and commercialization of therapies that are designed to harness the body's natural immune system for the treatment of patients with challenging diseases. Our primary technologies related to the cyclic GMP-AMP Synthase – Stimulator of Interferon Genes (cGAS-STING) and A Proliferation Inducing Ligand (APRIL) pathways have led to what we believe is a strong pipeline of clinical candidates that are being investigated in cancer, autoimmune and inflammatory diseases. We are collaborating with leading global pharmaceutical companies to help expand and drive our product pipeline. Our strategy is to rapidly advance first- or best-in-class therapies from our STING and APRIL technologies through clinical development and regulatory approval.

Our STING pathway activator technology is designed to activate the intracellular STING receptor, which may result in a potent tumor-specific immune response. We are developing STING pathway activator product candidates in oncology under our worldwide collaboration with Novartis Pharmaceuticals Corporation, or Novartis. ADU-S100 (MIW815), the first STING pathway activator to enter the clinic, is being investigated in a Phase 2 clinical trial of ADU-S100 in combination with KEYTRUDA® (pembrolizumab), an approved anti-PD-1 monoclonal antibody, as first-line treatment for patients with recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN). We are preparing to initiate a Phase 1 clinical trial of ADU-S100 as a single agent administered intravesically in patients with non-muscle invasive bladder cancer (NMIBC) who are unresponsive to Bacillus Calmette-Guerin (BCG), an approved intravesical immunotherapy, in the second half of 2020. ADU-S100 (MIW815) has also been evaluated in a Phase 1 clinical trial as a single agent and in a Phase 1b combination trial with spartalizumab (PDR001), an investigational anti-PD-1 monoclonal antibody, in patients with cutaneously accessible metastatic solid tumors or lymphomas.

APRIL is a soluble factor that binds to B-cell maturation antigen, or BCMA, and transmembrane activator and CAML interactor, or TACI, receptors thereby inducing signaling, and is believed to be implicated in IgA nephropathy and other indications. BION-1301, a first-in-class fully blocking monoclonal antibody that blocks APRIL binding to both the BCMA and TACI receptors, is being evaluated in an ongoing Phase 1 clinical trial in healthy volunteers and patients with IgA nephropathy.

In addition to our current STING pathway product candidates that activate the STING receptor, we are developing product candidates that are designed to prevent or control immune responses through the STING pathway as part of our cGAS-STING pathway inhibitor program under a research collaboration and exclusive license agreement with Eli Lilly and Company, or Lilly. Our cGAS-STING pathway inhibitor program involves the research and development of novel inhibitor product candidates for autoimmune and other inflammatory diseases.

We have intellectual property protection on our STING and APRIL technologies and each of our product candidates, some of which we believe can be maintained into 2040.

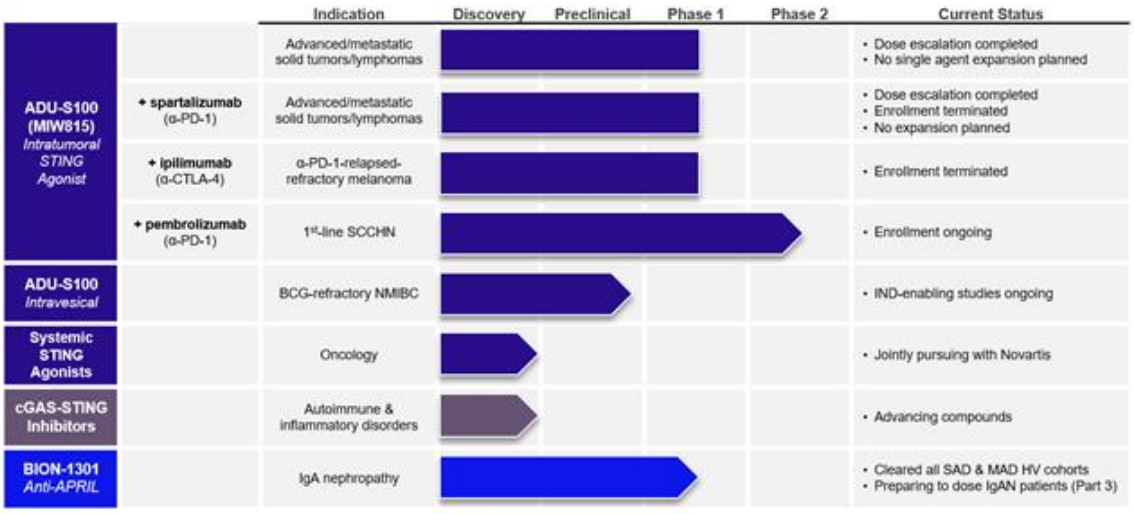
Our Strategy

We aim to discover, develop and commercialize therapies to treat challenging diseases based on our cGAS-STING and APRIL pathway technologies. Key elements of our strategy include:

- **Rapidly advance therapies from our STING and APRIL technologies through discovery, clinical development and regulatory approval.** We are developing novel drug candidates by leveraging our proprietary technologies and understanding of the cGAS-STING and APRIL pathways. We have proprietary technologies that we believe can generate novel and combinable therapies to target disease indications with significant unmet medical need.
- **Expand on the value of our product candidates through partnerships.** We may decide to selectively partner product candidates in certain geographies and where we believe a partner could bring additional resources and expertise to maximize the value of our product candidates. We have strategic partnerships with Novartis for STING pathway activator product candidates in oncology, Lilly for cGAS-STING pathway inhibitor product candidates in autoimmune and inflammatory diseases and Merck Sharp and Dohme B.V., or Merck, to advance an anti-CD27 agonist. We believe these partnerships have the potential to drive significant value through the extensive capabilities of these organizations.

- **Maximize the value of our proprietary STING and APRIL pathway programs through the retention of commercial rights in key markets.** We retain U.S. commercial rights for STING pathway activator product candidates in oncology developed in collaboration with Novartis. In addition, we maintain full ownership of our APRIL pathway product candidates.
- **Leverage the expertise of our scientific founders and key advisors to develop innovative technologies at the forefront of immunotherapy.** 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 and immunotherapy. 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 immunotherapy. We strive to protect our commercially important discoveries and product candidates by applying for, maintaining and defending our patent rights.

Our Pipeline



SCCHN = squamous cell carcinoma of the head and neck; BCG = Bacillus Calmette-Guerin; NMIBC = non-muscle invasive bladder cancer

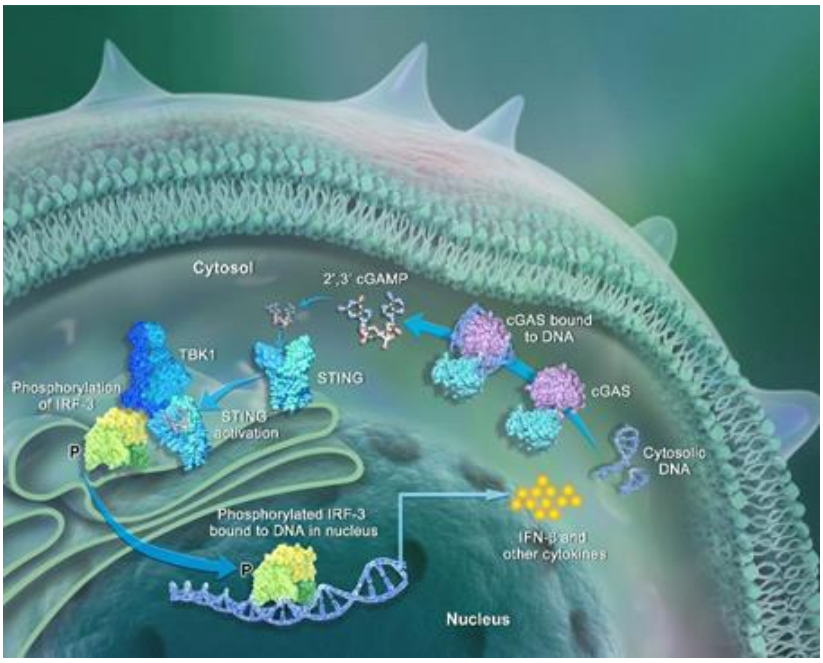
STING Pathway Technology

We believe key attributes of our STING pathway technology include:

- *Early Evidence of Potency.* Our STING pathway activator product candidates have demonstrated significant anti-tumor activity in preclinical studies as well as early signs of clinical activity.
- *Novel Mechanism.* Our STING Pathway 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 activator product candidates can be delivered via intratumoral injection, intravesical instillation and via new systemic delivery formulations and other novel modalities.
- *Combinability*. Based on their mechanism of action and results from preclinical studies and observations from early clinical studies, we believe our STING pathway activator product candidates may exert synergistic or additive benefit when combined with conventional and novel therapies, such as chemotherapy, radiotherapy and checkpoint inhibitors, among others.
- *Ease of Manufacture.* Our STING pathway activator product candidates are small molecules manufactured through a relatively simple and cost-effective process.
- *Broad Applicability.* We believe our STING pathway product candidates have broad application in oncology as well as autoimmune and inflammatory diseases (cGAS-STING pathway antagonist program).

The STING receptor is known to be a central mediator of innate immunity and is critical for immune surveillance. Ongoing 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 synthetic proprietary small molecule immune modulators that target and activate the STING receptor with application across diverse diseases. The STING receptor is generally expressed at high levels in immune cells, including dendritic cells, or DCs, that are critical for tumor antigen-presentation, and many other cells in the body. Once activated, the STING receptor initiates a profound innate immune response, inducing the expression of a broad profile of cytokines, including interferons and chemokines. In addition to this cytokine profile, the enhanced tumor antigen-presenting capacity subsequently has been demonstrated in preclinical models to lead to the development of an effective tumor antigen-specific T cell adaptive immune response.

Natural ligands for STING occur in cells as cyclic dinucleotides, or CDNs, either produced by bacteria infecting a host cell or by mammalian cells through the upstream enzyme, cGAS, upon sensing the presence of double-stranded (ds) DNA in the cytosol. Endogenously produced CDNs, including 2’,3’ cGAMP, bind with high affinity and activate all known human allelic variant STING proteins. We are advancing through development novel synthetic STING pathway product candidates with further improved properties that potently activate all STING proteins.



STING Pathway Activator Product Candidates

We envision multiple STING pathway product opportunities, particularly in combination with other treatments. In preclinical animal models, our data have shown that our proprietary STING pathway activator product candidates can be combined with checkpoint inhibitors such as those targeting PD-1 and CTLA-4, and conventional cancer treatments such as chemotherapy and radiotherapy.

ADU-S100

Our lead STING pathway product candidate is ADU-S100 (also known as MIW815), which differs from naturally occurring CDNs through the provision of proprietary modifications 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 pathway product candidates in oncology.

ADU-S100 Preclinical Studies

In preclinical mouse tumor models, intratumoral (IT) injection of ADU-S100 induced tumor shrinkage and generated substantial immune responses capable of providing long-lasting systemic antigen-specific T cell immunity to prevent further growth of distal, untreated tumor metastases, sometimes referred to as an abscopal effect. Preclinical tumor therapy experiments using ADU-S100 via intratumoral injection indicate that in addition to the production of IFN-β, activation of CD8+ T cell responses is a hallmark of successful STING pathway activator therapy leading to immune-mediated rejection of injected and distant tumors and long-term and systemic immunity. We therefore believe ADU-S100 has the potential to bridge innate to adaptive immunity in tumors that are not otherwise rejected.

ADU-S100 directly activates natural killer cells and could potentially enhance Antibody-Dependent Cellular Cytotoxicity, or ADCC, representing an important mechanism of action of several established monoclonal antibody cancer therapies. Therefore, another opportunity could be to conjugate our STING pathway activator product candidates to enhance ADCC.

We are advancing development of ADU-S100 in clinical trials designed to further assess its potential.

Head and Neck Cancer Overview

Cancers that are known collectively as head and neck cancers often begin in the squamous cells that line the moist, mucosal surfaces inside the head and neck, including the oral cavity, larynx, nasal cavity, paranasal sinuses, thyroid and salivary glands. These squamous cell cancers are often referred to as squamous cell carcinoma of the head and neck, or SCCHN. The symptoms of head and neck cancers may include a lump or a sore that does not heal, a sore throat that does not go away, difficulty in swallowing and a change or hoarseness in the voice. SCCHN accounts for over 90 percent of head and neck cancers and is the sixth most common cancer by incidence worldwide. Each year, SCCHN is diagnosed in more than 600,000 people globally, with 50,000 new cases and more than 10,000 deaths occurring in the United States alone. Rates of death due to SCCHN have declined only slightly in the United States over the past three decades, and the all-stage survival rates of 61 percent at five years and 50 percent at 10 years illustrate the need for improved therapy.

Phase 2 ADU-S100 in Combination with anti-PD-1 antibody in SCCHN (Ongoing)

In September 2019, we initiated a Phase 2 clinical trial of ADU-S100 in combination with KEYTRUDA® (pembrolizumab), an approved anti-PD-1 monoclonal antibody, as first-line treatment for patients with recurrent or metastatic SCCHN. The Phase 2, open-label, multicenter trial is designed to evaluate the efficacy and safety of ADU-S100 (MIW815) administered intratumorally in combination with pembrolizumab in the first-line setting. The planned population will consist of 34 adults with PD-L1 positive recurrent or metastatic head and neck cancer.

Non-Muscle Invasive Bladder Cancer Overview

Globally, bladder cancer accounts for approximately 390,000 cases and 150,000 deaths each year. In developed areas of the world, such as North America and Western Europe, these bladder cancers are predominantly urothelial. Approximately 70 percent of new urothelial bladder cancer cases are classified as non-muscle invasive. Non-muscle invasive bladder cancer, or NMIBC, includes Ta (papillary), T1 (submucosal invasive) tumors, and Tis (carcinoma in situ), which account for approximately 70, 20, and 10 percent of non-muscle invasive cancers, respectively. NMIBC is a local, superficial disease in which ablation of the tumor may be sufficient to control the disease. Bacillus Calmette-Guerin (BCG) is the most commonly used agent for intravesical therapy. The American Urological Association (AUA), American Association of Clinical Urologists (AACU), Bladder Cancer Advocacy Network (BCAN), Society of Urologic Oncology (SUO), the Large Urology Group Practice Association (LUGPA) and the Urology Care Foundation (UCF) remain concerned about a global shortage of BCG and its effects on the care of bladder cancer patients. The global shortage of BCG due to the growing use and need for this product around the world is a significant issue, and additional treatment options are needed.

Scientific Rationale for Preclinical Studies of ADU-S100 in NMIBC

ADU-S100 is a small molecule with potential to induce a local innate immune response in patients with NMIBC. Patients who are unresponsive to BCG have a tumor microenvironment enriched with ADU-S100 targets. In addition, mechanisms leading to a BCG-refractory state may not interfere with a response to ADU-S100. As a result, there is potential for a single agent therapeutic application of ADU-S100 in patients with BCG-refractory NMIBC. Given intravesical administration is the current standard of care, it is an attractive alternative to systemic delivery. BCG-refractory patients constitute a high unmet medical need recognized by the FDA with an approval pathway outlined in guidance from February 2018.

In preclinical models, ADU-S100 activates an immune response in the bladder after intravesicular delivery and controls tumors. We have demonstrated preclinical anti-tumor efficacy in the standard orthotopic model (MB49 bladder tumor). Local cytokine induction was observed with intravesicular delivery of ADU-S100.

We are preparing to initiate a Phase 1 clinical trial of ADU-S100 as a single agent administered intravesically in patients with NMIBC who are unresponsive to BCG in the second half of 2020.

Systemic STING Agonists

We continue to jointly pursue STING pathway activation through systemic delivery as a therapeutic strategy under our collaboration and license agreement with Novartis.

cGAS-STING Pathway Inhibitor Program

We are also pursuing product opportunities that inhibit or antagonize the STING pathway. According to recent publications, over-production of type I IFN has been linked to the pathophysiology of several autoimmune and inflammatory diseases. Furthermore, genetic mutations found in proteins regulating the STING pathway were linked to certain inflammatory diseases, including severe childhood inflammatory syndromes.

Our cGAS-STING pathway inhibitor product candidates are small molecules that are being designed to bind and block the pathway to reduce excessive type I interferon production that drive certain autoimmune and inflammatory diseases. These small molecules originate from several high throughput screens and are further optimized to impart adequate potency and systemic bioavailability. We believe these product candidates may have broad application in the treatment of autoimmune and inflammatory diseases. In December 2018, we entered into a research collaboration and exclusive license agreement with Lilly for our cGAS-STING Pathway Inhibitor program for the research and development of novel product candidates for autoimmune and other inflammatory diseases.

APRIL Pathway Technology

We believe key attributes of our APRIL pathway technology include:

- *Early Evidence of Potency.* BION-1301, a humanized antibody that blocks APRIL from binding to both the BCMA and TACI receptors, has been shown in preclinical studies to reduce serum IgA levels in mice and monkeys, demonstrating compelling rationale for its use in IgA nephropathy.
- *Novel Mechanism.* Blocking APRIL is a distinct approach to inhibit its activity on both the BCMA and TACI receptors that appears to have immunomodulatory properties.
- *Versatility.* APRIL is implicated in the pathogenesis of multiple indications including IgA nephropathy and other diseases that involve plasma cells.
- *Ease of Manufacture.* BION-1301 is a biologic that can be manufactured through well-established processes.
- *Broad Applicability.* BION-1301 is a monoclonal antibody, an established therapeutic class to treat cancer as well as autoimmune diseases.

Patients with IgA nephropathy have significantly higher levels of APRIL than healthy controls, and higher APRIL levels in these patients correlates with poor prognosis in the form of increased galactose-deficient immunoglobulin A (Gd-IgA), increased proteinuria and decreased estimated glomerular filtration rate (eGFR). Gd-IgA is recognized as a critical autoantigen to which IgA nephropathy patients develop autoantibodies, resulting in the formation and deposition of immune complexes in the kidneys, which ultimately causes local inflammation and functional damage. We know from published literature that APRIL is a soluble factor that functions via binding to the BCMA and TACI receptors, and that APRIL critically drives IgA class switching through TACI and survival of IgA-producing plasma cells through BCMA. Our experiments demonstrate that blocking APRIL inhibits the survival and immunoglobulin production of human plasma cells. We have also demonstrated that IgA-producing plasma cells are more sensitive to immunomodulation by BION-1301, possibly due to their enhanced expression of TACI and BCMA. BION-1301 also downregulates IgG- and IgM-producing plasma cells, which is critical because autoantibodies targeting Gd-IgA can be of all Ig classes. Blocking APRIL is a distinct approach to potentially downmodulate two key processes in the pathogenesis of IgA nephropathy: reducing circulating levels of IgA, Gd-IgA and anti-Gd-IgA autoantibodies as well as immune complex formation. We believe BION-1301 represents the first potential disease-modifying treatment for IgA nephropathy.

APRIL Product Candidates

BION-1301

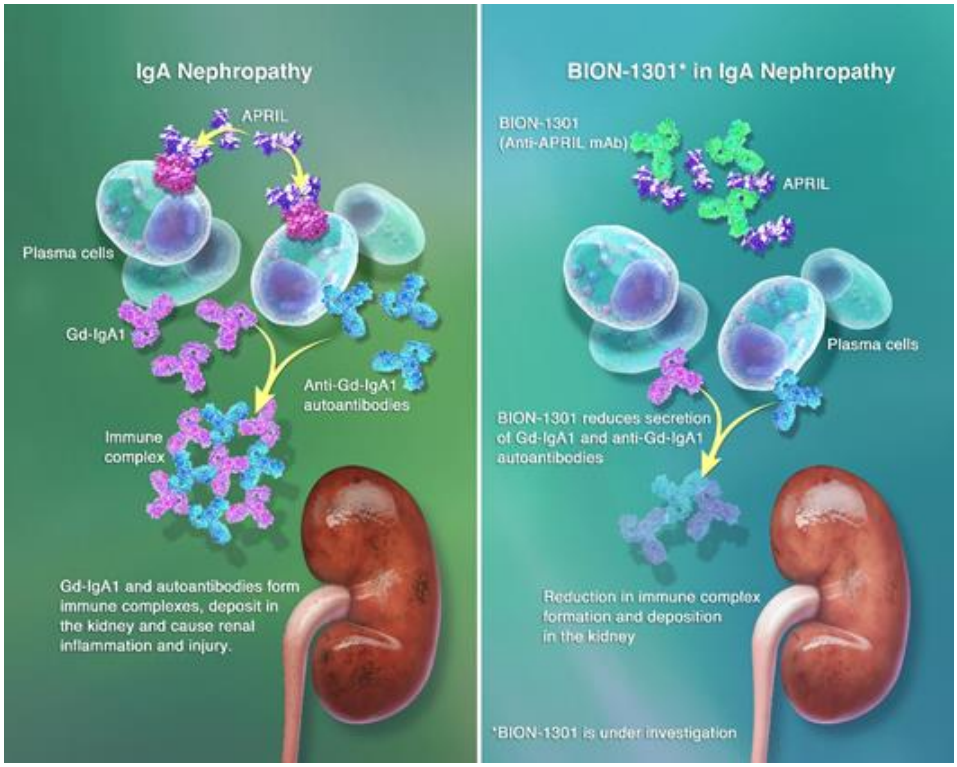
BION-1301 is a first-in-class, humanized IgG4 monoclonal antibody that fully blocks APRIL binding to both the BCMA and TACI receptors and is being developed as a novel therapy for IgA nephropathy.

Preclinical studies have demonstrated that BION-1301 binds to a specifically defined epitope on APRIL, resulting in complete blockade of APRIL-induced receptor activation. Dosing of BION-1301 in non-human primates led to a significant reduction of blood IgA levels and established a favorable safety profile. Additional preclinical studies demonstrated that hAPRIL transgenic mice produce rising levels of IgA as well as IgA deposits in the kidney. Administration of mouse anti-human APRIL was shown to reduce levels of IgA in both the serum and the kidney. In patients with IgA nephropathy, BION-1301 has the potential to neutralize APRIL, inhibit secretion of Gd-IgA, and thereby reduce immune complex formation and kidney deposition. BION-1301 is currently being evaluated in a Phase 1 clinical trial.

IgA Nephropathy Overview

IgA nephropathy is a chronic autoimmune kidney disease characterized by the accumulation of autoantibodies binding to Gd-IgA, ultimately leading to the deposition of immune complexes in the glomeruli of the kidneys. This results in inflammation that damages the glomeruli, causing proteinuria and microscopic hematuria. As the disease advances, patients with IgA nephropathy may require dialysis or kidney transplantation. There is no available treatment to reduce production of Gd-IgA associated with IgA nephropathy.

Up to approximately 50 percent of patients with IgA nephropathy progress to end-stage renal disease (ESRD) within 20 years. No cure currently exists for IgA nephropathy and treatments are targeted towards preventing progression to ESRD and alleviating symptoms. IgA nephropathy is the most prevalent primary chronic glomerular disease worldwide. While prevalence varies geographically, biopsy and dialysis registry data suggest a higher incidence of IgA nephropathy in East Asian populations and lower incidence in African populations. Variations in disease prevalence may reflect regional differences in screening for kidney disease and kidney biopsy practices. Many patients with IgA nephropathy are detected on routine urine screening because their only clinical manifestation is asymptomatic hematuria and/or proteinuria. Prevalence may therefore appear to be higher in countries with an active urine testing program and a low threshold for the performance of renal biopsy in patients with isolated asymptomatic hematuria, such as Japan and Korea, where testing is routinely performed in schools and in the workplace. Conversely, clinicians in North America seldom biopsy a patient with isolated hematuria or mild proteinuria, resulting in an apparently lower disease prevalence.



Phase 1 BION 1301 in IgA Nephropathy (Ongoing)

In the first half of 2019, we initiated a Phase 1 clinical trial of BION-1301 in IgA nephropathy in healthy volunteers. As part of this study protocol, we will begin dosing IgA nephropathy patients in the first half of 2020. The primary objectives of this clinical trial are to:

- Assess the safety profile of BION-1301 in healthy volunteers and IgA nephropathy patients,
- Determine the PK/PD relationship in healthy volunteers and IgA nephropathy patients, and
- Establish proof-of-mechanism: reduction in IgA in healthy volunteers and/or a reduction in Gd-IgA in IgA nephropathy patients.

Other Programs

Anti-CD27 Agonist

CD27 is a co-stimulatory receptor expressed on different immune cells, such as T-lymphocytes and NK (natural killer) cells. It has been recognized as having an important role in priming, enhancing and sustaining a productive anti-cancer (CD8+ T-cell) adaptive

immune response. In preclinical studies, anti-CD27 activation was shown to enhance T-cell response, which in combination with immune checkpoint inhibition demonstrated the ability to achieve complete tumor eradication.

In 2014, we entered into a worldwide exclusive license agreement with Merck for the development and commercialization of anti-CD27 agonists, including MK-5890, which was identified with our proprietary B-select monoclonal antibody technology. MK-5890 is a humanized agonist monoclonal antibody that binds to CD27 to provide a costimulatory signal that enhances T-cell-mediated responses. MK-5890 is currently being evaluated by Merck in a Phase 1 clinical trial for the treatment of advanced solid tumors and in a Phase 2 clinical trial in combination with pembrolizumab in patients with advanced squamous or non-squamous NSCLC that have been previously treated with anti-PD-L1 therapy.

Manufacturing

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.

STING Pathway 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 contracts with a CMO to produce, release and stability test the ADU-S100 API and drug product. Under our collaboration agreement with Novartis, Novartis has manufacturing rights for the manufacture of ADU-S100.

APRIL Pathway Candidates

Manufacturing of B-select product candidates includes generation of engineered cell lines that express and secrete the antibody product candidates. After selection of clones that secrete the desired amounts of product candidates, cell banks are generated and stored to preserve identity and characteristics. Process development, upstream and downstream, is undertaken to select optimal conditions for growth and productivity, quality standards and yield. In addition, activities are undertaken to identify formulation composition to establish stability characteristics. We contract with a CMO to develop, produce and release drug substance and drug product for our antibody candidates targeting APRIL and CTLA-4.

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 protections afforded through data exclusively, patent term extensions and regulatory exclusivity, where available.

Through licensing and through developing our own portfolio, we have rights to more than 150 issued patents and more than 250 pending applications in the United States and foreign countries. Patent families within the portfolio are directed to our STING and APRIL technologies as well as our other non-core programs.

STING Pathway Technology

We own and license families of patents and patent applications directed to our STING pathway product candidates, which expire, or if issued would expire, between 2025 and 2040. In particular, we own four issued U.S. patents, seven pending U.S. patent applications, including corresponding foreign issued patents and pending patent applications, two priority filings, and four international filings directed to stereochemically pure cyclic purine dinucleotides and certain other substituted cyclic purine dinucleotides, and uses and derivatives thereof, which if issued would expire between 2033 and 2040, not including any patent term extensions that may be available under U.S. or foreign laws and assuming continued payment of any applicable fees. Within this portfolio are U.S. and foreign patent applications directed to compositions and methods for activating STING utilizing our STING pathway product candidates that are jointly owned with the Regents of the University of California, and which, if issued, would expire in 2034, and U.S., International and foreign patent applications directed to certain cyclic purine dinucleotides, and uses and derivatives thereof, that are jointly owned with Novartis, which, if issued, would expire in between 2036 and 2039. We also license a family of patents from Karagen Pharmaceuticals directed to certain STING pathway molecules and their use in modulating immune response in a patient, which expire in 2025, not including any patent term extensions that may be available under U.S. laws and assuming continued payment of any applicable fees; a family of patents from the Regents of the University of California also directed to certain STING pathway 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 pathway molecules and their uses, with three issued U.S.

patents, one pending U.S. patent application and corresponding foreign issued patents and pending patent applications that, if issued, would expire in 2034.

Antibody Product Candidates

We own seven issued U.S. patents, five pending U.S. patent applications, including corresponding foreign issued patents and pending patent applications, and one International filing to cover our antibody product candidates and use thereof. The issued U.S. patents that we own expire between 2030 and 2037, not including any patent term extensions that may be available under U.S. laws. Regarding the pending patent applications, if these claims were to be issued, they would expire between 2034 and 2040.

cGAS-STING Pathway Inhibitor Program

We own two issued U.S. patents and corresponding issued foreign patents, one pending U.S. patent application, and three International filings to cover our cGAS-STING Pathway Inhibitor product candidates and use thereof. The issued U.S. and foreign patents that we own expire in 2034, not including any patent term extensions that may be available under U.S. and foreign laws. Regarding the pending patent applications, if these claims were to be issued, they would expire in 2038 or 2039.

