ADURO BIOTECH, INC.
Form 424B4
April 15, 2015
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Filed pursuant to 424(b)(4)
Registration No. 333-202667

PROSPECTUS

7,000,000 Shares

Common Stock

This is an initial public offering of shares of common stock of Aduro Biotech, Inc. We are selling 7,000,000 shares of our common stock in this offering.

The public offering price of our common stock is $17.00 per share. Our common stock has been approved for listing on the NASDAQ Global Select Market under the symbol ADRO.

We are an emerging growth company under applicable Securities and Exchange Commission rules and will be subject to reduced public company reporting requirements.

Investing in our common stock involves risks that are described in the Risk Factors section beginning on page 12 of this prospectus.

	Per Share	Total
Public offering price	$ 17.00	$ 119,000,000
Underwriting discount[(1)]	$1.19	$8,330,000
Proceeds to us, before expenses	$ 15.81	$ 110,670,000

(1) We refer you to Underwriting beginning on page 164 for additional information regarding total underwriting compensation.

The underwriters may also exercise their option to purchase up to an additional 1,050,000 shares from us, at the public offering price, less the underwriting discount for 30 days after the date of this prospectus.

Johnson & Johnson Innovation-JJDC, Inc., an existing stockholder, has agreed to purchase approximately $10.0 million of shares of our common stock in this offering at the initial public offering price. Certain other of our existing stockholders, including stockholders affiliated with our directors, have agreed to purchase an additional approximately $12.5 million of shares of our common stock in this offering at the initial public offering price.

In addition, Novartis Institutes for BioMedical Research, Inc., an existing stockholder and an affiliate of Novartis Pharmaceuticals Corporation, a collaboration partner, has entered into a stock purchase agreement with us to purchase approximately $25.0 million of shares of our common stock at a price per share equal to the initial public offering price in a separate private placement transaction that is expected to close concurrently with this offering. The sale of such shares will not be registered under the Securities Act of 1933, as amended. The closing of this offering is not conditioned upon the closing of such concurrent private placement.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The shares will be ready for delivery on or about April 20, 2015.

BofA Merrill Lynch **Leerink Partners**

William Blair **Canaccord Genuity**

The date of this prospectus April 14, 2015.

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Neither we nor the underwriters have authorized anyone to provide you with any information or to make any representation, other than those contained in this prospectus or any free writing prospectus we have prepared. We take no responsibility for, and provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares offered hereby, but only in circumstances and in jurisdictions where it is lawful to so do. The information contained in this prospectus is accurate only as of its date, regardless of the time of delivery of this prospectus or of any sale of our common stock.

Neither we nor any of the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. You are required to inform yourself about, and to observe any restrictions relating to, this offering and the distribution of this prospectus.

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PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our common stock, you should read the entire prospectus carefully, including the sections titled Risk Factors and Management s Discussion and Analysis of Financial Condition and Results of Operations and our financial statements and related notes included elsewhere in this prospectus. Unless the context suggests otherwise, references in this prospectus to Aduro, Aduro Biotech, we, us and our refer to Aduro Biotech, Inc.

ADURO BIOTECH, INC.

Overview

We are a clinical-stage immuno-oncology company focused on the development of first-in-class technology platforms designed to stimulate robust and durable immune responses against cancer, and our lead product candidate is in a randomized controlled Phase 2b clinical trial in metastatic pancreatic cancer. Immuno-oncology encompasses a class of therapies that leverage the patient s immune system to slow the growth and spread of, or eliminate, tumor cells. We believe a critical distinguishing factor in our approach to immuno-oncology is that our novel therapies initiate powerful innate immune responses and drive targeted, durable adaptive immune responses. The immunotherapy field is rapidly advancing with new immuno-oncology combinations that focus on strengthening therapeutic efficacy in a wide range of cancers. We intend to pursue a broad strategy of combining our technology platforms with conventional and novel immuno-oncology therapies, based on their mechanisms of action, safety profiles and versatility. Our pipeline of immuno-oncology product candidates is derived from two proprietary technology platforms: Live, Attenuated, Double-Deleted, or LADD, *Listeria monocytogenes* and cyclic dinucleotides, or CDNs. Our lead LADD product candidate, CRS-207, is currently being developed in metastatic pancreatic cancer and unresectable malignant pleural mesothelioma. In a completed randomized controlled Phase 2a clinical trial in metastatic pancreatic cancer patients, CRS-207 demonstrated a statistically significant improvement in overall survival when combined with GVAX Pancreas, a cellular vaccine product candidate. The 93-patient two-arm Phase 2a clinical trial was designed to compare the combination of CRS-207 and GVAX Pancreas versus GVAX Pancreas alone. The trial met the primary efficacy endpoint of overall survival at an interim analysis and was stopped upon recommendation from the Data Monitoring Committee. Based on the data from this study, our lead immuno-oncology regimen of CRS-207 and GVAX Pancreas was granted Breakthrough Therapy designation by the U.S. Food and Drug Administration, or FDA. Breakthrough Therapy designation is intended to expedite the development and review of products that treat serious or life-threatening conditions. We have obtained orphan drug designations from the FDA for CRS-207 and GVAX Pancreas for the treatment of pancreatic cancer and for CRS-207 for the treatment of mesothelioma. Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biologic intended to treat a rare disease or condition. Orphan drug designation entitles a party to certain financial incentives and can provide limited market exclusivity in certain circumstances. We are developing a pipeline of proprietary product candidates, including two product candidates in collaboration with Janssen Biotech, Inc., or Janssen, targeting prostate and lung cancers. In addition, we established a worldwide collaboration with Novartis Pharmaceuticals Corporation, or Novartis, for CDN product candidates in oncology. We have intellectual property protection on both of our technology platforms and each of our product candidates, which we believe we will maintain into the 2030s.

Immuno-oncology is an emerging field of cancer therapy that aims to activate the immune system in the tumor microenvironment to create and enhance anti-tumor immune responses, as well as to overcome the immuno-suppressive mechanisms that cancer cells have developed against the immune system. Recent developments in the field of immuno-oncology, including checkpoint inhibitors therapies that have mechanisms focused on unmasking hidden cancer cells have shown the potential to provide dramatic efficacy responses and extended survival,

even in cancers where conventional therapies, such as surgery, chemotherapy and radiotherapy, have failed.

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Product candidates from our two immuno-oncology technology platforms are engineered to prime and enhance a patient s innate and tumor-specific adaptive immune responses to deliver enhanced efficacy over current therapies. Since our product candidates act by stimulating the patient s own immune system, we believe they have the potential to be safer and more tolerable than existing therapies, such as chemotherapy and radiotherapy. Based on the mechanism of action and safety profile of our technology platforms, we intend to build a deep pipeline of LADD- and CDN-based product candidates that can be readily combinable and synergistic with both conventional and novel therapies, such as checkpoint inhibitors.

Our vision is to leverage our scientific expertise and understanding of the body s natural defense systems, including the interplay between the innate and adaptive immune responses, to develop safe and effective therapies for the benefit of patients.

Our Proprietary Technology Platforms and Pipeline

Live, Attenuated, Double-Deleted Listeria Monocytogenes

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

Early Evidence of Efficacy. Our randomized controlled Phase 2a clinical trial in patients with metastatic pancreatic cancer who had received or refused prior therapy demonstrated improved overall survival.

Novel Mechanism. Our LADD product candidates are designed to initiate a powerful innate immune response and drive a targeted, durable adaptive immune response.

Early Evidence of Safety in Preclinical Studies and Clinical Trials. Through our proprietary deletion of two genes that contribute to *Listeria* s virulence, we substantially reduce the natural disease-causing properties of *Listeria*, creating stable product candidates suitable for therapeutic use.

Versatility. Individual LADD product candidates can be engineered to target a wide range of cancers by promoting anti-tumor immune responses against antigens associated with specific tumors.

Combinability. The mechanisms of action and safety profile of our LADD product candidates may give them the potential for combination with conventional and novel therapies, such as cellular vaccines, chemotherapy, radiotherapy and checkpoint inhibitors, among others.

Repeatable Administration. Our LADD product candidates are not neutralized by the patient s immune system and are designed for repeat administration, thus allowing a chronic therapy for a sustained tumor antigen-specific response.

Cost-effectiveness. Our LADD product candidates are not personalized for each patient and can be manufactured through a relatively simple and cost-effective fermentation process.

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Cyclic Dinucleotides

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

Early Evidence of Potency. Our CDN product candidates have demonstrated significant anti-tumor activity in pre-clinical studies.

Novel Mechanism. Our CDN 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 CDN product candidates can be effectively delivered via intratumoral injection, systemic delivery via formulation and other novel modalities, such as conjugation with antibodies.

Combinability. Based on their mechanism of action, we believe our CDN product candidates may have synergistic or additive benefits of immune-mediated tumor killing mechanisms when combined with conventional and novel therapies, such as cellular vaccines, chemotherapy, radiotherapy and checkpoint inhibitors, among others.

Ease of Manufacture. Our CDN product candidates are small molecules manufactured through a relatively simple and cost-effective process.

Broad Applicability. We believe our CDN product candidates will have broad application in oncology and the potential to expand into other therapeutic areas such as infectious and autoimmune diseases.

Pipeline

Our most advanced immuno-oncology regimen, currently in a randomized controlled Phase 2b clinical trial known as ECLIPSE, assesses the combination of our lead LADD product candidate, CRS-207, with GVAX Pancreas to treat late-stage metastatic pancreatic cancer patients who have received at least one prior line of therapy. GVAX Pancreas

is an important synergistic combination candidate because it is designed to induce T cells against an array of pancreatic cancer antigens and enable a broad-based immune response and has demonstrated a favorable safety profile in clinical trials to date. We expect to report top line results from ECLIPSE in the first half of 2016. In addition, we are evaluating CRS-207 in combination with chemotherapy in unresectable malignant pleural mesothelioma and have a planned study of CRS-207 in combination with GVAX Pancreas and an anti-PD-1 checkpoint inhibitor in metastatic pancreatic cancer. We also have ongoing and planned clinical development programs evaluating LADD regimens for glioblastoma multiforme and ovarian cancer, and collaborations with Janssen for lung and prostate cancers.

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

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

Our Strategy

Our current focus is to develop and commercialize best-in-class cancer therapies using our LADD and CDN technology platforms. Key elements of our strategy include:

Rapidly advance CRS-207 through clinical development and regulatory approval. We are currently conducting our Phase 2b ECLIPSE clinical trial of CRS-207 in combination with GVAX Pancreas in patients with metastatic pancreatic cancer who have received at least one prior line of therapy. We expect to complete enrollment in the third quarter of 2015 and to report top line results in the first half of 2016.

Maximize the commercial value of our proprietary LADD and CDN technology platforms. We currently have global development, marketing and commercialization rights for our lead product candidate, CRS-207, as well as additional LADD product candidates. If we obtain regulatory approvals for CRS-207 in pancreatic cancer or other indications, we plan to build a commercial organization with a specialty sales force to market CRS-207. We also plan to retain commercial rights to additional LADD product candidates. In addition, we established a worldwide collaboration with Novartis for CDN product candidates in oncology. We also maintain worldwide rights to our CDN technology platform outside of oncology.

Develop novel drug candidates by leveraging our proprietary technology platforms and our understanding of combination therapy in immuno-oncology. We have proprietary technology platforms that we believe can generate novel and combinable therapies to target a wide range of cancers with significant unmet medical need. We plan to invest in these technology platforms to develop additional product candidates. We intend to further explore combination opportunities with conventional and novel treatments, including cellular vaccines, chemotherapy, radiotherapy and checkpoint inhibitors, among others.

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Expand on the value of our product candidates through collaborations. We may decide to selectively partner large and complex oncology indications, in certain geographies and where we believe a partner could bring additional resources and expertise to maximize the value of our product candidates. We entered into two strategic collaborations with Janssen for the treatment of prostate, lung and certain other cancers. We also established a worldwide development and commercialization collaboration with Novartis for CDN product candidates in oncology. We believe these collaborations have the potential to drive significant value through the extensive capabilities of these organizations.

Leverage the expertise of our scientific founders and key advisors to develop innovative technologies at the forefront of the immuno-oncology field. Our scientific founders and advisors are from some of the world s leading research institutions and have a history of seminal discoveries and significant experience in oncology, immuno-oncology and vaccines. As such, we plan to continue to leverage the collective talent of our scientists, clinicians and a network of highly influential advisors to inform our development strategy and enable our technology to be at the forefront of the immuno-oncology field. We strive to protect our commercially important discoveries and product candidates by applying for, maintaining and defending our patent rights. At March 31, 2015, our owned U.S. patent portfolio consisted of 21 issued patents and 14 pending patent applications.

Risks Associated with Our Business

Our business is subject to numerous risks and uncertainties, including those highlighted in the section titled Risk Factors immediately following this prospectus summary. Some of these risks are:

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

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

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

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.

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

We are subject to a complicated regulatory regime subject to change and may fail to obtain regulatory approval for any of our product candidates.

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Concurrent Private Placement

Novartis Institutes for BioMedical Research, Inc., or NIBR, an existing stockholder and an affiliate of Novartis, a collaboration partner, has entered into a stock purchase agreement with us to purchase approximately $25.0 million of shares of our common stock at the initial public offering price in a separate private placement transaction that is expected to close concurrently with this offering. The sale of such shares will not be registered under the Securities Act of 1933, as amended. The closing of this offering is not conditioned upon the closing of such concurrent private placement.

Financial Update

While we have not finalized our financial results for the quarter ended March 31, 2015, we expect to report that we had approximately $133.0 million of cash and cash equivalents as of March 31, 2015, which included NIBR s purchase of $25.0 million of Series E convertible preferred stock. In addition, we received $200.0 million from Novartis on April 2, 2015, representing the upfront payment associated with our collaboration agreement with Novartis. The March 31, 2015 expected cash balance is preliminary and is subject to change upon completion of our procedures to prepare the consolidated financial statements as of and for the quarter ended March 31, 2015. Additional information and disclosures would be required for a more complete understanding of our financial position and results of operations as of March 31, 2015.

Corporate Information

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

Aduro, Aduro Biotech, the Aduro logo and other trade names, trademarks or service marks of Aduro appearing in this prospectus are the property of Aduro. Trade names, trademarks and service marks of other companies appearing in this prospectus are the property of their respective holders.

JOBS Act

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

available under the JOBS Act for complying with new or revised accounting standards.

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THE OFFERING

Common stock offered by us	7,000,000 shares.
Common stock to be outstanding after this offering and the concurrent private placement	58,950,504 shares.
Underwriters option to purchase additional shares	1,050,000 shares.
Use of proceeds	Our net proceeds from this offering, excluding the proceeds from the concurrent private placement, will be approximately $107.7 million, or approximately $124.3 million if the underwriters exercise in full their option to purchase additional shares of our common stock, after deducting the underwriting discount and estimated offering expenses payable by us. Our net proceeds from the concurrent private placement will be $25.0 million. We intend to use the net proceeds from this offering and the concurrent private placement, together with our existing cash and cash equivalents, to complete our Phase 2b ECLIPSE and STELLAR clinical trials, to advance the development of CRS-207 in pancreatic cancer and mesothelioma, and for planned clinical development programs evaluating LADD regimens for glioblastoma multiforme and ovarian cancer, to manufacture CRS-207 and GVAX Pancreas at commercial scale in preparation for potential regulatory approval, for other planned research and development programs involving our LADD and CDN platforms, and for general corporate and working capital purposes. See Use of Proceeds for additional information.
Risk factors	See Risk Factors beginning on page 12 and the other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in our common stock.
Reserved Share Program	At our request, the underwriters have reserved for sale, at the initial public offering price, up to 350,000 shares offered by this prospectus for sale to certain of our directors, officers, employees, business associates and related persons through a Reserved Share Program. If these persons purchase reserved shares it will reduce the number of shares available for

	sale to the general public. Any reserved shares that are not so purchased will be offered by the underwriters to the general public on the same terms as the other shares offered by this prospectus.
NASDAQ Global Select Market symbol	ADRO

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The number of shares of common stock to be outstanding after this offering and the concurrent private placement is based on 50,479,916 shares of our common stock (including preferred stock on an as-converted to common stock basis) outstanding at December 31, 2014, and excludes the following:

- 1,699,940 shares of common stock issuable upon the conversion of Series E convertible preferred stock issued after December 31, 2014;
- 5,970,382 shares of common stock issuable upon the exercise of outstanding stock options at December 31, 2014, with a weighted-average exercise price of $0.80 per share;
- 3,181,929 shares of common stock issuable upon the exercise of outstanding options that were granted after December 31, 2014, with a weighted-average exercise price of $1.82 per share;
- 77,755 shares of common stock issuable upon the exercise of preferred stock warrants at December 31, 2014, with a weighted-average exercise price of $1.69 per share;
- 1,154,270 shares of common stock issuable upon the exercise of outstanding common stock warrants at December 31, 2014, with a weighted-average exercise price of $0.25 per share;
- 332,826 shares of common stock reserved for future issuance under our 2009 Stock Plan, which will become available for issuance under our 2015 Equity Incentive Plan, or 2015 Plan, after consummation of this offering;
- 6,134,292 shares of common stock, subject to increase on an annual basis, reserved for future issuance under our 2015 Plan, which will become effective immediately prior to the consummation of this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this benefit plan; and
- 720,000 shares of common stock to be reserved for issuance under our 2015 Employee Stock Purchase Plan, which will become effective immediately prior to the consummation of this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this benefit plan.

In addition, unless we specifically state otherwise, all information in this prospectus assumes:

- the automatic conversion of all outstanding shares of our preferred stock at December 31, 2014 into an aggregate of 50,117,919 shares of common stock upon the closing of this offering;

the automatic conversion of all outstanding warrants exercisable for shares of our preferred stock at December 31, 2014 into warrants exercisable for 77,755 shares of our common stock upon the closing of this offering;

the filing and effectiveness of our amended and restated certificate of incorporation in Delaware and the adoption of our amended and restated bylaws, each of which will occur immediately following the completion of this offering;

no exercise of outstanding stock options or warrants subsequent to December 31, 2014; and

no exercise of the underwriters option to purchase up to an additional 1,050,000 shares of common stock.