General Considerations

As with other biopharmaceutical companies, our ability to maintain and solidify a proprietary position for our 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.

Certain of our product candidates may be subject to The Biologics Price Competition and Innovation Act of 2009, or BPCIA. The BPCIA established an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The new abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as “interchangeable” based on their similarity to an existing brand product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until twelve years after the original branded product was approved under a BLA. The BPCIA is complex and is still in the process of being interpreted and implemented by the FDA. As a result, its ultimate impact and implementation are subject to uncertainty.

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, we may be subject to patent litigation. Alternatively, we might decide to initiate litigation in an attempt to have a court or tribunal 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. It is possible that these 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

Novartis Agreement

In March 2015, we entered into a collaboration and license agreement with Novartis Pharmaceuticals Corporation, or Novartis, pursuant to which we are collaborating worldwide with Novartis regarding the development and 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, 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.

Under the Novartis Agreement, we received an upfront payment of $200.0 million from Novartis in April 2015. In 2016, we earned a $35.0 million development milestone upon initiation of a Phase 1 trial for the first STING product candidate, ADU-S100. We are eligible to receive up to an additional $215.0 million in development milestones and up to an additional $250.0 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; provided that under the agreement either party may opt out of early stage clinical trials subject to an obligation to fund and participate in any pivotal trials and reimburse certain early development costs if development of the product progresses into pivotal trials.

We 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 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 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, we may elect for such region to either reduce by 50% or to eliminate in our development and commercialization 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 any net sales of product for such region, as described above.

In December 2019, Novartis removed ADU-S100 (MIW815), from its portfolio based on clinical data generated to date. This decision was not the result of any safety concern. Novartis has begun winding down the ongoing Phase 1b dose escalation clinical trial to evaluate the safety and preliminary efficacy of ADU-S100 in combination with spartalizumab (PDR001), Novartis' investigational anti-PD-1 monoclonal antibody, in advanced, metastatic treatment-refractory solid tumors or lymphomas, and no dose expansion cohorts will be opened. Novartis is also terminating enrollment of the ongoing Phase 1 clinical trial arm evaluating ADU-S100 in relapsed and refractory melanoma in combination with YERVOY® (ipilimumab), an approved anti-CTLA-4 antibody. Per protocol, patients currently enrolled or consented in these trials will remain on treatment until progression or toxicity. The SCCHN and NMIBC studies evaluating ADU-S100 are being solely funded by Aduro. Under the terms of the collaboration and license agreement, if Novartis opts out of funding an early stage clinical trial and the product progresses into a pivotal clinical trial, then Novartis would be required to fund and participate in the pivotal clinical trial, and Novartis may have certain reimbursement obligations for prior development expenses for the early stage clinical trial.

The collaboration and license agreement between Novartis and Aduro remains in effect, and both parties continue to jointly pursue STING pathway activation through systemic delivery as a therapeutic strategy.

Lilly Agreement

On December 18, 2018, we entered into a research collaboration and exclusive license agreement with Lilly for our cGAS-STING Pathway Inhibitor program for the research and development of novel immunotherapies for autoimmune and other inflammatory diseases. Pursuant to this agreement, or the Lilly Agreement, we granted an exclusive and worldwide license under certain intellectual property rights controlled by us to research, develop, manufacture and commercialize certain cGAS-STING products for the treatment of autoimmune and other inflammatory diseases. The license granted is sublicensable during a specified time period.

Under the terms of the Lilly Agreement, we received an upfront payment of $12.0 million in the first quarter of 2019 and will be eligible for development and commercial milestones of up to approximately $620.0 million per product. Lilly is also obligated to pay us tiered royalty payments at percentages in the single to low-double digits based on annual net sales of the licensed products. Lilly must pay such royalties on a product-by-product and country-by-country basis until the latest to occur of (i) the expiration of the last-to-expire valid claim of certain patents, (ii) the expiration of the data exclusivity period in such country or (iii) a specified anniversary of the first commercial sale of such product in such country. We will be reimbursed for up to a certain amount of research funding spent during the research term. In addition, we have the option to co-fund the clinical development of each product in exchange for an increase in royalty payments and a reduction in certain milestone payments to the extent relevant to such co-funded product. Lilly will be responsible for all costs of global commercialization.

The Lilly Agreement will remain in effect until the expiration of all payment obligations and may be terminated by Lilly following specified notice period, or by either party in the event of an uncured material breach of the other party or bankruptcy of the other party.

Merck Agreement

In connection with the acquisition of Aduro Biotech Europe Holdings, Europe B.V., or Aduro Biotech Europe, in October 2015, we became party to an Exclusive Patent and Know How License and Research Collaboration Agreement with Merck Sharp and Dohme B.V., or Merck, pursuant to which we have exclusively licensed our anti-CD27 antibody to Merck. This agreement, or the Merck Agreement, sets forth the parties' respective obligations for development, and commercialization of certain antibody product candidates.

Since the execution of the Merck Agreement, we have received $5.0 million in connection with achievement of development milestones for our anti-CD27 antibody. In February 2020, we earned an additional $10 million development milestone payment for the initiation of a Phase 2 clinical trial of anti-CD27 antibody (Note 16). Under the Merck Agreement we are eligible to receive future contingent payments, including up to $297.0 million in potential development milestone payments, and up to $135.0 million in commercial and net sales milestones for a product candidate. In addition, we are eligible to receive royalties in the mid-single digits to low teens based on net sales of the product.

Our Research and Development and License Agreements

STING Pathway License 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 pathway technologies 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 UC Berkeley, or 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 terminate the agreement upon 90 days' advance written notice in the event we challenge the validity or unenforceability of any licensed patent.

Memorial Sloan Kettering Cancer Center 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 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. In May and October 2016, the parties amended the license to further expand its scope, which now covers all products covered by the licensed intellectual property.

Under the MSK Agreement, we paid MSK upfront fees of $50,000 in 2015 and an additional $2.0 million in 2016 in connection with the second amendment of the MSK Agreement. Under the amended MSK Agreement we are required to pay MSK development and regulatory milestone payments totaling up to $875,000 for each licensed product and commercialization milestone payments totaling up to $4.5 million 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 immunotherapy 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 immunotherapy products.

Our competitors in the STING pathway activator technology include Merck & Co., Inc., Bristol-Myers Squibb Company/IFM Therapeutics, GlaxoSmithKline plc, Synlogic, Inc., Spring Bank Pharmaceuticals, Inc., Codiak Biosciences, Inc., Eisai, Co., Ltd./H3 Biomedicine, Inc., AbbVie (following its acquisition of Mavupharma), Curadev, Trillium Therapeutics Inc., Mersana Therapeutics, Stingray Therapeutics, Ryvu Therapeutics, Cancer Therapeutics CRC, ImmuneSensor Therapeutics, Nimbus Therapeutics and STINGINN LLC. Our competitors for the anti-APRIL program include Otsuka Pharmaceutical Co., Ltd. (following its acquisition of Visterra, Inc.) and Merck KGaA (EMD Serono). Our competitors for the cGAS-STING pathway inhibitor program include Pfizer Inc., Spring Bank Pharmaceuticals, Inc., GlaxoSmithKline plc, Curadev, Sirenas, LLC, Nimbus Therapeutics/Bristol-Myers Squibb Company, IFM Due (a subsidiary of IFM Therapeutics, LLC), AbbVie (following its acquisition of Mavupharma), ImmuneSensor Therapeutics and STINGINN LLC. 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 and the Netherlands, 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 investigational new drug, or IND, application, 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 biologics license application, or BLA, for any biologic or a new drug application, or 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.

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.

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 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.

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 program fee for marketed 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. Under PDUFA, the FDA has agreed to certain performance goals to complete the review of BLAs. The FDA may give a priority review designation to biological products that offer significant improvements in safety or efficacy, or provide a treatment where no adequate therapy exists. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under current PDUFA guidelines. Under the current PDUFA agreement, these six- and ten-month review periods are measured from the “filing” date rather than the receipt date for original BLAs, which typically adds approximately two months to the timeline for review and decision from the date of submission.

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. 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. 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.

There can be no assurance that we will receive orphan drug designation for any indications or for any 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, 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.

Breakthrough Therapy designation 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 work closely with the sponsor to expedite the development and review of such product.

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. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or 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 processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. This 12-year period of data exclusivity may be extended by six months, for a total of 12.5 years, if the FDA requests that the innovator company conduct certain pediatric clinical investigations of the product.

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 choose 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. 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, impose 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, 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. Manufacturers must submit reports by the 90th day of each calendar year. 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.

Among the Affordable Care Act's provisions of importance to the pharmaceutical and biotechnology industries 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 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.

Some of the provisions of the Affordable Care Act have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the Affordable Care Act. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseverable feature of the Affordable Care Act, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the Affordable Care Act are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court's decision that the individual mandate was unconstitutional but remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. It is unclear how these decisions, subsequent appeals, if any, and other efforts to challenge, repeal or replace the Affordable Care Act will impact the Affordable Care Act and our business. Thus, the full impact of the Affordable Care Act (or other similar legislation) on our business remains unclear.

Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. For example, the Budget Control Act of 2011 resulted in 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 2027 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, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. 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 and enacted federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drugs. Further, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, to encourage importation from other countries and bulk purchasing. 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. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our future revenue potential and results.

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, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. 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, also 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, 2019, we had 96 full-time employees, 74 of whom were engaged in research and development activities and 22 of whom were engaged in finance, business development, facilities, human resources and administrative support. As of December 31, 2019, of our full-time employees, 26 hold Ph.D. or M.D. degrees. 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 740 Heinz Avenue, 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. The following filings are available through our website as soon as reasonably practicable after we file them with the SEC: Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, as well as any amendments to such reports and all other filings pursuant to Section 13(a) or 15 (d) of the Securities Act.

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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 consolidated 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 an immunotherapy 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 efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. We have financed our operations primarily through the sale of common stock, and licensing agreements with pharmaceutical partners. 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. We incurred a net loss of $82.4 million, $95.4 million and $91.9 million for the years ended December 31, 2019, 2018 and 2017, respectively. At December 31, 2019, we had an accumulated deficit of $486.9 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.

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, 2019, our cash and cash equivalents and marketable securities were $213.6 million. We expect to continue to spend substantial amounts to continue the 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 are 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;
- competing therapies and combinations; and
- other 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 collaboration and license agreement with Novartis, which may be terminated by Novartis upon 180 days' notice, our license agreement with Merck, which may be terminated by Merck upon 120 days' notice, and our collaboration and license agreement with Lilly, which may be terminated following a specified notice period. 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, including our "at-the-market" offering, 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.

Our corporate strategy and restructuring plan may not be successful.

On January 9, 2020, we announced a restructuring plan to further extend our operating capital and align personnel towards executing our clinical development strategy. The success of this restructuring will depend on our ability to reduce operating expenses, reduce our facilities footprint, close our operations in the Netherlands, retain senior management and other highly qualified personnel and generate multiple clinical data readouts over the next several years. In connection with the restructuring we intend to reduce our workforce by approximately 59%. Our workforce after these actions may not be sufficient to fully execute our strategy, and we may not be able to effectively attract or retain senior management or other qualified employees needed to implement this strategy. If we are unable to successfully execute our strategy, our business, financial condition and results of operations may be materially and adversely affected.

We intend to sublease a significant amount of space in our headquarters in Berkeley, California. If we are unable to sublease our facilities on favorable terms or if our subtenants are unable to meet their obligations under the subleases, we may be responsible for unexpected costs, which could impact our financial performance.

At December 31, 2019, we had approximately 110,853 square feet of leased space in Berkeley. In connection with our restructuring plan, we expect to sublease a significant portion of our Berkeley facility to third parties. In the event that we are unable to sublease our excess space on favorable terms, or at all, or if we are able to sublease space but our subtenants fail to make lease payments to us or otherwise default on their obligations to us, we could incur substantial unanticipated payment obligations to landlord. In the event our estimates regarding our ability to sublet our available space are incorrect, we would be required to adjust our restructuring or impairment reserves, which could have a material impact on our financial results.

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

Our 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 do not have any products that have gained regulatory approval. Our immunotherapy product candidates are designed to stimulate and/or regulate innate and adaptive immune responses as potential treatments for cancer, autoimmune and inflammatory diseases. Any products we develop may not effectively modulate the immune response. The scientific evidence to support the feasibility of immunotherapy product candidates is preliminary and limited. Our business and future success depend on our ability to obtain regulatory approval of, and then successfully commercialize, our product candidates. Advancing these novel 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;
- successful completion of our clinical trials, including a favorable risk-benefit outcome;

- receipt of marketing approvals from the U.S. Food and Drug Administration, or FDA, and similar regulatory authorities outside the United States;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- establishing commercial manufacturing, supply and distribution arrangements;
- establishing a commercial infrastructure;
- acceptance of our products 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 our products following regulatory approval; and
- qualifying for, identifying, registering, maintaining, enforcing and defending intellectual property rights and claims covering our products.

All of our product candidates 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 regulatory approval for any of our product candidates. If we are unable to develop or receive marketing approval for our product candidates in a timely manner or at all, our business, financial condition and results of operations may be materially and adversely affected.

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

A key element of our strategy is to use and expand our technologies 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 indications, 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. See also the risk factor titled, “Our corporate strategy and restructuring plan may not be successful.”

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, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective, or in the case of biologics, safe, pure and potent, 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. Additionally, because our product candidates are based on new technologies and costs to treat potential side effects that may result from our product candidates are uncertain, our clinical trial costs may be significantly higher than for more conventional therapeutic technologies or drug products.

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. 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. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs. The outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs. We cannot

guarantee that the FDA or foreign regulatory authorities will interpret trial results as we do, and more trials could be required before we are able to submit applications seeking 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, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Even if regulatory approval is secured for any of our product candidates, the terms of such approval may limit the scope and use of our product candidate, which may also limit its commercial potential. Furthermore, 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, which may lead to the FDA or comparable foreign regulatory authorities delaying, limiting or denying approval of our product candidates.

Any delay, suspension, termination or request to repeat or redesign a trial could increase our costs and prevent or significantly delay our ability to commercialize our product candidates.

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. The commencement or completion of clinical trials can be delayed or aborted for a variety of reasons, including delays or failures related to:

- generating sufficient preclinical, toxicology or other in vivo or in vitro data to support the initiation of human clinical studies;
- obtaining regulatory approval to commence a trial;
- identifying and recruiting suitable clinical investigators;
- 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/ethics committee, or IRB/EC, approval at each site;
- recruiting suitable patients to participate in a trial;
- achieving an acceptable distribution of such patients based on treating institution and geography;
- patients not completing a trial or not completing post-treatment follow-up;
- clinical sites deviating from trial protocol, instructions or dropping out of a trial;
- regulatory agency-imposed clinical holds;
- 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/ECs 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 a clinical hold or suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, a negative finding from an inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using 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.

If we experience delays in the completion, or termination, of any clinical trial for our product candidates, the commercial prospects of that product candidate will be harmed, and our ability to generate product revenues from the product candidate 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.

In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Any delays to our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize our product candidates and our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects significantly.

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

From time to time, we may publicly disclose preliminary or topline data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available.

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

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

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

Actual or potential conflicts of interest arising from our relationships with investigators could adversely impact the FDA approval process.

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 provide 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.

Our product candidates may cause undesirable side effects or may 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.

Side effects or adverse events associated with the use of our product candidates may be observed at any time, including in clinical trials or when a product is commercialized, and any such side effects or adverse events could cause us or regulatory authorities to interrupt, delay or halt clinical trials, result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities, or negatively affect our ability to market our product candidates. 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 our product candidates have experienced drug-related side effects or adverse events, or AEs, including AEs that were considered moderate or severe. Examples of the AEs experienced include among others, fevers, chills, injection sight pain, headaches, increased lipase and elevated amylase, tumor pain, dyspnea and respiratory failure. We cannot provide assurances that there will not be further adverse events.

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, require us to conduct additional animal or human studies 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, if side effects are observed in competing product candidates that are perceived to have similarities to ours, regulators or patients may infer that our product candidates could cause similar side effects. Any of these occurrences may materially and adversely affect our business, financial condition and results of operations.

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;
- the 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 materially and adversely affect our business, financial condition and results of operations.

We may encounter difficulties enrolling patients in our clinical trials.

The timely completion of clinical trials in accordance with their protocols depends on, among other things, our ability to enroll a sufficient number of patients who remain in the studies until their 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. Because the number of qualified clinical investigators is limited, we 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 sites. Moreover, because our product candidates represent a departure from more commonly used treatment methods, in some cases potential patients and their doctors may be inclined to use conventional therapies rather than enroll patients in our clinical trials.

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.

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

Our projections of the number of people who have the indications that we are targeting 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 indications. 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. If the market opportunities for our product candidates are smaller than we estimate, our business, financial condition and results of operations may be materially and adversely affected.

Additionally, 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. Initially our oncology product candidates may only be approved 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.

We are subject to a multitude of manufacturing, supply chain, storage and distribution 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 and biologic 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 product candidates 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 product candidates 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 product candidates, including leading to significant delays in the availability of product candidates for our clinical studies, 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 product candidates are sensitive to temperature, which must be controlled 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 candidate 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 materially and adversely affect our business, financial condition and 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 marketing capabilities and no sales or distribution capabilities and have no marketed products. We intend to develop an in-house commercial 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 conducting clinical trials and marketing our product candidates internationally could materially and adversely affect our business, financial condition and results of operations.

We conduct clinical trials, and plan to seek regulatory approval of our product candidates, outside of the United States and, accordingly, we are subject to additional risks related to operating in foreign countries in conducting clinical trials and if we obtain the necessary approvals, including:

- differing legal and regulatory requirements in foreign countries, including future legal and regulatory requirements of the United Kingdom (where we are conducting a clinical trial) following the withdrawal of the United Kingdom from the European Union;
- 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, including any instability resulting from the withdrawal of the United Kingdom from the European Union;
- 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, including clinical trials;
- 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 to and protecting our contractual and intellectual property rights, including 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 natural or man-made disasters and geo-political actions, including pandemics, war and terrorism.

These and other risks associated with our international operations may materially and adversely affect our business, financial condition and results of operations.

We face significant competition from other biotechnology and pharmaceutical companies, and our business, financial condition and results of operations 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, biotechnology companies, specialty pharmaceutical companies, universities and other research institutions continue to invest time and resources in developing novel approaches to immunotherapies. Promising results have spurred significant competition from major pharmaceutical and biotechnology companies alike. Our competitors in the STING pathway activator technology include Merck & Co., Inc., Bristol-Myers Squibb Company/IFM Therapeutics, GlaxoSmithKline plc, Synlogic, Inc., Spring Bank Pharmaceuticals, Inc., Codiak Biosciences, Inc., Eisai, Co., Ltd./H3 Biomedicine, Inc., AbbVie (following its acquisition of Mavupharma), Curadev, Trillium Therapeutics Inc., Mersana Therapeutics, Stingray Therapeutics, Ryvu Therapeutics, Cancer Therapeutics CRC, ImmuneSensor Therapeutics, Nimbus Therapeutics and STINGINN LLC. Our competitors for the anti-APRIL program include Otsuka Pharmaceutical Co., Ltd. (following its acquisition of Visterra, Inc.) and Merck KGaA (EMD Serono). Our competitors for the cGAS-STING pathway inhibitor program include Pfizer Inc., Spring Bank Pharmaceuticals, Inc., GlaxoSmithKline plc, Curadev, Sirenas, LLC, Nimbus Therapeutics/ Bristol-Myers Squibb Company, IFM Due (a subsidiary of IFM Therapeutics, LLC), AbbVie (following its acquisition of Mavupharma), ImmuneSensor Therapeutics and STINGINN LLC. 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. 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 prices of our competitors' products could limit the demand and the prices 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, our Chief Medical Officer, our Interim Chief Financial Officer and our Chief Administrative 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. The Northern California 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.

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. As previously disclosed, our prior Interim Chief Financial Officer resigned effective as of January 22, 2020. We do not maintain "key person" insurance policies on the lives of these individuals or the lives of any of our other employees.

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

As our development and commercialization plans and strategies develop, 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 or reasonable economic terms when needed, or at all. 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.

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 succeed in further developing and commercializing 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, consultants or vendors, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors, consultants or vendors are vulnerable to damage from computer viruses and unauthorized access. Any such material system failure or security breach 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 or outages, 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, in some cases 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.

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

The use of STING or APRIL product candidates as potential immunotherapy treatments, even if approved, may not become broadly accepted by physicians, patients, hospitals and others in the medical community. Additional factors will influence whether our product candidates are accepted in the market, including:

- the clinical indications for which our product candidates may be approved;
- physicians, hospitals 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;
- product labeling or product insert requirements of the FDA or other regulatory authorities, including limitations or warnings;
- 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;
- adverse publicity or ethical or social controversies related to the use of our technologies or similar technologies;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

If our product candidates are approved but fail to achieve or maintain market acceptance among physicians, patients, hospitals or others in the medical community, we will not be able to generate significant revenue.

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.

We currently hold product liability insurance in amounts that we believe are 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 sufficient product liability insurance at an acceptable cost to protect against potential product liability claims, which could inhibit the commercialization of products we develop, alone or with collaborators. Our insurance policies may have 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.

We have, and we may seek to enter into additional, collaboration agreements with other pharmaceutical or biotechnology companies. 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 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. We have also entered into a research collaboration and exclusive license agreement with Lilly for our cGAS-STING Pathway Inhibitor program for the research and development of novel immunotherapies for autoimmune and other inflammatory diseases and a worldwide development and commercialization agreement with Merck for the development of an anti-CD27 antibody. 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. Any termination of our collaboration agreements, or a decision by a partner to reduce its development efforts under a collaboration agreement, will terminate or reduce 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. For example, effective December 2019, Novartis determined to remove ADU-S100 from its portfolio and we are funding the current ADU-S100 trials on our own.

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 with us, and as a result our product candidates may never be successfully commercialized.

Further, our 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. In addition, we could have disputes with our collaborators, including regarding development plans or 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, meet expected deadlines, or otherwise conduct the trials as required or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize our product candidates when expected or at all.

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 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 GCP, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce GCP 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 requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with GCP requirements. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure or any failure by these third parties to comply with these regulations 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.

If our relationships with any third parties conducting our trials are terminated, we may be unable to enter into arrangements with alternative third parties on commercially reasonable terms, or at all. 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 and adverse effect on our business, financial condition and results of operations.

We rely on third party contract manufacturers to provide clinical supplies of our product candidates. If these parties do not successfully carry out their contractual duties or encounter problems in manufacturing our product candidates, it could increase our costs, limit supply of our product candidates and interfere with obtaining product commercialization approvals.

We currently rely on outside vendors to manufacture clinical supplies of our product candidates and have limited experience manufacturing our product candidates. In order to develop our product candidates, apply for regulatory approvals and commercialize our products, if approved, we will need to develop, contract for, or otherwise arrange for the necessary manufacturing capabilities.

We may manufacture limited quantities of clinical trial materials ourselves in the future, but we currently rely on a limited number of contract manufacturing organizations, or CMOs, for our clinical product supplies. There are risks inherent in the manufacture of drug and biologic products that could affect the ability of our CMOs to meet our delivery time requirements or provide adequate amounts of material to meet our needs. Manufacturers of biologic products often encounter difficulties in production, particularly in scaling up and validating initial production. Typical manufacturing problems include longer lead times, low product yields, quality control failures, product instability, operator error, shortages of raw materials, shortages of qualified facilities or personnel, storage mistakes and unpredictable production costs. If contaminants are discovered in our supply of our product candidates or in the manufacturing facilities, manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination, thereby interrupting supply.

If in the future we develop our own manufacturing capabilities by building our own manufacturing facilities, we will incur significant expenditures. In addition, the construction and qualification of a drug substance facility may take several years to complete and there are many risks inherent in the construction of a new facility that could result in delays and additional costs, including the need to obtain access to necessary equipment and third-party technology, if any. In addition, we would likely need to continue to hire and train qualified employees to staff our facilities.

The manufacturing process for any products that we may develop is subject to the FDA and foreign regulatory authority approval process and we will need to meet, and will need to contract with CMOs who can meet, all applicable FDA and foreign regulatory authority requirements on an ongoing basis. In addition, if we receive the necessary regulatory approval for any product candidate, we also expect to rely on third parties to produce materials required for commercial supply. If we are unable to obtain or maintain CMOs for these product candidates, or to do so on commercially reasonable terms, we may not be able to successfully develop and commercialize our products.

To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, we depend, and will depend in the future, on these third parties to perform their obligations in a timely manner and consistent with contractual and regulatory requirements. The failure of any CMO to perform its obligations as expected, or, to the extent we manufacture all or a portion of our product candidates ourselves, our failure to execute on our manufacturing requirements, could materially and adversely affect our business, financial condition and results of operations.

If any CMO with whom we contract fails to perform its 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 materials 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 not realize the benefits of acquisitions or strategic transactions, including our acquisition of Aduro Biotech Europe.

We acquired Aduro Biotech Europe in October 2015, and may acquire or license other businesses, products or technologies, as well as pursue strategic alliances, joint ventures or investments in complementary businesses. The success of acquisitions 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 identification, negotiation or management of any 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;
- stock issuances that dilute existing stockholders;
- competition for appropriate strategic alternatives;
- difficulty negotiating or executing any such arrangements; 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, subsequent to our acquisition of Aduro Biotech Europe we have incurred intangible asset impairment charges of $9.0 million and related reductions in deferred tax benefit of $2.2 million related to the Aduro Biotech Europe business. Further, in January 2020, we announced plans to shut down our Netherlands operations, which could result in additional impairment and other charges and limit the further development of product candidates that originated from the Netherlands operations. While BION-1301 was originally developed by Aduro Biotech Europe, it is currently uncertain whether the efforts of our Aduro Biotech Europe acquisition will result in any product candidates that are ultimately approved for sale. Additionally, foreign acquisitions, including our acquisition of Aduro Biotech Europe, 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. See also the risk factor titled, “Impairment of goodwill and other intangible assets may result in significant impairment charges, which would adversely affect our financial condition and results of operations.”

Risks Related to Government Regulation

The FDA regulatory approval process is lengthy, time-consuming and inherently unpredictable, and we may experience significant delays in the clinical development and regulatory approval of our product candidates or ultimately be unable to obtain regulatory approval for our product candidates, in which case our business will be substantially harmed.

We will not be permitted to market any of our product candidates in the United States until approval from the FDA is received. 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. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other data. We have not previously submitted a biologics license application, or BLA, or a new drug application, 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 oncology product candidates regardless of cancer type or origin, which the FDA may have difficulty accepting if our clinical trials only involve 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, NDA 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.

For instance, in the European Economic Area, or EEA, which is comprised of the Member States of the EU plus Norway, Iceland and Liechtenstein, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. There are two types of MAs:

- Community MAs – These are issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the EMA, and are valid throughout the entire territory of the EEA. The Centralized Procedure is compulsory for human medicines derived from biotechnology processes or advanced therapy medicinal products (such as gene therapy, somatic cell therapy and tissue engineered products), products that contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, neurodegenerative disorders, diabetes, autoimmune diseases and other immune dysfunctions, viral diseases, and officially designated orphan medicines. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA; for products that constitute a significant therapeutic, scientific or technical innovation; or for products that are in the interest of public health in the EU.
- National MAs – These are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member State through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure.

Requirements for the conduct of clinical trials in the European Union including GCP are set forth in the Clinical Trials Directive 2001/20/EC and the GCP Directive 2005/28/EC. Pursuant to Directive 2001/20/EC and Directive 2005/28/EC, as amended, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the EU member states. Under this system, approval must be obtained from the competent national authority of each EU. member state in which a study is planned to be conducted. Furthermore, a clinical trial may only be started after a competent ethics committee has issued a favorable opinion on the clinical trial application in that country.

In April 2014, the EU passed the new Clinical Trials Regulation, (EU) No 536/2014, which will replace the current Clinical Trials Directive 2001/20/EC. To ensure that the rules for clinical trials are identical throughout the European Union, the new EU clinical trials legislation was passed as a regulation that is directly applicable in all EU member states. All clinical trials performed in the European Union are required to be conducted in accordance with the Clinical Trials Directive 2001/20/EC until the new Clinical Trials Regulation (EU) No 536/2014 becomes applicable. According to the current plans of EMA, the new Clinical Trials Regulation will become applicable in 2020.

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 products 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 candidates. We will be required to immediately report any serious and unexpected adverse events and certain quality or production problems with our products to regulatory authorities along with other periodic reports. 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 and registration, as well as continued compliance with cGMP and GCP for any clinical trials that we conduct post-approval. We will also have to comply with requirements concerning advertising and promotion for any of our product candidates that receive regulatory 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 adverse publicity;
- holds on clinical trials;
- refusal by regulatory authorities to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of regulatory 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.

Any new legislation addressing drug or biologic products could result in delays in product development or commercialization, or increased costs to assure compliance. In addition, 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.

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

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

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

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 insurance coverage and reimbursement from third-party payors. In addition, because our product candidates represent new treatments, 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. Additionally, obtaining coverage and adequate reimbursement for our products may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. Separate reimbursement for the product itself or the treatment or procedure in which our product is used may not be available. A decision by a third-party payor not to cover or separately reimburse for our products or procedures using our products, could reduce physician utilization of our products once approved. Assuming there is coverage for our product candidates, or procedures using our product candidates by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high.

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.

Our product candidates may be subject to government price controls that may affect our revenue.

There has been heightened governmental scrutiny in the United States and abroad of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. In the United States, at the federal level such scrutiny has resulted in several recent congressional inquiries and proposed legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. Congress and the Trump administration have each indicated that they will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Outside of the United States, particularly in the EU, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed.

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, 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 health care systems 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 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.

Some of the provisions of the Affordable Care Act have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the Affordable Care Act. The Tax Act includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year (this requirement was commonly referred to as the “individual mandate”). On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseverable feature of the Affordable Care Act, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the Affordable Care Act are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court's decision that the individual mandate was unconstitutional but remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. It is unclear how these decisions, subsequent appeals, if any, and other efforts to challenge, repeal or replace the Affordable Care Act will impact the Affordable Care Act and our business. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs.

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, included 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 2029 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. For example, there have been several recent Congressional inquiries and proposed and enacted legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer’s patient programs, and reform government program reimbursement methodologies for pharmaceutical products. At the federal level, Congress and the Trump administration have each indicated that it will continue to pursue new legislative and/or administrative measures to control drug costs. Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. 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 prices that we believe are 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.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the regulatory approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA’s approval process may significantly delay or prevent regulatory approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

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 current and future arrangements with third-party payors, healthcare providers, patients 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 research, develop, 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, including the federal False Claims Act, 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 Payments 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), their immediate family members, certain other healthcare professionals starting in 2022, 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 pricing information; 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, including our consulting arrangements with physicians, some of whom receive stock options as compensation for services provided, 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 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 a material and adverse effect on our business, financial condition and results of operations.

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, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, 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.

If we or 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 us and our third-party manufacturers. We and 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 and 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 materially and adversely affect our business, financial condition and results of operations.

We are subject to governmental regulation and other legal obligations related to privacy, data protection and information security. Compliance with these requirements could result in additional costs and liabilities to us or inhibit our ability to collect and process data, and the failure to comply with such requirements could have a material adverse effect on our business, financial condition or results of operations.

Privacy and data security have become significant issues in the United States, Europe and in many other jurisdictions where we may in the future conduct our operations. As we receive, collect, process, use and store personal and confidential data, we are subject to diverse laws and regulations relating to data privacy and security, including, in the United States, HIPAA, and, in the EU and in the EEA, Regulation 2016/679, known as the General Data Protection Regulation, or GDPR. Compliance with these privacy and data security requirements is rigorous and time-intensive and may increase our cost of doing business, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation and reputational harm, which could materially and adversely affect our business, financial condition and results of operations.

In addition, the regulatory framework for the receipt, collection, processing, use, safeguarding, sharing and transfer of personal and confidential data is rapidly evolving and is likely to remain uncertain for the foreseeable future as new global privacy rules are being enacted and existing ones are being updated and strengthened. For example, on May 25, 2018, the GDPR took effect in Europe. The GDPR is directly applicable in each EU member state and applies to companies established in the EU as well as companies that collect and use personal data to offer goods or services to, or monitor the behavior of, individuals in the EU, including, for example, through the conduct of clinical trials. GDPR introduces more stringent data protection obligations for processors and controllers of personal data, and penalties and fines for failure to comply with GDPR are significant, including fines of up to €20 million or 4% of total worldwide annual turnover, whichever is higher.

In addition, on June 28, 2018, California enacted the California Consumer Privacy Act, or CCPA, which took effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability, and similar laws have been proposed at the federal level and in other states.

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 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. 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, or USPTO, 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 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 also 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 and adversely affect our business, financial condition and results of operations. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar negative impact on our business, financial condition and results of operations.

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 generally 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.

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 Karagen Pharmaceuticals, Inc. and the Regents of the University of California and a consortium of universities led by Memorial Sloan Kettering related to STING Activators, 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 Lilly and Merck rights to control certain matters related to our intellectual rights for our licensed products. Our inability to control the filing, prosecution, maintenance and enforcement of such patents could materially and adversely affect our business, financial condition and results of operations.

As part of our license and collaboration agreements with Merck and Lilly related to anti-CD27 and cGAS STING pathway molecules, respectively, we have granted Merck and Lilly the first rights to prosecute certain patent rights and we are required to consult with Merck and Lilly with respect to infringement and defense matters related to certain licensed patents. Further, Merck has rights to determine the strategy for patent term extensions for anti-CD27 and we are required to cooperate with Lilly with respect to obtaining patent term extensions for certain patents related to the cGAS STING pathway program. Our inability to control these intellectual property rights could materially harm our business. For example, if a third party is infringing our patent covering anti-CD27, by marketing a product that is identical or similar to anti-CD27, Merck would have the initial right to enforce the patent against the third party and may make decisions with which we may not agree. Further, Merck 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 for the sale of products relating to such patents.

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 licensors' 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 generic or biosimilar 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 materially and adversely affect our business, financial condition and results of operations. 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 STING Activators, which, expire, or if issued will expire, between 2025 and 2038, subject to any extensions. 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 branded 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 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 involves 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.

For instance, under the Leahy-Smith America Invents Act, or the Leahy-Smith Act, U.S. patent applications containing or at that at any time contained a claim not entitled to priority before March 16, 2013 are subject to a “first to file” system, in which the first inventor to file a patent application will be entitled to the patent. This “first to file” system requires us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our product candidates. Furthermore, for United States applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third-party or instituted by the USPTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications.

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 and adverse effect on our business, financial condition and results of operations.

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 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 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 and adversely affect 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 Novartis, Merck and Lilly, 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 our 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 net operating loss carryforwards to offset future taxable income, and our ability to use 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, 2019, we reported U.S. federal, state and foreign NOLs of approximately $153.8 million, $107.8 million, and $66.5 million, respectively.

Under Section 382 of the Internal Revenue Code of 1986, as amended (Code), our ability to utilize NOL carryforwards or other tax attributes, such as federal 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 believe that we may have experienced an ownership change under Section 382, which 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 the ownership of our stock. As a result, the amount of the NOLs and tax credit carryforwards presented in our financial statements could be limited and may expire unutilized.

Impairment of goodwill and other intangible assets may result in significant impairment charges, which would adversely affect our financial condition and results of operations.

Goodwill and other intangible assets represent a significant portion of our assets. Goodwill is the excess of cost over the fair market value of net assets acquired in business combinations. We review our goodwill and acquired IPR&D intangible assets at least annually for impairment. Impairment may result from, among other things, failure to realize the anticipated benefits of past or any future acquisitions or strategic transactions, decisions to discontinue acquired businesses or assets, deterioration in our stock price, adverse market conditions and adverse changes in applicable laws or regulations. For example, in 2018 and 2019, we have incurred IPR&D intangible impairment charges related to our acquired entity, Aduro Biotech Europe.
Any impairment of goodwill or other intangible assets would result in a non-cash charge against earnings, which would adversely affect our results of operations.

Risks Related to Ownership of Our Common Stock

The price of our common 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 and as a result of the factors discussed in this "Risk Factors" section and elsewhere in this Annual Report on Form 10-K among others.

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 could materially and adversely affect our business, financial condition and results of operations.

If our stock price trades below $1.00 for 30 consecutive trading days, our common stock may be subject to delisting from the Nasdaq Global Select Market.

If at any time the bid price of our common stock closes at below $1.00 per share for more than 30 consecutive trading days, we may be subject to delisting from the Nasdaq Global Select Market. If we receive a delisting notice, we would have 180 calendar days to regain compliance, which would mean having a bid price above the minimum of $1.00 for at least 10 consecutive days in the 180-day period. During this 180-day period, we would anticipate reviewing our options to regain compliance with the minimum bid requirements, including conducting a reverse stock split. To the extent that we are unable to resolve any listing deficiency, there is a risk that our common stock may be delisted from Nasdaq, which would adversely impact liquidity of our common stock and potentially result in even lower bid prices for our common stock. As of December 31, 2019, our stock had traded at a 52-week low of $0.94 per share, and a 52-week high of $4.41 per share. Our closing share price on December 31, 2019 was $1.18.

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.

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

Our principal stockholders and management own a significant percentage of our common 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 other stockholders believe are in their best interests.

Our reported financial results may be adversely affected by changes in accounting principles generally accepted in the United States.

We prepare our financial statements in conformity with accounting principles generally accepted in the United States. These accounting principles are subject to interpretation by the Financial Accounting Standards Board, or FASB, and the SEC. A change in these policies or interpretations could have a significant effect on our reported financial results, may retroactively affect previously reported results, could cause unexpected financial reporting fluctuations, and may require us to make costly changes to our operational processes and accounting systems.

Our revenue to date has been primarily derived from research and license agreements, which can result in significant fluctuation in our revenue from period to period, and our past revenue is therefore not necessarily indicative of our future revenue.

Our revenue is primarily derived from our research and license agreements, from which we receive upfront fees, contract research payments, milestone and other contingent payments based on clinical progress, regulatory progress or net sales achievements and royalties. Significant variations in the timing of receipt of cash payments and our recognition of revenue can result from significant payments based on the execution of new research and license agreements, the timing of clinical outcomes, regulatory approval, commercial launch or the achievement of certain annual sales thresholds. The amount of our revenue derived from research and license agreements in any given period will depend on a number of unpredictable factors, including our ability to find and

maintain suitable collaboration partners, the timing of the negotiation and conclusion of collaboration agreements with such partners, whether and when we or our collaboration partners achieve clinical, regulatory and sales milestones, the timing of regulatory approvals in one or more major markets, reimbursement levels by private and government payers, and the market introduction of new drugs or generic versions of the approved drug, as well as other factors. Our past revenue generated from these agreements is not necessarily indicative of our future revenue. If any of our existing or future collaboration partners terminates our collaboration, fails to develop, obtain regulatory approval for, manufacture or ultimately commercialize any product candidate under our collaboration agreement, our business, financial condition, and results of operations could be materially and adversely affected.

Once we are no longer an emerging growth company we will be subject to additional laws and regulations affecting public companies that will increase our costs and the demands on management and could harm our operating results.

As a public company 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 as well as other disclosure and corporate governance requirements. However, as an emerging growth company we may take advantage of exemptions from various requirements such as an exemption from the requirement to have our independent auditors attest to our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act of 2002 as well as an exemption from the “say on pay” voting requirements pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010. Once we are no longer an emerging growth company, we will be required to comply with these additional legal and regulatory requirements applicable to public companies and will incur significant legal, accounting and other expenses to do so. If we are not able to comply with the requirements in a timely manner or at all, our financial condition or the market price of our common stock may be harmed. For example, if we or our independent auditor identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses we could face additional costs to remedy those deficiencies, the market price of our stock could decline or we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

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 $1.07 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.

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. For example, on August 2, 2017, we filed a registration statement on Form S-3 to register for resale shares held by Morningside Venture (IV) Investments Limited and Ultimate Keen Limited, which together hold 14,908,031 shares of our common stock. 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, nonemployee 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. Further, the number of shares of our common stock reserved for issuance under our 2015 ESPP will automatically increase on January 1 of each year, beginning on January 1, 2016 and continuing through and including January 1, 2025, by 1% of the total number of shares of common 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 means that all stockholder actions must 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 stockholders to elect directors of their choosing or cause us to take other corporate actions stockholders may 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 amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

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

If securities or industry analysts publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. 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 common stock could decrease, which might cause our stock price and trading volume to decline.

Regardless of accuracy, unfavorable interpretations of our financial information and other public disclosures could have a negative impact on our stock price. If our financial performance fails to meet analyst estimates, for any of the reasons discussed above or otherwise, or one or more of the analysts who cover us downgrade our common stock or change their opinion of our common stock, our stock price would likely decline.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

We moved into our corporate office and laboratory facility located in Berkeley, California in August 2016. We lease approximately 110,853 square feet pursuant to an Office/Laboratory lease that was entered into in September 2015, or the Heinz Lease. We began incurring rent expense when the landlord delivered possession of the facility to us in March 2016. The Heinz Lease has an initial term of approximately thirteen and a half years expiring on December 31, 2029. We have the right to further extend the Heinz Lease 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. We are subleasing approximately 30,052 square feet in our Heinz facility under subleases that expire on or before February 28, 2021.

We also lease a research and development facility in Oss, the Netherlands, for employees of Aduro Biotech Europe. The term of the Oss lease has been extended through December 2020, with a one-year renewal option.

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.

On March 4, 2020, the last reported sale price of our common stock on the Nasdaq Global Select Market was $3.35 per share.

Holders of Record

As of March 4, 2020, we had 103 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.

Recent Sales of Unregistered Securities

None.

Repurchases of Shares or of Company Equity Securities

None.

Item 6. Selected Financial Data

A smaller reporting company is not required to provide the information required by this Item.

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 our consolidated financial statements included elsewhere in this Annual Report of the Form 10-K. For discussion related to changes in financial condition and the results of operations for fiscal year 2017, refer to Part II Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for fiscal year 2018, which was filed with the Securities and Exchange Commission on February 27, 2019. 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 an immunotherapy company focused on the discovery, development and commercialization of therapies that are designed to harness the body's natural immune system for the treatment of patients with challenging diseases. Our primary technologies related to the cyclic GMP-AMP Synthase–Stimulator of Interferon Genes (cGAS-STING) and A Proliferation Inducing Ligand (APRIL) pathways have led to what we believe is a strong pipeline of clinical candidates that are being investigated in cancer, autoimmune and inflammatory diseases. We are collaborating with leading global pharmaceutical companies to help expand and drive our product pipeline. Our strategy is to rapidly advance first- or best-in-class therapies from our STING and APRIL technologies through clinical development and regulatory approval. Our lead STING pathway activator product candidate, ADU-S100 (MIW815), is designed to selectively modulate innate and adaptive immune responses to enhance immune control in oncology. Our anti-APRIL antibody product candidate, BION-1301, is designed to suppress the autoimmune response in patients with IgA nephropathy (IgAN).

Our STING pathway activator technology is designed to activate the intracellular STING receptor, which may result in a potent tumor-specific immune response. We are developing STING pathway activator product candidates in oncology under our worldwide collaboration with Novartis. ADU-S100 (MIW815), the first STING pathway activator to enter the clinic, is being investigated in a Phase 2 clinical trial of ADU-S100 in combination with KEYTRUDA® (pembrolizumab), an approved anti-PD-1 monoclonal antibody, as first-line treatment for patients with recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN). We are preparing to initiate a Phase 1 clinical trial of ADU-S100 as a single agent administered intravesically in patients with non-muscle invasive bladder cancer (NMIBC) who are unresponsive to Bacillus Calmette-Guerin (BCG), an approved intravesical immunotherapy, in the second half of 2020. ADU-S100 has also been evaluated in a Phase 1 clinical trial as a single agent and in a Phase 1b combination trial with spartalizumab (PDR001), an investigational anti-PD-1 monoclonal antibody, in patients with cutaneously accessible metastatic solid tumors or lymphomas.

APRIL is a soluble factor that binds to B-cell maturation antigen, or BCMA, and transmembrane activator and CAML interactor, or TACI, receptors thereby inducing signaling, and is believed to be implicated in IgA nephropathy and other indications. We are developing BION-1301, a first-in-class monoclonal antibody that fully blocks APRIL binding to both of its natural ligands, the BCMA and TACI receptors. BION-1301 is being evaluated in a Phase 1 clinical trial for the treatment of IgA nephropathy, a chronic autoimmune kidney disease with unclear causality. Because there currently are no approved therapies for IgA nephropathy with curative intent, we believe there is opportunity for BION-1301 to address a significant unmet patient need. We have completed dosing healthy volunteers in the first-in-human study of BION-1301 in IgA nephropathy and expect to begin dosing patients with IgA nephropathy in the first half of 2020.

In addition to our current STING pathway product candidates that activate the STING receptor, we are developing product candidates that are designed to prevent or control immune responses through the STING pathway as part of our cGAS-STING pathway inhibitor program under a research collaboration and exclusive license agreement with Eli Lilly and Company, or Lilly. Our cGAS-STING pathway inhibitor program involves the research and development of novel inhibitor product candidates for autoimmune and other inflammatory diseases.

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 licensing agreements with pharmaceutical partners. We incurred a net loss of $82.4 million and $95.4 million for the years ended December 31, 2019 and 2018, respectively. At December 31, 2019, our cash, cash equivalents and marketable securities totaled $213.6 million and our accumulated deficit was $486.9 million. We have intellectual property protection on our STING and APRIL programs and each of our product candidates, some of which we believe can be maintained into 2040.

In January 2020, the Company's Board of Directors approved a restructuring to further extend the Company's operating capital and align personnel towards executing the clinical development strategy. Under the restructuring plan, the Company intends to reduce its workforce by 51 employees (approximately 59% of total employees) and close the Aduro Biotech Europe headquarters in Oss, the Netherlands. The Company estimates that it will incur aggregate charges of approximately $6.1 million, including $2.0 million in one-time severance and employee termination related costs, approximately $3.8 million in one-time retention costs and relocation costs of approximately $0.3 million. The restructuring is expected to be substantially complete by the end of the third quarter 2020. The reduction in ongoing operating expenses is expected to extend our cash, cash equivalents and marketable securities into 2023, exclusive of potential future milestone payments from our partnerships with Novartis, Lilly and Merck.

Components of Operating Results

Revenue

We have not generated any revenue from product sales. Our revenue to date has been primarily derived from our collaboration and license agreements. Our collaboration agreements may include the transfer of intellectual property rights in the form of licenses, promises to provide research and development services and promises to participate on certain development committees with the collaboration party. The terms of such agreements include payment to us of one or more of the following: nonrefundable upfront fees, payment for research and development services, development, regulatory and commercial milestone payments, and royalties on net sales of licensed products.

Revenue associated with nonrefundable upfront license fees where the license fees and research and development activities cannot be accounted for as separate performance obligations is deferred and recognized as revenue over the expected period of performance based on a cost-based input method. Revenue from contingent development, regulatory and commercial milestones, when not deemed probable of significant reversal of cumulative revenue, is also recognized over the performance period based on a similar method. Where we have no remaining performance obligations, revenue from such milestones is recognized when the accomplishment of the milestones is deemed probable.

We expect that any revenue we generate from our current collaboration, research and license agreements and any future collaboration partners will fluctuate from year to year as a result of the timing and number 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 agreements with Novartis, Lilly and Merck. 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 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 technologies may be affected by a variety of factors including: the quality of our product candidates, early clinical data, investment in our clinical programs, competition, manufacturing capability and commercial viability. We may never succeed in obtaining 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, insurance expenses, investor relations activities, administrative services and other consulting fees. Allocated expenses consist of rent expense related to our offices and research and development facility.

Interest Income, Net

Interest income, net primarily consists of interest income from our cash equivalents and marketable securities.

Other Expense, Net

Other expense, net primarily consists of foreign currency transaction gains and losses.

Income Tax Benefit

We are subject to income taxes in the United States and foreign jurisdictions in which we do business. These foreign jurisdictions have statutory tax rates different from those in the United States. Accordingly, our effective tax rates will vary depending on the relative proportion of foreign to U.S. income, the availability of research and development tax credits, changes in the valuation of our deferred tax assets and liabilities and changes in tax laws. We regularly assess the likelihood of adverse outcomes resulting from the examination of our tax returns by the Internal Revenue Service, or IRS, and other tax authorities to determine the adequacy of our income tax reserves and expense. Should actual events or results differ from our current expectations, charges or credits to our income tax expense may become necessary.

Results of Operations

Comparison of the Years Ended December 31, 2019 and 2018

	Year Ended December 31,		Change
	2019	2018	$
		(in thousands)	
Revenue:			
Collaboration and license revenue	$ 17,258	$ 15,087	$ 2,171
Total revenue	17,258	15,087	2,171
Operating expenses:			
Research and development	67,045	75,836	(8,791)
General and administrative	34,795	36,035	(1,240)
Loss on impairment of intangible assets	5,006	3,992	1,014
Amortization of intangible assets	554	584	(30)
Total operating expenses	107,400	116,447	(9,047)
Loss from operations	(90,142)	(101,360)	11,218
Interest income, net	5,451	5,284	167
Other expense, net	(93)	(64)	(29)
Loss before income tax	(84,784)	(96,140)	11,356
Income tax benefit	2,412	783	1,629
Net loss	$ (82,372)	$ (95,357)	$ 12,985

Revenue

Total revenue increased by $2.2 million for the year ended December 31, 2019 as compared to the year ended December 31, 2018. The increase was primarily due to ratable recognition of the upfront milestone payment received under our Lilly collaboration. The increase was offset by a reduction in the revenue recognized for our Novartis collaboration and by the milestone payment received under our collaboration with Merck upon its initiation of a phase 1 trial in 2018. The following table is a summary of our collaboration and license revenue for the years ended December 31, 2019 and 2018:

	Year Ended December 31,		Change
	2019	2018	$
		(in thousands)	
Collaboration and license revenue:			
Eli Lilly	$ 9,050	$ —	$ 9,050
Novartis	8,208	11,896	(3,688)
Merck	—	3,004	(3,004)
Other	—	187	(187)
Total collaboration and license revenue	$ 17,258	$ 15,087	$ 2,171

Research and Development Expenses

The following table summarizes our research and development costs by program incurred during the years ended December 31, 2019 and 2018. Each year, we present and describe our research and development expenses based on programs and categories that are considered critical to us at that time and all other non-critical programs and categories are reported in Other R&D and Other, respectively. Therefore, the presentation in the Research and Development Expense tables may change from year to year.

	Year Ended December 31,		
	2019	2018	Change
	(in thousands)		
APRIL	$ 20,227	$ 11,873	$ 8,354
STING	13,435	9,154	4,281
cGAS-STING	4,327	4,209	118
Other R&D	15,290	32,695	(17,405)
Subtotal	53,279	57,931	(4,652)
Stock-based compensation	6,376	9,745	(3,369)
Facility costs and depreciation	7,390	8,160	(770)
Total research and development	$ 67,045	$ 75,836	$ (8,791)

	Year Ended December 31,		Change
	2019	2018	$
	(in thousands)		
Clinical trial and research expenses	$ 29,415	$ 29,448	$ (33)
Compensation and related personnel costs	17,353	21,308	(3,955)
Facility costs and depreciation	7,390	8,160	(770)
Stock-based compensation expense	6,376	9,745	(3,369)
Professional services	5,596	6,531	(935)
Other	915	644	271
Total research and development	$ 67,045	$ 75,836	$ (8,791)

Research and development expenses allocated to our programs were $67.0 million for the year ended December 31, 2019, a decrease of $8.8 million compared to the year ended December 31, 2018. The decrease was primarily due to lower costs related to our programs that are winding down partially offset by higher costs as a result of focused spending towards our STING and APRIL programs. The decrease was attributable to lower compensation and related personnel costs as well as stock-based compensation in 2019 due to reduced headcount as a result of our strategic reset and restructuring in January 2019, or the 2019 Reset. In addition, there was a decrease in professional services due to lower consulting and temporary help expenses and a decrease in facility costs due to sublease income.

In January 2020, we implemented another restructuring to extend our cash runway and continue to focus on our critical programs. The impact of the January 2020 restructuring on operating expenses will occur in 2020.

General and Administrative Expenses

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

	Year Ended December 31,		Change
	2019	2018	$
	(in thousands)		
Professional services	$ 13,362	$ 11,148	$ 2,214
Compensation and related personnel costs	9,348	10,243	(895)
Stock-based compensation expense	6,063	7,729	(1,666)
Facility costs and depreciation	3,592	4,076	(484)
Other	2,430	2,839	(409)
Total general and administrative	$ 34,795	$ 36,035	$ (1,240)

General and administrative expenses were $34.8 million for the year ended December 31, 2019, a decrease of $1.2 million compared to the year ended December 31, 2018. The decrease was primarily due to lower compensation and related personnel costs as well as lower stock-based compensation expense due to reduced headcount as a result of our 2019 Reset. This decrease was partially offset by higher professional services costs due to consulting services.

Loss on impairment of intangible assets

Loss on impairment of intangible assets was $5.0 million for the year ended December 31, 2019, an increase of $1.0 million compared to the year ended December 31, 2018. The loss was recorded due to our decision to discontinue one of our acquired early research programs in the third quarter of 2019 resulting in impairment of an acquired IPR&D asset.

Interest Income, Net

Interest income, net was $5.5 million for the year ended December 31, 2019, an increase of $0.2 million, compared to the year ended December 31, 2018. The increase in interest income earned in 2019 was primarily due to favorable interest rates.

Income tax benefit

Income tax benefit was $2.4 million for the year ended December 31, 2019 compared to an income tax benefit of $0.8 million for the year ended December 31, 2018. The change was primarily related to a $2.2 million reduction in the deferred tax liability associated with the impairment of an acquired IPR&D asset.

Liquidity and Capital Resources

To date, our operations have been financed primarily through the public issuance of common stock, sale of convertible preferred stock and proceeds from our collaboration and license agreements. At December 31, 2019, we had cash, cash equivalents and marketable securities of $213.6 million. We believe that our available cash, cash equivalents and marketable securities will be sufficient to fund our planned operations into 2023. 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 August 2017, we entered into an “at-the-market” sales agreement, as amended in February 2019, or the 2017 Sales Agreement, with Cowen and Company, LLC, or Cowen, through which we may offer and sell shares of our common stock having an aggregate offering price of up to $100.0 million through Cowen, acting as sales agent. We agreed to pay Cowen a commission of up to 3% of the gross proceeds of sales made through the arrangement. There were no sales of shares of common stock pursuant to the 2017 Sales Agreement during the year ended December 31, 2019. As of December 31, 2019, we had an aggregate of $81.5 million remaining for future sales under the 2017 Sales Agreement, subject to the continued effectiveness of our shelf registration statement on Form S-3 (Registration No. 333-219639) or an effective replacement shelf registration statement.

Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, clinical and development costs including 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, manufacturing and potential commercialization of our product candidates.

We plan to continue to fund our operations and capital funding needs through equity and/or debt financing and potential milestones from existing collaboration agreements. We may also consider entering into additional collaboration arrangements or selectively partnering for clinical development and commercialization or outlicensing non-core assets. 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, financial condition and results of operations.

Cash Flows

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

	Year Ended December 31,	
	2019	2018
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (65,508)	$ (68,759)
Investing activities	(1,763)	39,407
Financing activities	743	(1,495)
Effect of exchange rate changes	(158)	(457)
Net change in cash, cash equivalents, and restricted cash	$ (66,686)	$ (31,304)

Operating Activities

Net cash used in operating activities was $65.5 million for the year ended December 31, 2019, compared to $68.8 million for the year ended December 31, 2018. The decrease in net cash used in operating activities during 2019 was primarily due to the receipt of $12.0 million upfront payment from Lilly under our collaboration.

Investing Activities

Net cash used in investing activities was $1.8 million for the year ended December 31, 2019, compared to net cash provided by investing activities of $39.4 million for the year ended December 31, 2018. The change was primarily due to a higher level of marketable securities purchases in 2019 as compared to 2018.

Financing Activities

Net cash provided by financing activities was $0.7 million for the year ended December 31, 2019, compared to net cash used in financing activities of $1.5 million for the year ended December 31, 2018. The change is primarily due to the payment of contingent consideration of $3.5 million during 2018 partially offset by proceeds from the issuance of common stock under our stock incentive plans.

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

Revenue from research activities under our collaboration arrangements is recognized when our customer obtains control of the promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. Revenue generated from our collaboration arrangements is not subject to repayment and typically includes upfront fees, development, regulatory and commercial milestone payments and royalties on the licensee's future product sales.

Our collaboration agreements may include the transfer of intellectual property rights in the form of licenses, promises to provide research and development services and promises to participate on certain development committees with the collaboration party. We assess whether the promises in these agreements are considered distinct performance obligations that should be accounted for separately. Judgment is required to determine whether licenses to our intellectual property are distinct from the research and development services or participation on development committees.