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On April 1, 2015, we effected a 0.72-for-1 reverse split of its common stock. Upon the effectiveness of the reverse stock split, (i) every 1 share of outstanding common stock was combined into 0.72 of a share of common stock, (ii) the number of shares of common stock for which each outstanding option or warrant to purchase common stock is exercisable was proportionally decreased on a 0.72-for-1 basis, (iii) the exercise price of each outstanding option or warrant to purchase common stock was proportionately increased on a 0.72-for-1 basis, and (iv) the conversion ratio for each share of preferred stock which is convertible into our common stock was proportionately reduced on a 0.72-for-1 basis. All of the outstanding common stock share numbers (including shares of common stock into which our outstanding preferred stock shares are convertible), warrants, share prices, exercise prices and per share amounts have been adjusted in this prospectus, on a retroactive basis, to reflect this 0.72-for-1 reverse stock split for all periods presented. The par value per share and the authorized number of shares of common stock and preferred stock were not adjusted as a result of the reverse stock split.

Johnson & Johnson Innovation-JJDC, Inc., or JJDC, an existing stockholder, has agreed to purchase approximately $10.0 million of shares of our common stock in this offering at the initial public offering price. Certain other of our existing stockholders, including stockholders affiliated with our directors, have agreed to purchase an additional approximately $12.5 million of shares of our common stock in this offering at the initial public offering price.

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SUMMARY CONSOLIDATED FINANCIAL DATA

The following tables summarize our consolidated financial data. You should read this summary financial data together with the sections titled Selected Consolidated Financial Data and Management s Discussion and Analysis of Financial Condition and Results of Operations as well as our audited consolidated financial statements included elsewhere in this prospectus.

Except as otherwise noted, the summary consolidated statements of operations and consolidated balance sheet data presented below as of and for the years ended December 31, 2013 and 2014 are derived from our audited consolidated financial statements included elsewhere in this prospectus. Our results of operations for any prior period are not necessarily indicative of results of operations that should be expected in any future periods.

	Year Ended December 31,	
	2013	2014
	(in thousands, except share and per share information)	
Consolidated Statements of Operations Data:		
Revenue:		
Collaboration and license revenue	$	$ 13,038[3]
Grant revenue	828	351
Total revenue	828	13,389
Operating expenses:		
Research and development[1]	10,687	23,513
General and administrative[1]	4,677	8,994
Total operating expenses	15,364	32,507
Loss from operations	(14,536)	(19,118)
Interest expense	(1,371)	(2,395)[4]
Gain on extinguishment of convertible promissory notes		3,553[5]
Other (expense) income, net	(147)	946
Net loss and comprehensive loss	$ (16,054)	$ (17,014)
Net loss per common share, basic and diluted[2]	$ (55.80)	$ (53.06)
Shares used in computing net loss per common share, basic and diluted[2]	287,711	320,686
Pro forma net loss per common share, basic and diluted[2]		$ (0.70)
Shares used in computing pro forma net loss per common share, basic and diluted[2]		28,042,827

(1) Includes stock-based compensation as follows:

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

(2) See Note 16 to our audited consolidated financial statements included elsewhere in this prospectus for an explanation of the calculations of our basic and diluted net loss per common share, pro forma net loss per common share, and the weighted-average number of shares used in the computation of the per share amounts.

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(3) Represents the revenue recognized in connection with our collaboration agreements entered into with Janssen Biotech, Inc. in May and November 2014. See Note 7 to our audited consolidated financial statements included elsewhere in this prospectus.

(4) Includes amortization of debt discount associated with convertible promissory notes due to the issuance of warrants and beneficial conversion feature associated with such convertible promissory notes. See Note 5 to our audited consolidated financial statements included elsewhere in this prospectus.

(5) Upon the conversion of convertible promissory notes issued to related parties into Series C convertible preferred stock in May 2014, a gain on extinguishment was recorded because the amount allocated to reacquire the convertible promissory notes was less than the carrying value of the notes. See Note 5 to our audited consolidated financial statements included elsewhere in this prospectus.

	At December 31, 2014		
			Pro Forma
	Actual	Pro Forma[1]	As Adjusted[2]
		(in thousands)	
Consolidated Balance Sheet Data:			
Cash and cash equivalents	$ 119,456	$ 119,456	$ 252,126
Working capital	81,006	81,006	213,676
Total assets	126,462	126,462	259,132
Convertible preferred stock warrant liability	100		
Common stock warrant liability	889	889	889
Convertible preferred stock	139,963		
Accumulated deficit	(61,643)	(61,643)	(61,643)
Total stockholders (deficit) equity	(61,297)	78,766	211,436

(1) The pro forma column has been derived from the unaudited pro forma information from our audited consolidated financial statements included elsewhere in this prospectus, and reflects the automatic conversion of all outstanding shares of our convertible preferred stock and convertible preferred stock warrants into common stock and common stock warrants, respectively, immediately prior to the closing of this offering.

(2) The pro forma as adjusted column further reflects the receipt of the net proceeds from the sale of 8,470,588 shares of common stock in this offering and the concurrent private placement at the initial public offering price of $17.00 per share, after deducting the underwriting discount and estimated expenses payable by us.

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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 prospectus, including our financial statements and related notes, before investing in our common stock. While we believe that the risks and uncertainties described below are the material risks currently facing us, additional risks that we do not yet know of or that we currently think are immaterial may also arise and materially affect our business. If any of the following risks materialize, our business, financial condition and results of operations could be materially and adversely affected. In that case, the trading price of our common stock could decline, and you may lose some or all of your investment.

Risks Related to Our Business

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

We are a clinical-stage biopharmaceutical company with a limited operating history. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We have financed our operations primarily through the sale of equity securities and convertible debt securities. Since our inception, most of our resources have been dedicated to the preclinical and clinical development of our product candidates. The size of our future net losses will depend, in part, on our future expenses and our ability to generate revenue, if any. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception. For the years ended December 31, 2013 and 2014, we reported a net loss of $16.1 million and $17.0 million, respectively. At December 31, 2014, we had an accumulated deficit of $61.6 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates.

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

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

Our operations have consumed substantial amounts of cash since inception. At December 31, 2014, our cash and cash equivalents were $119.5 million. We expect to continue to spend substantial amounts to continue the clinical development of our product candidates. If we are able to gain regulatory approval for any of our product candidates, we will require significant additional amounts of cash in order to launch and commercialize any such product candidates. In addition, other unanticipated costs may arise. Because the design and outcome of our planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates.

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

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

If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making

capital expenditures or declaring dividends. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of or suspend one or more of our clinical trials or research and development programs or our commercialization efforts.

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

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

We are developing our pipeline of immuno-oncology product candidates via two technology platforms: Live, Attenuated, Double-Deleted, or LADD, *Listeria monocytogenes* and cyclic dinucleotides, or CDNs. Immuno-oncology encompasses a class of therapies that leverage the patient s immune system to slow the

growth and spread of, or eliminate, tumor cells. Any products we develop may not effectively modulate the immune response to slow the spread of or eliminate cancer cells. The scientific evidence to support the feasibility of developing product candidates based on impacting the anti-tumor immune response is preliminary and limited. Advancing these novel immuno-oncology therapies creates significant challenges for us, including, among others:

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

maintaining and growing an organization of scientists and business people who can develop and commercialize our products and technology.

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

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

A key element of our strategy is to use and expand our technology platforms to build a pipeline of product candidates, combine our product candidates with existing and novel therapies, and progress these product candidates and combinations through clinical development for the treatment of various diseases. Although our research and development efforts to date have resulted in a pipeline of product candidates directed at various cancers, we may not be able to develop product candidates that are safe and effective. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for

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clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. If we do not continue to successfully develop and begin to commercialize product candidates, we will face difficulty in obtaining product revenues in future periods.

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

We do not have any products that have gained regulatory approval. Our business and future success depend on our ability to obtain regulatory approval of and then successfully commercialize our lead product candidate, CRS-207, and GVAX Pancreas. CRS-207, GVAX Pancreas and our other product candidates are in the early stages of development. We are currently conducting our Phase 2b ECLIPSE clinical trial of CRS-207 in combination with GVAX Pancreas to treat late-stage metastatic pancreatic cancer patients who have received at least one prior line of therapy. Our ability to develop, obtain regulatory approval for, and successfully commercialize CRS-207 and GVAX Pancreas effectively will depend on several factors, including the following:

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

qualifying for, identifying, registering, maintaining, enforcing and defending intellectual property rights and claims covering the product.

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

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

Before obtaining regulatory approvals for the commercial sale of our product candidates, including CRS-207, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. For example, the positive results generated to date in preclinical studies and in our Phase 2a metastatic pancreatic cancer study for CRS-207 do not ensure that future studies will demonstrate similar results. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. We cannot be certain that we will not face similar setbacks. Most product candidates that commence clinical trials are never approved as commercial products.

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

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

manufacturing sufficient quantities of product candidate for use in clinical trials.

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

Furthermore, we rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over

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their actual performance. If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive cash compensation in connection with such services. We also give grants to investigators institutions from time to time. If certain of these relationships exceed specific financial thresholds, they must be reported to the FDA If these relationships and any related compensation paid results in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay in approval, or rejection, of our marketing applications by the FDA. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

In addition, even if the trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and we may need to conduct additional trials before we submit applications seeking regulatory approval of our product candidates.

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

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

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics.

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

If unacceptable side effects arise in the development of our product candidates, we could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims.

In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates

could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly.

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

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

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

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

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

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial s primary endpoints;
- the proximity of patients to study sites;
- the design of the trial;

our ability to recruit clinical trial investigators with the appropriate competencies and experience;

clinicians and patients perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;

our ability to obtain and maintain patient consents; and

the risk that patients enrolled in clinical trials will drop out of the trials before completion.

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

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

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

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

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

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

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

We have obtained orphan drug designations from the FDA for CRS-207 and GVAX Pancreas for the treatment of pancreatic cancer and for CRS-207 for the treatment of mesothelioma, but we may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biologic intended to treat a rare disease or condition, which is defined as one occurring in a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug or biologic will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled

to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a full Biologics License Application, or BLA, to market the same biologic for the

same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity.

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

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

In 2012, the FDA established a new Breakthrough Therapy designation, which is intended to expedite the development and review of products that treat serious or life-threatening conditions where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation of a product candidate as a Breakthrough Therapy provides potential benefits that include but are not limited to more frequent meetings with the FDA to discuss the development plan for the product candidate and ensure collection of appropriate data needed to support approval; more frequent written correspondence from FDA about such things as the design of the proposed clinical trials and use of biomarkers; intensive guidance on an efficient drug development program; organizational commitment involving senior managers; and eligibility for rolling review and priority review. Breakthrough Therapy designation does not change the standards for product approval. We have obtained Breakthrough Therapy designation for our CRS-207 and GVAX Pancreas combination. Despite the potential advantages of Breakthrough Therapy designation, we may fail to obtain regulatory approval of CRS-207 and GVAX Pancreas, and if we do obtain approval, we may fail to do so on an accelerated basis. In addition, while we intend to seek Breakthrough Therapy designation for other product candidates, we may never receive such designation.

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

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

Even if we obtain FDA approval to market additional product candidates for the treatment of cancer, we cannot assure you that any such product candidates will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. If we are unable to successfully develop and commercialize additional product candidates, our commercial opportunity will be limited. Moreover, a failure in

obtaining regulatory approval of additional product candidates may have a negative effect on the approval process of any other, or result in losing approval of any approved, product candidate.

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

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

- The manufacturing of drug products is susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment or vendor or operator error. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If foreign microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our products are made, these manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

- The manufacturing facilities in which our product candidates are made could be adversely affected by equipment failures, labor shortages, natural disasters, power failures and numerous other factors.

- We and our contract manufacturers must comply with the FDA s cGMP regulations and guidelines. Any failure to follow cGMP or other regulatory requirements or any delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our products as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our products, including leading to significant delays in the availability of products for our clinical studies or the termination or hold on a clinical study, or the delay or prevention of a filing or approval of marketing applications for our product candidates. Significant noncompliance could also result in the imposition of sanctions, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation. If we are not able to maintain regulatory compliance, we may not be permitted to market our products and/or may be subject to product recalls, seizures, injunctions, or criminal prosecution.

- Our LADD product candidates and GVAX Pancreas are temperature sensitive and must be frozen during storage and transportation, which adds complexity and expense. We rely on third parties to provide controlled temperature storage and shipping. If any third-party provider fails to maintain proper temperature control or if a shipment is delayed in transit for a prolonged period of time, the product could become unsuitable for use.

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

medical community, which could adversely affect our ability to operate our business and our results of operations.

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

We currently have no sales, marketing or distribution capabilities and have no experience in marketing products. We intend to develop an in-house marketing organization and sales force, which will require significant

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capital expenditures, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

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

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

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

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

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;

potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;

challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;

production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and

business interruptions resulting from geo-political actions, including war and terrorism.

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

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

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

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

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

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

We conduct our operations at our facility in Northern California. This region is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in our

market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all.

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

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

At March 31, 2015, we had 53 full-time employees, including 41 employees engaged in research and development. As our development and commercialization plans and strategies develop, and as we transition into operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

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

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

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

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

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

Despite the implementation of security measures, our internal computer systems and those of our future CROs and other contractors and consultants are vulnerable to damage from computer viruses and unauthorized

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

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

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

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

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

Effective upon the completion of this offering, we intend to adopt a code of business conduct and ethics, but it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent these activities may not be effective in controlling unknown or

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unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment of operations, any of which could adversely affect our ability to operate our business and our results of operations. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations.

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

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

- the clinical indications for which our product candidates are approved;
- physicians, hospitals, cancer treatment centers and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA;
- the timing of market introduction of our product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;

- the availability of adequate coverage, reimbursement and pricing by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

In addition, we are utilizing replication competent vectors, and adverse publicity due to the ethical and social controversies surrounding the therapeutic use of such technologies, and reported side effects from any

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clinical trials using these technologies or the failure of such trials to demonstrate that these therapies are safe and effective may limit market acceptance our product candidates. If our product candidates are approved but fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers or others in the medical community, we will not be able to generate significant revenue.

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

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

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

decreased demand for our product candidates;

injury to our reputation;

withdrawal of clinical trial participants;

initiation of investigations by regulators;

costs to defend the related litigation;

a diversion of management s time and our resources;

substantial monetary awards to trial participants or patients;

product recalls, withdrawals or labeling, marketing or promotional restrictions;

loss of revenue;

exhaustion of any available insurance and our capital resources;

the inability to commercialize any product candidate; and

a decline in our share price.

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

We currently hold $5.0 million in product liability insurance in the aggregate, which we believe is customary for similarly situated companies and adequate to provide us with insurance coverage for foreseeable risks, but which may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly

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expensive. We may not be able to maintain insurance at a reasonable cost or in an amount adequate to satisfy any liability that may arise, if at all. Our insurance policy contains various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

Risks Related to Our Reliance on Third Parties

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

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

Our commercialization strategy for our product candidates may depend on our ability to enter into agreements with collaborators to obtain assistance and funding for the development and potential commercialization of our product candidates in the territories in which we seek to partner. Despite our efforts, we may be unable to secure additional collaborative licensing or other arrangements that are necessary for us to further develop and commercialize our product candidates. Supporting diligence activities conducted by potential collaborators and negotiating the financial and other terms of a collaboration agreement are long and complex processes with uncertain results. Even if we are successful in entering into one or more collaboration agreements, collaborations may involve greater uncertainty for us, as we have less control over certain aspects of our collaborative programs than we do over our proprietary development and commercialization programs. For example, under our collaboration and license agreement with Novartis, we are responsible for a share of the worldwide joint development costs, which may be significant. If we elect to reduce our share of development funding as provided for under the agreement, our share in profits would decrease or convert to a royalty. We may determine that continuing a collaboration under the terms provided is not in our best interest, and we may terminate the collaboration. Our potential future collaborators could delay or terminate their agreements, and as a result our product candidates may never be successfully commercialized.

Further, our potential future collaborators may develop alternative products or pursue alternative technologies either on their own or in collaboration with others, including our competitors, and the priorities or

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

We rely and will rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.

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

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

Switching or adding third parties to conduct our clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines.

Though we carefully manage our relationships with third parties conducting our clinical

trials, we cannot assure you that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

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

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

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

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

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

- We may be unable to identify manufacturers on acceptable terms or at all.
- Our third-party manufacturers might be unable to timely formulate and manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any.
- Contract manufacturers may not be able to execute our manufacturing procedures appropriately.
- Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store

and distribute our products.

Manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers compliance with these regulations and standards.

We may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our products.

Our third-party manufacturers could breach or terminate their agreement with us.

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

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

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

We may form or seek strategic alliances, create joint ventures or collaborations or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

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

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by our third-party manufacturers. Our manufacturers are subject to federal, state

and local laws and regulations in the United States governing the use, manufacture, storage,

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

Risks Related to Government Regulation

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

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate s clinical development and may vary among jurisdictions. We have not previously submitted a BLA or NDA to the FDA, or similar marketing applications filings to comparable foreign authorities. A BLA or NDA must include extensive preclinical and clinical data and supporting information to establish the product candidate s safety, purity and potency, or safety and effectiveness for each desired indication. The BLA or NDA must also include significant information regarding the chemistry, manufacturing and controls for the product. We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. For example, the FDA has limited experience with commercial development of immunotherapies for cancer. We also intend to obtain regulatory approval of future product candidates regardless of cancer type or origin, which the FDA may have difficulty accepting if our clinical trials only involved cancers of certain origins. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and approval may not be obtained.

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

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate s clinical and other benefits outweigh its safety risks;

the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;

the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA or other submission or to obtain regulatory approval in the United States or elsewhere;

- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; or

- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

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

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

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

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

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

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

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

FDA may also require a risk evaluation and mitigation strategy, or REMS, as a condition of approval of our product candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient

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

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

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

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

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

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

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

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

a covered benefit under its health plan;

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safe, effective and medically necessary;

appropriate for the specific patient;

cost-effective; and

neither experimental nor investigational.