The transaction price in each agreement is allocated to the identified performance obligations based on the standalone selling price, or SSP, of each distinct performance obligation. Due to the early stage of our licensed technology, the license of such technology is typically combined with the research and development services and committee participation as one combined performance obligation.

Revenue associated with nonrefundable upfront license fees where the license fees and research and development activities cannot be accounted for as separate performance obligations is deferred and recognized as revenue over the expected period of performance using a cost-based input method. We utilize judgment to assess the pattern of delivery of the performance obligation. A cost-based input method of revenue recognition requires management to make estimates of costs to complete our performance obligations. In making such estimates, significant judgment is required to evaluate assumptions related to cost estimates. The cumulative effect of revisions to estimated costs to complete our performance obligations will be recorded in the period in which changes are identified and amounts can be reasonably estimated. A significant change in the assumptions and estimates could have a material impact on the timing and amount of revenue recognized in future periods.

At the inception of each agreement that includes development, regulatory or commercial milestone payments, we evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price by using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. The transaction price is allocated to each performance obligation in the agreement based on relative SSP. Milestone payments that are not within our or the licensee's control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. At the end of each subsequent reporting period, we re-evaluate the probability of achievement of each such milestone and any related constraint, and if necessary, adjust our estimates of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

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 research and development 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 recorded an impairment loss of $5.0 million and $4.0 million related to IPR&D during the years ended December 31, 2019 and 2018, respectively. No impairment of IPR&D has been recorded in prior years. We have not had an impairment of goodwill since inception.

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

Effective September 30, 2019, we adopted ASU 2017-04, Intangibles – Goodwill and Other (Topic 350), the standard update that simplifies the subsequent measurement of goodwill by eliminating Step 2 from the goodwill impairment test. We test goodwill for impairment on an annual basis on November 1, or more frequently if an impairment indicator exists. Based on our impairment assessment of goodwill as of September 30, 2019 and November 1, 2019, we concluded that there was no impairment to goodwill as the fair value of our single reporting unit exceeded the carrying value. Refer to Notes 2 and 5 to our consolidated financial statements for additional information.

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. We recorded an impairment loss of $1.2 million related to lab equipment that was previously recorded in construction in progress during the year ended December 31, 2019. No impairment of Long-Lived Assets has been recorded in prior years.

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 consolidated 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 account for stock-based compensation for all share-based awards made to employees and directors, including employee stock options, restricted stock units and employee stock purchases related to the Employee Stock Purchase Plan, by measuring the cost of awards of equity instruments 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 $8.1 million and $11.7 million during the years ended December 31, 2019 and 2018, 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. Since the IPO, we have used the market closing price of our common stock as reported on the Nasdaq Global Select Market.

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. Because 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.

We recognize compensation expense for stock awards for the portion of the share-based awards that are expected to vest. Therefore, 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.

Leases

We have entered into lease agreements for our corporate office and laboratory facilities. Effective January 1, 2019, we adopted Accounting Standard Codification, or ASC, Topic 842, Leases, or ASC Topic 842, using the optional transition method and applied the standard to leases that existed at that date. Under the optional transition method, we do not need to restate the comparative periods in transition and will continue to present financial information and disclosures for periods before January 1, 2019 in accordance with ASC Topic 840. We have elected the package of practical expedients allowed under ASC Topic 842, which permits us to account for our existing operating leases as operating leases under the new guidance, without reassessing our prior conclusions about lease identification, lease classification and initial direct costs. As a result of the adoption of the new lease accounting guidance on January 1, 2019, we recognized operating lease right-of-use (ROU) assets of approximately $22.1 million and operating lease liabilities of approximately $33.8 million.

We determine the initial classification and measurement of our operating lease ROU assets and operating lease liabilities at the lease commencement date and thereafter if modified. The lease term includes any renewal options and termination options that we are reasonably certain to exercise. The present value of lease payments is determined by using the interest rate implicit in the lease, if that rate is readily determinable; otherwise, we use our incremental borrowing rate. The incremental borrowing rate is determined by using a portfolio approach based on the rate of interest that we would pay to borrow on a collateralized basis an amount equal to the lease payments for a similar term and in a similar economic environment.

Rent expense for operating leases is recognized on a straight-line basis over the reasonably assured lease term based on the total lease payments and is included in operating expenses in the consolidated statements of operations and comprehensive income (loss).

For all leases, rent payments that are based on a fixed index or rate at the lease commencement date are included in the measurement of operating lease ROU assets and operating lease liabilities at the lease commencement date.

We have elected the practical expedient to not separate lease and non-lease components for our real estate leases. Our non-lease components are primarily related to property maintenance, which varies based on future outcomes, and thus is recognized in rent expense when incurred.

In the event of a lease modification due to a change in terms or conditions of an existing agreement, we would need to reevaluate the contract to determine whether the modification affects our initial conclusions under ASC 842. A lease modification would require us to (1) reassess the lease classification on the effective date of the lease modification, (2) remeasure and reallocate consideration, (3) revise the ROU asset and lease liability balances based on updated lease payments and discount rate, and (4) determine whether a gain or a loss will be recognized in the income statement associated with the change in the ROU asset and lease liability.

Income Taxes

The benefit for income taxes was $2.4 million for the year ended December 31, 2019, an increase of $1.6 million compared to the year ended December 31, 2018. The income tax benefit recorded during 2019 was primarily related to the reduction in the deferred tax liability associated with the impairment of Acquired IPR&D intangible assets.

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. A full valuation allowance is maintained on the U.S. net deferred tax assets. A partial valuation allowance is maintained on the Netherlands Net Operating Loss deferred tax asset. We intend to maintain the valuation allowance on the remaining net federal and state deferred tax assets until sufficient positive evidence exists to support valuation allowance reversals.

At December 31, 2019, we had net operating loss, or NOL, carryforwards (before tax effects) for federal, state and foreign income tax purposes of $153.8 million, $107.8 million and $66.5 million, respectively. These federal, state and foreign NOL carryforwards will begin to expire in 2027, 2033 and 2024, respectively, if not utilized. In addition, we have federal and state tax credit carryforwards of $38.3 million and $10.3 million, respectively, to offset future income tax liabilities. The federal tax credits can be carried forward for 20 years and will start to expire in 2034, if not utilized, while the state 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 federal tax credits, in any taxable year may be limited if we have experienced an “ownership change.”

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, 2019:

	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	$ 5,659	$ 10,792	$ 11,251	$ 30,155	$ 57,857
Total contractual obligations	$ 5,659	$ 10,792	$ 11,251	$ 30,155	$ 57,857

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 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 $1.07 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

For information with respect to recently issued accounting standards and the impact of these standards on our consolidated financial statements, refer to Note “2. Basis of Presentation, Use of Estimates and Recent Accounting Pronouncements” in our consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K.

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

A smaller reporting company is not required to provide the information required by this Item.

Item 8. Financial Statements and Supplementary Data.

ADURO BIOTECH, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of Aduro Biotech, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Aduro Biotech, Inc. and subsidiaries (the "Company") as of December 31, 2019 and 2018, the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows, for each of the three years in the period ended December 31, 2019, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

Change in Accounting Principle

As discussed in Note 2 to the financial statements, the Company changed its method of accounting for revenue recognition due to the adoption of ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606), effective January 1, 2018, and the Company changed its method of accounting for leases due to the adoption of ASC Topic 842, Leases, effective January 1, 2019.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting 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.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Deloitte & Touche LLP
San Francisco, California
March 9, 2020

We have served as the Company's auditor since 2014.

ADURO BIOTECH, INC.
Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 59,624	$ 126,310
Marketable securities	153,978	140,129
Accounts receivable	342	12,037
Prepaid expenses and other current assets	3,958	4,500
Total current assets	217,902	282,976
Marketable securities	—	11,434
Property and equipment, net	24,688	29,157
Operating lease right-of-use assets	21,110	—
Goodwill	8,167	8,334
Intangible assets, net	18,978	25,135
Restricted cash	468	468
Total assets	$ 291,313	$ 357,504
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 414	$ 1,457
Accrued clinical trial and manufacturing expenses	4,253	2,542
Accrued expenses and other liabilities	8,181	10,518
Operating lease liabilities	1,803	—
Deferred revenue	6,950	16,000
Total current liabilities	21,601	30,517
Deferred rent	—	11,063
Contingent consideration	1,051	998
Deferred revenue	166,963	172,671
Deferred tax liabilities	3,527	6,104
Operating lease liabilities	31,636	—
Other long-term liabilities	940	840
Total liabilities	225,718	222,193
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized at December 31, 2019 and 2018; and no shares issued and outstanding at December 31, 2019 and 2018	—	—
Common stock, $0.0001 par value; 300,000,000 shares authorized at December 31, 2019 and 2018; 80,735,688 and 79,571,714 shares issued and outstanding at December 31, 2019 and 2018	8	8
Additional paid-in capital	552,077	538,895
Accumulated other comprehensive income	414	940
Accumulated deficit	(486,904)	(404,532)
Total stockholders' equity	65,595	135,311
Total liabilities and stockholders' equity	$ 291,313	$ 357,504

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,		
	2019	2018	2017
Revenue:			
Collaboration and license revenue	$ 17,258	$ 15,087	$ 17,109
Grant revenue	—	—	130
Total revenue	17,258	15,087	17,239
Operating expenses:			
Research and development	67,045	75,836	89,382
General and administrative	34,795	36,035	33,751
Loss on impairment of intangible assets	5,006	3,992	—
Amortization of intangible assets	554	584	559
Total operating expenses	107,400	116,447	123,692
Loss from operations	(90,142)	(101,360)	(106,453)
Interest income, net	5,451	5,284	3,444
Other expense, net	(93)	(64)	(218)
Loss before income tax	(84,784)	(96,140)	(103,227)
Income tax benefit	2,412	783	11,364
Net loss	$ (82,372)	$ (95,357)	$ (91,863)
Net loss per common share, basic and diluted	$ (1.03)	$ (1.21)	$ (1.26)
Shares used in computing net loss per common share, basic and diluted	80,110,711	78,812,407	72,901,215

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

ADURO BIOTECH, INC.
Consolidated Statements of Comprehensive Loss

	Year Ended December 31,		
	2019	2018	2017
Net loss	$ (82,372)	$ (95,357)	$ (91,863)
Other comprehensive (loss) income:			
Unrealized gain (loss) on marketable securities, net of tax of $0	239	121	(155)
Foreign currency translation adjustments, net of tax of $0	(765)	(1,074)	3,732
Comprehensive loss	$ (82,898)	$ (96,310)	$ (88,286)

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

ADURO BIOTECH, INC.
Consolidated Statements of Stockholders' Equity
(In thousands, except share amounts)

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Income (Loss)	Deficit	Equity
Balance at December 31, 2016	67,918,246	7	420,897	(1,684)	(192,000)	227,220
Issuance of common stock upon exercise of stock options	2,041,862	—	2,304	—	—	2,304
Issuance of common stock upon exercise of warrants	28,243	—	40	—	—	40
Issuance of common stock under Employee Stock Purchase Plan	103,562	—	828	—	—	828
Issuance of common stock upon at the market offering (Note 9)	7,494,438	1	78,990	—	—	78,991
Release of restricted stock units	149,850	—	—	—	—	—
Stock-based compensation	—	—	16,376	—	—	16,376
Other comprehensive income	—	—	—	3,577	—	3,577
Net loss	—	—	—	—	(91,863)	(91,863)
Balance at December 31, 2017	77,736,201	8	519,435	1,893	(283,863)	237,473
Issuance of common stock upon exercise of stock options	1,404,422	—	1,457	—	—	1,457
Issuance of common stock upon exercise of warrants	3,317	—	—	—	—	—
Issuance of common stock under Employee Stock Purchase Plan	111,321	—	529	—	—	529
Release of restricted stock units	316,453	—	—	—	—	—
Stock-based compensation	—	—	17,474	—	—	17,474
Other comprehensive loss	—	—	—	(953)	—	(953)
Cumulative effect of changes in accounting principles related to revenue recognition	—	—	—	—	(25,312)	(25,312)
Net loss	—	—	—	—	(95,357)	(95,357)
Balance at December 31, 2018	79,571,714	8	538,895	940	(404,532)	135,311
Issuance of common stock upon exercise of stock options	548,523	—	530	—	—	530
Issuance of common stock under Employee Stock Purchase Plan	111,331	—	213	—	—	213
Release of restricted stock units	504,120	—	—	—	—	—
Stock-based compensation	—	—	12,439	—	—	12,439
Other comprehensive loss	—	—	—	(526)	—	(526)
Net loss	—	—	—	—	(82,372)	(82,372)
Balance at December 31, 2019	80,735,688	8	552,077	414	(486,904)	65,595

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,		
	2019	**2018**	**2017**
Cash Flows from Operating Activities			
Net loss	$ (82,372)	$ (95,357)	$ (91,863)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	4,309	4,369	3,426
Amortization of intangibles	554	584	559
Impairment of property and equipment	1,177	—	—
Impairment of intangible assets	5,006	3,992	—
Non-cash lease expense	947	—	—
Accretion of discounts and amortization of premiums on marketable securities	(1,670)	(1,067)	621
Realized gain on investments	(4)	—	—
Stock-based compensation	12,439	17,474	16,376
Loss from remeasurement of fair value of contingent consideration	73	635	2,824
Loss on disposal of property and equipment	6	27	9
Deferred income tax	(2,450)	(146)	6,180
Changes in operating assets and liabilities:			
Payment of contingent consideration	—	(3,322)	—
Accounts receivable	11,695	(11,048)	149
Income tax receivable	—	17,495	(17,495)
Prepaid expenses and other assets	526	1,006	1,535
Accounts payable	(799)	533	(1,206)
Deferred revenue	(14,758)	288	(14,944)
Accrued clinical trial and manufacturing expenses	1,730	(3,300)	924
Accrued expenses and other liabilities	(1,583)	(922)	4,049
Operating lease liabilities	(334)	—	—
Net cash used in operating activities	(65,508)	(68,759)	(88,856)
Cash Flows from Investing Activities			
Purchase of marketable securities	(283,097)	(226,953)	(260,435)
Proceeds from maturities of marketable securities	282,594	268,684	354,530
Purchase of property and equipment	(1,260)	(2,365)	(5,154)
Proceeds from sale of property and equipment	—	41	—
Net cash (used in) provided by investing activities	(1,763)	39,407	88,941
Cash Flows from Financing Activities			
Payment of contingent consideration	—	(3,481)	—
Proceeds from issuance of common stock, net of offering costs	—	—	78,991
Proceeds from exercise of stock options and warrants	530	1,457	2,235
Proceeds from employee stock purchase plan	213	529	828
Net cash provided by (used in) financing activities	743	(1,495)	82,054
Effect of exchange rate changes on cash	(158)	(457)	543
Net (decrease) increase in cash, cash equivalents, and restricted cash	(66,686)	(31,304)	82,682
Cash, cash equivalents, and restricted cash at beginning of period	126,778	158,082	75,400
Cash, cash equivalents, and restricted cash at end of period	$ 60,092	$ 126,778	$ 158,082
Supplemental Disclosure			
Cash paid for taxes	$ —	$ —	$ 1,106
Supplemental Disclosure of Non-Cash Investing and Financing Activities			
Purchase of property and equipment in accounts payable and accrued liabilities	$ 31	$ 331	$ 2,790
Reconciliation of Cash, Cash Equivalents and Restricted Cash			
Cash and cash equivalents	$ 59,624	$ 126,310	$ 157,614
Restricted cash	468	468	468
Total cash, cash equivalents and restricted cash	$ 60,092	$ 126,778	$ 158,082

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

1. Organization and Nature of Business

Aduro Biotech, Inc., and its wholly owned subsidiaries, or the Company, is an immunotherapy company focused on the discovery, development and commercialization of therapies that are designed to harness the body's natural immune system for the treatment of patients with challenging diseases. The Company is located in Berkeley, California and its wholly-owned subsidiary, Aduro Biotech Holdings, Europe B.V., or Aduro Biotech Europe, is based in the Netherlands. The Company operates in one business segment.

The Company's product candidates in the Stimulator of Interferon Genes (STING) and A Proliferation Inducing Ligand (APRIL) pathways are being investigated in cancer, autoimmune and inflammatory diseases. The Company's lead STING pathway activator product candidate, ADU-S100 (MIW815), is designed to selectively modulate innate and adaptive immune responses to enhance immune control in oncology. The Company's anti-APRIL antibody product candidate, BION-1301, is designed to suppress the autoimmune response in patients with IgA nephropathy. The Company is collaborating with a number of leading global pharmaceutical companies to help expand and drive its product pipeline. The Company's strategy is to rapidly advance best-in-class therapies from its STING and APRIL programs through clinical development and regulatory approval.

2. Basis of Presentation, Use of Estimates and Recent Accounting Pronouncements

Basis of Presentation

The consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles, 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.

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, contingent consideration, income taxes, right-of-use assets, lease obligations, stock-based compensation, and valuation of intangibles, property, and goodwill. 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.

Adoption of ASU 2014-09, Revenue from Contracts with Customers (Topic 606)

The Company adopted the guidance under ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606) on January 1, 2018 using the modified retrospective method. The Company recognized the cumulative effect of initially applying the new revenue standard as an adjustment to the opening balance of its accumulated deficit. The comparative information has not been restated and continues to be reported under the accounting standards in effect for that period. The change in the pattern of revenue recognition upon adoption of Topic 606 for milestone payments and performance obligations delivered over time resulted in an increase in the balance of deferred revenue and an increase in the accumulated deficit balance of $25.3 million on January 1, 2018.

Revenue Recognition

The Company recognizes revenue when its customers obtain control of the promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services.

Collaboration and license revenue

The Company's 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. The terms of such agreements include payment to the Company of one or more of the following: nonrefundable upfront fees, payment for research and development services, development, regulatory and commercial milestone payments, and royalties on net sales of licensed products. The Company assesses whether the promises in these agreements are considered distinct performance obligations that should be accounted for separately. Judgment is required to determine whether the license to the Company's intellectual property is distinct from the research and development services or participation on development committees.

The transaction price in each agreement is allocated to the identified performance obligations based on the standalone selling price, or SSP, of each distinct performance obligation. Judgment is required to determine SSP. In instances where SSP is not directly observable, such as when a license or service is not sold separately, SSP is determined using information that may include market conditions and other observable inputs. Due to the early stage of the Company's licensed technology, the license of such technology is typically combined with the research and development services and committee participation as one performance obligation.

Revenue associated with nonrefundable upfront license fees where the license fees and research and development services cannot be accounted for as separate performance obligations is deferred and recognized as revenue over the expected period of performance using a cost-based input methodology. The Company utilizes judgment to assess the pattern of delivery of the performance obligation.

At the inception of each agreement that includes development, regulatory or commercial milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price by using the most likely amount method. If it is probable that a significant reversal of cumulative revenue would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received or the underlying activity has been completed. The transaction price is then allocated to each performance obligation in the agreement based on relative SSP. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of each such milestone and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

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, 2019 and 2018, 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.

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. 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 subtenants. 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 research and development 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 recorded an impairment loss of $5.0 million and $4.0 million related to IPR&D intangible assets during the year ended December 31, 2019 and 2018, respectively. No impairment of IPR&D has been recorded in years prior to 2018. The Company has not had an impairment of goodwill since inception.

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 recorded an impairment loss of $1.2 million related to lab equipment that was previously recorded in construction in progress during the year ended December 31, 2019. No impairment of Long-Lived Assets has been recorded in prior years.

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 includes these costs in accrued liabilities in the consolidated balance sheets and within research and development expenses in the consolidated statement of operations and comprehensive loss. 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.

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.

Leases

On January 1, 2019, the Company adopted the new standard on leases, Accounting Standard Codification 842, which establishes a comprehensive new lease accounting model. The following steps were taken to be consistent with the guidance in accounting for leases under the new standard. The Company determines if an arrangement is a lease at inception. The Company elected the practical expedient package that allows the Company to not need to reassess whether any expired or existing contracts are or contain leases, the lease classification for any expired or existing leases, and the initial direct costs for any existing leases. The Company elected the practical expedient to adopt the policy to not separate lease and non-lease components for its real estate leases. Operating leases are included in operating lease right-of-use (ROU) assets and operating lease liabilities on the Company's consolidated balance sheets. Operating lease ROU assets represent the Company's right to use an underlying asset for the lease term and operating lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease ROU assets and operating lease liabilities are recognized based on the present value of lease payments over the lease term. As most of the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate, obtained from the Company's bank and the financial statements of a known public company and adjusted for an appropriate level of risk based on the remaining term of the lease and the Company's current financial condition, in determining the present value of lease payments. The operating lease ROU asset also includes any lease payments made and excludes lease incentives. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise such options to extend or terminate the lease. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

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.

On January 1, 2019, the Company adopted Accounting Standards Update, or ASU, No. 2018-07, simplifying its accounting for share-based payments to non-employees by aligning it with the accounting for share-based payments to employees, with certain exceptions. The Company measured its stock-based awards made to non-employees based on the estimated fair values of the awards as of the adoption date of January 1, 2019 using the Black-Scholes option-pricing model. Stock-based compensation expense is recognized over the remaining 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.

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. 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 income (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.

Recent Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board, or FASB, issued ASU No. 2016-13, Financial Instruments—Credit Losses (Topic 326). The standard changes how entities will measure credit losses for most financial assets and certain other instruments that are not measured at fair value through net income. Financial assets measured at amortized cost will be presented at the net amount expected to be collected by using an allowance for credit losses. The standard is effective for fiscal years and interim periods beginning after December 15, 2019. Early adoption is permitted for all periods beginning after December 15, 2018. The Company has evaluated the impact of this guidance and has concluded that adoption of the standard will not have a material impact on its consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13 – Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement. The standard eliminates certain disclosure requirements for fair value measurements for all entities, requires public entities to disclose certain new information, and modifies some disclosure requirements. The new standard is effective for fiscal years and interim periods beginning after December 15, 2019. Early adoption is permitted upon issuance of this ASU. Entities making this election to early adopt are permitted to early adopt the eliminated or modified disclosure requirements and delay the adoption of the new disclosure requirements until their effective date. The Company is currently evaluating the impact of this guidance and has determined that adoption of the standard would result in the Company no longer being required to disclose (1) the amount of and the reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, (2) the policy for timing of transfers between levels, and (3) the valuation process for Level 3 fair value measurements. Additionally, the Company will be required to disclose (1) the changes in unrealized gains and losses for the period included in other comprehensive income (loss) for recurring Level 3 fair value measurements held at the end of the reporting period and (2) the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements.

In November 2019, the FASB issued ASU No. 2019-08 – Compensation–Stock Compensation (Topic 718) and Revenue from Contracts with Customers (Topic 606) Fair Value Measurement. The standard requires that an entity measure and classify share-based payment awards granted to a customer by applying the guidance in Topic 718. Since the Company has adopted ASU No. 2018-07, the standard in this update is effective in the fiscal years beginning after December 15, 2019, and the interim periods within those fiscal years beginning after December 15, 2019. The Company has evaluated the impact of this guidance and has concluded that adoption of the standard will have no impact on its consolidated financial statements.

In December 2019, the FASB issued ASU No. 2019-12 – Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes (ASU 2019-12). The standard update simplifies the accounting for income taxes by removing certain exceptions to the general principles in ASC 740 and also improves consistent application by clarifying and amending existing guidance. The standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. The Company is assessing the impact of this guidance and is continuing to evaluate its impact on the consolidated financial statements.

Recently Adopted Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) (ASC 842), which establishes a comprehensive new lease accounting model. The new standard: (a) clarifies the definition of a lease; (b) requires a dual approach to lease classification similar to current lease classifications; and (c) causes lessees to recognize leases on the balance sheet as a lease liability with a corresponding ROU asset for leases with a lease-term of more than twelve months. The new standard is effective for fiscal years and interim periods beginning after December 15, 2018, with early adoption permitted. A modified retrospective transition approach is required for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. In July 2018, the FASB issued ASU No. 2018-11, Leases (Topic 842): Targeted Improvements, an update which provides another transition method, the optional transition method, which allows entities to initially apply the new lease standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. The Company adopted the new standard on January 1, 2019 using the optional transition method.

The Company identified all leases and reviewed the leases to determine the impact of ASC 842 on its consolidated financial statements. The Company has elected to apply all of the practical expedients as a package, which include not reassessing (1) whether any expired or existing contracts are or contain leases, (2) lease classification for any expired or existing leases, and (3) initial direct costs for any existing leases. The Company also elected the practical expedient to not separate lease and non-lease components for its real estate leases. Based on the Company’s assessment, the Company concluded that the adoption of the new standard resulted in the recording of a $22.1 million ROU asset and a $33.8 million lease liability and a derecognition of $11.7 million of deferred rent on the consolidated balance sheet on January 1, 2019. The Company’s adoption of ASU No. 2016-02, as amended, did not have a material impact on its consolidated statements of operations or consolidated statements of cash flows.

In January 2017, the FASB issued ASU No. 2017-04, Intangibles – Goodwill and Other (Topic 350). The standard update simplifies the subsequent measurement of goodwill by eliminating Step 2 from the goodwill impairment test. Instead of computing the implied fair value of goodwill under Step 2, the Company would perform its annual or interim goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. If the carrying amount of a reporting unit exceeds its fair value, an impairment loss shall be recognized in an amount equal to that excess, limited to the total amount of goodwill allocated to that reporting unit. The standard also eliminated the requirement to perform Step 2 of the goodwill impairment test for any reporting unit, with a zero or negative carrying amount, that fails the qualitative test. The new standard is effective for fiscal years and interim periods beginning after December 15, 2019. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The Company early adopted the new standard on September 30, 2019. Refer to Note 5 for additional information.

In February 2018, the FASB issued ASU No. 2018-02, Income Statement-Reporting Comprehensive Income (Topic 220). The standard update allows for a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the Tax Cuts and Jobs Act of 2017, or the Tax Act. Consequently, the ASU 2018-02 eliminates the stranded tax effects resulting from the Tax Act. The new standard is effective for fiscal years and interim periods beginning after December 15, 2018. Early adoption is permitted, including adoption in any interim period for reporting periods for which financial statements have not yet been issued. The new standard should be applied either in the period of adoption or retrospectively to each period (or periods) in which the effect of the change in the U.S. federal corporate income tax rate in the Tax Act is recognized. The Company adopted the new standard on January 1, 2019 and due to the full valuation allowance, the Company concluded that there is no impact on its consolidated financial statements.

In June 2018, the FASB issued ASU No. 2018-07 – Compensation-Stock Compensation (Topic 718): Improvements to Non-employee Shared-Based Payment Accounting. The standard update expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees. The new standard simplifies several aspects of Topic 718 by expanding the scope of the following areas to account for non-employee shared-based payment transactions: (1) overall measurement objective, (2) measurement date, (3) awards with performance conditions, and (4) classification reassessment of certain equity-classified awards. The new standard is effective for fiscal years and interim periods beginning after December 15, 2018. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606. The Company adopted the new standard on January 1, 2019. As a result, existing non-employee awards were measured as of the adoption date and the related expense will be recognized over the remaining requisite service period using the straight-line method. New awards made to non-employees will be measured at the grant date.

In March 2019, the FASB issued ASU No. 2019-01 – Leases (Topic 842): Codification Improvements. The standard clarifies the codification more generally and/or corrects unintended application of the guidance. The amendments in this standard include the following items: (Issue 1) Determining the fair value of the underlying asset by lessors that are not manufacturers or dealers, (Issue 2) Presentation on the statement of cash flows—sales-type and direct financing leases and (Issue 3) Transition disclosures related to Topic 250, Accounting Changes and Error Corrections. The amendments in this standard clarify the FASB's original intent by explicitly providing an exception to the paragraph 250-10-50-3 interim disclosure requirements in the Topic 842 transition disclosure requirements. The new standard is effective on the adoption date of ASU No. 2016-02. The Company adopted the standard on January 1, 2019 and concluded that adoption of the standard did not have a material impact on its consolidated financial statements.

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 cash equivalents consisting of corporate debt securities and commercial paper along with the Company's marketable securities consisting of available-for-sale securities 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 the contingent consideration liability.

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, 2019			
	Level 1	Level 2	Level 3	Total
Financial Assets:				
Money market funds	$ 39,994	$ —	$ —	$ 39,994
U.S. government and agency securities	—	43,333	—	43,333
Corporate debt securities	—	54,590	—	54,590
Commercial paper	—	67,536	—	67,536
Total	$ 39,994	$ 165,459	$ —	$ 205,453
Financial Liabilities:				
Contingent consideration related to acquisition	$ —	$ —	$ 1,051	$ 1,051
Total	$ —	$ —	$ 1,051	$ 1,051

	December 31, 2018			
	Level 1	Level 2	Level 3	Total
Financial Assets:				
Money market funds	$ 22,082	$ —	$ —	$ 22,082
U.S. government and agency securities	—	59,001	—	59,001
Corporate debt securities	—	70,964	—	70,964
Commercial paper	—	89,702	—	89,702
Total	$ 22,082	$ 219,667	$ —	$ 241,749
Financial Liabilities:				
Contingent consideration related to acquisition	$ —	$ —	$ 998	$ 998
Total	$ —	$ —	$ 998	$ 998

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. Changes in the fair value of the liability for contingent consideration, except for the impact of foreign currency, will be recognized in the consolidated statement of operations until settlement.

In the third quarter of 2018, the Company received regulatory authorization to conduct clinical studies for a specified antibody product candidate, which triggered payment of contingent consideration. A total of $6.8 million was paid to the former shareholders of BioNovion Holding B.V. under the terms of the 2015 share sale agreement pursuant to which the Company acquired BioNovion.

The Company did not have any financial assets and liabilities measured at fair value on a non-recurring basis as of December 31, 2019 and 2018. During the years ended December 31, 2019 and 2018, 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
Balance at December 31, 2017	$ 7,588
Net increase in fair value upon revaluation	635
Payment of contingent consideration	(6,803)
Foreign currency impact	(422)
Balance at December 31, 2018	998
Net increase in fair value upon revaluation	73
Foreign currency impact	(20)
Balance at December 31, 2019	$ 1,051

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, 2019			
	Amortized cost	Unrealized gains	Unrealized losses	Estimated Fair Value
Cash and cash equivalents:				
Cash	$ 8,149	$ —	$ —	$ 8,149
Money market funds	39,994	—	—	39,994
Commercial paper	11,482	—	(1)	11,481
Total cash and cash equivalents	$ 59,625	$ —	$ (1)	$ 59,624
Marketable securities:				
U.S. government and agency securities	$ 43,295	$ 40	$ (2)	$ 43,333
Corporate debt securities	54,563	33	(6)	54,590
Commercial paper	56,055	7	(7)	56,055
Total marketable securities	$ 153,913	$ 80	$ (15)	$ 153,978

	December 31, 2018			
	Amortized cost	Unrealized gains	Unrealized losses	Estimated Fair Value
Cash and cash equivalents:				
Cash	$ 36,124	$ —	$ —	$ 36,124
Money market funds	22,082	—	—	22,082
Commercial paper	62,413	—	—	62,413
Corporate debt securities	5,694	—	(3)	5,691
Total cash and cash equivalents	$ 126,313	$ —	$ (3)	$ 126,310
Marketable securities:				
U.S. government and agency securities	$ 59,127	$ 16	$ (142)	$ 59,001
Corporate debt securities	65,319	3	(49)	65,273
Commercial paper	27,289	—	—	27,289
Total marketable securities	$ 151,735	$ 19	$ (191)	$ 151,563

The amortized cost and estimated fair value of the Company's available-for-sale marketable securities by contractual maturity are summarized below as of December 31, 2019 (in thousands):

	Amortized cost	Unrealized gains	Unrealized losses	Estimated Fair Value
Mature in one year or less	$ 153,913	$ 80	$ (15)	$ 153,978
Total available-for-sale marketable securities	$ 153,913	$ 80	$ (15)	$ 153,978

4. Balance Sheet Components

Property and Equipment, Net

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

	December 31,	
	2019	2018
Leasehold improvements	$ 27,288	$ 26,961
Lab equipment	8,817	8,281
Computer and office equipment	2,334	2,292
Furniture and fixtures	1,590	1,560
Construction in progress	190	1,458
Total property and equipment	40,219	40,552
Less: accumulated depreciation	(15,531)	(11,395)
Property and equipment, net	$ 24,688	$ 29,157

Depreciation expense for the years ended December 31, 2019, 2018 and 2017 was $4.3 million, $4.4 million, and $3.4 million, respectively. As part of the Company's efforts to wind down programs and prioritize spending, the Company recorded an impairment charge of $1.2 million for the year ended December 31, 2019 related to lab equipment that was previously recorded in construction in progress to research and development expenses within the consolidated statement of operations.

Accrued Expenses and Other Liabilities

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

	December 31,	
	2019	2018
Compensation and related benefits	$ 3,677	$ 4,619
Professional and consulting services	2,845	2,185
Accrued research expense	890	1,859
Deferred rent	—	653
Accrued property and equipment	31	101
Other	738	1,101
Total accrued expenses and other liabilities	$ 8,181	$ 10,518

5. Goodwill and Intangible Assets

Goodwill

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

Balance at December 31, 2017	$ 8,723
Foreign currency translation adjustment	(389)
Balance at December 31, 2018	8,334
Foreign currency translation adjustment	(167)
Balance at December 31, 2019	$ 8,167

The Company tests goodwill for impairment on an annual basis on November 1, or more frequently if an impairment indicator exists. To determine if an impairment has occurred, the Company performs a quantitative test in which the Company compares the fair value of its single reporting unit to its carrying value. If the carrying value of the reporting unit exceeds the fair value of the reporting unit, the Company records an impairment loss equal to that difference. During the third quarter of 2019, as a result of the significant decline in the Company's stock price, the Company performed a quantitative assessment of goodwill and concluded that there was no impairment to goodwill. The fair value of the Company's reporting unit exceeded its carrying value by 4.0%.

Intangible assets

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

	December 31, 2019			
	Gross Carrying Amount	Impairment	(1) Accumulated Amortization	Net Book Value
Intangible assets with finite lives:				
License agreement	$ 11,091	$ —	$ 2,311	$ 8,780
Total intangible assets with finite lives	11,091	—	2,311	8,780
Acquired IPR&D assets	15,297	5,099	—	10,198
Total intangible assets	$ 26,388	$ 5,099	$ 2,311	$ 18,978

	December 31, 2018			
	Gross Carrying Amount	Impairment	(1) Accumulated Amortization	Net Book Value
Intangible assets with finite lives:				
License agreement	$ 11,318	$ —	$ 1,792	$ 9,526
Total intangible assets with finite lives	11,318	—	1,792	9,526
Acquired IPR&D assets	19,626	4,017	—	15,609
Total intangible assets	$ 30,944	$ 4,017	$ 1,792	$ 25,135

(1) The amount includes effects of foreign currency exchange rates.

Intangible assets are carried at cost less accumulated amortization and impairment. Amortization is over a period of 20 years and the amortization expense is recorded in operating expenses. The Company tests its Acquired IPR&D intangible assets for impairment on an annual basis, or more frequently if an impairment indicator exists. Due to the Company's decisions to discontinue certain of its acquired early research programs in the years ended December 31, 2019 and 2018, the Company recorded impairment charges of $5.0 million and $4.0 million, respectively. The impairment charge for the Acquired IPR&D assets were recorded to loss on impairment of intangible assets in the statement of operations. The impairment charges resulted in a reduction of $2.2 million in the deferred tax liability of its foreign subsidiary.

Amortization expense was $0.6 million, $0.6 million, and $0.6 million for the years ended December 31, 2019, 2018, and 2017, respectively. Based on finite-lived intangible assets recorded as of December 31, 2019, the estimated future amortization expense for the next five years is as follows (in thousands):

Year Ending December 31,	Estimated Amortization Expense
2020	$ 555
2021	555
2022	555
2023	555
2024	555

6. Collaboration Agreements

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. During the second quarter of 2016, the Company earned a $35.0 million development milestone upon initiation of a Phase 1 trial for the first STING product candidate, ADU-S100, and recognized the payment as revenue in the period. The Company is also eligible to receive up to an additional $215.0 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; provided that either party may opt out of early stage clinical trials subject to an obligation to fund and participate in any pivotal trials and reimburse certain early development costs if development of the product progresses into pivotal trials.

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.

For revenue recognition purposes, the Company determined that the duration of the contract begins on the effective date in March 2015 and ends upon receipt of regulatory approval, estimated to occur in 2028. The Company's performance period commenced in May 2015. The transaction price consists of the $200.0 million upfront fee, a $35.0 million milestone payment received in the second quarter of 2016 upon commencement of a Phase 1 study, and $2.1 million in reimbursement of research and development costs through December 31, 2019. The Company determined that the remaining potential milestone payments are probable of significant reversal of cumulative revenue as their achievement is highly dependent on the successful completion of Phase 1 studies. Therefore, these payments are not included in the transaction price. Any consideration related to sales-based royalties and profit-sharing payments will be recognized when the related sales occur as they were determined to relate predominantly to the license granted to Novartis and have been excluded from the transaction price. The transaction price of $237.1 million is allocated to one combined performance obligation. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

The Company concluded that it will utilize a cost-based input method to measure its progress toward completion of its performance obligation and to calculate the corresponding amount of revenue to recognize each period. The Company believes this is the best measure of progress because other measures do not reflect how the Company transfers its performance obligation to Novartis. In applying the cost-based input method of revenue recognition, the Company uses actual clinical study enrollment figures as well as actual costs incurred relative to budgeted costs expected to be incurred for the combined performance obligation. These costs consist primarily of internal full-time equivalent effort and third-party contract costs relative to the level of patient enrollment in the study. Revenue will be recognized based on the level of costs incurred relative to the total budgeted costs for the performance obligations. A cost-based input method of revenue recognition requires management to make estimates of costs to complete the Company's performance obligation. In making such estimates, significant judgment is required to evaluate assumptions related to cost estimates. The cumulative effect of revisions to estimated costs to complete the Company's performance obligation will be recorded in the period in which changes are identified and amounts can be reasonably estimated. A significant change in these assumptions and estimates could have a material impact on the timing and amount of revenue recognized in future periods.

Cost-sharing payments from Novartis are included in the transaction price and subject to the cost-based input method to determine the amount to be recognized in license and collaboration revenue in the Company's consolidated statements of operations, while cost-sharing payments to Novartis are accounted for as research and development expenses in the Company's consolidated statements of operations.

If the Company recognizes revenue from the sale of any products commercialized pursuant to this collaboration in the United States, it 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 from the sale of any products commercialized pursuant to this collaboration in such countries. Profit sharing payments made to or received from Novartis will be aggregated by product by territory and reported as expenses or revenues, as applicable.

In December 2019, the Company received notification that Novartis has removed ADU-S100 (MIW815), an intratumoral STING pathway activator product candidate, from Novartis' portfolio based on clinical data generated to date. This decision was not the result of any safety concern. The collaboration and license agreement between Novartis and Aduro remains in effect, and both parties continue to jointly pursue STING pathway activation through systemic delivery as a therapeutic strategy. The removal of ADU-S100 from Novartis' portfolio did not have an impact on the overall transaction price nor the revenue recognition methodology being utilized by the Company.

The Company is funding the squamous cell carcinoma of the head and neck (SCCHN) and non-muscle invasive bladder cancer (NMIBC) studies evaluating ADU-S100 itself because Novartis has opted out of these trials.

For the years ended December 31, 2019, 2018, and 2017, the Company recognized revenue from its collaboration with Novartis totaling $8.2 million, $11.9 million and $14.9 million, respectively. The remaining balance of the upfront fee of $169.0 million and $176.7 million is included in deferred revenue at December 31, 2019 and 2018, respectively.

Lilly Agreement

On December 18, 2018, the Company entered into a research collaboration and exclusive license agreement, or the Lilly Agreement, with Lilly for its cGAS-STING Pathway Inhibitor program for the research and development of novel immunotherapies for autoimmune and other inflammatory diseases. Pursuant to the Lilly Agreement, the Company granted an exclusive and worldwide license under certain intellectual property rights controlled by the Company to research, develop, manufacture and commercialize certain cGAS-STING products for the treatment of autoimmune and other inflammatory diseases. The license granted is sublicensable during a specified time period.

Under the terms of the Lilly Agreement, the Company received an upfront payment of $12.0 million in the first quarter of 2019. The Company will also be eligible for development and commercial milestones of up to approximately $620.0 million per product. Lilly is also obligated to pay the Company tiered royalty payments at percentages in the single to low-double digits based on annual net sales of the licensed products. Lilly must pay such royalties on a product-by-product and country-by-country basis until the latest to occur of (i) the expiration of the last-to-expire valid claim of certain patents, (ii) the expiration of the data exclusivity period in such country or (iii) a specified anniversary of the first commercial sale of such product in such country. The Company will be reimbursed for up to a certain amount of research funding spent during the research term. In addition, the Company has the option to co-fund the clinical development of each product in exchange for an increase in royalty payments and a reduction in certain milestone payments to the extent relevant to such co-funded product. Lilly will be responsible for all costs of global commercialization.

For revenue recognition purposes, the Company determined that the Company's performance period commenced in January 2019 and ends upon completion of the research term, estimated to occur in 2021. The transaction price consists of the $12.0 million upfront fee and variable consideration related to reimbursement of research and development costs. The Company determined that the remaining potential milestone payments are probable of significant reversal of cumulative revenue as their achievement is highly dependent on the successful completion of research activities and advancement through clinical studies. Therefore, these potential milestone payments are not included in the transaction price. Any consideration related to sales-based royalties and profit-sharing payments will be recognized when the related sales occur as they were determined to relate predominantly to the license granted to Lilly and have been excluded from the transaction price. The transaction price is allocated to one combined performance obligation. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

The Company concluded that it will utilize a cost-based input method to measure its progress toward completion of its performance obligation and to calculate the corresponding amount of revenue to recognize each period. The Company believes this is the best measure of progress because other measures do not reflect how the Company transfers its performance obligation to Lilly. In applying the cost-based input method of revenue recognition, the Company uses actual costs incurred relative to budgeted costs expected to be incurred for the combined performance obligation. These costs consist primarily of internal full-time equivalent effort and third-party contract costs. Revenue will be recognized based on the level of costs incurred relative to the total budgeted costs for the performance obligation. A cost-based input method of revenue recognition requires management to make estimates of costs to complete the Company's performance obligation. In making such estimates, significant judgment is required to evaluate assumptions related to cost estimates. The cumulative effect of revisions to estimated costs to complete the Company's performance obligation will be recorded in the period in which changes are identified and amounts can be reasonably estimated. A significant change in these assumptions and estimates could have a material impact on the timing and amount of revenue recognized in future periods.

For the year ended December 31, 2019, the Company recognized $9.1 million in revenue from the Lilly Agreement. The Company recorded $4.9 million in deferred revenue at December 31, 2019.

Merck License Agreement

In connection with the acquisition of Aduro Biotech Europe in October 2015, the Company became party to an agreement with Merck Sharp & Dohme Corp., or Merck. The agreement sets forth the parties' respective obligations for development, commercialization, regulatory and manufacturing and supply activities for antibody product candidates. The Company identified the following promises 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 determined that the promises were not distinct which resulted in them being combined into one performance obligation. The Company completed its performance obligation under the agreement by the end of 2016.

The Company received a milestone payment of $2.0 million in 2017 for the initiation of a Good Laboratory Practice, or GLP toxicology study and $3.0 million in the first quarter of 2018 for the initiation of a Phase 1 trial for the anti-CD27 antibody. Both payments were recognized in revenue when received as the Company had no remaining performance obligation. The Company is eligible to receive future contingent payments, including up to $307.0 million in potential development milestone payments, and up to $135.0 million in commercial and net sales milestones for a product candidate. In addition, the Company is eligible to receive royalties in the mid-single digits to low teens based on net sales of the product. Future milestone payments and royalties will be recognized when earned as the Company has no remaining performance obligations under this agreement.

7. Research and Development and License Agreements

For the years ended December 31, 2019, 2018 and 2017, respectively, the Company recorded $1.1 million, $0.8 million and $0.8 million in upfront payments, milestone payments and sublicensing fees from its research and development and license agreements described below.

STING Pathway License 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.

UCB Vance Agreement

In September 2014, the Company entered into a license agreement with University of California on behalf of its Berkeley campus, or 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.

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. In May and October 2016, the parties amended the license to further expand its scope, which now covers all products covered by the licensed intellectual property.

Under the MSK Agreement, the Company paid MSK upfront fees of $50,000 in January 2015 and an additional $2.0 million in connection with the second amendment to the MSK Agreement in October 2016. Under the terms of the amended MSK Agreement the Company is required to pay MSK development and regulatory milestone payments totaling up to $875,000 for each licensed product and commercialization milestone payments totaling up to $4.5 million for each licensed product, subject to a cap of $4.5 million per licensed product. The Company is also required to pay MSK royalties based on net sales of licensed products by Aduro and its 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. The Company's 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. The Company is 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 the Company's 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 the Company fails to pay any undisputed amounts owed under the agreement and does not cure such failure within 30 days after receiving notice of such failure.

8. Commitments and Contingencies

Leases

The Company leases one facility in Berkeley, California under an operating lease that has a remaining lease term of approximately 10 years. The Company also leases one facility in Oss, the Netherlands, under an operating lease that expires in December 2020. Both leases contain an option to extend for an additional term, however, the Company is not reasonably certain to exercise the option for either lease.

The Company is subleasing approximately 30,052 square feet in its Berkeley facility under subleases that expire on or prior to February 28, 2021. Sublease income was $1.6 million, $1.3 million, and $46,000 for each of the year ended December 31, 2019, 2018, and 2017, respectively.

During 2016, the Company established a letter of credit with Bank of America Merrill Lynch as security for the Berkeley lease in the amount of $0.5 million. The letter of credit is collateralized by a certificate of deposit for $0.5 million which has been included in restricted cash in the consolidated balance sheet as of December 31, 2019.

Future minimum payments under the leases at December 31, 2018 prior to the adoption of the new lease standard, ASC 842, were as follows (in thousands):

Year Ending December 31,	Amounts
2019	$ 5,519
2020	5,669
2021	5,332
2022	5,460
2023	5,570
Thereafter	35,836
Total future minimum lease payments	$ 63,386

As of January 1, 2019, the Company recognized ROU assets and lease liabilities for its operating leases. Aside from the operating leases, there were no other leases, including finance leases, recognized as of January 1, 2019.

The maturity of the Company's operating lease liabilities as of December 31, 2019 is as follows (in thousands):

Undiscounted Lease Payments	Amounts
2020	$ 5,659
2021	5,332
2022	5,460
2023	5,570
2024	5,681
Thereafter	30,155
Total undiscounted lease payments	57,857
Present value adjustment	24,418
Total net lease liability	$ 33,439
Net lease liability - current	$ 1,803
Net lease liability - non-current	31,636
Total net lease liability	$ 33,439

Straight-line rent expense recognized for operating leases was $5.0 million, $5.8 million, and $5.3 million for the years ended December 31, 2019, 2018, and 2017, respectively. Variable lease payments, including non-lease components such as common area maintenance fees, recognized as rent expense for operating leases were $1.2 million for the year ended December 31, 2019.

The following information represents supplemental disclosure for the consolidated statement of cash flows related to operating leases (in thousands):

	Year ended December 31, 2019
Cash flows from operating activities	
Cash paid for amounts included in the measurement of lease liabilities	$ 5,509

The following summarizes additional information related to operating leases:

	December 31, 2019
Weighted-average remaining lease terms (in years)	
Operating leases	9.9
Weighted-average discount rate	
Operating leases	12%

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

The Company is not party to any material legal proceedings at this time. From time to time, the Company may become involved in various legal proceedings that arise in the ordinary course of its business.

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 obligations, including payment obligations for costs or expenses 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.

9. Common Stock

The Company had reserved shares of common stock for future issuance as follows:

	December 31, 2019
Options issued and outstanding	10,297,444
Shares available for future stock option grants	8,751,436
Restricted stock units	798,943
Common stock warrants	50,162
Total	19,897,985

At-the-Market Sales Agreement

In August 2017, the Company entered into a subsequent "at-the-market" sales agreement, as amended in February 2019, or the 2017 Sales Agreement, with Cowen, through which the Company may offer and sell shares of its common stock having an aggregate offering of up to $100.0 million through Cowen, as the Company's sales agent. The Company will pay Cowen a commission of up to 3% of the gross proceeds of sales made through the arrangement. During the year ended December 31, 2017, the Company received net proceeds of $18.5 million, after deducting commissions and expenses payable by the Company, from the sale of 1,670,649 shares of common stock pursuant to the 2017 Sales Agreement. There were no sales of shares of common stock pursuant to the 2017 Sales Agreement during the years ended December 31, 2019 and 2018. As of December 31, 2019, the Company had an aggregate of $81.5 million remaining for future sales under the 2017 Sales Agreement, subject to the continued effectiveness of its shelf registration statement on Form S-3 (Registration No. 333-219639) or an effective replacement shelf registration statement.

10. Warrants

The Company had issued and outstanding warrants as follows:

	Warrants Outstanding					
	December 31, 2019	December 31, 2018	Issuance Date		Exercise Price per Share	Terms (Years)
Type of Security:						
Common	—	720	January 2009	$	34.73	10.8
Common	—	288	February 2009	$	34.73	10.0
Common	—	360	March 2009	$	34.73	10.0
Common	—	144	April 2009	$	34.73	10.0
Common	—	13,235	July 2009	$	1.89	10.0
Common	2,400	2,400	April 2011	$	1.88	10.0
Common	19,867	19,867	April 2011	$	0.01	10.0
Common	6,031	6,031	October 2011	$	0.01	9.5
Common	19,078	19,078	September 2013	$	0.02	10.0
Common	2,786	2,786	December 2013	$	0.02	10.0
Total	50,162	64,909				

11. 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 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.

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. On January 1, 2019, the shares issuable under the 2015 Plan increased by 3,182,868. The Company had 8,751,436 shares available for future grant under the 2015 Plan as of December 31, 2019.

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, 2019, 2,769,320 options under the 2009 Plan remained outstanding.

Stock option activity under the Company's stock option plan was as follows:

	Options Outstanding			
	Shares Available for Grant	Number of Options	Weighted-Average Exercise Price	Aggregate Intrinsic Value
				(In thousands)
Balance—December 31, 2018	7,255,050	8,986,010	$ 7.54	$ 5,458
Authorized	3,182,868	—		
RSUs forfeited, net of grants	297,155	—		
Granted	(5,140,100)	5,140,100	3.55	
Exercised	—	(548,523)	0.97	
Canceled	3,156,463 (1)	(3,280,143)	8.80	
Balance—December 31, 2019	8,751,436	10,297,444	$ 5.49	$ 680
Options exercisable—December 31, 2019		5,702,112	$ 6.59	$ 670
Options vested and expected to vest—December 31, 2019		9,492,970	$ 5.63	$ 678

(1) The amount excludes 123,680 canceled options for the year ended December 31, 2019 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 closing price of the Company's common stock.

The aggregate intrinsic value of options exercised was $1.2 million, $9.1 million and $19.2 million for the years ended December 31, 2019, 2018 and 2017, respectively.

The weighted-average grant date fair value of employee options granted during the years ended December 31, 2019, 2018 and 2017 were $2.27, $3.96 and $6.91 per share, respectively.

At December 31, 2019, the weighted-average remaining contractual life was 5.6 years and 6.9 years for exercisable options and vested and expected to vest options, respectively. The weighted-average remaining contractual life of options outstanding was 7.1 years, 6.6 years and 6.8 years at December 31, 2019, 2018 and 2017, respectively.

As of December 31, 2019, the total unrecognized compensation expense related to unvested options, net of estimated forfeitures, was $9.7 million, which the Company expects to recognize over an estimated weighted-average period of 2.9 years.

Restricted Stock Units (RSUs)

In September 2016, the Company's board of directors authorized the issuance of restricted stock units, or RSUs, under the 2015 Plan and adopted a form of restricted stock unit grant notice and restricted stock unit award agreement, which is intended to serve as a standard form agreement for RSU grants issued to employees, executive officers, directors and consultants.

The following table summarizes RSU activity:

	RSUs Outstanding	
	Number of Restricted Stock Units	Weighted-Average Grant Date Fair Value Per Share
Balance—December 31, 2018	1,600,218	$ 8.81
Granted	275,000	1.74
Vested	(504,120)	7.38
Forfeited	(572,155)	8.63
Balance—December 31, 2019	798,943	$ 7.40

The fair value of RSUs is determined on the date of grant based on the market price of the Company's common stock on that date. As of December 31, 2019, there was $4.1 million of unrecognized stock-based compensation expense, net of estimated forfeitures, related to RSUs which is expected to be recognized over a weighted-average period of 1.9 years.

2015 Employee Stock Purchase Plan

In March 2015, the Company's board of directors adopted and in April 2015 the Company's stockholders approved the 2015 Employee Stock Purchase Plan, or 2015 ESPP, which became effective upon the IPO. The 2015 ESPP is intended to qualify as an employee stock purchase plan under Section 423 of the Code and is administered by the Company's board of directors or a committee of the board of directors.

The number of shares of common stock initially reserved for issuance under the 2015 ESPP was 720,000 shares with an automatic annual increase to the shares issuable under the 2015 ESPP to the lower of (i) 1% 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. There was no annual increase of shares issuable under the 2015 ESPP on January 1, 2019. The Company had 1,570,337 shares available for future issuance under the 2015 ESPP as of December 31, 2019. Employees purchased 111,331 shares for $0.2 million under the 2015 ESPP during the year ended December 31, 2019.

The following table summarizes the assumptions used in the Black-Scholes option-pricing model to determine fair value of the Company's common shares to be issued under the 2015 ESPP:

	Year Ended December 31,		
	2019	2018	2017
Expected term (in years)	0.5	0.5	0.5
Volatility	47.6% - 62.5%	62.5%	49.3%
Risk-free interest rate	1.59% - 2.43%	2.37%	1.39%
Dividend yield	—%	—%	—%

As of December 31, 2019, there was $45,000 of unrecognized stock-based compensation expense related to the 2015 ESPP, which is expected to be recognized over a weighted-average period of 0.4 years.

Stock-based Compensation Expense

Total stock-based compensation expense recognized was as follows (in thousands):

	Year Ended December 31,		
	2019	2018	2017
Research and development	$ 6,376	$ 9,745	$ 9,205
General and administrative	6,063	7,729	7,171
Total stock-based compensation expense	$ 12,439	$ 17,474	$ 16,376

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—Since the Company's IPO, it has used the market closing price of its common stock as reported on the Nasdaq Global Select Market.

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—Because 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,		
	2019	2018	2017
Expected term (in years)	5.3 - 6.1	5.3 - 6.1	5.3 - 6.5
Volatility	67.2% - 70.9%	70.5% - 71.7%	71.8 - 74.1%
Risk-free interest rate	1.52% - 2.60%	2.38% - 3.08%	1.78 - 2.25%
Dividend yield	—%	—%	—%

For the years ended December 31, 2019, 2018 and 2017, the Company recognized $8.0 million, $11.5 million and $11.4 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.

The Company uses the fair value method to value options granted to non-employees. For the years ended December 31, 2019, 2018 and 2017, the Company recognized stock-based compensation of $0.1 million, $0.2 million and $0.5 million, respectively, related to options granted to non-employees. Beginning on January 1, 2019, the Company adopted ASU 2018-07 and measured its stock-based awards made to non-employees based on the estimated fair values of the awards using the Black-Scholes option-pricing model and recognized expense over the remaining requisite service period using the straight-line method. As a result, the stock-based compensation amount recognized for the year ended December 31, 2019 reflects the adoption of ASU 2018-07 as of January 1, 2019 while the stock-based compensation amount recognized for the years ended December 31, 2018 and 2017 reflects the amount prior to the recently adopted standard.

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,		
	2019	2018	2017
Expected term (in years)	6.2 - 9.7	6.0 - 9.7	6.7 - 10.0
Volatility	70.5 - 70.8%	70.5 - 71.7%	72.2 - 73.0%
Risk-free interest rate	2.66 - 3.19%	2.66 - 3.19%	2.24 - 2.45%
Dividend yield	—%	—%	—%

12. Income Taxes

The components of loss before income tax benefit were as follows (in thousands):

	Year Ended December 31,		
	2019	2018	2017
Domestic	$ (61,292)	$ (77,066)	$ (76,503)
Foreign	(23,492)	(19,074)	(26,724)
Total	$ (84,784)	$ (96,140)	$ (103,227)

The income tax benefit consists of the following (in thousands):

	Year Ended December 31,		
	2019	2018	2017
Current income tax benefit:			
Federal	$ —	$ (637)	$ (17,544)
State	—	—	—
Foreign	—	—	—
Total	$ —	$ (637)	$ (17,544)
Deferred income tax benefit:			
Federal	—	—	6,319
State	—	—	—
Foreign	(2,412)	(146)	(139)
Total	(2,412)	(146)	6,180
Total income tax benefit	$ (2,412)	$ (783)	$ (11,364)

A reconciliation of the statutory U.S. federal rate to the Company's effective tax rate is as follows:

	Year Ended December 31,		
	2019	2018	2017
Expected provision at statutory rate federal rate	(21.0%)	(21.0%)	(35.0%)
State taxes, net of federal benefits	—	—	—
U.S. tax credits	(3.8)	(2.8)	(6.4)
Add back of Orphan Drug Credit	—	—	1.4
Incentive stock option compensation	2.7	1.3	(3.2)
Tax Cuts and Jobs Act impact	—	—	29.0
Other	(2.7)	(2.6)	(0.4)
Foreign income tax rate differential	0.5	0.5	3.4
Change in valuation allowance	24.1	23.8	0.2
Intangible Asset Impairment	(2.7)	—	—
Total	(2.9%)	(0.8%)	(11.0%)

The decrease in the effective tax rate from (0.8%) during 2018 to (2.9%) during 2019 was primarily related to the deferred tax benefit associated with the acquired IPR&D asset impairments.