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

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

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

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

covered under Medicare Part D.

Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending

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a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation s automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013, and will remain in effect through 2024 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

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

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

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

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

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

the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;

federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other third-party payors that are false or fraudulent or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government;

the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating these statutes without actual knowledge of the statutes or specific intent to violate them;

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization;

the federal Physician Payment Sunshine Act, created under the Affordable Care Act, and its implementing regulations, which require manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children s Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services, or HHS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members and payments or other transfers of value made to such physician owners;

federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and

analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians

and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our business activities could be subject to challenge under one or more of such laws. The scope and enforcement of each of these laws is uncertain and subject to

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rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time-and resource-consuming and can divert management s attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

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

Risks Related to Our Intellectual Property

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

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

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

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

often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or in some cases not at all, until they are

issued as a patent. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions.

Our pending applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, issued patents that we own or have licensed from third parties may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in the loss of patent protection, the narrowing of claims in such patents or the invalidity or unenforceability of such patents, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection for our technology and products. Protecting against the unauthorized use of our or our licensor s patented technology, trademarks and other intellectual property rights is expensive, difficult and may in some cases not be possible. In some cases, it may be difficult or impossible to detect third-party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult. For example, two of our patents, U.S. Patent Nos. 7,842,289 and 7,935,804, related to our LADD technology platform were challenged in an *ex parte* reexamination proceeding, which is now concluded. No claims of U.S. Patent No. 7,842,289 were canceled or amended as a result of the e*x parte* reexamination. Of the original 84 claims of U.S. Patent No. 7,935,804, 12 were amended and 22 were canceled to overcome the objections raised in the e*x parte* reexamination, but we believe the remaining claims still cover our LADD technology platform.

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

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

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

In addition, we are testing our product candidates administered with other product candidates or products that are covered by patents held by other companies or institutions. In the event that a labeling instruction is required in product packaging recommending that combination, we could be accused of, or held

liable for, infringement of the third-party patents covering the product candidate or product recommended for administration with our product candidates. In such a case, we could be required to obtain a license from the other company or institution to use the required or desired package labeling, which may not be available on commercially reasonable terms, or at all.

We are aware of certain U.S. and foreign patents owned by a certain third party with claims that are broadly directed to a *Listeria* vaccine strain that contains certain proteins, some of which expire as late as 2021. These patents could be construed to cover CRS-207. In addition, we are aware of certain U.S. and foreign patents owned by a certain third party with claims that are broadly directed methods of using *Listeria*-based vaccines to treat certain cancers, which expire in 2017. The patents expiring in 2017 may be construed to cover our LADD product candidate, CRS-207, as well as the product candidates licensed to Janssen, ADU-214 and ADU-741. Notwithstanding, we do not currently expect a product launch prior to 2017 and, therefore, the patents expiring in 2017 would not appear relevant to our commercialization plans unless our approval was accelerated or they somehow were extended. Generally, conducting clinical trials and other development activities in the United States is not considered an act of infringement. If and when products are approved by the FDA, that certain third party may then seek to enforce its patents by filing a patent infringement lawsuit against us or our licensee(s). In such lawsuit, we or our licensee(s) may incur substantial expenses defending our rights or our licensee(s) rights to commercialize such product candidates, and in connection with such lawsuit and under certain circumstances, it is possible that we or our licensee(s) could be required to cease or delay the commercialization of a product candidate and/or be required to pay monetary damages or other amounts, including royalties on the sales of such products. Moreover, such lawsuit may also consume substantial time and resources of our or our licensee(s) management team and board of directors. The threat or consequences of such a lawsuit may also result in royalty and other monetary obligations, which may adversely affect our results of operations and financial condition.

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

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

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

As part of the agreements with Janssen related to ADU-214, ADU-741 and GVAX Prostate, we have granted Janssen the initial right and responsibility to file, prosecute, maintain and enforce any patents and patent applications that

contain pending or issued claims that are specifically directed to the antigens contained in ADU-214, ADU-741 and GVAX Prostate. For example, if a third party is infringing one of the antigen-specific patents by marketing a product that is identical or similar to ADU-214 for the treatment of lung cancer (such as a

biosimilar of ADU-214), Janssen would have the initial right to enforce the antigen-specific patents against the third party. If we do not have the ability to control the enforcement of the antigen-specific patents against a third party that is marketing a product that is identical or similar to ADU-214, ADV-741 or GVAX Prostate, our business may be materially harmed.

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

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

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

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

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

The laws of certain foreign countries may not protect our rights to the same extent as the laws of the United States, and these foreign laws may also be subject to change. For example, methods of treatment and manufacturing

processes may not be patentable in certain jurisdictions, and the requirements for patentability may differ in certain countries, particularly developing countries. Furthermore, generic and/or biosimilar product manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors patents, requiring us or our licensors to engage in complex, lengthy and costly litigation or other proceedings.

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Generic or biosimilar product manufacturers may develop, seek approval for, and launch biosimilar versions or generic versions, respectively, of our products. The FDA has published four draft guidance documents on biosimilar product development. For the FDA to approve a biosimilar product as interchangeable with a reference product, the agency must find that the biosimilar product can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biosimilar and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. However, complexities associated with the larger, and often more complex, structures of biological products, as well as the process by which such products are manufactured, pose significant hurdles to implementation, which are still being worked out by the FDA. To date, no biosimilar or interchangeable biologic has been licensed under the Biologics Price Competition and Innovation Act of 2009, or BPCIA, framework, although such approvals have occurred in Europe, and it is anticipated that the FDA will approve a biosimilar in the relatively near future. If any of our product candidates are approved by the FDA, the approval of a biologic product biosimilar to one of our products could have a material impact on our business. In particular, a biosimilar could be significantly less costly to bring to market and priced significantly lower than our products, if approved by the FDA. See Business Government Regulation and Product Approval U.S. Patent Term Restoration and Marketing Exclusivity for a more detailed description of the BPCIA.

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

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

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

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

The BPCIA established legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as interchangeable based on its similarity to an existing brand product. Under the BPCIA,

an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. The law is complex and is still being interpreted and

implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

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

Additionally, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. The extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

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

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involve technological and legal complexity, and obtaining and enforcing pharmaceutical patents is costly, time-consuming, and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. For example, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our and our licensors ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our and our licensors ability to obtain new patents or to enforce existing patents and patents we and our licensors may obtain in the future. Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our and our licensors patent applications and the enforcement or defense of our or our licensors issued patents.

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

submission, proceeding or litigation could reduce the scope of, or invalidate, our or our licensors patent rights, which could adversely affect our competitive position.

The USPTO is currently developing regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in

particular, the first to file provisions, did not become effective until March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents and those licensed to us.

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

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our product candidates, our competitive position would be adversely affected.

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

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

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

Many of our employees and our licensors employees, including our senior management, were previously employed at universities or at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, including each member of our senior management, executed proprietary

rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such previous employment. Although we try to ensure that our employees do not

use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such third party. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

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

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

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

The patents of others may have an adverse effect on our business.

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

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, know-how and confidential and proprietary information. To maintain the confidentiality of trade secrets and proprietary information, we will enter into confidentiality agreements with our employees, consultants and collaborators upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual s relationship with us be kept confidential and not disclosed to third parties. Our agreements with employees also provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and

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individuals with whom we have these agreements may not comply with their terms. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our employees, consultants or contractors use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions.

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

Risks Related to our Financial Results

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.

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

In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award as determined by our board of directors, 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, after the closing of this offering, 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;

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any delays in regulatory review or approval of CRS-207 or any of our other product candidates;

the level of demand for our product candidates, if approved, which may fluctuate significantly and be difficult to predict;

the risk/benefit profile, cost and reimbursement policies with respect to our products candidates, if approved, and existing and potential future drugs that compete with our product candidates;

our ability to commercialize our product candidates, if approved, inside and outside of the United States, either independently or working with third parties;

our ability to establish and maintain collaborations, licensing or other arrangements;

our ability to adequately support future growth;

potential unforeseen business disruptions that increase our costs or expenses;

future accounting pronouncements or changes in our accounting policies; and

the changing and volatile global economic environment.

The cumulative effect of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue and/or earnings guidance we may provide.

We previously identified a material weakness in our internal control over financial reporting at December 31, 2012 and December 31, 2013, and we may identify additional material weaknesses in the future that may cause us to fail to meet our reporting obligations or result in material misstatements of our financial statements. If we fail to remediate any material weaknesses or if we fail to establish and maintain effective control over financial reporting, our ability to accurately and timely report our financial results could be adversely affected.

In connection with the contemporaneous audit of our consolidated financial statements for the years ended December 31, 2012 and 2013, we identified a control deficiency in the design and operation of our internal control over financial reporting that constituted a material weakness. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of

our financial statements will not be prevented or detected on a timely basis.

The material weakness identified in our internal control over financial reporting related to our lack of sufficient financial reporting and accounting personnel with the technical expertise to appropriately account for complex, non-routine transactions, primarily related to convertible debt and equity. The material weakness resulted in adjustments to our consolidated financial statements for the years ended December 31, 2012 and 2013. During 2013 and 2014, we took certain actions that remediated the material weakness, which included hiring additional personnel with public company financial reporting expertise to build our financial management and reporting infrastructure, and engaging a third party to provide additional advisory services with respect to technical accounting matters. We intend to further develop and document our accounting policies and financial reporting procedures. However, we cannot assure you that these measures will be sufficient to remediate or prevent future material weaknesses or significant deficiencies from occurring. We also cannot assure you that we have identified all of our existing material weaknesses.

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Neither we nor our independent registered public accounting firm has performed an evaluation of our internal control over financial reporting during any period in accordance with the provisions of the Sarbanes-Oxley Act. In light of the control deficiencies and the resulting material weakness that were previously identified as a result of the limited procedures performed, we believe that it is possible that, had we and our independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, additional material weaknesses and significant control deficiencies may have been identified. However, for as long as we remain an emerging growth company as defined in the JOBS Act, we intend to take advantage of the exemption permitting us not to comply with the requirement that our independent registered public accounting firm provide an attestation on the effectiveness of our internal control over financial reporting.

If we identify future material weaknesses in our internal controls over financial reporting or fail to meet the demands that will be placed upon us as a public company, including the requirements of the Sarbanes-Oxley Act, we may be unable to accurately report our financial results, or report them within the timeframes required by law or stock exchange regulations. Failure to comply with Section 404 of the Sarbanes-Oxley Act could also potentially subject us to sanctions or investigations by the SEC or other regulatory authorities. We cannot assure that in the future, additional material weaknesses will not exist or otherwise be discovered, any of which could adversely affect our reputation, financial condition and results of operations.

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

In general, 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, 2014, we reported U.S. federal and state NOLs of approximately $51.2 million and $6.0 million, respectively. In general, an ownership change occurs if the aggregate stock ownership of 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. We performed a Section 382 analysis and believe that we experienced multiple ownership changes under Section 382 of the Code. As a result of the ownership changes, we estimate that the utilization of $42.4 million and $5.0 million of federal and state NOLs, respectively, is subject to annual limitations under Section 382. Furthermore, future changes in our stock ownership, such as certain stock issuances (including in connection with this offering) and transfers between stockholders, some of which changes are outside of our control, could result in ownership changes under Section 382 of the Code. For these reasons, we may not be able to utilize a material portion of our NOLs and tax credit carryforwards, even if we attain profitability.

Risks Related to This Offering and Ownership of our Common Stock

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

The trading price of our common stock following this offering is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this Risk Factors section and elsewhere in this prospectus, these factors include:

the commencement, enrollment or results of the planned clinical trials of our product candidates or any future clinical trials we may conduct, or changes in the development status of our product candidates;

any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority s review of such

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filings, including without limitation the FDA s issuance of a refusal to file letter or a request for additional information;

adverse results or delays in clinical trials;

our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;

adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;

changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements for approvals;

adverse developments concerning our manufacturers;

our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;

our inability to establish collaborations if needed;

our failure to commercialize our product candidates;

additions or departures of key scientific or management personnel;

unanticipated serious safety concerns related to the use of our product candidates;

introduction of new products or services offered by us or our competitors;

announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;

our ability to effectively manage our growth;

the size and growth of our initial cancer target markets;

our ability to successfully treat additional types of cancers or at different stages;

actual or anticipated variations in quarterly operating results;

our cash position;

our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;

publication of research reports about us or our industry, or immuno-oncology in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;

changes in the market valuations of similar companies;

overall performance of the equity markets;

sales of our common stock by us or our stockholders in the future;

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trading volume of our common stock;

changes in accounting practices;

ineffectiveness of our internal controls;

disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;

significant lawsuits, including patent or stockholder litigation;

general political and economic conditions; and

other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the NASDAQ Global Select Market and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. If the market price of our common stock after this offering does not exceed the initial public offering price, you may not realize any return on your investment in us and may lose some or all of your investment. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company s securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management s attention and resources, which would harm our business, operating results or financial condition.

We do not know whether an active, liquid and orderly trading market will develop for our common stock or what the market price of our common stock will be and as a result it may be difficult for you to sell your shares of our common stock.

Prior to this offering there has been no public market for shares of our common stock. Although we have applied to have our common stock listed on the NASDAQ Global Select Market, an active trading market for our shares may never develop or be sustained following this offering. You may not be able to sell your shares quickly or at the market price if trading in shares of our common stock is not active. The initial public offering price for our common stock will be determined through negotiations with the underwriters, and the negotiated price may not be indicative of the market price of the common stock after the offering. As a result of these and other factors, you may be unable to resell your shares of our common stock at or above the initial public offering price. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration.

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

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

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our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

At December 31, 2014, we had $119.5 million of cash and cash equivalents. While we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents since December 31, 2014, we cannot assure you that further deterioration of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or our ability to meet our financing objectives. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

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

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

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

Prior to this offering, our executive officers, directors, and 5% stockholders beneficially owned approximately 74.5% of our voting stock at March 31, 2015, and, upon the closing of this offering and the concurrent private placement, that same group will hold approximately 66.3% of our outstanding voting stock (assuming no exercise of the underwriters option to purchase additional shares). In addition, Morningside Venture (VI) Investments Limited, or MVIL, and Ultimate Keen Limited, or UKL, beneficially own approximately 35.5% and 10.7%, respectively, of our outstanding voting stock prior to the offering and will hold approximately 31.3% and 9.2%, respectively, of our outstanding voting stock upon the closing of the offering (assuming no exercise of the underwriters option to purchase additional shares). UKL acquired shares of our stock from MVIL. MVIL and UKL have voted together in the past with respect to our common stock and plan to continue to act together with respect to our common stock. Together, they beneficially own approximately 46.2% of our outstanding voting stock prior to the offering and will hold approximately 40.5% of our outstanding voting stock upon the closing of the offering (assuming no exercise of the underwriters option to purchase additional shares). Therefore, even after this offering and the concurrent private placement, these stockholders will have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

The concurrent private placement and the potential purchases of shares in this offering by certain of our principal stockholders and their affiliated entities will reduce the available public float for our common stock.

NIBR has entered into a stock purchase agreement with us to purchase approximately $25.0 million of shares of our common stock at a price per share equal to the initial public offering price (or 1,470,588 shares based on the initial public offering price of $17.00 per share) in a private placement that would close concurrently with this offering. The sale of these shares to NIBR will not be registered in this offering. In addition, certain of our existing stockholders and their affiliated entities, including stockholders affiliated with our directors, have agreed to purchase approximately $22.5 million of shares of our common stock at a price per share equal to the initial public offering price (or approximately 1,323,528 shares based on the initial public offering price of $17.00 per share).

The concurrent private placement and the potential purchases in this offering by certain of our existing stockholders and their affiliated entities may reduce the available public float for our common stock because our existing stockholders and their affiliates will be restricted from selling any shares purchased by them pursuant to

either lock-up agreements or securities laws restrictions. As a result, the concurrent private placement and the sale of common stock to our existing stockholders and their affiliates may reduce the liquidity of our common stock relative to what it would have been had these shares been purchased by investors that were not affiliated with us.

If you purchase our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares.

The initial public offering price is substantially higher than the net tangible book value per share of our common stock. Investors purchasing common stock in this offering will pay a price per share that substantially exceeds the book value of our tangible assets after subtracting our liabilities. As a result, investors purchasing common stock in this offering will incur immediate dilution of $13.41 per share, based on an initial public offering price of $17.00 per share. Further, investors purchasing common stock in this offering and the concurrent private placement will contribute approximately 51.4% of the total amount invested by stockholders since our inception, but will own only approximately 14.4% of the shares of common stock outstanding after giving effect to this offering and the concurrent private placement.

This dilution is due to our investors who purchased shares prior to this offering having paid substantially less when they purchased their shares than the price offered to the public in this offering and the exercise of stock options granted to our employees. To the extent outstanding options or warrants are exercised, there will be further dilution to new investors. As a result of the dilution to investors purchasing shares in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of our liquidation. For a further description of the dilution that you will experience immediately after this offering, see Dilution.

We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years following the year in which we complete this offering, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of this offering, (b) in which we have total annual gross revenue of at least $1.0 billion or (c) 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 (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

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

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same

new or revised accounting standards as other public companies that are not emerging growth companies. As a result, changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

We will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. We will be subject to the reporting requirements of the Securities Exchange Act of 1934, which will require, among other things, that we file with the Securities and Exchange Commission, or the SEC, annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and the NASDAQ Global Select Market to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as say on pay and proxy access. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period and up to five years from the pricing of this offering. We intend to take advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

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.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lock-up and other legal restrictions on resale discussed in this prospectus lapse, the trading price of our common stock could decline. Based on 50,479,916 shares of common stock outstanding, after giving effect to the conversion of preferred stock, at December 31, 2014, upon the closing of this offering and the concurrent private placement we will have outstanding a total of 58,950,504 shares of common stock. Of these shares, only the shares of common stock sold in this offering by us, plus any shares sold upon exercise of the underwriters option to purchase additional shares, will be freely tradable without restriction in the public market immediately following this offering. Merrill, Lynch, Pierce, Fenner & Smith Incorporated and Leerink Partners LLC, however, may, in their sole

discretion, permit our officers, directors and other stockholders who are subject to these lock-up agreements to sell shares prior to the expiration of the lock-up agreements.

We expect that the lock-up agreements pertaining to this offering will expire after 180 days from the date of this prospectus. In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our 2015 Plan, will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

After this offering, the holders of 47,701,554 shares of our common stock at December 31, 2014 will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to the 180-day lock-up agreements described above. See Description of Capital Stock Registration Rights. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

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, including shares of common stock sold in this offering.

Pursuant to our 2015 Plan, certain amendments of which became effective on the business day prior to the public trading date of our common stock, our management is authorized to grant stock options to our employees, directors and consultants.

Initially, the aggregate number of shares of our common stock that may be issued pursuant to stock awards under our 2015 Plan is 6,134,292 shares. Additionally, the number of shares of our common stock reserved for issuance under our 2015 Plan will automatically increase on January 1 of each year, beginning on January 1, 2016 and continuing through and including January 1, 2025, by 4% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors. Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

We have broad discretion in the use of the net proceeds from this offering and the concurrent private placement and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from this offering and the concurrent private placement, including for any of the purposes described in the section entitled Use of Proceeds, and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of the net proceeds from this offering and the concurrent private placement, their ultimate use may vary substantially from their currently intended use. Our management might not apply our net proceeds in ways that ultimately increase the value of your

investment. We expect to use the net proceeds from this offering and the concurrent private placement, together with our existing cash and cash equivalents, to complete our Phase 2b ECLIPSE clinical trial, to advance the development of CRS-207 in pancreatic cancer and mesothelioma, for

planned clinical development programs evaluating LADD regimens for glioblastoma multiforme and ovarian cancer, to manufacture CRS-207 and GVAX Pancreas at commercial scale in preparation for potential regulatory approval, for development of CDN product candidates and other planned research and development programs, and for general corporate and working capital purposes. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from this offering and the concurrent private placement in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders. If we do not invest or apply the net proceeds from this offering and the concurrent private placement in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

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, which are to become effective immediately following the closing of this offering, contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer, or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and

the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

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

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

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

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

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

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the sections titled Prospectus Summary, Risk Factors, Use of Proceeds, Management s Discussion and Analysis of Financial Condition and Results of Operations and Business, 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 prospectus, 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 similar expressions. These forward-looking statements include, but are not limited to, statements concerning the following:

- our history of net operating losses and uncertainty regarding our ability to achieve profitability;
- our ability to fund our working capital needs;
- our ability to develop and commercialize our product candidates;
- our ability to use and expand our technology platforms to build a pipeline of product candidates;
- our dependence on our lead product candidate, CRS-207, and GVAX Pancreas;
- our ability to obtain and maintain regulatory approval of our product candidates;
- our inability to operate in a competitive industry and compete successfully against competitors that have greater resources than we do;
- our ability to retain and attract key personnel;
- our products may not gain market acceptance;
- our reliance on third parties; and
- our ability to obtain and adequately protect intellectual property rights for our product candidates.

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 this prospectus in greater detail under the heading Risk Factors and elsewhere in this prospectus. 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 prospectus, 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 prospectus 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.

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INDUSTRY AND MARKET DATA

This prospectus also contains estimates, projections and other information concerning our industry, the market in which we operate and our business. Unless otherwise indicated, information contained in this prospectus concerning our industry and the market in which we operate, including our general expectations and market position, market opportunity and market size, is based on information from various sources, such as reports, research surveys, studies and similar data prepared by third parties, industry, medical and general publications, government data and similar sources and is subject to a number of assumptions and limitations. Although we are responsible for all of the disclosure contained in this prospectus and we believe the information from the third-party sources included in this prospectus is reliable, such information is inherently imprecise. The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section titled Risk Factors. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us. In some cases, we do not expressly refer to the sources from which these data are derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph are derived from the same sources, unless otherwise expressly stated or the context otherwise requires.

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USE OF PROCEEDS

We estimate that the net proceeds from the sale of 7,000,000 shares of common stock in this offering, excluding the proceeds from the concurrent private placement, will be approximately $107.7 million, after deducting the underwriting discount and estimated offering expenses payable by us. If the underwriters exercise their option to purchase additional shares in full, we estimate that the net proceeds will be approximately $124.3 million after deducting the underwriting discount and estimated offering expenses payable by us. Our net proceeds from the concurrent private placement will be $25.0 million.

We are undertaking this offering in order to access the public capital markets and to increase our liquidity. At December 31, 2014, we had cash and cash equivalents of $119.5 million. We intend to use the net proceeds of this offering and the concurrent private placement, together with our existing cash and cash equivalents, as follows:

- approximately $15.0 million to complete our ongoing ECLIPSE and STELLAR Phase 2b clinical trials in pancreatic cancer;
- approximately $40.0 million to advance the development of CRS-207 in additional indications, including planned Phase 2 clinical trials in mesothelioma and ovarian cancer;
- approximately $35.0 million to manufacture CRS-207 and GVAX Pancreas at commercial scale in preparation for potential regulatory approval;
- approximately $30.0 million for other research and development programs involving our LADD and CDN platforms, including ADU-S100; and
- the remainder for general corporate and working capital purposes.

However, due to the uncertainties inherent in the product development process, it is difficult to estimate with certainty the exact amounts of the net proceeds from this offering and the concurrent private placement that may be used for the above purposes. The amount and timing of our actual expenditures will depend upon numerous factors, including the results of our research and development efforts, the timing and success of our ongoing preclinical studies and clinical trials or preclinical studies and clinical trials we may commence in the future and the timing of regulatory submissions. As a result, our management will have broad discretion over the use of the net proceeds from this offering and the concurrent private placement.

We believe opportunities may exist from time to time to expand our current business through acquisitions or in-licenses of complementary companies, medicines or technologies. While we have no current agreements, commitments or understandings for any specific acquisitions or in-licenses at this time, we may use a portion of the net proceeds for these.

Pending the use of the proceeds from this offering and the concurrent private placement, we intend to invest the net proceeds in interest-bearing, investment-grade securities, certificates of deposit or direct or guaranteed obligations of the U.S. government.

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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.

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CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization at December 31, 2014, as follows:

- on an actual basis;
- on a pro forma basis to reflect (i) the conversion of all outstanding shares of our convertible preferred stock into 50,117,919 shares of common stock and (ii) the reclassification to additional paid-in capital of our preferred stock warrant liability in connection with the conversion of our outstanding preferred stock warrants into common stock warrants; and
- on a pro forma as adjusted basis to further reflect the receipt of the estimated net proceeds from the sale of 8,470,588 shares of common stock in this offering and the concurrent private placement, after deducting the underwriting discount and estimated expenses payable by us.

You should read this table in conjunction with Selected Consolidated Financial Data and Management s Discussion and Analysis of Financial Condition and Results of Operations and our consolidated financial statements included elsewhere in this prospectus.

	At December 31, 2014		
	Actual	Pro Forma	Pro Forma as Adjusted
	(in thousands, except share and per share data)		
Cash and cash equivalents	$ 119,456	$ 119,456	$ 252,126
Convertible preferred stock warrant liability	$ 100	$	$
Convertible preferred stock, $0.0001 par value per share; 69,716,345 shares authorized, 69,608,339 shares issued and outstanding, actual; no shares authorized, issued and outstanding, pro forma and pro forma as adjusted	139,963		
Stockholders (deficit) equity:			
Preferred stock, $0.0001 par value per share; no shares authorized, issued or outstanding, actual; 10,000,000 shares authorized, no shares issued and outstanding, pro forma and pro forma as adjusted			
Common stock, $0.0001 par value per share; 85,000,000 shares authorized, 361,997 shares issued and outstanding, actual; 300,000,000 shares authorized, 50,479,916 shares issued and outstanding, pro forma; 58,950,504 shares issued and outstanding, pro forma as adjusted		5	6
Additional paid-in capital	346	140,404	273,073
Accumulated deficit	(61,643)	(61,643)	(61,643)

Total stockholders (deficit) equity	(61,297)	78,766	211,436
Total capitalization	$ 78,766	$ 78,766	$ 211,436

The number of shares of common stock in the table above excludes:

- 1,699,940 shares of common stock issuable upon the conversion of Series E convertible preferred stock issued after December 31, 2014;
- 5,970,382 shares of common stock issuable upon the exercise of outstanding stock options at December 31, 2014, with a weighted-average exercise price of $0.80 per share;

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3,181,929 shares of common stock issuable upon the exercise of outstanding options that were granted after December 31, 2014, with a weighted-average exercise price of $1.82 per share;

77,755 shares of common stock issuable upon the exercise of preferred stock warrants at December 31, 2014, with a weighted-average exercise price of $1.69 per share;

1,154,270 shares of common stock issuable upon the exercise of outstanding common stock warrants at December 31, 2014, with a weighted-average exercise price of $0.25 per share;

332,826 shares of common stock reserved for future issuance under our 2009 Stock Plan, which will become available for issuance under our 2015 Plan after consummation of this offering;

6,134,292 shares of common stock, subject to increase on an annual basis, reserved for future issuance under our 2015 Plan, which will become effective immediately prior to the consummation of this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this benefit plan; and

720,000 shares of common stock to be reserved for issuance under our ESPP, which will become effective immediately prior to the consummation of this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this benefit plan.

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DILUTION

If you invest in our common stock, your interest will be diluted to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering.

Net tangible book value per share is determined by dividing our total tangible assets less our total liabilities by the number of shares of common stock outstanding. Our historical net tangible book deficit at December 31, 2014, was $(61.3) million, or $(169.30) per share of common stock. Our pro forma net tangible book value at December 31, 2014, before giving effect to this offering and the concurrent private placement, was $78.8 million, or $1.56 per share of common stock, based on the total number of shares of our common stock outstanding at December 31, 2014, after giving effect to the conversion of all outstanding shares of our convertible preferred stock into common stock. Pro forma net tangible book value, before giving effect to this offering and the concurrent private placement, gives effect to the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 50,117,919 shares of our common stock.

Dilution per share to new investors represents the difference between the amount per share paid by purchasers of shares of common stock in this offering and the concurrent private placement and the pro forma as adjusted net tangible book value per share of common stock immediately after completion of this offering and the concurrent private placement. After giving effect to our sale of shares of common stock in this offering and the concurrent private placement at the initial public offering price of $17.00 per share, after deducting the underwriting discount and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value at December 31, 2014 would have been $211.4 million, or $3.59 per share. This represents an immediate increase in pro forma net tangible book value of $2.03 per share to existing stockholders and an immediate dilution of $13.41 per share to investors participating in this offering, as illustrated in the following table:

Initial public offering price per share		$ 17.00
Historical net tangible book value (deficit) per share at December 31, 2014	$ (169.30)	
Pro forma net tangible book value per share at December 31, 2014, before giving effect to this offering and the concurrent private placement	1.56	
Increase in pro forma net tangible book value (deficit) per share attributable to new investors purchasing shares in this offering and the concurrent private placement	$ 2.03	
Pro forma as adjusted net tangible book value per share after giving effect to this offering and the concurrent private placement		3.59
Dilution per share to investors participating in this offering and the concurrent private placement		$ 13.41

If the underwriters option to purchase additional shares is exercised in full, the pro forma as adjusted net tangible book value per share after this offering would be $3.80 per share, the increase in pro forma as adjusted net tangible book value per share to existing stockholders would be $2.24 per share and the dilution to new investors purchasing shares in this offering would be $13.20 per share.

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The following table presents, on a pro forma as adjusted basis described above, the differences between the existing stockholders and the purchasers of shares in this offering and the concurrent private placement with respect to the number of shares purchased from us, the total consideration paid, which includes net proceeds received from the issuance of common and convertible preferred stock and cash received from the exercise of stock options (in thousands, except per share amounts and percentages):

	Total Shares		Total Consideration		Average Price per Share
	Number	Percent	Amount	Percent	
Existing stockholders before this offering	50,480	85.6%	$ 136,358	48.6%	$ 2.70
Concurrent private placement investor	1,471	2.5	25,000	8.9	17.00
Investors participating in this offering	7,000	11.9	119,000	42.5	17.00
Total	58,951	100%	$ 280,358	100%	$ 4.76

The calculations above are based on 50,479,916 shares outstanding at December 31, 2014 after giving effect to the conversion of all outstanding shares of convertible preferred stock into common stock and exclude:

- 1,699,940 shares of common stock issuable upon the conversion of Series E convertible preferred stock issued after December 31, 2014;
- 5,970,382 shares of common stock issuable upon the exercise of outstanding stock options at December 31, 2014, with a weighted-average exercise price of $0.80 per share;
- 3,181,929 shares of common stock issuable upon the exercise of outstanding options that were granted after December 31, 2014, with a weighted-average exercise price of $1.82 per share;
- 77,755 shares of common stock issuable upon the exercise of preferred stock warrants at December 31, 2014, with a weighted-average exercise price of $1.69 per share;
- 1,154,270 shares of common stock issuable upon the exercise of outstanding common stock warrants at December 31, 2014, with a weighted-average exercise price of $0.25 per share;
- 332,826 shares of common stock reserved for future issuance under our 2009 Stock Plan, which will become available for issuance under our 2015 Plan after consummation of this offering;

6,134,292 shares of common stock, subject to increase on an annual basis, reserved for future issuance under our 2015 Plan, which will become effective immediately prior to the consummation of this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this benefit plan; and

720,000 shares of common stock to be reserved for issuance under our ESPP, which will become effective immediately prior to the consummation of this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this benefit plan.

To the extent that any outstanding options are exercised, new options are issued under our stock-based compensation plans or we issue additional shares of common stock in the future, there will be further dilution to investors participating in this offering.

JJDC, an existing stockholder, has agreed to purchase approximately $10.0 million of shares of our common stock in this offering at the initial public offering price. Certain other of our existing stockholders, including stockholders affiliated with our directors, have agreed to purchase an additional approximately $12.5 million of shares of our common stock in this offering at the initial public offering price.

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SELECTED CONSOLIDATED FINANCIAL DATA

The selected consolidated financial data included in this section are not intended to replace the consolidated financial statements included elsewhere in this prospectus. We derived the selected consolidated statements of operations data for the years ended December 31, 2013 and 2014 and the selected consolidated balance sheet data at December 31, 2013 and 2014 from our audited consolidated financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected in the future. You should read the selected historical consolidated financial data below in conjunction with the section titled Management s Discussion and Analysis of Financial Condition and Results of Operations and the audited consolidated financial statements included elsewhere in this prospectus.

	Year Ended December 31,	
	2013	2014
	(in thousands, except share and per share data)	
Consolidated Statements of Operations Data:		
Revenue:		
Collaboration and license revenue	$	$ 13,038[3]
Grant revenue	828	351
Total revenue	828	13,389
Operating expenses:		
Research and development[1]	10,687	23,513
General and administrative[1]	4,677	8,994
Total operating expenses	15,364	32,507
Loss from operations	(14,536)	(19,118)
Interest expense	(1,371)	(2,395)[4]
Gain on extinguishment of convertible promissory notes		3,553[5]
Other (expense) income, net	(147)	946
Net loss and comprehensive loss	$ (16,054)	$ (17,014)
Net loss per common share, basic and diluted[2]	$ (55.80)	$ (53.06)
Shares used in computing net loss per common share, basic and diluted[2]	287,711	320,686
Pro forma net loss per common share, basic and diluted[2]		$ (0.70)
Shares used in computing pro forma net loss per common share, basic and diluted[2]		28,042,827

(1) Includes stock-based compensation as follows:

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

(2) See Note 16 to our audited consolidated financial statements included elsewhere in this prospectus for an explanation of the calculations of our basic and diluted net loss per common share, pro forma net loss per common share and the weighted-average number of shares used in the computation of the per share amounts.

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(3) Represents the revenue recognized in connection with our collaboration agreements entered into with Janssen in May and November 2014. See Note 7 to our audited consolidated financial statements included elsewhere in this prospectus.

(4) Includes amortization of debt discount associated with convertible promissory notes due to the issuance of warrants and beneficial conversion feature associated with such convertible promissory notes. See Note 5 to our audited consolidated financial statements included elsewhere in this prospectus.

(5) Upon the conversion of convertible promissory notes to related parties into Series C convertible preferred stock in May 2014, a gain on extinguishment was recorded because the amount allocated to reacquire the convertible notes was less than the carrying value of the notes. See Note 5 to our audited consolidated financial statements included elsewhere in this prospectus.