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):

	Year Ended December 31,	
	2019	2018
Deferred tax assets:		
Net operating loss carryforwards	$ 56,442	$ 38,562
Tax credits	40,637	41,193
Stock-based compensation	6,911	6,326
Deferred revenue	35,357	34,897
Lease liability	7,846	—
Accruals and reserves	830	3,659
Gross deferred tax assets	148,023	124,637
Valuation allowance	(138,534)	(119,451)
Total deferred tax assets	9,489	5,186
Deferred tax liabilities:		
Tangible assets	(3,226)	(3,728)
Intangible assets	(4,877)	(7,562)
Right-of-use assets	(4,913)	—
Total deferred tax liabilities	(13,016)	(11,290)
Net deferred tax liabilities	$ (3,527)	$ (6,104)

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 consolidated cumulative losses, the Company determined that, based on all available evidence, there was substantial uncertainty as to whether it will recover a majority of its recorded net deferred taxes in future periods. As a result, the Company recorded a valuation allowance against the U.S. net deferred tax assets at December 31, 2019 and the net deferred tax assets at December 31, 2018. The net valuation allowance increased by $19.1 million and $26.2 million in 2019 and 2018, respectively.

At December 31, 2019, the Company has generated net operating loss, or NOL, carryforwards (before tax effects) for federal, state and foreign income tax purposes of $153.8 million, $107.8 million and $66.5 million, respectively. These federal, state and foreign NOL carryforwards will begin to expire in 2027, 2033 and 2025, respectively, if not utilized. In addition, the Company has federal and state tax credit carryforwards of $38.3 million and $10.3 million, respectively, to offset future income tax liabilities. The federal 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 Code, the Company's ability to utilize NOL carryforwards or other tax attributes, such as federal 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. The Company experienced an ownership change that it believes under Section 382 of the Code will result in limitations in its 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 tax 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, 2019 and 2018 is as follows (in thousands):

	Year Ended December 31,	
	2019	2018
Balance at beginning of year	$ 5,206	$ 4,090
Additions based on tax positions related to prior year	10	3
Reductions based on tax positions related to prior year	—	(7)
Additions based on tax positions related to current year	1,349	—
Reductions based on tax positions related to current year	—	1,120
Balance at end of year	$ 6,565	$ 5,206

Without regard to the valuation allowance, $0.8 million of unrecognized tax benefits included in the consolidated balance sheet 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, 2016 through December 31, 2018. 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 consolidated statements of operations. At December 31, 2019, the Company has recorded no interest and penalties.

13. 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 Code.

14. Net Loss per Common Share

Because the Company was in a loss position for all periods presented, diluted net loss per common share is the same as basic 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,		
	2019	2018	2017
Options to purchase common stock	10,297,444	8,986,010	9,076,018
Common stock warrants	50,162	64,909	69,378
Restricted stock awards	798,943	1,600,218	1,436,623
Total	11,146,549	10,651,137	10,582,019

15. Selected Quarterly Financial Data (Unaudited)

The following interim financial information presents the Company's 2019 and 2018 results of operations on a quarterly basis (in thousands, except per share amounts):

	Quarter Ended			
	March 31, 2019	June 30, 2019	September 30, 2019	December 31, 2019
Total revenue	$ 3,938	$ 4,888	$ 4,799	$ 3,633
Net loss	(23,427)	(18,578)	(20,952)	(19,415)
Net loss per common share, basic	(0.29)	(0.23)	(0.26)	(0.24)
Net loss per common share, diluted	(0.29)	(0.23)	(0.26)	(0.24)

	Quarter Ended			
	March 31, 2018	June 30, 2018	September 30, 2018	December 31, 2018
Total revenue	$ 6,627	$ 2,639	$ 3,063	$ 2,758
Net loss	(21,494)	(24,397)	(23,146)	(26,320)
Net loss per common share, basic	(0.28)	(0.31)	(0.29)	(0.33)
Net loss per common share, diluted	(0.28)	(0.31)	(0.29)	(0.33)

16. Subsequent Events

Restructuring

On January 8, 2020, the Board of Directors of Aduro Biotech, Inc. approved a restructuring that is intended to result in the termination of approximately 59% of the Company's employee workforce, or approximately 51 employees. The restructuring was approved in connection with the Company's restructuring plan to further extend the Company's operating capital and align personnel towards executing its clinical development strategy. The restructuring is expected to be substantially complete by the end of the third quarter of 2020.

As a result of the restructuring, the Company estimates that it will incur aggregate charges of approximately $6.1 million, including $2.0 million in one-time severance and employee termination related costs, approximately $3.8 million in one-time retention costs and relocation costs of approximately $0.3 million.

In connection with the Company's restructuring plan, the Company is also terminating its lease of a research and development facility in Oss, the Netherlands as of June 30, 2020. The Company is currently evaluating the impact of this lease termination.

Merck collaboration agreement

On February 6, 2020, the Company announced that it has earned a $10.0 million development milestone payment under its exclusive license and research agreement with Merck (known as MSD outside the United States and Canada) for Merck's initiation of a Phase 2 clinical trial of MK-5890, an anti-CD27 agonist, in non-small cell lung cancer (NSCLC).

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 Interim Chief 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, 2019. Based on that evaluation, our President and Chief Executive Officer and our Interim Chief Financial Officer have concluded that, as of December 31, 2019, our disclosure controls and procedures were, in design and operation, effective.

Management's report on internal control over financial reporting.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Securities Exchange Act of 1934, as amended. Our management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the 2013 framework in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on its evaluation under the framework in Internal Control—Integrated Framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2019.

Changes in internal control over financial reporting.

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

Attestation Report of the Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm due to an exemption established by the JOBS Act for “emerging growth companies.”

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 2020 Annual Meeting of Stockholders, or the Proxy Statement, which will be filed no later than 120 days after the end of our fiscal year ended December 31, 2019, 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 and our equity compensation plans 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 below.

(c) See Item 15(a)2 above.

Exhibit No.	Description of Exhibit	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
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	
4.3	Description of Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.					X
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†	License Agreement between Karagen Pharmaceuticals, Inc. and Aduro Biotech, Inc., dated June 20, 2012.	S-1	333-202667	10.26	03/11/2015	
10.14†	Exclusive License between Aduro Biotech, Inc. and the Regents of the University of California, dated September 25, 2014.	S-1	333-202667	10.27	03/11/2015	

Exhibit No.	Description of Exhibit	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
10.15†	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	
10.16†	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	
10.17†	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	
10.18	Letter Agreement between Aduro Biotech, Inc. and Karagen Pharmaceuticals, Inc. dated June 5, 2015.	10-Q	001-37345	10.38	08/11/2015	
10.19†	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	
10.20+	Offer of Employment between Blaine Templeman and Aduro Biotech, Inc., dated September 18, 2015.	10-Q	001-37345	10.2	11/23/2015	
10.21	First Amendment to Lease, dated April 26, 2016.	10-Q	001-37345	10.2	08/03/2016	
10.22	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement.	8-K	001-37345	10.1	09/14/2016	
10.23	Amended and Restated Severance Plan, dated as of December 9, 2016.	10-K	001-37345	10.44	03/01/2017	
10.24†	Amendment No. 1 to Exclusive License Agreement between Aduro Biotech, Inc. and the Memorial Sloan Kettering Cancer Center, dated May 27, 2016.	10-K	001-37345	10.45	03/01/2017	
10.25†	Amendment No. 2 to Exclusive License Agreement between Aduro Biotech, Inc. and the Memorial Sloan Kettering Cancer Center, dated October 10, 2016.	10-K	001-37345	10.46	03/01/2017	
10.26	Common Stock Sales Agreement between Aduro Biotech, Inc. and Cowen and Company, LLC, dated August 2, 2017.	10-Q	001-37345	10.1	08/02/2017	
10.27+	Employment Agreement between Aduro Biotech Holdings, Europe B.V. and Mr. Andrea Van Elsas dated October 30, 2015.	10-K	001-37345	10.37	03/01/2018	
10.28+	Addendum to Employment Agreement between Aduro Biotech Holdings, Europe B.V. and Mr. Andrea Van Elsas dated October 4, 2017.	10-K	001-37345	10.38	03/01/2018	

Exhibit No.	Description of Exhibit	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
10.29#	Research Collaboration and Exclusive License Agreement between Aduro Biotech, Inc. and Eli Lilly and Company, dated December 18, 2018.	10-K	001-37345	10.41	02/27/2019	
10.30	Amendment No. 1 to Sales Agreement between Aduro Biotech, Inc. and Cowen and Company, LLC, dated February 27, 2019.	10-K	001-37345	10.42	02/27/2019	
10.31+	Aduro Biotech, Inc. Non-Employee Director Compensation Policy.	10-Q	001-37345	10.1	05/07/2019	
10.32+	Offer of Employment Letter of Chief Medical Officer.	10-Q	001-37345	10.2	08/01/2019	
10.33+	Consulting Agreement dated January 22, 2020, between the Company and Danforth Advisors, LLC.	8-K	001-37345	10.1	01/23/2020	
10.34+	Retention Bonus Agreement dated January 9, 2020, between the Company and Blaine Templeman.					X
10.35+	Retention Bonus Agreement dated January 9, 2020, between the Company and Celeste Ferber.					X
10.36+	Retention Bonus Agreement dated January 9, 2020, between the Company and Dimitry Nuyten.					X
10.37+	Amendment No. 2 to Executive Employment Agreement dated January 13, 2020, between the Company and Stephen T. Isaacs.					X
10.38+	Retention Bonus Agreement dated January 10, 2020, between the Company and Stephen T. Isaacs.					X
21.1	Subsidiaries of the Registrant					X
23.1	Consent of Deloitte & Touche LLP, independent registered public accounting firm.					X
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

Exhibit No.	Description of Exhibit	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
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.

Confidential treatment has been requested for a portion of this exhibit.

(c) See Item 15(a)2 above.

Item 16. Form 10-K Summary.

None.

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 9th day of March 2020.

ADURO BIOTECH, INC.

By: /s/ Stephen T. Isaacs
Stephen T. Isaacs
Chairman, President and Chief Executive Officer
(principal executive officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Stephen T. Isaacs and William G. Kachioff, 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 9, 2020
/s/ William G. Kachioff William G. Kachioff	Interim Chief Financial Officer (principal financial and accounting officer)	March 9, 2020
/s/ William M. Greenman William M. Greenman	Director	March 9, 2020
/s/ Ross Haghighat Ross Haghighat	Director	March 9, 2020
/s/ Stephanie Monaghan O’Brien Stephanie Monaghan O’Brien	Director	March 9, 2020
/s/ Stephen A. Sherwin Stephen A. Sherwin	Director	March 9, 2020
/s/ David H. Mack David H. Mack	Director	March 9, 2020
/s/ Frank Karbe Frank Karbe	Director	March 9, 2020

Exhibit 4.3

DESCRIPTION OF REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of December 31, 2019, Aduro Biotech, Inc. had common stock, $0.0001 par value per share, registered under Section 12 of the Securities Exchange Act of 1934, as amended, and listed on The Nasdaq Global Select Market under the trading symbol "ADRO."

DESCRIPTION OF CAPITAL STOCK

Our certificate of incorporation authorizes us to issue up to 300,000,000 shares of common stock, $0.0001 par value per share, and 10,000,000 shares of preferred stock, $0.0001 par value per share. As of December 31, 2019, 80,735,688 shares of common stock were outstanding and no shares of preferred stock were outstanding.

The following is a summary description of the material terms of our capital stock. The description of capital stock is intended as a summary and is qualified in its entirety by reference to our certificate of incorporation, bylaws and amended and restated investor rights agreement, copies of which are incorporated by reference as Exhibits 3.1, 3.2 and 4.2, respectively, to our Annual Report on Form 10-K.

Common Stock

Voting Rights

Each holder of our common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Under our certificate of incorporation and bylaws, our stockholders do not have cumulative voting rights. Because of this, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose.

Dividends

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

Liquidation

In the event of our liquidation, dissolution or winding up, holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then-outstanding shares of preferred stock.

Rights and Preferences

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

Registration Rights

We are party to an amended and restated investors' rights agreement that provides that holders of our common stock, including certain holders of 5% of our capital stock and entities affiliated with certain of our directors, have certain registration rights, as set forth below. The registration of shares of our common stock pursuant to the exercise of registration rights described below would enable the holders to sell these shares without restriction under the Securities Act of 1933, as amended (the "Securities Act") when the applicable registration statement is declared effective. We will pay the registration expenses, other than the underwriting discount, of the shares registered pursuant to the demand, piggyback and Form S-3 registrations described below.

Generally, in an underwritten offering, the managing underwriter, if any, has the right, subject to specified conditions, to limit the number of shares such holders may include. The demand, piggyback and Form S-3 registration rights described below will expire upon the earlier of April 20, 2020, which is five years following the completion of our initial public offering, or when all investors, considered with their affiliates, can sell all of their shares in a 90-day period under Rule 144.

Demand Registration Rights

Upon the written request of certain of the holders of the registrable securities then outstanding that we file a registration statement under the Securities Act covering the registration of registrable securities having an aggregate offering price to the public of not less than $5.0 million, we will be required to use our best efforts to register all or a portion of their registrable securities that holders may request to be registered. We are not required to effect such registrations on more than two occasions.

Piggyback Registration Rights

In the event that we propose to register any of our securities under the Securities Act in a future offering, either for our own account or for the account of other security holders, the holders of registrable securities will be entitled to certain “piggyback” registration rights allowing them to include their shares in such registration, subject to certain marketing and other limitations. As a result, whenever we propose to file a registration statement under the Securities Act, including a registration statement on Form S-3 as discussed below, other than with respect to a demand registration or a registration statement on Forms S-4 or S-8 or related to stock issued upon conversion of debt securities, the holders of these shares are entitled to notice of the registration and have the right, subject to limitations that the underwriters may impose on the number of shares included in the registration, to include their shares in the registration.

Form S-3 Registration Rights

The holders of registrable securities are entitled to certain Form S-3 registration rights. Such request for registration on Form S-3 must cover securities the aggregate offering price of which, before payment of the underwriting discount, equals or exceeds $1.5 million.

Anti-Takeover Provisions

Certificate of Incorporation and Bylaws

Our certificate of incorporation and bylaws provide that all stockholder actions must be effected at a duly called meeting of stockholders and not by written consent. A special meeting of stockholders may be called by the chairman of our board of directors, the majority of our whole board of directors, or our chief executive officer.

Our certificate of incorporation provides for our board of directors to be divided into three classes, with staggered three-year terms. As a result, only one class of directors is elected at each annual meeting of stockholders, with the other classes continuing for the remainder of their respective three-year terms. Stockholders have no cumulative voting rights, and the stockholders representing a majority of the shares of common stock entitled to vote in any election of directors may elect all of the directors standing for election. In addition, our certificate of incorporation provides that stockholders may remove directors only for cause and only by the affirmative vote of the holders of at least sixty-six and two-thirds percent (66-2/3%) in voting power of our stock entitled to vote thereon.

Our certificate of incorporation further provides that the affirmative vote of holders of at least sixty-six and two-thirds percent (66-2/3%) of the voting power of all of the then outstanding shares of voting stock, voting as a single class, will be required to amend certain provisions of our certificate of incorporation, including provisions relating to the size of the board, removal of directors, special meetings, actions by written consent and cumulative voting. The affirmative vote of holders of at least sixty-six and two-thirds percent (66-2/3%) of the voting power of all of the then outstanding shares of voting stock, voting as a single class, is required to amend or repeal our bylaws, although our bylaws may be amended by a simple majority vote of our board of directors.

The foregoing provisions make it more difficult for our existing stockholders to replace our board of directors as well as for another party to obtain control of us by replacing our board of directors. Since our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to cause a change in control of us.

These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage certain types of transactions that may involve an actual or threatened acquisition of us. These provisions are also designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging a change of control of our company or changes in our board of directors that our stockholders might consider favorable. As a consequence, these provisions also may inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts.

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the Delaware General Corporation Law (the “DGCL”), which prohibits a Delaware corporation from engaging in a business combination with any interested stockholder for a period of three years following the date the person became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested holder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (a) by persons who are directors and also officers and (b) pursuant to employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; and
- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 of the DGCL defines business combination to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation.

Section 203 of the DGCL defines an “interested stockholder” as an entity or person who, together with the entity’s or person’s affiliates and associates, beneficially owns, or is an affiliate of the corporation and within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation. A Delaware corporation may “opt out” of these provisions with an express provision in its certificate of incorporation. We have not opted out of these provisions, which may as a result, discourage or prevent mergers or other takeover or change of control attempts of us.

Choice of Forum

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our certificate of incorporation or our bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A. The transfer agent and registrar's address is 250 Royall Street, Canton, Massachusetts 02021.

Exhibit 10.34

RETENTION BONUS AGREEMENT

This RETENTION BONUS AGREEMENT ("Agreement") is entered into as of January 9, 2020, by and between Aduro Biotech, Inc. (the "Company") and Blaine Templeman (the "Employee").

This Agreement is being entered into with reference to the following recitals:

A. The Company employs Employee, on an at-will basis, in the position of Chief Administrative Officer and Chief Legal Officer;

B. Employee is eligible for benefits under the terms of the Aduro Biotech, Inc. Amended And Restated Severance And Summary Plan Description ("Severance Plan") as a Tier I Participant. For purposes of this Agreement, the terms "Cause," "Change in Control," "Disability," "Good Reason," "Separation from Service," and "Involuntary Termination" will be defined as set forth in the Severance Plan.

C. The Company has identified Employee's continued employment with the Company as important to the ongoing success of the Company's operations;

D. To ensure the successful completion of certain duties and responsibilities by Employee, the Company desires to retain Employee through September 30, 2020 (the "Retention Date"); and

E. The Company is entering into this Agreement to provide additional consideration to incentivize Employee to remain employed by the Company at least through the Retention Date.

NOW, THEREFORE, in consideration of the promises and the mutual covenants contained herein, the Company and Employee agree as follows:

1. Retention Bonus. Employee is eligible to earn a retention bonus in the gross amount of Three Hundred Five Thousand Four Hundred Twenty-four and 00/100 Dollars ($305,424.00) ("Retention Bonus") under the terms of this Agreement. If Employee remains employed through the Retention Date, the Retention Bonus will be paid to Employee within 15 days after September 30, 2020.

2. Involuntary Termination. If Employee is subject to an Involuntary Termination or a termination due to the Employee's death or Disability on or prior to the Retention Date, Employee will be entitled to, and the Company will pay, the Retention Bonus within 15 days after Employee's Separation from Service instead of after the Retention Date.

3. Tax Withholding. Employee acknowledges that such Retention Bonus shall constitute wages, and that with respect to any payments or benefits under this Agreement the Company shall deduct all amounts it is required to deduct and withhold under any applicable federal, state or local tax laws (including, for the avoidance of doubt, any applicable income or employment taxes required to be deducted and withheld from such payments).

4. At-Will Employment. If the Company terminates Employee's employment for Cause or if Employee resigns his/her employment without Good Reason prior to the Retention Date, Employee shall not have earned and shall not be entitled to the payment of any unpaid portion of the Retention Bonus.

5. General Release of Claims.

5.1 In exchange for the consideration provided for in this Agreement, the adequacy of which Employee hereby acknowledges, Employee irrevocably and unconditionally releases all claims described below that Employee may have against the following persons or entities (the "Releasees"): Aduro, all of Aduro's related or affiliated organizations, including all of Aduro's and its related or affiliated organizations' predecessors and successors; and, with respect to each such entity, all of its past and present employees, officers, directors, partners, principals, representatives, assigns, attorneys, agents, insurers, employee benefit programs (and the trustees, administrators, fiduciaries and insurers of such programs) and any other persons acting by, through, under, or in concert with any of the persons or entities listed in this Subsection.

5.2 The claims released include all claims, promises, offers, debts, causes of action or similar rights of any type or nature Employee has or had against Releasees, including but not limited to those which in any way relate to Employee's employment with Aduro, except as prohibited by law. This includes (but is not limited to) a release and waiver of any common law contract or tort claims, the Fair Labor Standards Act and any local wage and hour laws, or other claims that may have arisen under any federal or local anti-discrimination statutes or laws, such as Title VII of the Civil Rights Act of 1964; § 1981 of the Civil Rights Act of 1866 and Executive Order 11246; the Fair Labor Standards Act; the Employee Retirement and Income Security Act; the Americans with Disabilities Act, 42 U.S.C. § 1981; the Workers Adjustment and Retraining Notification Act, as amended; the Family and Medical Leave Act; the California Civil Code; the California Constitution; and any and all other laws and regulations relating to employment termination, employment discrimination, whistleblowing, harassment or retaliation, claims for wages, hours, benefits, compensation, equity incentive pay, and any and all claims for attorneys' fees and costs, inasmuch as is permissible by law and by the respective governmental enforcement agencies for the above-listed laws, except, however, Employee does not release any claims under the state anti-discrimination law, the California Fair Employment and Housing Act, California Government Code section 12900, *et seq.*

5.3 This Agreement does not waive rights or claims (i) under federal or state law that Employee cannot, as a matter of law, waive by private agreement, including without limitation any right of indemnification under Labor Code Section 2802 and any right to accrued benefits; (ii) that may arise after the Employee executes this Agreement; (iii) to indemnification under any agreement between Employee and the Company or under the Company's certificate of incorporation, bylaws or other organizational documents, each as amended; (iv) under the Company's director and officer liability insurance; (v) to vested or unvested compensation or other pay (in, each case, in whatever form) or vested or unvested benefits (in whatever form), including, without limitation, severance benefits or vested or unvested rights or claims based on written agreements or employee or director benefit arrangements; or (vi) by Employee in his or her capacity as a stockholder of the Company. Additionally, nothing in this Agreement precludes Employee from filing a charge or complaint with or participating in any investigation or proceeding before the Equal Employment Opportunity Commission or National Labor Relations Board. However, while Employee may file a charge and participate in any proceeding conducted by the Equal Employment Opportunity Commission or National Labor Relations Board, by signing this Agreement, Employee waives his/her right to bring a lawsuit against the Released Parties (or any of them) and waives his/her right to any individual monetary recovery in any action or lawsuit initiated by the Equal Employment Opportunity Commission or National Labor Relations Board. Furthermore, this Agreement is not a release of claims under the California Fair Employment and Housing Act, California Government Code section 12900, *et seq.*, and nothing in this Agreement precludes Employee from filing a charge or complaint with or participating in any investigation or proceeding before the

California Department of Fair Employment and Housing. Furthermore, nothing in this Agreement prohibits Employee from reporting possible violations of federal law or regulation to any governmental agency or entity, including but not limited to the Department of Justice, the Securities and Exchange Commission, the Congress, and any agency Inspector General, or making other disclosures that are protected under the whistleblower provisions of federal law or regulation. Employee does not need the prior authorization of Aduro to make any such reports or disclosures and Employee is not required to notify Aduro that Employee has made such reports or disclosures. Further, nothing in this Agreement prohibits Employee or any person from testifying about alleged criminal conduct or sexual harassment when the party has been compelled or requested to do so by lawful process.

6. Covenant Not to Sue. Employee has not, and will not, directly or indirectly institute any legal action against the Released Parties based upon, arising out of, or relating to any claims released in this Agreement, to the extent allowed by law. Employee has not, and will not, directly or indirectly encourage and/or solicit any third party to institute any legal action against the Released Parties, to the extent allowed by law.

7. No Workplace Injuries. Employee has not sustained any workplace injury of any kind during Employee's employment with Aduro, and Employee does not intend to file any claim for or seek any workers' compensation benefits.

8. Severance Benefits. Employee shall continue to be eligible for Severance Benefits as set forth in the Severance Plan regardless of whether Employee executes this Agreement. However, if Employee does execute this Agreement, Employee shall, in addition to any severance benefits under the Severance Plan, have the right to exercise any vested Outstanding Stock Awards held by Employee at the time of Separation of Service (including any options that are accelerated upon such termination) until the earlier of (i) 18 months following the Employee's Separation of Service (or longer period set forth in the terms of such option grant), (ii) the applicable expiration date of the option or (iii) the date of a Change in Control in which a stock option is canceled and not otherwise assumed or continued or replaced.

8.1 The Severance Plan, and in particular Section V. of the Severance Plan, shall control with respect to tax treatment, offset, and the application of Section 409A of the Internal Revenue Code to the benefits provided under this Agreement. In addition, Section III(c) of the Severance Plan shall control with respect to the treatment of any payment or benefit that would constitute a payment under Section 280G of the Internal Revenue Code.

9. No Consideration Unless Employee Complies With This Agreement. Employee acknowledges that he/she will not receive the Retention Bonus and other benefits set forth herein, unless Employee executes this Agreement and fulfills the promises contained herein. Aduro has no independent legal duty to provide Employee with the consideration set forth in this Agreement, absent the terms of the Agreement itself.

10. Confidentiality. In recognition of Employee's privacy interests and because this is an arrangement that has been made available to Employee personally, the parties have a mutual interest in keeping this Agreement confidential to the extent permitted by law. Nothing in this Agreement is intended to limit Employees rights under California Labor Code Sections 232 or 1197.5 regarding disclosure of wages. Further, this provision will not apply to disclosures required by law or to disclosures to the Employee's spouse, accountant, or attorney, provided such persons are advised of the confidential nature of the Agreement.

11. Acknowledgement. Employee has read this Agreement, has the authority to sign it, fully understands the contents of this Agreement, freely, voluntarily and without coercion enters into this Agreement, and is signing it with full knowledge that it is intended, to the maximum extent permitted by law, as a complete release and waiver of any and all claims set forth in this Agreement.

12. Entire Understanding. This Agreement embodies the entire understanding of the parties and supersedes all prior or contemporaneous oral or written agreements between the parties with respect to the subject matter hereof, and constitutes a single integrated agreement. There are no promises, terms, conditions, or obligations, oral or written, express or implied, other than those contained herein, with respect to such subject matter. For the avoidance of doubt, the Severance Plan remains in full force and effect and this Agreement is intended to provide benefits in addition to those provided under the Severance Plan.

13. Modification. This Agreement may not be amended or modified except in a writing signed by the Company and Employee, and no provision may be waived except in a writing signed by the party waiving compliance.

14. Severability. In the event any provision of this Agreement is held to be void, null or unenforceable, the remaining portions shall remain in full force and effect.

15. No Admission of Wrongdoing. Neither this Agreement nor the furnishing of the consideration for this Agreement shall be deemed or construed as an admission of liability or wrongdoing on the part of the Released Parties, nor shall they be admissible as evidence in any proceeding other than for the enforcement of this Agreement.

16. No Reliance. Employee has not relied on any representations, promises, or agreements of any kind made to Employee in connection with Employee's decision to accept this Agreement, except for those set forth in this Agreement.

17. Governing Law. This Agreement shall be governed and conformed in accordance with the laws of the State of Delaware, without regard to its conflicts of law principles.

18. No Assignment. No party shall have the right to assign any right or obligation hereunder without obtaining the prior written consent of each the other parties hereto.

19. Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which taken together shall constitute one and the same instrument. This Agreement may be executed in facsimile copy or electronic copy actually received by the recipient's e-mail system with the same binding effect as the original.

PLEASE READ CAREFULLY. THIS AGREEMENT INCLUDES A RELEASE OF CLAIMS.

To accept this offer and state your intention to be bound by the terms of this Agreement, Employee must sign and return this letter to Violet Torneros by January 16, 2020. If Employee does not return this letter, signed, on or before that date, this offer will lapse and may no longer be accepted by Employee.

Executed on January 13, 2020

/s/ Blaine Templeman
Blaine Templeman

Executed on January 13, 2020

/s/ Stephen Isaacs
for ADURO BIOTECH, INC.