	At December 31,	
	2013	2014
	(in thousands)	
Consolidated Balance Sheet Data:		
Cash and cash equivalents	$ 8,532	$ 119,456
Working capital	(5,075)	81,006
Total assets	9,880	126,462
Note payable to related party	200	
Convertible promissory notes payable to related parties, net	12,789	
Convertible preferred stock warrant liability	72	100
Common stock warrant liability	505	889
Convertible preferred stock	32,224	139,963
Accumulated deficit	(44,629)	(61,643)
Total stockholders deficit	(38,758)	(61,297)

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MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with the section of this prospectus titled Selected Consolidated Financial Data and our consolidated financial statements included elsewhere in this prospectus. This discussion and other parts of this prospectus 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 prospectus, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage immuno-oncology company focused on the development of first-in-class technology platforms designed to stimulate robust and durable immune responses against cancer, and our lead product candidate is in a randomized controlled Phase 2b clinical trial in metastatic pancreatic cancer. Immuno- oncology encompasses a class of therapies that leverage the patient s immune system to slow the growth and spread of, or eliminate, tumor cells. We believe a critical distinguishing factor in our approach to immuno- oncology is that our novel therapies initiate powerful innate immune responses and drive targeted, durable adaptive immune responses. The immunotherapy field is rapidly advancing with new immuno-oncology combinations that focus on strengthening therapeutic efficacy in a wide range of cancers. We intend to pursue a broad strategy of combining our technology platforms with conventional and novel immuno-oncology therapies, based on their mechanisms of action, safety profiles and versatility. Our pipeline of immuno-oncology product candidates is derived from two proprietary technology platforms: Live, Attenuated, Double-Deleted, or LADD, *Listeria monocytogenes* and cyclic dinucleotides, or CDNs. Our lead LADD product candidate, CRS-207, is currently being developed in metastatic pancreatic cancer and unresectable malignant pleural mesothelioma. In a completed randomized controlled Phase 2a clinical trial in metastatic pancreatic cancer patients, CRS-207 demonstrated a statistically significant improvement in overall survival when combined with GVAX Pancreas, a cellular vaccine product candidate. The 93-patient two-arm Phase 2a clinical trial was designed to compare the combination of CRS-207 and GVAX Pancreas versus GVAX Pancreas alone. The trial met the primary efficacy endpoint of overall survival at an interim analysis and was stopped upon recommendation from the Data Monitoring Committee. Based on the data from this study, our lead immuno-oncology regimen of CRS-207 and GVAX Pancreas was granted Breakthrough Therapy designation by the U.S. Food and Drug Administration, or FDA. Breakthrough Therapy designation is intended to expedite the development and review of products that treat serious or life-threatening conditions. We have obtained orphan drug designations from the FDA for CRS-207 and GVAX Pancreas for the treatment of pancreatic cancer and for CRS-207 for the treatment of mesothelioma. Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biologic intended to treat a rare disease or condition. Orphan drug designation entitles a party to certain financial incentives and can provide limited market exclusivity in certain circumstances. We are developing a pipeline of proprietary product candidates, including two product candidates in collaboration with Janssen Biotech, Inc., or Janssen, targeting prostate and lung cancer. In addition, we established a worldwide collaboration with Novartis Pharmaceuticals Corporation, or Novartis, for CDN product candidates in oncology. We have intellectual property protection on both of our technology platforms and each of our product candidates, which we believe we will maintain into the 2030s.

Both of our technology platforms, LADD and CDN, are designed to activate and stimulate a patient s immune system to specifically target cancer cells. Our LADD technology platform is based on a naturally pathogenic bacterium, *Listeria monocytogenes*, which induces a strong innate immune response. In order to engineer this bacterium for therapeutic use, we modify the *Listeria* with two proprietary gene deletions, substantially reducing its natural disease-causing properties. We then engineer specific LADD product candidates to express and secrete tumor antigens

that stimulate the adaptive immune system to mount a powerful cellular attack on tumors. The intended effect is to prime and enhance the innate and adaptive immune responses and deliver an antigen-specific T cell attack against the target tumor cells. Our proprietary CDN technology platform comprises synthetic small molecule immune modulators that target and activate Stimulator of Interferon Genes, or STING,

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receptors that are generally expressed at high levels in immune cells. Once activated, STING receptors prime and enhance the innate immune response by signaling through multiple distinct pathways. These signals activate the expression of a broad profile of cytokines that initiate the development of an effective adaptive immune response. Recent advancements reported in numerous leading scientific journals have created interest in the potential for STING receptor-targeting drug candidates for a broad range of therapeutic applications.

Our pipeline of product candidates has the potential to be applicable to a variety of cancers and to be combinable with many conventional and emerging cancer therapies, including cellular vaccines, chemotherapy, radiotherapy and checkpoint inhibitors, among others. Our most advanced immuno-oncology regimen, currently in a Phase 2b clinical trial known as ECLIPSE, assesses the combination of our lead LADD product candidate, CRS-207, with GVAX Pancreas to treat late-stage metastatic pancreatic cancer patients who have received at least one prior line of therapy. GVAX Pancreas is a potentially synergistic combination candidate that is designed to induce T cells against an array of pancreatic cancer antigens to enable a broad-based immune response, and has demonstrated a favorable safety profile in clinical trial to date. We expect to report top line results from ECLIPSE in the first half of 2016. In addition, we are evaluating CRS-207 in combination with chemotherapy in unresectable malignant pleural mesothelioma and have a planned study of CRS-207 in combination with GVAX Pancreas and an anti-PD-1 checkpoint inhibitor in metastatic pancreatic cancer. We also have ongoing and planned clinical development programs evaluating LADD regimens for glioblastoma multiforme and ovarian cancer, and collaborations with Janssen for lung and prostate cancers. We also envision multiple product opportunities for the CDN technology platform. Because STING receptors are known to be important for immune surveillance and control of cancer progression, we believe that STING receptors represent an attractive target for novel drug candidates. We are developing CDN product candidates as impactful therapies that are intended to prime and enhance the innate and adaptive immune responses. Based on their mechanism of action, our CDN product candidates may also have synergistic or additive benefits when combined with other cancer therapies.

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 convertible preferred stock, the issuance of convertible promissory notes, revenue from government grants and licensing agreements with pharmaceutical partners. We incurred a net loss of $16.1 million and $17.0 million for the years ended December 31, 2013 and 2014, respectively. At December 31, 2014, our accumulated deficit was $61.6 million.

Financial Operations Overview

Revenue

We have not generated any revenue from product sales. Our revenue to date has been primarily derived from research and development grants from the U.S. government and two separate research and license agreements we entered into with Janssen, which became effective in May 2014 and in November 2014. We recognize revenue related to research and development grants when the related research expenses are incurred and our specific performance obligations under the terms of the respective contracts are satisfied. We recognize revenue from upfront payments under our Janssen agreements ratably over the term of our estimated period of performance under the agreement. In addition to receiving upfront payments, we may also be entitled to milestone and other contingent payments upon achieving predefined objectives. Revenue from milestones, if they are nonrefundable and deemed substantive, are recognized upon successful accomplishment of the milestones. To the extent that non-substantive milestones are achieved and we have remaining performance obligations, milestones are deferred and recognized as revenue over the estimated remaining period of performance.

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

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Research and Development Expenses

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

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

General and Administrative Expenses

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

Interest Expense

Interest expense consists of amortization of debt discount associated with convertible promissory note warrants, issuance of the equity component of a convertible promissory note and beneficial conversion features associated with certain convertible promissory notes, as well as stated interest costs associated with our borrowings.

Gain on Extinguishment of Convertible Promissory Notes

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

Other Income (Expense), Net

Other income (expense), net, consists of gains and losses from the remeasurement of the fair value of our liabilities related to our convertible preferred stock warrants and common stock warrants, the change in the fair value of the preferred stock derivative liability associated with our obligation to issue additional shares of Series C convertible preferred stock, and interest income earned on our cash and cash equivalents.

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Our convertible preferred stock warrants are exercisable into shares that are contingently redeemable and our common stock warrants are subject to performance conditions that may result in the issuance of a variable number of shares. As such, we have classified these warrants as liabilities in the consolidated balance sheets at their estimated fair values, and we record the change in the estimated fair values each reporting period as other income (expense), net. We will continue to record adjustments to the estimated fair values of the convertible preferred stock and common stock warrants until they are exercised or expire.

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

Results of Operations

Comparison of the Years Ended December 31, 2013 and 2014

	Year Ended December 31,		Change
	2013	2014	$
	(in thousands)		
Revenue:			
Collaboration and license revenue	$	$ 13,038	$ 13,038
Grant revenue	828	351	(477)
Total revenue	828	13,389	12,561
Operating expenses:			
Research and development	10,687	23,513	12,826
General and administrative	4,677	8,994	4,317
Total operating expenses	15,364	32,507	17,143
Loss from operations	(14,536)	(19,118)	(4,582)
Interest expense	(1,371)	(2,395)	(1,024)
Gain on extinguishment of convertible promissory notes		3,553	3,553
Other income (expense), net	(147)	946	1,093
Net loss and comprehensive loss	$ (16,054)	$ (17,014)	$ (960)

Revenue

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

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

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Research and Development Expenses

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

	Year Ended December 31,		Change
	2013	2014	$
	(in thousands)		
Clinical development	$ 3,196	$ 7,547	$ 4,351
Contract manufacturing	1,323	5,246	3,923
Other research and development costs	1,244	3,611	2,367
Compensation and related personnel costs	3,245	5,212	1,967
Licensing fees	461	1,617	1,156
Facility costs	218	280	62
Acquired GVAX technology	1,000		(1,000)
Total research and development	$ 10,687	$ 23,513	$ 12,826

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

General and Administrative Expenses

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

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

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

Interest Expense

Interest expense was $2.4 million for the year ended December 31, 2014, an increase of $1.0 million, compared to the year ended 2013. The increase was primarily attributed to the amortization of debt discount

associated with the warrants and beneficial conversion feature associated with our convertible promissory notes payable to related parties.

Gain on Extinguishment of Convertible Promissory Notes

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

Other Income (Expense), Net

Other income (expense), net increased by $1.1 million for the year ended December 31, 2014, compared to the year ended 2013. The increase was primarily due to the remeasurement of the fair value of the preferred stock derivative liability associated with the future issuance of our Series C convertible preferred stock. At December 31, 2014, there was no obligation remaining related to the future issuance of our Series C convertible preferred stock and therefore no preferred stock derivative liability on the consolidated balance sheets. The increase was partially offset by other expenses recognized for remeasurement of common and preferred stock warrants.

Liquidity and Capital Resources

Our operations have been financed primarily by net proceeds from the sale of convertible preferred stock, issuance of convertible promissory notes, revenue from government grants and proceeds from our Janssen research and license agreements. At December 31, 2014, we had cash and cash equivalents of $119.5 million.

Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, third-party clinical research and development services, laboratory and related supplies, clinical costs and other regulatory expenses. Cash used to fund operating expenses is impacted by the timing of when we pay expenses, as reflected in the change in our outstanding accounts payable and accrued expenses. We expect to incur substantial expenditures in the foreseeable future for the development and potential commercialization of our product candidates. Specifically, we have incurred and we expect to continue to incur substantial expenses in connection with our Phase 2b ECLIPSE clinical trial for metastatic pancreatic cancer.

We plan to continue to fund our operations and capital funding needs through equity and/or debt financing. We may also consider entering into additional collaboration arrangements or selectively partnering for clinical development and commercialization. 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. If we are not able to secure adequate additional funding, we may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible and/or suspend or curtail planned programs. Any of these actions could harm our business, results of operations, financial condition and future prospects.

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Cash Flows

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

	Year Ended December 31,	
	2013	2014
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (14,232)	$ 19,365
Investing activities	(170)	(782)
Financing activities	19,239	92,341
Net change in cash and cash equivalents	$ 4,837	$ 110,924

Operating Activities

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

Investing Activities

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

Financing Activities

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

Operating Capital Requirements and Plan of Operations

We do not expect to generate significant revenue from product sales unless and until we obtain regulatory approval of and commercialize our current or any future product candidates. We anticipate that we will continue to generate losses for the foreseeable future, and we expect the losses to increase as we continue the development of and seek regulatory approvals for our product candidates and begin to commercialize any approved products. We are subject to all of the risks pertinent to the development of new products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may harm our business. Upon the closing of this offering, we

expect to incur additional costs associated with operating as a public company and we anticipate that we will need substantial additional funding in connection with our continuing operations.

We believe that our existing capital resources, not including potential milestone payments and the proceeds we receive from this offering, will be sufficient to meet our projected operating requirements through

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the end of 2016. If we need to raise additional capital to fund our operations and complete our ongoing and planned clinical studies, funding may not be available to us on acceptable terms, or at all.

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

- the scope, rate of progress, results and cost of our clinical studies and other related activities;
- the cost of manufacturing clinical supplies and establishing commercial supplies of our product candidate and any other products that we may develop;
- the cost, timing and outcomes of regulatory approvals;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish, including any required milestone and royalty payments thereunder; and
- the emergence of competing technologies or other adverse market developments.

Critical Accounting Polices and Significant Judgments and Estimates

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

Revenue Recognition

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

Revenues from research activities made under collaboration arrangements are recognized when there is persuasive evidence that an arrangement exists, services have been rendered, the price is fixed or determinable and collectability is reasonably assured. Revenue generated from our collaboration arrangements is not subject to repayment and typically includes upfront fees, milestone payments and royalties on future licensee s product sales. Our obligations under collaboration agreements may include the transfer of intellectual property rights in the form of licenses, obligations to provide research and development services and obligations to participate on certain development committees with the collaboration party. We make judgments that affect the period over which we recognize revenue. On a quarterly basis, we review our estimated period of performance for our

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collaboration and license revenue based on the progress under the arrangement and account for the impact of any changes in estimated periods of performance on a prospective basis. We record amounts received prior to satisfying the above revenue recognition criteria as deferred revenue until all applicable revenue recognition criteria are met. Deferred revenue represents the portion of research or license payments received that have not been earned.

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

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

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 expense in the statement of operations and comprehensive loss. These costs are a significant component of our research and development expenses. We record accrued expenses for these costs based on the estimated amount of work completed and in accordance with agreements established with these third parties.

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

Stock-Based Compensation

We recognize compensation costs related to stock options granted to employees and directors based on the estimated fair value of the awards on the date of grant, net of estimated forfeitures. We estimate the grant date

fair value using the Black-Scholes option-pricing model. The grant date fair value of the stock-based awards is generally recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective awards.

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

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

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

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

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

In addition to the Black-Scholes assumptions, we estimate our forfeiture rate based on an analysis of our actual forfeitures and will continue to evaluate the adequacy of the forfeiture rate based on actual forfeiture experience, analysis of employee turnover behavior and other factors. The impact from any forfeiture rate adjustment would be recognized in full in the period of adjustment, and if the actual number of future forfeitures differs from our estimates, we might be required to record adjustments to stock-based compensation in future periods.

Historically, for all periods prior to this offering, the fair value of the shares of common stock underlying our share-based awards were estimated on each grant date by our board of directors. In order to determine the fair value of our common stock underlying option grants, our board of directors considered, among other things, contemporaneous valuations of our common stock prepared by an unrelated third-party valuation firm at February 28, 2013, March 31, 2014, June 30, 2014, September 30, 2014 and December 31, 2014 in accordance with the guidance provide by the American Institute of Certified Public Accountants Practice Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. Given the absence of a public trading market for our common stock, our board of directors exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of our common stock, including our stage of development; progress of our research and development efforts; the rights, preferences and privileges of our preferred stock relative to those of our common stock; equity market conditions affecting comparable public companies and the lack of marketability of our common stock.

The unrelated third-party valuations were prepared using the discounted cash flow approach to estimate our aggregate enterprise value at each valuation date. To arrive at the estimated fair value of our common stock, the enterprise value was allocated across our classes and series of capital stock using the Probability Weighted Expected Return Method, or PWERM, or Option Pricing Method, or OPM. The PWERM is a scenario-based analysis that estimates the value per share of common stock based on the probability-weighted present value of

expected future equity values for the common stock, under various possible future liquidity event scenarios, including initial public offering, sale of the company, dissolution and staying private. The OPM values each equity class by creating a series of call options on the equity value, with exercise prices based on the liquidation preferences, participation rights and strike prices of derivatives.

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

The intrinsic value of all outstanding options at December 31, 2014 was $96.9 million based on the initial public offering price of $17.00 per share.

Estimated Fair Value of Convertible Preferred Stock Warrants and Common Stock Warrants

Warrants for shares that are contingently redeemable, such as our convertible preferred stock, and common stock warrants subject to performance conditions that may result in the issuance of a variable number of shares are accounted for as freestanding financial instruments. These warrants are classified as liabilities on our consolidated balance sheets and are recorded at their estimated fair value. At the end of each reporting period, changes in the estimated fair value during the period are recorded as a component of other income (expense), net. We will continue to adjust these liabilities for changes in fair value until the earlier of the conversion to common stock warrants, performance conditions met, expiration or the exercise of the warrants.

We estimate the fair values of our convertible preferred stock warrants and common stock warrants using an option pricing model based on inputs as of the valuation measurement dates, including the fair values of our convertible preferred stock and common stock, the estimated volatility of the price of our convertible preferred stock and common stock, the expected term of the warrants and the risk-free interest rates.

Estimated Fair Value of Preferred Stock Derivative Liability

We have determined that our obligation to issue and our investor s obligation to purchase additional shares of convertible preferred stock represented a freestanding financial instrument, which we accounted for as a liability. The freestanding convertible preferred stock derivative liability was initially recorded at fair value, with fair value changes recognized at each balance sheet date as increases or decreases to other income (expense), net in the statement of operations and comprehensive loss. At the time of the exercise of the option, we remeasured the obligation to fair value with the change recognized in other income (expense), net on the consolidated statements of operations and comprehensive loss. The remaining value of the option subsequent to remeasurement was recorded as a capital transaction.

Income Taxes

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

At December 31, 2014, we generated net operating loss, or NOL, carryforwards (before tax effects) for federal and state income tax purposes of $51.2 million and $6.0 million, respectively. These federal and state NOL carryforwards will begin to expire in 2027 and 2017, respectively, if not utilized. In addition, we generated federal and state research and development tax credit carryforwards of $0.3 million and $0.9 million,

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respectively, to offset future income tax liabilities. The federal research and development tax credits can be carried forward for 20 years and will start to expire in 2034, if not utilized, while the state research and development tax credits can be carried forward indefinitely. Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, our ability to utilize NOL carryforwards or other tax attributes, such as research tax credits, in any taxable year may be limited if we have experienced an ownership change. We performed a Section 382 analysis and believe that we experienced multiple ownership changes under Section 382 of the Code and as a result our federal and state NOLs and tax credits are subject to limitation.

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.

Contractual Obligations and Other Commitments

The following table summarizes our contractual obligations at December 31, 2014:

	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	$ 392	$ 261	$	$	$ 653
Total contractual obligations	$ 392	$ 261	$	$	$ 653

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.

Off-Balance Sheet Arrangements

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

Quantitative and Qualitative Disclosures about Market Risk

At December 31, 2014, we had cash and cash equivalents of $119.5 million, which consisted primarily of bank deposits. Such interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations of

interest income have not been significant.

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

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JOBS Act Accounting Election

We are an emerging growth company, as defined in the JOBS Act of 2012. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards, and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2014-09 (Accounting Standards Codification Topic, or ASC, 606), *Revenue from Contracts with Customers*. ASU 2014-09 affects any entity that either enters into contracts with customers to transfer goods and services or enters into contracts for the transfer of nonfinancial assets. ASU 2014-09 will replace most existing revenue recognition guidance when it becomes effective. The standard s core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In doing so, companies will need to use more judgment and make more estimates than under the currently effective guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. ASU 2014-09 is effective for annual periods beginning after December 15, 2016, including interim periods within that period. Early adoption is not permitted. We are currently evaluating the impact of this guidance on our consolidated financial statements.

In June 2014, the FASB issued ASU 2014-10, *Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation.* ASU 2014-10 simplifies the accounting guidance by removing all incremental financial reporting requirements for development stage entities. The amendments related to the elimination of the inception-to-date information and other disclosure requirements of Topic 915 should be applied retrospectively and are effective for annual reporting periods beginning after December 15, 2014 and interim periods therein. The Company has elected to early adopt this guidance and, accordingly, there is no inception to date information presented in these consolidated financial statements.

In August 2014, the FASB issued ASU 2014-15, *Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern*. ASU 2014-15 requires management to evaluate whether there is substantial doubt about an entity s ability to continue as a going concern and to provide related footnote disclosures. In doing so, companies will have reduced diversity in the timing and content of footnote disclosures than under today s guidance. ASU 2014-15 is effective for the first quarter of 2016 with early adoption permitted. We do not believe the impact of adopting ASU 2014-15 on our consolidated financial statements will be material.

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BUSINESS

Overview

We are a clinical-stage immuno-oncology company focused on the development of first-in-class technology platforms designed to stimulate robust and durable immune responses against cancer, and our lead product candidate is in a randomized controlled Phase 2b clinical trial in metastatic pancreatic cancer. Immuno-oncology encompasses a class of therapies that leverage the patient s immune system to slow the growth and spread of, or eliminate, tumor cells. We believe a critical distinguishing factor in our approach to immuno-oncology is that our novel therapies initiate powerful innate immune responses and drive targeted, durable adaptive immune responses. Another key attribute of our approach to immuno-oncology is the versatility of our technology platforms to generate customized and combinable therapies to target a wide range of cancers. Our pipeline of immuno-oncology product candidates is derived from two proprietary technology platforms: Live, Attenuated, Double-Deleted, or LADD, *Listeria monocytogenes* and cyclic dinucleotides, or CDNs. Our lead LADD product candidate, CRS-207, is currently being developed in metastatic pancreatic cancer and unresectable malignant pleural mesothelioma. In a completed randomized controlled Phase 2a clinical trial in metastatic pancreatic cancer patients, CRS-207 demonstrated a statistically significant improvement in overall survival when combined with GVAX Pancreas, a cellular vaccine product candidate. The 93-patient two-arm Phase 2a clinical trial was designed to compare the combination of CRS-207 and GVAX Pancreas versus GVAX Pancreas alone. The trial met the primary efficacy endpoint of overall survival at an interim analysis and was stopped upon recommendation from the Data Monitoring Committee. Based on the data from this study, our lead immuno-oncology regimen of CRS-207 and GVAX Pancreas was granted Breakthrough Therapy designation by the U.S. Food and Drug Administration, or FDA. Breakthrough Therapy designation is intended to expedite the development and review of products that treat serious or life-threatening conditions. We have obtained orphan drug designations from the FDA for CRS-207 and GVAX Pancreas for the treatment of pancreatic cancer and for CRS-207 for the treatment of mesothelioma. Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biologic intended to treat a rare disease or condition. Orphan drug designation entitles a party to certain financial incentives and can provide limited market exclusivity in certain circumstances. We are developing a pipeline of proprietary product candidates, including two product candidates in collaboration with Janssen Biotech, Inc., or Janssen, targeting prostate and lung cancers. In addition, we established a worldwide collaboration with Novartis Pharmaceuticals Corporation, or Novatis, for CDN product candidates in oncology. We have intellectual property protection on both of our technology platforms and each of our product candidates, which we believe we will maintain into the 2030s.

Despite recent advances in the treatment of cancer over the past few decades, cancer remains the second leading cause of death in the United States and cancer treatment represents a major unmet medical need. Immuno-oncology is an emerging field of cancer therapy that aims to activate the immune system in the tumor microenvironment to create and enhance anti-tumor immune responses, as well as to overcome the immuno-suppressive mechanisms that cancer cells have developed against the immune system. Recent developments in the field of immuno-oncology, including checkpoint inhibitors therapies that have mechanisms focused on unmasking hidden cancer cells have shown the potential to provide dramatic efficacy responses and extended survival, even in cancers where conventional therapies such as surgery, chemotherapy and radiotherapy have failed. Based on these advancements, immuno-oncology is becoming a new frontier for cancer drug development, and we believe it is one of the most promising areas of research and development within the pharmaceutical industry.

Both of our technology platforms, LADD and CDN, are designed to activate and stimulate a patient s immune system to specifically target cancer cells. Our LADD technology platform is based on a naturally pathogenic bacterium, *Listeria monocytogenes*, which induces a strong innate immune response. In order to engineer this bacterium for therapeutic use, we modify the *Listeria* with two proprietary gene deletions, substantially reducing its natural

disease-causing properties. We then engineer specific LADD product candidates to express and secrete tumor antigens that stimulate the adaptive immune system to mount a powerful cellular attack on tumors. The intended effect is to prime and enhance the innate and adaptive immune responses and deliver an antigen-specific T cell attack against the target tumor cells. Our proprietary CDN technology platform comprises synthetic small molecule immune modulators that target and activate Stimulator of Interferon Genes, or STING,

receptors that are generally expressed at high levels in immune cells. Once activated, STING receptors prime and enhance the innate immune response by signaling through multiple distinct pathways. These signals activate the expression of a broad profile of cytokines that initiate the development of an effective adaptive immune response. Recent advancements reported in numerous leading scientific journals have created interest in the potential for STING receptor-targeting drug candidates for a broad range of therapeutic applications.

Our pipeline of product candidates has the potential to be applicable to a variety of cancers and to be combinable with many conventional and emerging cancer therapies, including cellular vaccines, chemotherapy, radiotherapy and checkpoint inhibitors, among others. Our most advanced immuno-oncology regimen, currently in a Phase 2b clinical trial known as ECLIPSE, assesses the combination of our lead LADD product candidate, CRS-207, with GVAX Pancreas, to treat late-stage metastatic pancreatic cancer patients who have received at least one prior line of therapy. GVAX Pancreas is a potentially synergistic combination candidate that is designed to induce T cells against an array of pancreatic cancer antigens to enable a broad-based immune response and has demonstrated a favorable safety profile in clinical trial to date. We expect to report top line results from ECLIPSE in the first half of 2016. In addition, we are evaluating CRS-207 in combination with chemotherapy in unresectable malignant pleural mesothelioma and have a planned study of CRS-207 in combination with GVAX Pancreas and an anti-PD-1 checkpoint inhibitor in metastatic pancreatic cancer. We also have ongoing and planned clinical development programs evaluating LADD regimens for glioblastoma multiforme and ovarian cancer, and with Janssen in lung and prostate cancers.

We also envision multiple product opportunities for the CDN technology platform. Because STING receptors are known to be critical for immune surveillance and control of cancer progression, we believe that STING receptors represent an attractive target for novel drug candidates. We are developing CDN product candidates as impactful therapies that are intended to prime and enhance the innate and adaptive immune responses, and we have entered into a worldwide collaboration with Novartis for CDN product candidates in oncology. Based on their mechanism of action, our CDN product candidates may also have synergistic or additive benefits when combined with other cancer therapies.

Our vision is to leverage our scientific expertise and understanding of the body s natural defense systems, including the interplay between the innate and adaptive immune responses, to develop safe and effective therapies for the benefit of patients.

Our Proprietary Technology Platforms

We have developed first-in-class technology platforms, LADD and CDN, to prime and enhance immune responses to cancer in indications with significant unmet medical need. We believe our technology platforms represent innovative approaches in immuno-oncology that leverage the potential of the patient s immune system to initiate a powerful innate immune response and to drive a targeted and durable adaptive immune response against cancer.

Live, Attenuated, Double-Deleted **Listeria Monocytogenes**

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

technology platform include:

Early Evidence of Efficacy. Our randomized controlled Phase 2a clinical trial in patients with metastatic pancreatic cancer who had received or refused prior therapy demonstrated improved overall survival.

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Novel Mechanism. Our LADD product candidates are designed to initiate a powerful innate immune response and drive a targeted, durable adaptive immune response.

Early Evidence of Safety in Preclinical Studies and Clinical Trials. Through our proprietary deletion of two genes that contribute to *Listeria* s virulence, we substantially reduce the natural disease-causing properties of *Listeria*, creating stable product candidates suitable for therapeutic use.

Versatility. Individual LADD product candidates can be engineered to target a wide range of cancers by promoting anti-tumor immune responses against antigens associated with specific tumors.

Combinability. The mechanisms of action and safety profile of our LADD product candidates may give them the potential for combination with conventional and novel therapies, such as cellular vaccines, chemotherapy, radiotherapy and checkpoint inhibitors, among others.

Repeatable Administration. Our LADD product candidates are not neutralized by the patient s immune system and are designed for repeat administration, thus allowing a chronic therapy for a sustained tumor antigen-specific response.

Cost-effectiveness. Our LADD product candidates are not personalized for each patient and can be manufactured through a relatively simple and cost-effective fermentation process.

We have engineered and developed proprietary LADD product candidates that are currently under evaluation in clinical trials in metastatic pancreatic cancer, unresectable malignant pleural mesothelioma and glioblastoma multiforme. Further, we are planning additional clinical development programs in indications with significant unmet medical need, such as ovarian, lung and prostate cancers. For large or complex indications, we are pursuing collaborations on a product-by-product basis. As part of this strategy, in May 2014 we entered into a collaboration with Janssen for the development of a LADD product candidate for prostate cancer. Subsequently, we entered into a second collaboration with Janssen for the development of a LADD product candidate for lung cancer, and this agreement became effective in November 2014. In July 2014, our lead immuno-oncology regimen of CRS-207 combined with GVAX Pancreas was granted Breakthrough Therapy designation by the FDA based on Phase 2a clinical trial results that showed a statistically significant improvement in overall survival in patients with metastatic pancreatic cancer who had received or refused prior therapy.

Cyclic Dinucleotides

Our proprietary CDN product candidates are synthetic small molecule immune modulators that are designed to target and activate a receptor known as the STING receptor. Once activated, the STING receptor initiates a profound innate immune response by signaling through three distinct pathways, inducing the expression of a broad profile of cytokines that activate the development of an effective tumor antigen-specific T cell adaptive immune response. The STING receptor is generally expressed at high levels in the cytosol of immune cells, including DCs. Recent advancements reported in numerous leading scientific journals have created interest in the potential for STING receptor-targeting drug candidates across diverse applications. We believe the STING receptor represents an attractive target for novel drug candidates because it is known to be critical for immune surveillance and control of cancer progression. We are developing CDN product candidates as therapies that are intended to prime and enhance the innate and adaptive

immune response, and we have entered into a worldwide collaboration agreement with Novartis for CDN product candidates in oncology. Our proprietary synthetic CDN product candidates are significantly more potent than naturally occurring CDN molecules, indicating high translational potential as a therapeutic approach to elicit an effective immune response. We believe key attributes of our CDN technology platform are:

Early Evidence of Potency. Our CDN product candidates have demonstrated significant anti-tumor activity in pre-clinical studies.

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Novel Mechanism. Our CDN 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 CDN product candidates can be effectively delivered via intratumoral, or IT, injection, systemic delivery via formulation and other novel modalities such as conjugation with antibodies.

Combinability. Based on their mechanism of action, we believe our CDN product candidates may have synergistic or additive benefits of immune-mediated tumor killing mechanisms when combined with conventional and novel therapies such as cellular vaccines, chemotherapy, radiotherapy and checkpoint inhibitors, among others.

Ease of Manufacture. Our CDN product candidates are small molecules manufactured through a relatively simple and cost-effective process.

Broad Applicability. We believe our CDN product candidates will have broad application in oncology and the potential to expand into other therapeutic areas such as infectious and autoimmune diseases.

Our preclinical studies utilizing our synthetic CDN derivatives resulted in eradication of treated tumors and induction of systemic tumor-specific immunity in several aggressive preclinical tumor models. Based on the results of these preclinical studies, we believe our proprietary CDN derivatives are significantly more potent than natural stimulators of the STING receptor.

Key Advantages of the Aduro Approach

Immuno-oncology is an emerging field of cancer treatment that aims to directly activate the immune system in the tumor microenvironment to create and enhance anti-tumor immune responses, as well as to overcome the immuno-suppressive mechanisms that cancer cells have developed against the immune system. There are two general approaches to immuno-oncology: create and expand the anti-tumor immune response and remove the brakes placed on the immune response by the tumor s defenses. By focusing on the create and expand approach, our technology platforms are designed to prime and enhance innate and tumor-specific adaptive immune responses against the target tumor cells.

We believe several advantages to our approach include:

Our product candidates are engineered to prime and enhance both the innate and adaptive immune responses against tumors. We believe that leveraging both the innate and adaptive immune responses is a novel approach to immuno-oncology that differentiates our technology platforms from current and conventional therapies and has the potential to create best-in-class cancer therapies. Our LADD product candidates efficiently enter circulating APCs, priming and enhancing a potent innate immune response and an adaptive immune response to fight cancer. By stimulating the expression of a broad profile of cytokines, our CDN product candidates are designed to directly activate the tumor microenvironment and enhance recognition of the tumor by the immune system, leading to tumor

destruction and long-lasting anti-tumoral immunological memory. This proprietary synthetic molecule is significantly more potent than naturally occurring CDN molecules and toll-like receptor, or TLR, agonists, indicating a high potential as a therapeutic approach against diverse tumor types.

By working to stimulate the patient s immune system, our product candidates have the potential to be well-tolerated and safe, relative to many existing treatments. Because our

therapies are designed to prime and enhance the body s natural innate and adaptive immune responses, we believe that our approach may offer a safer treatment alternative to conventional oncology approaches such as chemotherapy, radiotherapy and antibody therapies. To date, our LADD product candidates have been well-tolerated in the clinical setting.

Based on their mechanism of action and safety profiles, our therapies have the potential to be readily combinable and synergistic with both conventional and novel therapies. Our most advanced regimen, currently in our Phase 2b ECLIPSE clinical trial, is an immuno-oncology regimen that assesses the combination of CRS-207, with GVAX Pancreas. In an earlier randomized controlled Phase 2a clinical trial, this combination regimen demonstrated a statistically significant overall survival benefit in patients with metastatic pancreatic cancer who had received or refused prior therapy, when compared to patients receiving GVAX Pancreas alone. GVAX Pancreas is a potentially synergistic combination candidate that is designed to induce T cells against an array of pancreatic cancer antigens to enable a broad-based immune response with a well-established, favorable safety profile. We believe CRS-207 has further potential to enhance therapeutic outcomes when combined with other cancer treatments. CRS-207 is also under investigation for use in combination with chemotherapy in patients with unresectable malignant pleural mesothelioma who have not received prior therapy. In preclinical studies, we have shown that our proprietary CDN product candidates can be co-formulated with designated recombinant proteins to induce potent antigen-specific helper T cell, or CD4+ T cell, and cytotoxic T cell, or CD8+ T cell, immunity.

Our create and expand approach to immuno-oncology may have a role alongside other potentially complementary immuno-oncology therapies that have mechanisms focused on the remove the brakes approach, such as checkpoint inhibitors. Many of the immuno-oncology therapies in development center on the remove the brakes approach, which works by overcoming immunosuppressive pathways that mask a tumor from the body s immune system. Some of the most advanced technologies are anti-PD-1/PD-L1 monoclonal antibodies, a class of checkpoint inhibitors that target these immunosuppressive pathways. By impairing the interaction of the inhibitory receptor PD-1 on T cells, which we refer to as removing the brakes, these checkpoint inhibitors strengthen the anti-tumor T cell response. We believe that our approach to create and expand the immune response will be synergistic to these remove the brakes approaches and allow our technology to play an important role in the overall immuno-oncology treatment paradigm.

Our versatile LADD and CDN technology platforms have produced a deep pipeline and have the potential to produce a breadth of future development opportunities. Our lead LADD product candidate, CRS-207, is engineered to stimulate a response to mesothelin, an antigen expressed by multiple tumor types. Thus, our ongoing clinical trials involving CRS-207 are focused on assessing CRS-207 for the treatment of mesothelin-based tumors in metastatic pancreatic cancer and unresectable malignant pleural mesothelioma. We anticipate conducting additional studies of CRS-207 in other tumor types that express high levels of mesothelin. We have developed other proprietary LADD product candidates to target prostate cancer, lung cancer and glioblastoma multiforme and intend to explore the development of additional LADD product candidates to target other cancers. With our CDN technology program, we are exploring various delivery methods and formulations, as well as the potential to expand their application into other disease areas beyond oncology. In addition, we have entered into a worldwide collaboration with Novatis for CDN product candidates in oncology.

Our Strategy

Our current focus is to develop and commercialize best-in-class cancer therapies using our LADD and CDN technology platforms. Key elements of our strategy include:

Rapidly advance CRS-207 through clinical development and regulatory approval. We are currently conducting our Phase 2b ECLIPSE clinical trial of CRS-207 in combination with GVAX

Pancreas in patients with metastatic pancreatic cancer who have received at least one prior line of therapy. We expect to complete enrollment in the third quarter of 2015 and to report top line results in the first half of 2016. Assuming positive clinical results in pancreatic cancer studies, we plan to seek regulatory approval of CRS-207 in the United States, Europe and other major geographies around the world.