Exhibit 10.35

RETENTION BONUS AGREEMENT

This RETENTION BONUS AGREEMENT ("Agreement") is entered into as of January 9, 2020, by and between Aduro Biotech, Inc. (the "Company") and Celeste Ferber (the "Employee").

This Agreement is being entered into with reference to the following recitals:

A. The Company employs Employee, on an at-will basis, in the position of Senior Vice President, General Counsel and Secretary;

B. Employee is eligible for benefits under the terms of the Aduro Biotech, Inc. Amended And Restated Severance And Summary Plan Description ("Severance Plan") as a Tier I Participant. For purposes of this Agreement, the terms "Cause," "Change in Control," "Disability," "Good Reason," "Separation from Service," and "Involuntary Termination" will be defined as set forth in the Severance Plan.

C. The Company has identified Employee's continued employment with the Company as important to the ongoing success of the Company's operations;

D. To ensure the successful completion of certain duties and responsibilities by Employee, the Company desires to retain Employee through September 30, 2020 (the "Retention Date"); and

E. The Company is entering into this Agreement to provide additional consideration to incentivize Employee to remain employed by the Company at least through the Retention Date.

NOW, THEREFORE, in consideration of the promises and the mutual covenants contained herein, the Company and Employee agree as follows:

1. Retention Bonus. Employee is eligible to earn a retention bonus in the gross amount of Two Hundred Twenty-five Thousand and 00/100 Dollars ($225,000.00) ("Retention Bonus") under the terms of this Agreement. If Employee remains employed through the Retention Date, the Retention Bonus will be paid to Employee within 15 days after September 30, 2020.

2. Involuntary Termination. If Employee is subject to an Involuntary Termination or a termination due to the Employee's death or Disability on or prior to the Retention Date, Employee will be entitled to, and the Company will pay, the Retention Bonus within 15 days after Employee's Separation from Service instead of after the Retention Date.

3. Tax Withholding. Employee acknowledges that such Retention Bonus shall constitute wages, and that with respect to any payments or benefits under this Agreement the Company shall deduct all amounts it is required to deduct and withhold under any applicable federal, state or local tax laws (including, for the avoidance of doubt, any applicable income or employment taxes required to be deducted and withheld from such payments).

4. At-Will Employment. If the Company terminates Employee's employment for Cause or if Employee resigns his/her employment without Good Reason prior to the Retention Date, Employee shall not have earned and shall not be entitled to the payment of any unpaid portion of the Retention Bonus.

5. General Release of Claims.

5.1 In exchange for the consideration provided for in this Agreement, the adequacy of which Employee hereby acknowledges, Employee irrevocably and unconditionally releases all claims described below that Employee may have against the following persons or entities (the "Releasees"): Aduro, all of Aduro's related or affiliated organizations, including all of Aduro's and its related or affiliated organizations' predecessors and successors; and, with respect to each such entity, all of its past and present employees, officers, directors, partners, principals, representatives, assigns, attorneys, agents, insurers, employee benefit programs (and the trustees, administrators, fiduciaries and insurers of such programs) and any other persons acting by, through, under, or in concert with any of the persons or entities listed in this Subsection.

5.2 The claims released include all claims, promises, offers, debts, causes of action or similar rights of any type or nature Employee has or had against Releasees, including but not limited to those which in any way relate to Employee's employment with Aduro, except as prohibited by law. This includes (but is not limited to) a release and waiver of any common law contract or tort claims, the Fair Labor Standards Act and any local wage and hour laws, or other claims that may have arisen under any federal or local anti-discrimination statutes or laws, such as Title VII of the Civil Rights Act of 1964; § 1981 of the Civil Rights Act of 1866 and Executive Order 11246; the Fair Labor Standards Act; the Employee Retirement and Income Security Act; the Americans with Disabilities Act, 42 U.S.C. § 1981; the Workers Adjustment and Retraining Notification Act, as amended; the Family and Medical Leave Act; the California Civil Code; the California Constitution; and any and all other laws and regulations relating to employment termination, employment discrimination, whistleblowing, harassment or retaliation, claims for wages, hours, benefits, compensation, equity incentive pay, and any and all claims for attorneys' fees and costs, inasmuch as is permissible by law and by the respective governmental enforcement agencies for the above-listed laws, except, however, Employee does not release any claims under the state anti-discrimination law, the California Fair Employment and Housing Act, California Government Code section 12900, *et seq.*

5.3 5.3 This Agreement does not waive rights or claims (i) under federal or state law that Employee cannot, as a matter of law, waive by private agreement, including without limitation any right of indemnification under Labor Code Section 2802 and any right to accrued benefits; (ii) that may arise after the Employee executes this Agreement; (iii) to indemnification under any agreement between Employee and the Company or under the Company's certificate of incorporation, bylaws or other organizational documents, each as amended; (iv) under the Company's director and officer liability insurance; (v) to vested or unvested compensation or other pay (in, each case, in whatever form) or vested or unvested benefits (in whatever form), including, without limitation, severance benefits or vested or unvested rights or claims based on written agreements or employee or director benefit arrangements; or (vi) by Employee in his or her capacity as a stockholder of the Company. Additionally, nothing in this Agreement precludes Employee from filing a charge or complaint with or participating in any investigation or proceeding before the Equal Employment Opportunity Commission or National Labor Relations Board. However, while Employee may file a charge and participate in any proceeding conducted by the Equal Employment Opportunity Commission or National Labor Relations Board, by signing this Agreement, Employee waives his/her right to bring a lawsuit against the Released Parties (or any of them) and waives his/her right to any individual monetary recovery in any action or lawsuit initiated by the Equal Employment Opportunity Commission or National Labor Relations Board. Furthermore, this Agreement is not a release of claims under the California Fair Employment and Housing Act, California Government Code section 12900, *et seq.*, and nothing in this Agreement precludes Employee from filing a charge or complaint with or participating in any investigation or proceeding before the

California Department of Fair Employment and Housing. Furthermore, nothing in this Agreement prohibits Employee from reporting possible violations of federal law or regulation to any governmental agency or entity, including but not limited to the Department of Justice, the Securities and Exchange Commission, the Congress, and any agency Inspector General, or making other disclosures that are protected under the whistleblower provisions of federal law or regulation. Employee does not need the prior authorization of Aduro to make any such reports or disclosures and Employee is not required to notify Aduro that Employee has made such reports or disclosures. Further, nothing in this Agreement prohibits Employee or any person from testifying about alleged criminal conduct or sexual harassment when the party has been compelled or requested to do so by lawful process.

6. Covenant Not to Sue. Employee has not, and will not, directly or indirectly institute any legal action against the Released Parties based upon, arising out of, or relating to any claims released in this Agreement, to the extent allowed by law. Employee has not, and will not, directly or indirectly encourage and/or solicit any third party to institute any legal action against the Released Parties, to the extent allowed by law.

7. No Workplace Injuries. Employee has not sustained any workplace injury of any kind during Employee's employment with Aduro, and Employee does not intend to file any claim for or seek any workers' compensation benefits.

8. Severance Benefits. Employee shall continue to be eligible for Severance Benefits as set forth in the Severance Plan regardless of whether Employee executes this Agreement. However, if Employee does execute this Agreement, Employee shall, in addition to any severance benefits under the Severance Plan, have the right to exercise any vested Outstanding Stock Awards held by Employee at the time of Separation of Service (including any options that are accelerated upon such termination) until the earlier of (i) 18 months following the Employee's Separation of Service (or longer period set forth in the terms of such option grant), (ii) the applicable expiration date of the option or (iii) the date of a Change in Control in which a stock option is canceled and not otherwise assumed or continued or replaced.

8.1 The Severance Plan, and in particular Section V. of the Severance Plan, shall control with respect to tax treatment, offset, and the application of Section 409A of the Internal Revenue Code to the benefits provided under this Agreement. In addition, Section III(c) of the Severance Plan shall control with respect to the treatment of any payment or benefit that would constitute a payment under Section 280G of the Internal Revenue Code.

9. No Consideration Unless Employee Complies With This Agreement. Employee acknowledges that he/she will not receive the Retention Bonus and other benefits set forth herein, unless Employee executes this Agreement and fulfills the promises contained herein. Aduro has no independent legal duty to provide Employee with the consideration set forth in this Agreement, absent the terms of the Agreement itself.

10. Confidentiality. In recognition of Employee's privacy interests and because this is an arrangement that has been made available to Employee personally, the parties have a mutual interest in keeping this Agreement confidential to the extent permitted by law. Nothing in this Agreement is intended to limit Employees rights under California Labor Code Sections 232 or 1197.5 regarding disclosure of wages. Further, this provision will not apply to disclosures required by law or to disclosures to the Employee's spouse, accountant, or attorney, provided such persons are advised of the confidential nature of the Agreement.

11. Acknowledgement. Employee has read this Agreement, has the authority to sign it, fully understands the contents of this Agreement, freely, voluntarily and without coercion enters into this Agreement, and is signing it with full knowledge that it is intended, to the maximum extent permitted by law, as a complete release and waiver of any and all claims set forth in this Agreement.

12. Entire Understanding. This Agreement embodies the entire understanding of the parties and supersedes all prior or contemporaneous oral or written agreements between the parties with respect to the subject matter hereof, and constitutes a single integrated agreement. There are no promises, terms, conditions, or obligations, oral or written, express or implied, other than those contained herein, with respect to such subject matter. For the avoidance of doubt, the Severance Plan remains in full force and effect and this Agreement is intended to provide benefits in addition to those provided under the Severance Plan.

13. Modification. This Agreement may not be amended or modified except in a writing signed by the Company and Employee, and no provision may be waived except in a writing signed by the party waiving compliance.

14. Severability. In the event any provision of this Agreement is held to be void, null or unenforceable, the remaining portions shall remain in full force and effect.

15. No Admission of Wrongdoing. Neither this Agreement nor the furnishing of the consideration for this Agreement shall be deemed or construed as an admission of liability or wrongdoing on the part of the Released Parties, nor shall they be admissible as evidence in any proceeding other than for the enforcement of this Agreement.

16. No Reliance. Employee has not relied on any representations, promises, or agreements of any kind made to Employee in connection with Employee's decision to accept this Agreement, except for those set forth in this Agreement.

17. Governing Law. This Agreement shall be governed and conformed in accordance with the laws of the State of Delaware, without regard to its conflicts of law principles.

18. No Assignment. No party shall have the right to assign any right or obligation hereunder without obtaining the prior written consent of each the other parties hereto.

19. Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which taken together shall constitute one and the same instrument. This Agreement may be executed in facsimile copy or electronic copy actually received by the recipient's e-mail system with the same binding effect as the original.

PLEASE READ CAREFULLY. THIS AGREEMENT INCLUDES A RELEASE OF CLAIMS.

To accept this offer and state your intention to be bound by the terms of this Agreement, Employee must sign and return this letter to Violet Torneros by January 16, 2020. If Employee does not return this letter, signed, on or before that date, this offer will lapse and may no longer be accepted by Employee.

Executed on January 14, 2020 /s/ Celeste Ferber
Celeste Ferber

Executed on January 14, 2020 /s/ Blaine Templeman
for ADURO BIOTECH, INC.

Exhibit 10.36

RETENTION BONUS AGREEMENT

This RETENTION BONUS AGREEMENT ("Agreement") is entered into as of January 9, 2020, by and between Aduro Biotech, Inc. (the "Company") and Dimitry Nuyten (the "Employee").

This Agreement is being entered into with reference to the following recitals:

A. The Company employs Employee, on an at-will basis, in the position of Chief Medical Officer;

B. Employee is eligible for benefits under the terms of the Aduro Biotech, Inc. Amended And Restated Severance And Summary Plan Description ("Severance Plan") as a Tier I Participant. For purposes of this Agreement, the terms "Cause," "Change in Control," "Disability," "Good Reason," "Separation from Service," and "Involuntary Termination" will be defined as set forth in the Severance Plan.

C. The Company has identified Employee's continued employment with the Company as important to the ongoing success of the Company's operations;

D. To ensure the successful completion of certain duties and responsibilities by Employee, the Company desires to retain Employee through September 30, 2020 (the "Retention Date"); and

E. The Company is entering into this Agreement to provide additional consideration to incentivize Employee to remain employed by the Company at least through the Retention Date.

NOW, THEREFORE, in consideration of the promises and the mutual covenants contained herein, the Company and Employee agree as follows:

1. Retention Bonus. Employee is eligible to earn a retention bonus in the gross amount of Two Hundred Sixty-four Thousand and 00/100 Dollars ($264,000.00) ("Retention Bonus") under the terms of this Agreement. If Employee remains employed through the Retention Date, the Retention Bonus will be paid to Employee within 15 days after September 30, 2020.

2. Involuntary Termination. If Employee is subject to an Involuntary Termination or a termination due to the Employee's death or Disability on or prior to the Retention Date, Employee will be entitled to, and the Company will pay, the Retention Bonus within 15 days after Employee's Separation from Service instead of after the Retention Date.

3. Tax Withholding. Employee acknowledges that such Retention Bonus shall constitute wages, and that with respect to any payments or benefits under this Agreement the Company shall deduct all amounts it is required to deduct and withhold under any applicable federal, state or local tax laws (including, for the avoidance of doubt, any applicable income or employment taxes required to be deducted and withheld from such payments).

4. At-Will Employment. If the Company terminates Employee's employment for Cause or if Employee resigns his/her employment without Good Reason prior to the Retention Date, Employee shall not have earned and shall not be entitled to the payment of any unpaid portion of the Retention Bonus.

5. General Release of Claims.

5.1 In exchange for the consideration provided for in this Agreement, the adequacy of which Employee hereby acknowledges, Employee irrevocably and unconditionally releases all claims described below that Employee may have against the following persons or entities (the "Releasees"): Aduro, all of Aduro's related or affiliated organizations, including all of Aduro's and its related or affiliated organizations' predecessors and successors; and, with respect to each such entity, all of its past and present employees, officers, directors, partners, principals, representatives, assigns, attorneys, agents, insurers, employee benefit programs (and the trustees, administrators, fiduciaries and insurers of such programs) and any other persons acting by, through, under, or in concert with any of the persons or entities listed in this Subsection.

5.2 The claims released include all claims, promises, offers, debts, causes of action or similar rights of any type or nature Employee has or had against Releasees, including but not limited to those which in any way relate to Employee's employment with Aduro, except as prohibited by law. This includes (but is not limited to) a release and waiver of any common law contract or tort claims, the Fair Labor Standards Act and any local wage and hour laws, or other claims that may have arisen under any federal or local anti-discrimination statutes or laws, such as Title VII of the Civil Rights Act of 1964; § 1981 of the Civil Rights Act of 1866 and Executive Order 11246; the Fair Labor Standards Act; the Employee Retirement and Income Security Act; the Americans with Disabilities Act, 42 U.S.C. § 1981; the Workers Adjustment and Retraining Notification Act, as amended; the Family and Medical Leave Act; the California Civil Code; the California Constitution; and any and all other laws and regulations relating to employment termination, employment discrimination, whistleblowing, harassment or retaliation, claims for wages, hours, benefits, compensation, equity incentive pay, and any and all claims for attorneys' fees and costs, inasmuch as is permissible by law and by the respective governmental enforcement agencies for the above-listed laws, except, however, Employee does not release any claims under the state anti-discrimination law, the California Fair Employment and Housing Act, California Government Code section 12900, *et seq.*

5.3 This Agreement does not waive rights or claims (i) under federal or state law that Employee cannot, as a matter of law, waive by private agreement, including without limitation any right of indemnification under Labor Code Section 2802 and any right to accrued benefits; (ii) that may arise after the Employee executes this Agreement; (iii) to indemnification under any agreement between Employee and the Company or under the Company's certificate of incorporation, bylaws or other organizational documents, each as amended; (iv) under the Company's director and officer liability insurance; (v) to vested or unvested compensation or other pay (in, each case, in whatever form) or vested or unvested benefits (in whatever form), including, without limitation, severance benefits or vested or unvested rights or claims based on written agreements or employee or director benefit arrangements; or (vi) by Employee in his or her capacity as a stockholder of the Company. Additionally, nothing in this Agreement precludes Employee from filing a charge or complaint with or participating in any investigation or proceeding before the Equal Employment Opportunity Commission or National Labor Relations Board. However, while Employee may file a charge and participate in any proceeding conducted by the Equal Employment Opportunity Commission or National Labor Relations Board, by signing this Agreement, Employee waives his/her right to bring a lawsuit against the Released Parties (or any of them) and waives his/her right to any individual monetary recovery in any action or lawsuit initiated by the Equal Employment Opportunity Commission or National Labor Relations Board. Furthermore, this Agreement is not a release of claims under the California Fair Employment and Housing Act, California Government Code section 12900, *et seq.*, and nothing in this Agreement precludes Employee from filing a charge or complaint with or participating in any investigation or

proceeding before the California Department of Fair Employment and Housing. Furthermore, nothing in this Agreement prohibits Employee from reporting possible violations of federal law or regulation to any governmental agency or entity, including but not limited to the Department of Justice, the Securities and Exchange Commission, the Congress, and any agency Inspector General, or making other disclosures that are protected under the whistleblower provisions of federal law or regulation. Employee does not need the prior authorization of Aduro to make any such reports or disclosures and Employee is not required to notify Aduro that Employee has made such reports or disclosures. Further, nothing in this Agreement prohibits Employee or any person from testifying about alleged criminal conduct or sexual harassment when the party has been compelled or requested to do so by lawful process.

6. Covenant Not to Sue. Employee has not, and will not, directly or indirectly institute any legal action against the Released Parties based upon, arising out of, or relating to any claims released in this Agreement, to the extent allowed by law. Employee has not, and will not, directly or indirectly encourage and/or solicit any third party to institute any legal action against the Released Parties, to the extent allowed by law.

7. No Workplace Injuries. Employee has not sustained any workplace injury of any kind during Employee's employment with Aduro, and Employee does not intend to file any claim for or seek any workers' compensation benefits.

8. Severance Benefits. Employee shall continue to be eligible for Severance Benefits as set forth in the Severance Plan regardless of whether Employee executes this Agreement. However, if Employee does execute this Agreement, Employee shall, in addition to any severance benefits under the Severance Plan, have the right to exercise any vested Outstanding Stock Awards held by Employee at the time of Separation of Service (including any options that are accelerated upon such termination) until the earlier of (i) 18 months following the Employee's Separation of Service (or longer period set forth in the terms of such option grant), (ii) the applicable expiration date of the option or (iii) the date of a Change in Control in which a stock option is canceled and not otherwise assumed or continued or replaced.

8.1 The Severance Plan, and in particular Section V. of the Severance Plan, shall control with respect to tax treatment, offset, and the application of Section 409A of the Internal Revenue Code to the benefits provided under this Agreement. In addition, Section III(c) of the Severance Plan shall control with respect to the treatment of any payment or benefit that would constitute a payment under Section 280G of the Internal Revenue Code.

9. No Consideration Unless Employee Complies With This Agreement. Employee acknowledges that he/she will not receive the Retention Bonus and other benefits set forth herein, unless Employee executes this Agreement and fulfills the promises contained herein. Aduro has no independent legal duty to provide Employee with the consideration set forth in this Agreement, absent the terms of the Agreement itself.

10. Confidentiality. In recognition of Employee's privacy interests and because this is an arrangement that has been made available to Employee personally, the parties have a mutual interest in keeping this Agreement confidential to the extent permitted by law. Nothing in this Agreement is intended to limit Employees rights under California Labor Code Sections 232 or 1197.5 regarding disclosure of wages. Further, this provision will not apply to disclosures required by law or to disclosures to the Employee's spouse, accountant, or attorney, provided such persons are advised of the confidential nature of the Agreement.

11. Acknowledgement. Employee has read this Agreement, has the authority to sign it, fully understands the contents of this Agreement, freely, voluntarily and without coercion enters into this Agreement, and is signing it with full knowledge that it is intended, to the maximum extent permitted by law, as a complete release and waiver of any and all claims set forth in this Agreement.

12. Entire Understanding. This Agreement embodies the entire understanding of the parties and supersedes all prior or contemporaneous oral or written agreements between the parties with respect to the subject matter hereof, and constitutes a single integrated agreement. There are no promises, terms, conditions, or obligations, oral or written, express or implied, other than those contained herein, with respect to such subject matter. For the avoidance of doubt, the Severance Plan remains in full force and effect and this Agreement is intended to provide benefits in addition to those provided under the Severance Plan.

13. Modification. This Agreement may not be amended or modified except in a writing signed by the Company and Employee, and no provision may be waived except in a writing signed by the party waiving compliance.

14. Severability. In the event any provision of this Agreement is held to be void, null or unenforceable, the remaining portions shall remain in full force and effect.

15. No Admission of Wrongdoing. Neither this Agreement nor the furnishing of the consideration for this Agreement shall be deemed or construed as an admission of liability or wrongdoing on the part of the Released Parties, nor shall they be admissible as evidence in any proceeding other than for the enforcement of this Agreement.

16. No Reliance. Employee has not relied on any representations, promises, or agreements of any kind made to Employee in connection with Employee's decision to accept this Agreement, except for those set forth in this Agreement.

17. Governing Law. This Agreement shall be governed and conformed in accordance with the laws of the State of Delaware, without regard to its conflicts of law principles.

18. No Assignment. No party shall have the right to assign any right or obligation hereunder without obtaining the prior written consent of each the other parties hereto.

19. Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which taken together shall constitute one and the same instrument. This Agreement may be executed in facsimile copy or electronic copy actually received by the recipient's e-mail system with the same binding effect as the original.

PLEASE READ CAREFULLY. THIS AGREEMENT INCLUDES A RELEASE OF CLAIMS.

To accept this offer and state your intention to be bound by the terms of this Agreement, Employee must sign and return this letter to Violet Torneros by January 16, 2020. If Employee does not return this letter, signed, on or before that date, this offer will lapse and may no longer be accepted by Employee.

Executed on 10 January, 2020	/s/ Dimitry Nuyten Dimitry Nuyten
Executed on January 13, 2020	/s/ Blaine Templeman for ADURO BIOTECH, INC.

Exhibit 10.37

SECOND AMENDMENT
TO
EXECUTIVE EMPLOYMENT AGREEMENT

This AMENDMENT TO EMPLOYMENT AGREEMENT (the "Amendment") is made as of this 13th day of January, 2020, by and between Aduro BioTech, a Delaware corporation (the "Company"), and Stephen T. Isaacs ("Executive") (collectively, the "Parties").

WHEREAS, the Parties wish to amend the Executive Employment Agreement between them dated as of February 26, 2010 and amended as of July 31, 2014 (as the same may have been previously amended to date, the "Agreement").

NOW, THEREFORE, the Parties agree to amend the Agreement as set forth below.

1. Amendment to Section 9(d). The first paragraph of Section 9(d) of the Agreement is hereby amended and restated to read in its entirety as follows:

"d. Termination by the Company without Just Cause. Company will have the unilateral right to terminate Executive's employment with Company at any time without Just Cause. In the event Executive is terminated without Just Cause (other than upon Permanent Disability) or resigns for Good Reason (as defined below), the Company's obligation to make payments hereunder shall cease upon the resulting termination of Executive's employment, and the Company shall have no obligation to make any payments to Executive except as provided in this paragraph 9(d). The Company shall pay Executive (1) on the date of termination of Executive's employment with Company (the "Termination Date"), any salary earned but unpaid prior to termination and all accrued but unused vacation and (2) within 90 days following the Termination Date, any business expenses referred to in paragraph 7(b) that were incurred but not reimbursed as of the Termination Date. Executive must submit appropriate documentation as required by paragraph 7(b) for any business expenses that were incurred prior to termination within such 90-day period or Executive will forfeit his right to reimbursement for those expenses. In addition, upon the execution and effectiveness of a separation agreement and general release of all claims in substantially the form (or as may be reasonably modified by the Company in good faith and in its reasonable discretion) attached as Exhibit A hereto (the "Release"), and, upon the written acknowledgment of his continuing obligations under paragraphs 8(b), 8(c) and 12(e) and under the Confidentiality Agreement, Executive shall be entitled to the following severance benefits:

(1) the Company shall pay to Executive eighteen (18) months of Executive's base salary as of the Termination Date (or such higher base salary prior to a reduction that qualifies as Good Reason), less standard deductions and withholdings ("Severance Payment");

(2) the Company shall pay directly to the insurance carrier(s) all applicable COBRA payments for a maximum period of 18 months (which will be less, if Executive ceases to be eligible for COBRA coverage before the end of such 18-month period) for Executive and any dependents to continue his/their health, dental and/or vision insurance; provided that the Company's obligation

to make such payments will cease if and when Executive becomes eligible to receive equivalent benefits from a new employer;

(3) The Company shall pay to Executive, on the sixtieth (60th) day after the Termination Date, a one-time cash lump sum payment that is equal to the product of Executive's unreduced target Bonus for the fiscal year in which the Termination Date occurs (such year, the "Fiscal Year") multiplied by 1.5; and

(4) All of Executive's then unvested Equity Awards shall become vested and exercisable on an accelerated basis as if Executive's Termination Date had occurred twelve (12) months later; provided, however, if Executive's Termination Date is within the period commencing on, and ending eighteen (18) months following, the closing of a Change in Control (as defined below) all of Executive's then unvested Equity Awards (to the extent such awards are outstanding, assumed, substituted or otherwise continued in connection with a Change in Control or granted on or after the Change in Control) that are held by Employee on the Termination Date will become 100% vested and exercisable (if applicable) on the Termination Date, contingent upon the Closing of the Change in Control. In the event that an Equity Award that is outstanding immediately prior to the consummation of a Change in Control is not assumed, substituted or otherwise continued in connection with a Change in Control, the vesting and exercisability of such Equity Award will become 100% vested and exercisable (if applicable) immediately prior to the effective time of the Change in Control, and in such case, to the extent reasonably practicable prior to the effective time of the Change in Control, the Company will provide to Employee notice of the right to exercise (if applicable) the vested stock awards, which exercise may be contingent upon the effectiveness of the Change in Control. Any Equity Awards (other than stock options) that are accelerated under this paragraph shall be settled at the time of such acceleration (or later in accordance with the applicable terms of the Equity Award to the extent required for compliance with Section 409A of the Internal Revenue Code of 1986, as amended ("Section 409A")); and

The Severance Payment shall be made in a lump-sum payment on the second month anniversary of the Executive's Termination Date; provided that the Executive's Release is effective (and not revocable) at such time. If the Release is not effective and non-revocable by the end of such 2 month period, then the Executive will forfeit the right to these benefits. Any COBRA payment due under this Agreement shall be made directly to the insurance carriers) in monthly installments for a maximum period of 18 months commencing on the second month anniversary of the Executive's termination; provided that the Executive's Release is effective (and non-revocable) at such time.

The term "Bonus" shall mean Executive's annual bonus opportunity for the Fiscal Year. Executive acknowledges and agrees that, absent this amendment, he would not otherwise be eligible to receive the full amount of his target bonus if he has not met the requirements for the payment of the bonus, including but not limited to the requirement to be employed by the Company on the date that such bonus is paid.

The term "Change in Control" shall mean one or more of the following: (i) the consummation of the acquisition by any entity, person, or group (other than the Company, an affiliate, or an

employee benefit plan maintained by the Company or any affiliate) of beneficial ownership of the capital stock of the Company representing more than 50% of the outstanding voting stock of the Company; (ii) the consummation of a merger, consolidation or similar transaction involving (directly or indirectly) the Company and, immediately after the consummation of such merger, consolidation or similar transaction, the stockholders of the Company immediately prior thereto do not own, directly or indirectly, either (A) outstanding voting securities representing more than 50% of the combined outstanding voting power of the surviving entity in such merger, consolidation or similar transaction or (B) more than 50% of the combined outstanding voting power of the parent of the surviving entity in such merger, consolidation or similar transaction, in each case in substantially the same proportions as their ownership (direct or indirect) of the outstanding voting securities of the Company immediately prior to such transaction; or (iii) the consummation of a sale, lease, exclusive license or other disposition of all or substantially all of the consolidated assets of the Company and its subsidiaries, other than a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the Company and its subsidiaries to an entity, more than fifty percent (50%) of the combined voting power of the voting securities of which are owned (directly or indirectly) by stockholders of the Company in substantially the same proportions as their ownership (direct or indirect) of the outstanding voting securities of the Company immediately prior to such sale, lease, license or other disposition. For purposes of this Agreement, only the first Change in Control occurring after the Effective Date will be a “Change in Control”. This definition of Change in Control is intended to conform to the definitions of “change in ownership of a corporation” and “change in ownership of a substantial portion of a corporation’s assets” provided in Treasury Regulation Sections 1.409A-3(i)(5)(v) and (vii) to the extent necessary to avoid the imposition of taxes under Section 409A.