Maximize the commercial value of our proprietary LADD and CDN technology platforms. We currently have global development, marketing and commercialization rights for our lead product candidate, CRS-207, as well as additional LADD product candidates. If we obtain regulatory approvals for CRS-207 in pancreatic cancer or other indications, we plan to build a commercial organization with a specialty sales force to market CRS-207. We also plan to retain commercial rights to additional LADD product candidates. In addition, we established a worldwide collaboration with Novartis for CDN product candidates in oncology. We also maintain worldwide rights to our CDN technology platform outside of oncology.

Develop novel drug candidates by leveraging our proprietary technology platforms and our understanding of combination therapy in immuno-oncology. We have proprietary technology platforms that we believe can generate novel and combinable therapies to target a wide range of cancers with significant unmet medical need. We plan to invest in these technology platforms to develop additional product candidates, and our current and future pipeline may be applicable to various tumor types due to the current efficacy data, safety profiles and combination potential of our current product candidates. We intend to further explore combination opportunities with conventional and novel treatments, including cellular vaccines, chemotherapy, radiotherapy and checkpoint inhibitors, among others.

Expand on the value of our product candidates through collaborations. We may decide to selectively partner large and complex oncology indications, in certain geographies and where we believe a partner could bring additional resources and expertise to maximize the value of our product candidates. We entered into two strategic collaborations with Janssen for the treatment of prostate, lung and certain other cancers. We also established a worldwide development and commercialization collaboration with Novartis for CDN product candidates in oncology. We believe these collaborations have the potential to drive significant value through the extensive capabilities of these organizations.

Leverage the expertise of our scientific founders and key advisors to develop innovative technologies at the forefront of the immuno-oncology field. Our scientific founders and advisors are from some of the world s leading research institutions and have a history of seminal discoveries and significant experience in oncology, immuno-oncology and vaccines. As such, we plan to continue to leverage the collective talent of our scientists, clinicians and a network of highly influential advisors to inform our development strategy and enable our technology to be at the forefront of the immuno-oncology field. We strive to protect our commercially important discoveries and product candidates by applying for, maintaining and defending our patent rights. At March 31, 2015, our owned U.S. patent portfolio consisted of 21 issued patents and 14 pending patent applications.

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Our Pipeline

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

Immuno-oncology and the Application of Our Technology Platform

Background on Immuno-Oncology

Cancer is a broad group of diseases in which cells divide and grow in an uncontrolled fashion, and spread via the bloodstream. In normal tissues, the rates of new cell growth and cell death are tightly regulated and kept in balance. In cancerous tissues, this balance is disrupted as a result of mutations, causing unregulated cell growth that leads to tumor formation. The immune system is designed to identify and eliminate tumor cells expressing foreign or abnormal antigens, although this process is often defective in cancer patients.

The immune system is generally divided into two subsystems: the innate immune system and the adaptive immune system. The innate immune system is the body s first line of immune defense and is non-specific, providing an immediate response to foreign bodies, including tumor antigens. The adaptive immune system provides a specific and long-lasting immune response against these threats. Within the innate immune system, natural killer cells, or NK cells, cytokines and APCs, such as DCs, are involved in tumor detection and destruction. NK cells can detect foreign or transformed cells, which no longer function normally, and cause them to self-eliminate through a process called apoptosis or programmed cell death. Cytokines can stimulate a broad-based immune response against cancer cells through multiple modalities, including activating T cells and causing them to proliferate. DCs act as messengers between the innate and the adaptive immune systems, by sampling the resulting fragments of destroyed cells. The DCs process foreign antigens, and present them on the cell surface to be recognized by T cells. T cells are a central component of the adaptive immune system. Within the T cell population, CD8+ T cells recognize and destroy cells expressing foreign antigens, whereas CD4+ T cells recognize foreign antigens and assist in the immune response. These cells can specifically target tumors based on antigen-specificity and further promote tumor destruction. Specificity, training T cells to recognize a specific antigen, and immunological memory, providing long-lasting protection against an antigen, are the two most important components of the adaptive immune system in fighting cancers.

In cancer, the immune system s natural strength has been diminished leading to a reduced capability to eradicate tumor cells. Immuno-oncology is an emerging field of cancer treatment that aims to activate the immune system in the tumor microenvironment to create and enhance anti-tumor immune responses, as well as to overcome the immuno-suppressive mechanisms that cancer cells have developed against the immune system. Recent developments in the field of immuno-oncology have shown the potential to provide dramatic efficacy

responses and extended survival, even in cancers where conventional therapies such as surgery, chemotherapy and radiotherapy have failed.

There are two general approaches to immuno-oncology: creating and expanding anti-tumor immune responses and removing the brakes, or overcoming the immuno-suppressive mechanisms that cancer cells have developed against the immune system.

Creating and Expanding

The create and expand approach to immuno-oncology involves harnessing the patient s immune system to identify and eradicate cancer cells. There have been many modalities within this approach, some of which have shown early promise, yet these individual approaches have inherent limitations in efficacy, safety or commercial viability. Some of these approaches and their potential limitations are as follows:

Cellular Vaccines: In this approach, irradiated human cancer cells, which are genetically modified to express immune system-stimulating cytokines, such as GM-CSF, to help stimulate the immune system, are administered to patients to recruit and activate DCs. These whole cancer cells contain the full spectrum of antigens expressed by a particular cancer cell line, thus allowing for antigen-specific T cell priming to numerous relevant antigens. Cellular vaccines have demonstrated the potential to generate both CD4+ and CD8+ T cell responses against tumor cells, though completed clinical trials to date have shown limitations in their effectiveness as a monotherapy.

Engineered CD8+ T Cells: In this approach, T cells are engineered outside of the body incorporating chimeric antigen receptors, or CARs, or T cell receptors, or TCRs, directed against specific tumor antigens. Following ex-vivo proliferation, CAR-T cells and TCR-T cells are infused back into the patient. Several engineered CD8+ T cell therapies have shown promising clinical results, yet these personalized therapies may have challenges with commercial-scale manufacturing and broad distribution.

Ex-Vivo Modulated Cancer Vaccines: In this approach, inactive APCs are isolated and removed from the body, then activated in a laboratory. Post-activation, the cells are administered to the patient with the aim of stimulating the tumor microenvironment into mounting a response against the cancer cells. This personalized approach has resulted in one approved product, sipuleucel-T, developed by Dendreon Corporation, but has been hampered by cumbersome manufacturing and handling requirements.

Oncolytic Viral Vaccines: In this approach, oncolytic viruses selectively lyse cancer cells causing an immune response through the release of tumor antigens. Though some promising results have been observed, efficacy as a monotherapy has been limited by inefficient delivery to tumors, balancing the optimal viral replication profile, and a limited ability to grow the induced immune response beyond the initial treatment site.

Peptide Vaccines: In this approach, partial or full tumor antigens are administered with a second agent called an immune adjuvant. Most cancer vaccine clinical trials have been performed with peptide

vaccines. Clinical outcomes using this approach have been disappointing, in part because this treatment mechanism has been shown to stimulate CD4+ T cells and other regulatory T cells, but not the CD8+ T cells that are necessary to kill cancer cells.

Vector-based Vaccines: In this approach, vector-based vaccines deliver tumor antigens to APCs in their genomic form through bacterial and viral vectors. We believe that this may be the most powerful method to generate a strong adaptive immune response against tumor cells. However, previously studied vector-based vaccines have had significant limitations due to their virulence and the effects of neutralizing antibodies, among other factors.

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Removing the Brakes

The remove the brakes approach to immuno-oncology is based on the premise of unmasking hidden cancer cells that have developed escape mechanisms to evade the immune system. The primary modality to this approach is classified within the category of checkpoint inhibitors. These therapies have demonstrated significant promise to treat a broad range of tumor types, yet they are not effective in many cancers. We believe our approach could be complementary to checkpoint inhibitors making them more effective in a broader range of cancers.

Checkpoint inhibitors are aimed at overcoming the defenses that tumor cells have developed against the immune system. Anti-CTLA-4 and anti-PD-1 are checkpoint inhibitors that have been studied in clinical trials for cancer. We believe that the efficacy of this approach as a monotherapy depends on the pre-existence of a T cell response against the tumor cells. Some patients immune systems are unable to recognize the tumor and therefore cannot generate the necessary immune response to eliminate the tumor following treatment with checkpoint inhibitors. Multiple preclinical models have shown an amplified anti-tumor effect against poorly immunogenic tumors when checkpoint inhibitors are combined with strong adaptive immune cell stimulators, such as cancer vaccines.

The Aduro Approach to Immuno-Oncology

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

Our Immuno-Oncology Technology Platforms

LADD Technology Platform Overview

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

There are a number of desirable features of the natural biology of *Listeria* that make it an attractive platform for immuno-oncology drug development, in particular is its ability to induce strong innate and adaptive immune responses by effective stimulation of CD4+ and CD8+ T cell immunity. There are also practical features of

Listeria-based vaccines, including that they are not neutralized by the patient s immune system, are designed

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for repeat administration and can be manufactured through a relatively simple and cost-effective fermentation process. We believe we have developed a LADD technology platform that is safe yet retains the potency of the natural, or unmodified, bacteria.

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

Upon intravenous administration, our LADD product candidates initially target APCs, including DCs. DCs circulate in the blood stream and continuously monitor their environment for danger signals by sampling proteins known as antigens from dying tumor cells and pathogens such as *Listeria*. Activated DCs release cytokines and process the sampled antigens and present them on the cell surface to be recognized by T cells, thereby training the T cells to specifically target the presented antigens. In this way, DCs are the primary initiators of both the innate and adaptive immune responses and serve as messengers between the innate and adaptive immune systems, as illustrated in the figure below. Our LADD product candidates are designed to leverage the combined effect of broad-based innate immune responses and antigen-specific T cell responses to initiate destruction of tumor cells while sparing normal tissue.

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LADD-Based Pipeline

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

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

* Programs under collaboration with Janssen.

The IND for CRS-207 for use in combination with GVAX Pancreas for pancreatic cancer was filed by Aduro in April 2011. The IND for CRS-207 in combination with GVAX Pancreas and nivolumab for pancreatic cancer was filed by The Johns Hopkins University, or JHU, in September 2014. The IND for CRS-207 for use in mesothelioma was filed by Cerus Corporation in June 2007.

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

We have not yet filed INDs for the two preclinical programs, ADU-741 for prostate cancer and ADU-214 for lung cancer.

CRS-207

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

CRS-207 in Pancreatic Cancer

Pancreatic Cancer Overview

Pancreatic cancer is the fourth leading cause of cancer deaths in the United States. In 2012, the estimated incidence according to Globocan was 43,000 in the Untied States and 338,000 worldwide. Pancreatic cancer is aggressive and often not diagnosed until it is too advanced for current treatments to be effective. Most patients are diagnosed after the age of 45, and 94% of patients die within five years from diagnosis. The majority of pancreatic cancer patients are treated with chemotherapy, but this cancer is highly resistant to chemotherapy. Approximately 20% of the pancreatic cancer patients are treated with surgery; however, even for those with successful surgical resection, the median

survival is approximately two years. Radiotherapy may be used for locally advanced tumors, but it is not curative. There are currently no approved treatments for second and third-line patients.

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CRS-207 with GVAX Pancreas in Pancreatic Cancer

CRS-207 combined with GVAX Pancreas is our lead LADD regimen. We are currently conducting our Phase 2b ECLIPSE clinical trial of CRS-207 in combination with GVAX Pancreas in patients with metastatic pancreatic cancer who have received at least one prior line of therapy in the metastatic setting.

About GVAX and GVAX Pancreas

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

Preclinical studies have shown the concept of synergy between immune checkpoint inhibitors such as anti-CTLA-4 antibodies and cancer vaccines such as GVAX. For example, researchers at JHU conducted a Phase 1b, open-label, randomized study to build on these preclinical observations by evaluating ipilimumab (a checkpoint inhibitor, anti-CTLA-4 antibody) alone or in combination with GVAX Pancreas for the treatment of previously treated, locally advanced, or metastatic pancreatic cancer. The primary objective of the study was to determine the safety profile. Secondary objectives included estimation of overall survival. A total of 30 patients with previously treated advanced pancreatic cancer were randomized (1:1). The median overall survival was 3.6 months for patients receiving ipilimumab, Arm 1, compared with 5.7 months for patients receiving ipilimumab in combination with GVAX Pancreas, Arm 2 (hazard ratio for death, or HR, = 0.51, p-value = 0.072). The one-year survival probability for patients in Arm 1 was 7% compared to 27% for patients in Arm 2. The hazard ratio is a measure of the risk of a particular event in one group compared to another group, over time. An HR lower than 1.00 indicates that the observed risk is lower in the treatment arm than in the control arm. A p-value is a measure of the statistical significance of the observed result. By convention, a p-value lower than 0.05 is considered statistically significant. Similar to prior ipilimumab studies, 20% of patients in each arm had grade 3/4 immune-related adverse events. The results of the study concluded that immune checkpoint blockade in combination with GVAX Pancreas has the potential for clinical benefit and should be evaluated further in a larger study.

Clinical Status

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

In a randomized controlled Phase 2a clinical trial the combination of CRS-207 with GVAX Pancreas demonstrated a statistically significant improvement in overall survival compared to GVAX Pancreas alone in patients with metastatic pancreatic cancer who previously received or refused prior chemotherapy. Based on these data, the FDA granted Breakthrough Therapy designation to the combination of CRS-207 and GVAX Pancreas. We have also obtained orphan drug designations for both GVAX Pancreas and CRS-207 for pancreatic cancer. We designed our Phase 2b ECLIPSE clinical trial based on the results we observed in the Phase 2a clinical trial. The ECLIPSE clinical trial is

being conducted to compare the clinical outcomes of the combination of CRS-207 and GVAX Pancreas to currently used single agent chemotherapies or to CRS-207 alone. We expect to complete enrollment in ECLIPSE in the third quarter of 2015 and to report top line results in the first half of 2016.

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Phase 2a (Completed)

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

The trial enrolled advanced-stage metastatic pancreatic cancer patients, with most patients having received two or more prior therapies in the metastatic setting. Patients were randomized in a two to one ratio in Arm A, which received GVAX Pancreas vaccine followed by four doses of CRS-207, or Arm B, which received six doses of GVAX Pancreas vaccine alone. In each arm, low dose cyclophosphamide was administered one day prior to GVAX Pancreas in order to enhance its immunogenicity and anti-tumor activity. Low dose cyclophosphamide inhibits T regulatory cells, and T regulatory cells may diminish a vaccine s efficacy. Patients were allowed to receive additional treatment courses (a treatment course contains six vaccinations) if they were clinically stable and perceived by the investigator to benefit from treatment. In both arms, treatments are administered at three week intervals, with a four week interval between treatment courses. After a four-week rest, clinically stable patients were offered additional courses.

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

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Phase 2a Overall Survival - Full Analysis Set

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

Phase 2a Overall Survival - Per Protocol Analysis Set

In addition to the 45 Arm A patients in the per protocol subset who received the combination of CRS-207 and GVAX Pancreas, three Arm B patients were crossed over into combination therapy. Of these 48 patients, nine survived longer than 24 months from randomization. None of the patients who received only GVAX Pancreas survived longer than 21 months. We continue to monitor the long-term survival of patients treated in our Phase 2a clinical trial. As of March 24, 2015, two patients continued to receive the combination treatment, one of whom was in the eighth course of combination treatment, and five patients remained in follow up.

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

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

Phase 2b ECLIPSE (Ongoing)

We are conducting our Phase 2b ECLIPSE clinical trial of CRS-207 in combination with GVAX Pancreas to treat late-stage metastatic pancreatic cancer patients who have received at least one prior line of therapy. The study is designed to evaluate the efficacy and safety of CRS-207 in combination with GVAX Pancreas, Arm A, compared to single agent chemotherapies, Arm C, commonly used in this setting. The study also includes an arm in which patients receive CRS-207 as a monotherapy, Arm B, to evaluate the contribution of GVAX Pancreas to the combination therapy. The three-arm trial will enroll approximately 300 patients at over 20 clinical trial sites in the United States and Canada.

Patients are being enrolled in two cohorts. The primary cohort will include approximately 190 patients who have received at least two prior treatment regimens for metastatic pancreatic cancer, or third+ line. The exploratory cohort will include approximately 110 patients who have received only one prior treatment regimen for metastatic pancreatic cancer, or second line. Patients will be randomized in a one to one to one ratio across each arm of the trial. Patients in Arm A will receive two doses of GVAX and four doses of CRS-207. Patients in Arm B will receive six doses of CRS-207. Patients in Arm C will receive a physician s choice of the following single-agent chemotherapies: gemcitabine, 5-Fluorouracil, capecitabine, irinotecan or erlotinib.

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

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

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The study is 80% powered (one-sided overall alpha = 0.15) for the primary endpoint comparison of third+ line patients receiving Arm A versus chemotherapy alone Arm C.

We expect to complete enrollment in the third quarter of 2015 and to report top line results in the first half of 2016. Following the completion of the ECLIPSE study, we plan to initiate a global Phase 3 trial in metastatic pancreatic cancer patients who have received prior chemotherapy. We expect the trial would be randomized to evaluate overall survival in patients treated with our therapy in comparison to standard of care.

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

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

About Anti-PD-1

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

Clinical Status

The investigator-sponsored randomized controlled Phase 2b clinical trial, or STELLAR, is supported by Aduro, Bristol-Myers Squibb, Stand Up to Cancer, PanCAN/AACR and the Lustgarten Foundation. STELLAR is designed to explore the synergistic effects on our treatment regimen in combination with nivolumab. The first patient was dosed in the first quarter of 2015.

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Phase 2b STELLAR (Ongoing)

Our Phase 2b STELLAR clinical trial is a randomized controlled Phase 2b clinical trial of CRS-207 in combination with GVAX Pancreas and nivolumab in patients with metastatic pancreatic cancer who have received only one prior line of therapy in the metastatic setting. The ongoing 88-patient randomized controlled two-arm Phase 2b clinical trial is anticipated to be conducted by leading investigators at up to five U.S. clinical trial sites. Patients receive either the combination therapy with nivolumab or the combination therapy alone. The primary endpoint of the trial is overall survival and secondary endpoints include evaluation of clinical and immune response and safety.