The term “Equity Awards” shall mean Executive’s Company equity compensation awards (including without limitation Executive’s Company stock options and restricted stock units and any other equity-based awards that may be granted to Executive from time to time by the Company (or an acquiror of the Company on or after a Change in Control) that are outstanding as of Executive’s Termination Date.

2. Amendment of Definition of Just Cause. Prong (vi) of the definition of “Just Cause” set forth in Section 9 of the Agreement is hereby deleted in its entirety.

3. Deletion of Section 10. Section 10 of the Agreement is hereby deleted in its entirety.

4. Addition of Exhibit A. The Exhibit attached as Exhibit A to this Amendment is hereby added as Exhibit A to the Agreement.

5. Aduro will pay the actual attorneys’ fees and costs incurred by Employee for engaging counsel to negotiate, review, and/or revise this Amendment and/or his Separation Agreement, up to a maximum amount of twenty-five thousand dollars ($25,000.00).

6.Other than as provided in this Amendment, the Agreement remains in full force and effect.

IN WITNESS WHEREOF, the Parties have each duly executed this Agreement as of the day and year first above written.

ADURO BIOTECH INC., A DELAWARE CORPORATION

By: /s/ Blaine Templeman
Name: Blaine Templeman
Its: Chief Administrative Officer, Chief Legal Officer

EXECUTIVE

/s/ Stephen T. Isaacs
Stephen T. Isaacs

EXHIBIT A

SEPARATION AGREEMENT AND GENERAL RELEASE OF ALL CLAIMS

This Separation Agreement and General Release, dated [DATE] (the “Agreement”), is made pursuant to that certain Employment Agreement dated as of February 26, 2010, as amended as of July 31, 2014 and ____, 20__ (as amended to date, the “Employment Agreement”) entered into by and between Stephen T. Isaacs (“Employee”) on the one hand, and Aduro BioTech, Inc. (the “Company”), on the other. This Agreement is entered into in consideration for and as condition precedent to the Company providing separation benefits to Employee pursuant to the Employment Agreement. It is understood and agreed that the Company is not otherwise obligated to provide such benefits under the terms of the Employment Agreement and that the Company is doing so as a direct result of Employee’s willingness to agree to the terms hereof. Collectively, Employee and the Company shall be referred to as the “Parties.”

1. Employee was formerly employed by the Company. Employee’s employment with the Company ended effective [DATE] (the “Termination Date”) as a result of a Qualifying Termination. [A Change in Control of the Company occurred on [DATE].]

2. The purpose of this Agreement is to resolve any and all disputes relating to Employee’s employment with the Company, and the termination thereof (the “Disputes”). The Parties desire to resolve the above-referenced Disputes, and all issues raised by the Disputes, without the further expenditure of time or the expense of contested litigation. Additionally, the Parties desire to resolve any known or unknown claims as more fully set forth below. For these reasons, they have entered into this Agreement.

3. Employee acknowledges and agrees that Employee has received all wages due to Employee through the Termination Date, including but not limited to all accrued but unused vacation, bonuses, commissions, options, benefits, and monies owed by the Company to Employee. Employee further agrees and acknowledges that Employee has been fully paid and reimbursed for any and all business expenses which Employee incurred during his/her employment with the Company.

4. The Company expressly denies any violation of any federal, state or local statute, ordinance, rule, regulation, policy, order or other law. The Company also expressly denies any liability to Employee. This Agreement is the compromise of disputed claims and nothing contained herein is to be construed as an admission of liability on the part of the Company hereby released, by whom liability is expressly denied. Accordingly, while this Agreement resolves all issues referenced herein, it does not constitute an adjudication or finding on the merits of the allegations in the Disputes and it is not, and shall not be construed as, an admission by the Company of any violation of federal, state or local statute, ordinance, rule, regulation, policy, order or other law, or of any liability alleged in the Disputes.

5. In consideration of and in return for the promises and covenants undertaken by the Company and Employee herein and the releases given by Employee herein, Employee shall receive the benefits provided by Section 9(d) of the Employment Agreement. Any tax liabilities resulting

from or arising out of the benefits to Employee referred to in this paragraph, shall be the sole and exclusive responsibility of Employee. Employee agrees to indemnify and hold the Company and the others released herein harmless from and for any tax liability (including, but not limited to, assessments, interest, and penalties) imposed on the Company by any taxing authority on account of the Company failing to withhold for tax purposes any amount from the benefits made as consideration of this Agreement.

6. Except for any rights created by this Agreement, in consideration of and in return for the promises and covenants undertaken herein by the Company, and for other good and valuable consideration, receipt of which is hereby acknowledged:

a. Employee does hereby acknowledge full and complete satisfaction of and does hereby release, absolve and discharge the Company, and each of its parents, subsidiaries, divisions, related companies and business concerns, past and present, as well as each of its partners, trustees, directors, officers, agents, attorneys, servants and employees, past and present, and each of them (hereinafter collectively referred to as “Releasees”) from any and all claims, demands, liens, agreements, contracts, covenants, actions, suits, causes of action, grievances, wages, vacation payments, severance payments, obligations, commissions, overtime payments, debts, profit sharing claims, expenses, damages, judgments, orders and liabilities of whatever kind or nature in law, equity or otherwise, whether known or unknown to Employee which Employee now owns or holds or has at anytime owned or held as against Releasees, or any of them, including specifically but not exclusively and without limiting the generality of the foregoing, any and all claims, demands, grievances, agreements, obligations and muses of action, known or unknown, suspected or unsuspected by Employee: (1) arising out of or in any way connected with the Disputes; or (2) arising out of Employee’s employment with the Company; or (3) arising out of or in any way connected with any claim, loss, damage or injury whatever, known or unknown, suspected or unsuspected, resulting from any act or omission by or on the part of the Releasees, or any of them, committed or omitted on or before the time Employee signs this Agreement. Additionally, Employee in any future claims may not use against Releasees as evidence any acts or omissions by or on the part of the Releasees, or any of them, committed or omitted on or before the time Employee signs this Agreement, and no such future claims may be based on any such acts or omissions. Also without limiting the generality of the foregoing, Employee specifically releases the Releasees from any claim for attorneys’ fees. EMPLOYEE ALSO SPECIFICALLY AGREES AND ACKNOWLEDGES EMPLOYEE IS WAIVING ANY RIGHT TO RECOVERY BASED ON STATE OR FEDERAL AGE, SEX, PREGNANCY, RACE, COLOR, NATIONAL ORIGIN, MARITAL STATUS, RELIGION, VETERAN STATUS, DISABILITY, SEXUAL ORIENTATION, MEDICAL CONDITION OR OTHER ANTI-DISCRIMINATION LAWS, INCLUDING, WITHOUT LIMITATION, TITLE VII OF THE CIVIL RIGHTS ACT OF 1964, THE AGE DISCRIMINATION IN EMPLOYMENT ACT, THE EQUAL PAY ACT, THE AMERICANS WITH DISABILITIES ACT, THE CALIFORNIA FAIR EMPLOYMENT AND HOUSING ACT, THE CALIFORNIA FAMILY RIGHTS ACT, CALIFORNIA LABOR CODE SECTION 970, THE FAMILY AND MEDICAL LEAVE ACT, THE EMPLOYEE RETIREMENT INCOME SECURITY ACT, THE WORKER ADJUSTMENT AND RETRAINING ACT, THE FAIR LABOR STANDARDS ACT, AND ANY OTHER SECTION OF THE CALIFORNIA LABOR OR GOVERNMENT CODE, ALL AS AMENDED, WHETHER SUCH CLAIM BE BASED UPON AN ACTION FILED BY

EMPLOYEE OR BY A GOVERNMENTAL AGENCY. This Release does not release claims (i) that cannot be released as a matter of law, including, but not limited to, my right to file a charge with or participate in a charge by the Equal Employment Opportunity Commission, or any other local, state, or federal administrative body or government agency that is authorized to enforce or administer laws related to employment, against the Company (with the understanding that any such filing or participation does not give me the right to recover any monetary damages against the Company; my release of claims herein bars me from recovering such monetary relief from the Company), (ii) that may arise after the Employee executes this Agreement; (ii) to indemnification under any agreement between Employee and the Company or under the Company's certificate of incorporation, bylaws or other organizational documents, each as amended; (iii) under the Company's director and officer liability insurance; (iv) for vested benefits under the Company's employee benefit plans; or (v) by Employee in his capacity as a stockholder of the Company.

7. Employee agrees and understands as follows: It is the intention of Employee in executing this instrument that it shall be effective as a bar to each and every claim, demand, grievance and cause of action hereinabove specified. In furtherance of this intention, Employee hereby expressly waives any and all rights and benefits conferred upon Employee by the provisions of Section 1542 of the California Civil Code and expressly consents that this Agreement shall be given full force and effect according to each and all of its express terms and provisions, including those relating to unknown and unsuspected claims, demands and causes of action, if any, as well as those relating to any other claims, demands and causes of action hereinabove specified, Section 1542 provides:

"A general release does not extend to claims that the creditor or releasing party does not know or suspect to exist in his or her favor at the time of executing the release and that, if known by him or her, would have materially affected his or her settlement with the debtor or released party.."

Having been so apprised, Employee nevertheless hereby voluntarily elects to and does waive the rights described in Civil Code section 1542 and elects to assume all risks for claims that now exist in Employee's favor, known or unknown, that are released under this Agreement.

8. Employee agrees: (1) the fact of and the terms and conditions of this Agreement; and (2) any and all actions by Releasees taken in accordance herewith, are confidential, and shall not be disclosed, discussed, publicized or revealed by the parties or their attorneys to any other person or entity, including but not limited to radio, television, press media, newspapers, magazines, professional journals and professional reports, excepting only the Parties' accountants, lawyers, immediate family members (mother, father, brother, sister, child, spouse), the persons necessary to carry out the terms of this Agreement or as required by law. Should Employee be asked about the Disputes or this Agreement, Employee shall limit Employee's response, if any, by stating that the matters have been amicably resolved.

9. In the event a government agency files or pursues a charge or complaint relating to Employee's employment with the Company and/or the Disputes, Employee agrees not to accept any monetary or other benefits arising out of the charge or Complaint.

10. Employee agrees not to make any derogatory, disparaging or negative comments about the Company, its products, officers, directors, or employees. Nothing in this section shall be construed to prevent Employee from providing information to any governmental agency to the extent required by law, or giving truthful testimony in response to direct questions asked pursuant to a lawful subpoena or other legal process. Further, nothing in this section is intended to prevent any party from disclosing factual information regarding any claim for sexual harassment, sex discrimination, or retaliation for reporting sexual harassment or sex discrimination.

11. If any provision of this Agreement or application thereof is held invalid, the invalidity shall not affect other provisions or applications of the Agreement which can be given effect without the invalid provision or application. To this end, the provisions of this Agreement are severable.

12. Employee agrees and understands that this Agreement may be treated as a complete defense to any legal, equitable, or administrative action that may be brought, instituted, or taken by Employee, or on Employee's behalf, against the Company or the Releasees, and shall forever be a complete bar to the commencement or prosecution of any claim, demand, lawsuit, charge, or other legal proceeding of any kind against the Company and the Releasees,

13. This Agreement and all covenants and releases set forth herein shall be binding upon and shall inure to the benefit of the respective Parties hereto, their legal successors, heirs, assigns, partners, representatives, parent companies, subsidiary companies, agents, attorneys, officers, employees, directors and shareholders.

14. The Parties hereto acknowledge each has read this Agreement, that each fully understands its rights, privileges and duties under the Agreement, that each has had an opportunity to consult and has consulted with an attorney of its choice and that each enters this Agreement freely and voluntarily.

15. This Agreement may not be released, discharged, abandoned, changed or modified in any manner, except by an instrument in writing signed by Employee and an officer of the Company. The failure of any Party to enforce at any time any of the provisions of this Agreement shall in no way be construed as a waiver of any such provision, nor in any way to affect the validity of this Agreement or any part thereof or the right of any Party thereafter to enforce each and every such provision. No waiver of any breach of this Agreement shall be held to be a waiver of any other or subsequent breach.

16. This Agreement and the provisions contained herein shall not be construed or interpreted for or against any party hereto because that party drafted or caused that party's legal representative to draft any of its provisions.

17. In the event of litigation arising out of or relating to this Agreement, the prevailing party shall be entitled to recover reasonable attorneys' fees and costs.

18. Employee acknowledges Employee may hereafter discover facts different from, or in addition to, those Employee now knows or believes to be true with respect to the claims, demands, liens, agreements, contracts, covenants, actions, suits, causes of action, wages, obligations, debts, expenses, damages, judgments, orders and liabilities herein released, and agrees the release herein shall be and remain in effect in all respects as a complete and general release as to all matters released herein, notwithstanding any such different or additional facts.

19. The undersigned each acknowledge and represent that no promise or representation not contained in this Agreement has been made to them and acknowledge and represent that this Agreement and the Employment Agreement contains the entire understanding between the Parties and contains all terms and conditions pertaining to the compromise and settlement of the subjects referenced herein. The undersigned further acknowledge that the terms of this Agreement are contractual and not a mere recital.

20. Employee expressly acknowledges, understands and agrees that this Agreement includes a waiver and release of all claims which Employee has or may have under the Age Discrimination in Employment Act of 1967, as amended, 29 U.S.C. §621, et seq. ("ADEA"). The terms and conditions of Paragraphs 20 through 22 apply to and are part of the waiver and release of ADEA claims under this Agreement. Company hereby advises Employee in writing to discuss this Agreement with an attorney before signing it. Employee acknowledges the Company has provided Employee at least forty-five days within which to review and consider this Agreement before signing it. If Employee elects not to use all forty-five days, then Employee knowingly and voluntarily waives any claim that Employee was not in fact given that period of time or did not use the entire forty-five days to consult an attorney and/or consider this Agreement.

21. Within three calendar days of signing and dating this Agreement, Employee shall deliver the signed original of this Agreement to [ ] of the Company. However, the Parties acknowledge and agree that Employee may revoke this Agreement for up to seven calendar days following Employee's execution of this Agreement and that it shall not become effective or enforceable until the revocation period has expired without revocation. The Parties further acknowledge and agree that such revocation must be in writing addressed to and received by [ ] of the Company not later than midnight on the seventh day following execution of this Agreement by Employee. If Employee revokes this Agreement under this Paragraph, this Agreement shall not be effective or enforceable and Employee will not receive the benefits described above, including those described in Paragraph 5.

22. If Employee does not revoke this Agreement in the timeframe specified in Paragraph 21 above, the Agreement shall be effective at 12:00:01 a.m. on the eighth day after it is signed by Employee (the "Effective Date").

23. This Agreement is intended to be exempt from or comply with the requirements of section 409A of the Internal Revenue Code of 1986 as amended ("Section 409A") and will be interpreted accordingly. While it is intended that all payments and benefits provided under this Agreement to Employee or on behalf of Employee will be exempt from or comply with Section 409A, the Company makes no representation or covenant to ensure that such payments and benefits are exempt from or compliant with Section 409A. The Company will have no liability to

Employee or any other party if a payment or benefit under this Agreement is challenged by any taxing authority or is ultimately determined not to be exempt from or compliant with Section 409A.

24. This Agreement may be executed in any number of counterparts, each of which so executed shall be deemed to be an original and such counterparts shall together constitute one and the same Agreement.

25. This Agreement shall be construed in accordance with, and be deemed governed by the Employee Retirement Income Security Act of 1974, as amended, and, to the extent applicable, the laws of the State of Delaware, without reference to the conflict of law provisions thereof.

I have read the foregoing Separation Agreement and General Release of All Claims, consisting of [ ] pages, and I accept and agree to the provisions contained therein and hereby execute it voluntarily and with full understanding of its consequences.

PLEASE READ CAREFULLY. THIS AGREEMENT CONTAINS A GENERAL RELEASE OF ALL KNOWN AND UNKNOWN CLAIMS.

Dated: _____

_____
Stephen T. Isaacs

Aduro BioTech, Inc.

Dated: _____

_____
Name:
Title:

Exhibit 10.38

RETENTION BONUS AGREEMENT

This RETENTION BONUS AGREEMENT ("Agreement") is entered into as of January 10, 2020, by and between Aduro Biotech, Inc. (the "Company") and Stephen T. Isaacs (the "Employee").

This Agreement is being entered into with reference to the following recitals:

A. The Company employs Employee, on an at-will basis, in the position of Chief Executive Officer and President;

B. Employee is eligible for severance benefits under his employment agreement with the Company, as amended (the "Employment Agreement"). For purposes of this Agreement, the terms "Just Cause," "Change in Control," "Permanent Disability," and "Good Reason" will be defined as set forth in the Employment Agreement.

C. The Company has identified Employee's continued employment with the Company as important to the ongoing success of the Company's operations;

D. To ensure the successful completion of certain duties and responsibilities by Employee, the Company desires to retain Employee through September 30, 2020 (the "Retention Date"); and

E. The Company is entering into this Agreement to provide additional consideration to incentivize Employee to remain employed by the Company at least through the Retention Date.

NOW, THEREFORE, in consideration of the promises and the mutual covenants contained herein, the Company and Employee agree as follows:

1. Retention Bonus. Employee is eligible to earn a retention bonus in the gross amount of $562,500 ("Retention Bonus") under the terms of this Agreement. If Employee remains employed through the Retention Date, the Retention Bonus will be paid to Employee within 15 days after September 30, 2020.

2. Involuntary Termination. If Employee is subject to (i) a termination by the Company without Just Cause or Employee resigns for Good Reason or (ii) a termination due to the Employee's death or Permanent Disability, in each case, on or prior to the Retention Date, Employee will be entitled to, and the Company will pay, the Retention Bonus within 15 days after Employee's termination of employment.

3. Tax Withholding. Employee acknowledges that such Retention Bonus shall constitute wages, and that with respect to any payments or benefits under this Agreement the Company shall deduct all amounts it is required to deduct and withhold under any applicable federal, state or local tax laws (including, for the avoidance of doubt, any applicable income or employment taxes required to be deducted and withheld from such payments).

4. At-Will Employment. If the Company terminates Employee's employment for Just Cause or if Employee resigns his/her employment without Good Reason prior to the Retention Date, Employee shall not have earned and shall not be entitled to the payment of any unpaid portion of the Retention Bonus.

5. General Release of Claims.

5.1 In exchange for the consideration provided for in this Agreement, the adequacy of which Employee hereby acknowledges, Employee irrevocably and unconditionally releases all claims described below that Employee may have against the following persons or entities (the "Releasees"): Aduro, all of Aduro's related or affiliated organizations, including all of Aduro's and its related or affiliated organizations' predecessors and successors; and, with respect to each such entity, all of its past and present employees, officers, directors, partners, principals, representatives, assigns, attorneys, agents, insurers, employee benefit programs (and the trustees, administrators, fiduciaries and insurers of such programs) and any other persons acting by, through, under, or in concert with any of the persons or entities listed in this Subsection.

5.2 The claims released include all claims, promises, offers, debts, causes of action or similar rights of any type or nature Employee has or had against Releasees, including but not limited to those which in any way relate to Employee's employment with Aduro, except as prohibited by law. This includes (but is not limited to) a release and waiver of any common law contract or tort claims, the Fair Labor Standards Act and any state or local wage and hour laws, or other claims that may have arisen under any federal or local anti-discrimination statutes or laws, such as Title VII of the Civil Rights Act of 1964; § 1981 of the Civil Rights Act of 1866 and Executive Order 11246; the Fair Labor Standards Act; the Employee Retirement and Income Security Act; the Americans with Disabilities Act, 42 U.S.C. § 1981; the Workers Adjustment and Retraining Notification Act, as amended; the Family and Medical Leave Act; the California Labor Code; the California Civil Code; the California Constitution; and any and all other laws and regulations relating to employment termination, employment discrimination, whistleblowing, harassment or retaliation, claims for wages, hours, benefits, compensation, equity incentive pay, and any and all claims for attorneys' fees and costs, inasmuch as is permissible by law and by the respective governmental enforcement agencies for the above-listed laws, except, however, Employee does not release any claims under the state anti-discrimination law, the California Fair Employment and Housing Act, California Government Code section 12900, *et seq.*

5.3 Notwithstanding the foregoing, this Agreement does not waive rights or claims (i) under federal or state law that Employee cannot, as a matter of law, waive by private agreement, including without limitation any right of indemnification under Labor Code Section 2802, (ii) that may arise after the Employee executes this Agreement; (iii) to indemnification under any agreement between Employee and the Company or under the Company's certificate of incorporation, bylaws or other organizational documents, each as amended; (iv) under the Company's director and officer liability insurance; (v) to vested or unvested compensation or other pay (in, each case, in whatever form) or vested or unvested benefits (in whatever form), including, without limitation, severance benefits or vested or unvested rights or claims under employment agreements or employee or director benefit arrangements; or (vi) by Employee in his capacity as a stockholder of the Company. Additionally, nothing in this Agreement precludes Employee from filing a charge or complaint with or participating in any investigation or proceeding before the Equal Employment Opportunity Commission or National Labor Relations Board. However, while Employee may file a charge and participate in any proceeding conducted by the Equal Employment Opportunity Commission or National Labor Relations Board, by signing this Agreement, Employee waives his/her right to bring a lawsuit against the Released Parties (or any of them) and waives his/her right to any individual monetary recovery in any action or lawsuit initiated by the Equal Employment Opportunity Commission or National Labor Relations Board. Furthermore, this Agreement is not a release of claims under the California Fair Employment and Housing Act, California Government Code section 12900, *et seq.*, and nothing in this Agreement precludes Employee from filing a charge or complaint with or participating in any investigation or

proceeding before the California Department of Fair Employment and Housing. Furthermore, nothing in this Agreement prohibits Employee from reporting possible violations of federal law or regulation to any governmental agency or entity, including but not limited to the Department of Justice, the Securities and Exchange Commission, the Congress, and any agency Inspector General, or making other disclosures that are protected under the whistleblower provisions of federal law or regulation. Employee does not need the prior authorization of Aduro to make any such reports or disclosures and Employee is not required to notify Aduro that Employee has made such reports or disclosures. Further, nothing in this Agreement prohibits Employee or any person from testifying about alleged criminal conduct or sexual harassment when the party has been compelled or requested to do so by lawful process.

6. Covenant Not to Sue. Employee has not, and will not, directly or indirectly institute any legal action against the Released Parties based upon, arising out of, or relating to any claims released in this Agreement, to the extent allowed by law. Employee has not, and will not, directly or indirectly encourage and/or solicit any third party to institute any legal action against the Released Parties, to the extent allowed by law.

7. No Workplace Injuries. Employee has not sustained any workplace injury of any kind during Employee's employment with Aduro, and Employee does not intend to file any claim for or seek any workers' compensation benefits.

8. Severance Benefits. Employee shall continue to be eligible for severance benefits as set forth in the Employment Agreement regardless of whether Employee executes this Agreement. However, if Employee does execute this Agreement, Employee shall, in addition to any severance benefits under the Employment Agreement, have the right to exercise any vested stock options held by Employee at the time of his termination of employment (including any options that are accelerated upon such termination) until the earlier of (i) 18 months following the Employee's termination of employment (or longer period set forth in the terms of such option grant), (ii) the applicable expiration date of the option or (iii) the date of a Change in Control in which a stock option is canceled and not otherwise assumed or continued or replaced.

9. No Consideration Unless Employee Complies With This Agreement. Employee acknowledges that he/she will not receive the Retention Bonus and other benefits set forth herein, unless Employee executes this Agreement and fulfills the promises contained herein. Aduro has no independent legal duty to provide Employee with the consideration set forth in this Agreement, absent the terms of the Agreement itself.

10. Confidentiality. In recognition of Employee's privacy interests and because this is an arrangement that has been made available to Employee personally, the parties have a mutual interest in keeping this Agreement confidential to the extent permitted by law. Nothing in this Agreement is intended to limit Employees rights under California Labor Code Sections 232 or 1197.5 regarding disclosure of wages. Further, this provision will not apply to disclosures required by law or to disclosures to the Employee's spouse, accountant, or attorney, provided such persons are advised of the confidential nature of the Agreement.

11. Acknowledgement. Employee has read this Agreement, has the authority to sign it, fully understands the contents of this Agreement, freely, voluntarily and without coercion enters into this Agreement.

12. Entire Understanding. This Agreement embodies the entire understanding of the parties and supersedes all prior or contemporaneous oral or written agreements between the parties with respect

to the subject matter hereof, and constitutes a single integrated agreement. There are no promises, terms, conditions, or obligations, oral or written, express or implied, other than those contained herein, with respect to such subject matter. For the avoidance of doubt, the Employment Agreement remains in full force and effect and this Agreement is intended to provide benefits in addition to those provided under the Employment Agreement.

13. Modification. This Agreement may not be amended or modified except in a writing signed by the Company and Employee, and no provision may be waived except in a writing signed by the party waiving compliance.

14. Severability. In the event any provision of this Agreement is held to be void, null or unenforceable, the remaining portions shall remain in full force and effect.

15. No Admission of Wrongdoing. Neither this Agreement nor the furnishing of the consideration for this Agreement shall be deemed or construed as an admission of liability or wrongdoing on the part of any person, nor shall they be admissible as evidence in any proceeding other than for the enforcement of this Agreement.

16. No Reliance. Employee has not relied on any representations, promises, or agreements of any kind made to Employee in connection with Employee's decision to accept this Agreement, except for those set forth in this Agreement.

17. Governing Law. This Agreement shall be governed and conformed in accordance with the laws of the State of Delaware, without regard to its conflicts of law principles.

18. No Assignment. No party shall have the right to assign any right or obligation hereunder without obtaining the prior written consent of each the other parties hereto.

19. Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which taken together shall constitute one and the same instrument. This Agreement may be executed in facsimile copy or electronic copy actually received by the recipient's e-mail system with the same binding effect as the original.

To accept this offer and state your intention to be bound by the terms of this Agreement, Employee must sign and return this letter to Violet Torneros by January 16, 2020. If Employee does not return this letter, signed, on or before that date, this offer will lapse and may no longer be accepted by Employee.

Executed on January 13, 2020	/s/ Stephen T. Isaacs Stephen T. Isaacs
Executed on January13, 2020	/s/ Blaine Templeman Blaine Templeman, Chief Administrative Officer, Chief Chief Legal Officer for ADURO BIOTECH, INC.

Exhibit 21.1

Subsidiaries of Registrant

Name of Subsidiary	Jurisdiction of Incorporation
• Aduro GVAX, Inc.	Delaware
• Aduro International (Bermuda) Ltd.	Bermuda
• Aduro Netherlands Cooperatief UA	Netherlands
• Aduro Biotech Holdings Europe B.V.	Netherlands
• Aduro Biotech, Europe B.V.	Netherlands

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-203508, 333-210016, 333-216373, 333-223382 and 333-229915 on Form S-8 and Registration Statement Nos. 333-219639 and 333-219640 on Form S-3 of our report dated March 9, 2020, relating to the consolidated financial statements of Aduro Biotech, Inc. and subsidiaries (the "Company") appearing in this Annual Report on Form 10-K of the Company for the year ended December 31, 2019.

/s/ Deloitte & Touche LLP
San Francisco, California
March 9, 2020

Exhibit 31.1

Certification of the Principal Executive Officer
Pursuant to
Securities Exchange Act Rules 13A-14(A) and 15D-14(A)

I, Stephen T. Isaacs, certify that:

1. I have reviewed this annual report on Form 10-K of Aduro Biotech, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13(a)-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 9, 2020

/s/ Stephen T. Isaacs
Stephen T. Isaacs
Chairman, President and Principal Executive Officer

Exhibit 31.2

Certification of Principal Financial Officer
Pursuant to
Securities Exchange Act Rules 13A-14(A) and 15D-14(A)

I, William G. Kachioff, certify that:

1. I have reviewed this annual report on Form 10-K of Aduro Biotech, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13(a)-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 9, 2020

/s/ William G. Kachioff
William G. Kachioff
Interim Chief Financial Officer

Exhibit 32.1

Certification Pursuant to
18 U.S.C. Section 1350,
As Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report of Aduro Biotech, Inc. (the "Company") on Form 10-K for the year ended December 31, 2019 (the "Report"), Stephen T. Isaacs, Chairman, President and Principal Executive Officer of the Company, and William G. Kachioff, Interim Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 9, 2020

/s/ Stephen T. Isaacs
Stephen T. Isaacs
Chairman, President and Principal Executive Officer

/s/ William G. Kachioff
William G. Kachioff
Interim Chief Financial Officer

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