We expect to complete enrollment in the first quarter of 2016 and to report data from an interim analysis in the second half of 2016.

CRS-207 in Mesothelioma

Mesothelioma Overview

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

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

CRS-207 with Chemotherapy in Mesothelioma

We are using CRS-207 in combination with standard-of-care chemotherapy for treatment in the front line-setting of unresectable malignant pleural mesothelioma. We have obtained orphan drug designation for CRS-207 for the treatment of mesothelioma.

About Chemotherapy

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

Clinical Status

We are enrolling a single-arm Phase 1b clinical trial of CRS-207 in combination with standard-of-care chemotherapy in patients with unresectable malignant pleural mesothelioma who have not received prior therapy. Based on encouraging results in the initial cohort of 16 patients, we have opened an expansion cohort of up to a total of 40 patients. We expect to finish enrollment in 2015 and report final top line results in 2016.

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Phase 1b (Ongoing)

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

In June 2014, data from scheduled radiologic time points of the first 16 patients, shown below, were presented at the ASCO conference. Of 16 evaluable patients with response data, 69%, or 11 of the 16 patients, had confirmed durable partial responses and 25%, or 4 of the 16 patients, experienced stable disease after CRS-207 and chemotherapy, for a 94% rate of disease control (the sum of partial responses and stable disease). Radiologic images were also read by an independent, central radiologist supporting our investigators findings. Based on these encouraging data, the protocol was amended to increase the enrollment in the trial by up to 24 patients for a total enrollment of up to 40 patients.

In October 2014, updated safety and efficacy data were presented at the International Mesothelioma Interest Group Conference. At the time of the presentation, estimated PFS was 7.5 months with one patient on study for more than 19 months, who continued to receive maintenance therapy with CRS-207 following the combination treatment.

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Phase 2 (Planned)

We anticipate initiating a randomized controlled Phase 2 clinical trial in North America, Europe and Australia to evaluate PFS, overall response rate, OS and safety of the combination therapy of CRS-207 and standard-of-care chemotherapy.

ADU-623 in Glioblastoma Multiforme

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

Glioblastoma Multiforme Overview

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

Clinical Status

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

Phase 1 (Ongoing)

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

ADU-741 in Prostate Cancer

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

Prostate Cancer Overview

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

Development Status

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

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ADU-214 in Lung Cancer

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

Lung Cancer Overview

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

Development Status

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

CDN Technology Platform Overview

Recent advancements reported in numerous leading scientific journals have generated significant interest and rationale for targeting the STING receptor as a novel therapeutic approach to immuno-oncology. We are developing a portfolio of synthetic proprietary CDN small molecule immune modulators that target and activate the STING receptor with applications across diverse diseases. The STING receptor is generally expressed at high levels in the cytosol of immune cells, including DCs. Once activated, the STING receptor initiates a profound innate immune response by signaling through three distinct pathways, inducing the expression of a broad profile of cytokines, including interferons and chemokines. This cytokine profile subsequently leads to the development of an effective tumor antigen-specific T cell adaptive immune response.

Naturally occurring CDNs that target the STING receptor are produced by bacteria that secrete CDNs into the host cell or by mammalian cells through cyclic GMP-AMP synthetase, or cGAS. cGAS is a recently discovered receptor that senses double-stranded, or ds, DNA in the cytosol of APCs, and in response synthesizes a CDN that is structurally distinct from the CDNs produced by bacteria. While both bacterial- and cGAS-produced CDNs target the STING receptor, CDNs produced by cGAS bind more tightly to STING than CDNs produced by bacteria. This stronger binding triggers a larger and more stable change in shape of the STING receptor, leading to the development of a more effective tumor antigen-specific immune response. Additionally, while some of the five unique STING receptors in humans respond poorly to CDNs produced by bacteria, all respond to CDNs produced by cGAS. All our novel synthetic CDN product candidates that we are advancing through preclinical development contain a structure based on the cGAS-produced CDN structure, thus stimulating potent innate immune responses to all of the known human STING receptors.

We have developed proprietary CDN derivative compounds that are significantly more potent than the natural cGAS-produced molecules, which can be demonstrated by comparing the expression levels the cytokines produced from signaling through three distinct pathways. The NF-kB pathway induces the expression of numerous

pro-inflammatory cytokines, including IL-6 and TNFa that stimulate a variety of immune cells. The IRF-3 pathway leads to the induction of IFN-b and co-regulated genes which orchestrate diverse innate immune responses. The STAT6 pathway leads to expression of chemokines, including CCL2 and CCL20, that are

involved in immune cell recruitment. The unique profile of cytokines induced through activating the STING receptor results in strong efficacy in numerous aggressive preclinical mouse models of cancer.

In healthy individuals, DCs and other APCs constantly sample nearby tumor and non-tumor cells, however, in cancer patients, tumors can produce immune-inhibitory molecules which can make the DCs non-functional. The activation of the STING receptor in the tumor microenvironment by IT injection of our proprietary CDN product candidates stimulate the maturation of the DCs, leading to the presentation of antigens found on the individual s unique tumor. The activated tumor-specific T cells induce tumor cell death both locally and systemically, resulting in significant and durable therapeutic efficacy in preclinical tumor models.

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CDN Product Candidates

We envision multiple immuno-oncology CDN product opportunities as a monotherapy or in combination with other cancer treatments. In preclinical animal models, our data have shown that our proprietary CDN product candidates can be combined with designated recombinant proteins to induce potent antigen-specific CD4+, which recognize foreign antigens and assist in the immune response, and CD8+, which recognize and destroy cells expressing foreign antigens, T cell immunity. We believe our CDN product candidates can also be combined with conventional cancer treatments such as chemotherapy and radiotherapy to enhance our CDN product candidates immune-mediated tumor killing mechanisms. We also believe that our CDN product candidates could alter the nature of the tumor microenvironment, thus allowing for improved responses to checkpoint inhibitors.

ADU-S100

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

ADU-S100 CDN Preclinical Studies

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

Further rationale for the approach of IT injection of CDN product candidates is the recent discovery by Dr. Thomas Gajewski of the University of Chicago that the STING-dependent innate immune sensing in the tumor microenvironment is a critical step in promoting spontaneous tumor-initiated T cell priming, subsequent infiltration of tumor lymphocytes and tumor regression. Analyses conducted with tumors isolated from melanoma patients have also revealed that tumors containing infiltrating activated T cells are characterized by an IFN-ß transcriptional signature. Studies in mice have demonstrated that IFN-ß signaling plays a critical role in tumor-initiated T cell priming. We believe that treatment strategies to induce IFN-ß signaling and DC activation in the tumor microenvironment to bridge the innate and adaptive immune responses have significant therapeutic potential. IT delivery of our synthetic CDN product candidates activate a tumor-specific T cell response that is unique to the individual s tumor; conceptually, a small molecule approach to patient-specific immuno-oncology treatments.

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Single Agent ADU-S100 (B16 Melanoma Therapeutic Model)

Proprietary CDN versus Naturally Occurring

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

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

Proprietary CDN versus TLR Ligands

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

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

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

Development Status

In March 2015, we established a worldwide collaboration with Novartis to further advance the research and development of CDN product candidates in oncology. We are currently conducting IND-enabling activities for ADU-S100, our first CDN product candidate.

CDN Product Opportunities

We envision multiple product opportunities for the CDN technology platform. We believe that our CDN product candidates can be used as a monotherapy to directly activate the tumor microenvironment, enhancing recognition of the tumor by the immune system and leading to tumor destruction. In preclinical animal models, we have shown that our proprietary CDN product candidates can be co-formulated with designated recombinant proteins to induce potent antigen-specific CD4+ and CD8+ T cell immunity. We believe that due to our CDN product candidates immune-mediated tumor killing mechanisms and ability to alter the nature of the tumor microenvironment our proprietary CDN product candidates could be combined with conventional and novel therapies, such as cellular vaccines, chemotherapy, radiotherapy and checkpoint inhibitors, among others.

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

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

Manufacturing

Overview

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

LADD Product Candidates

LADD product candidates are produced through a fermentation process and then concentrated and purified. The drug substance is diluted into a cryopreservative and filled into vials that are inspected, labeled and frozen as final drug product. We have contracts with IDT Biologika GmbH, or IDT, and Waisman Clinical BioManufacturing to produce and release LADD product candidates. We recently transitioned manufacturing of our lead LADD product candidate, CRS-207, to IDT, which can support commercial manufacturing.

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

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

GVAX Pancreas Product Candidates

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

Under our manufacturing services agreement with Lonza , which we entered into in August 2012, Lonza provides manufacturing services to produce cell lines for our GVAX Pancreas product candidates. We pay for manufacturing

services performed by Lonza under the agreement pursuant to statements of work entered into from time to time.

We may unilaterally terminate the agreement upon 45 days written notice to Lonza. Lonza may terminate the agreement upon 12 months written notice to us. Either party may terminate the agreement in the

event of the other party s insolvency or for the other party s material breach of the agreement if such breach remains uncured after 30 days of receiving written notice of such breach or after 90 days of receiving written notice of such breach if such breach is not capable of being cured within 30 days and the breaching party is making diligent efforts to cure such breach. Absent early termination, the agreement will continue until the fifth anniversary of the effective date of the original agreement.

CDN Product Candidates

Manufacturing for the CDN technology platform 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 CDN product candidates is a trade secret and we retain control and ownership of the process. We have contracted with a CMO to produce, release and stability test the ADU-S100 API. We have also entered into a drug product manufacturing and clinical supply agreement with a CMO for the formulation and fill/finish and release and stability testing of the drug product candidate.

Intellectual Property

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

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

Through licensing and through developing our own portfolio, we have rights to more than 100 issued patents and more than 50 pending applications in the United States and foreign countries. Families within the portfolio are directed to our LADD and CDN technology platforms, and to GVAX.

LADD Technology Platform

We own eleven issued U.S. patents, seven pending U.S. patent applications, and corresponding foreign issued patents and patent applications, and additionally we are the exclusive licensee to families of patents and patent applications, all relating to our LADD technology platform. The issued U.S. patents that we own expire between 2022 and 2027, not including any patent term extensions that may be available under U.S. laws. The patents and patent applications, if issued, cover attenuated *Listeria* strains that have deleted or disrupted genomic *actA* and *inlB* virulence genes in conjunction with the expression of non-*Listeria* polypeptides, as well as to *Listeria* strains that are engineered to express non-*Listeria* polypeptides, including cancer antigens or fragments thereof. There are also patents and patent applications, if issued, that cover proprietary antigen expression cassettes and methods which are applicable to *Listeria* generally and not limited to any particular strain or method of attenuation.

Antigen Expression

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

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

EGFRvIII Family

Within this portfolio are pending U.S. and corresponding foreign patent applications that we co-own with Providence Health & Services Oregon, a family of patent applications that are directed to *Listeria* strains that express EGFRvIII antigen. This technology is included in our ADU-623, ADU-214 and other product candidates. A patent that would issue from such application would expire in 2031.

Combination Therapy with LADD

Additionally, within this portfolio are U.S. patents and pending applications directed to compositions that can be used in conjunction with or as an adjuvant to the LADD technology platform. For example, we have received a notice of allowance in the United States to claims directed to a method of enhancing an immune response to mesothelin by administering a boost dose of an attenuated *Listeria* that encodes an active mesothelin antigen after administration of an effective amount of a tumor cell that encodes mouse GM-CSF. Claims directed to such method have been allowed and are expected to issue. If such claims issue, they could cover the use of CRS-207 and would expire in 2027. In addition, we have also filed a U.S. application and foreign applications directed to a method of treating cancer by administering a cancer antigen expressing *Listeria* after administration of an effective amount of radiotherapy. If such claims issue, they would expire in 2031.

CDN Family

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

GVAX Technology

We own ten issued U.S. patents and four pending U.S. patent applications and exclusively license multiple families of patents and patent applications that cover cell lines that express GM-CSF. This technology is referred to as GVAX. We license a family of patents from JHU that covers the first generation GVAX platform, including a U.S. patent specifically covering GVAX Pancreas. The patents in this family are expected to expire between 2016 and 2022; however, we have a license with JHU for continued exclusive use of the cell lines produced by JHU after the patents

expire. Additionally, in 2013, we entered into another license agreement with JHU relating to GVAX technology that includes toll-like receptor ligands. This GVAX technology includes two international patent applications, which, if issued, would expire in 2031 to 2032.

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Other Technology

In addition to the technologies described in detail above, we license or own other intellectual property directed to compositions and methods that could be used in conjunction with our *Listeria* technology platform. The intellectual property is directed to, for example, methods of administering our *Listeria* products in conjunction with other therapeutics. Additionally, we have licensed technology from UC Berkeley that enables us to integrate expression sequences more easily into *Listeria* and allows us to develop multivalent vaccines more quickly and efficiently. We have an exclusive license to this technology, which expires in 2023, subject to any extensions or disclaimers of the licensed patents.

General Considerations

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

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

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

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

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

regardless of the merit of the claims or the outcome of the litigation.

We may rely, in some circumstances, on trade secrets to protect our technology. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into

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confidentiality agreements with our employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Collaborations

Janssen ADU-741 Agreement

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

In partial consideration for the grant of this license, Janssen paid us $12.0 million as an upfront license fee. Additionally, under the Janssen ADU-741 Agreement we are eligible to receive from Janssen up to an aggregate of $7.5 million upon our achievement and performance of specified technology transfers and development and regulatory milestones pursuant to an agreed upon plan, an aggregate of $103.5 million upon Janssen s achievement of specified development and regulatory milestones, and an aggregate of $242.0 million upon Janssen s achievement of specified commercial milestones. Janssen is also obligated to pay us royalties on net sales of licensed products by Janssen, its affiliates and sublicensees at a rate ranging from the mid-single digits to the low teens based on the aggregate annual net sales of licensed products worldwide and based on the country of sale. Janssen s royalty obligation continues on a licensed product-by-licensed product and country-by-country basis until the later of (i) 12 years from the date of first commercial sale of such licensed product in such country, (ii) expiration of the last valid claim in the licensed patents covering the composition of matter or the approved method of use of such licensed product or (iii) the expiration of data exclusivity with respect to such licensed product in such country.

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

Janssen ADU-214 Agreement

In November 2014, a research and license agreement with Janssen became effective, pursuant to which we granted Janssen an exclusive worldwide license under intellectual property rights controlled by us to research,

develop, manufacture, use, sell and otherwise exploit products containing ADU-214 for any and all uses. Under this Agreement, or the Janssen ADU-214 Agreement, we also granted Janssen the right, subject to availability, to develop specified derivatives of the *Listeria* strain. Janssen will have exclusive rights to develop LADD product candidates in lung cancer and to develop and commercialize the licensed products and will assume responsibility for all research, development, manufacturing, regulatory and commercialization activities for the licensed products.

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

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

Janssen GVAX Prostate Agreement

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

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

The Janssen GVAX Prostate Agreement will continue in effect until the later of expiration of all of the licensed patents and on a licensed product-by-licensed product and country-by-country basis, the expiration of Janssen s royalty obligations with respect to such licensed product in such country. Either party may terminate

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

Novartis Agreement

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

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

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

We are responsible for 38% of the joint development costs worldwide and Novartis is responsible for the remaining 62% of the joint development costs worldwide. We will also receive 50% of all profits for any products commercialized pursuant to this collaboration in the United States and 45% of all profits for specified European countries and Japan. For each of these profit share countries, each party will be responsible for its respective commercial sharing percentage of all joint commercialization costs incurred in that country. For all other countries where we are not sharing profits, Novartis will be responsible for all commercialization costs and will pay us a royalty in the mid-teens on all net sales of product sold by Novartis, its affiliates and sublicensees, with such percentage subject to reduction post patent and data exclusivity expiration and subject to reduction, capped at a specified percentage, for royalties payable to third party licensors. Novartis royalty obligation will run on a country-by-country basis until the later of expiration of the last valid claim covering the product, expiration of data exclusivity for the product and 12 years after first commercial sale of the product in such country.

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

The Novartis Agreement will continue in effect until the later of (i) the date on which the parties mutually agree to cease the commercialization of products in the profit share region and (ii) the date on which

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Novartis royalty obligations cease. Either party may terminate the Novartis Agreement upon the other party s uncured material breach, for the other party s bankruptcy or insolvency, or for safety reasons. Additionally, Novartis may terminate the Novartis Agreement for convenience at any time after March 19, 2018 upon 180 days notice. Certain termination events are subject to a continuing license and a technology transfer.

Novartis Stock Purchase

Concurrent with the entry into the Novartis Agreement, we and Novartis Institutes for BioMedical Research, Inc., or NIBR, entered into a stock purchase agreement to purchase 2,361,029 shares of our Series E Preferred Stock (or 1,699,940 shares of common stock on an as-converted basis), representing 2.7% of our then-outstanding equity and convertible securities, for $25.0 million. Under the stock purchase agreement, NIBR is committed to purchase an additional $25.0 million of our common stock in a separate private placement transaction that is expected to close concurrently with the completion of this offering and at the initial price per share offered to the public. If this offering is not completed by December 15, 2015, NIBR will purchase 2,361,029 shares of our Series E Preferred Stock (or 1,699,940 shares of common stock on an as-converted basis) for $25.0 million.

Our Research and Development and License Agreements

Listeria-*Based Agreements*

JHU Listeria *Agreement*

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

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

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

UCB Listeria *Agreement*

In March 2012, we entered into a license agreement with the Regents of the University of California on behalf of its Berkeley campus, or UCB, granting us an exclusive, worldwide, sublicensable license to certain patent rights covering the use of the *Listeria monocytogenes* phage integration vector which accelerates the genetic engineering of *Listeria* to

express more than one antigen to make, use, import and commercialize products and to provide services for all fields of use. Under this agreement, or the UCB *Listeria* Agreement, we are obligated to use commercially reasonable efforts to develop, manufacture and sell licensed products and services and we are obligated to achieve specified development and regulatory milestones by specified dates.

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

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

GVAX-Based Agreements

ANI Agreement

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

Under the ANI Agreement, we paid ANI cash consideration of $1.0 million and will be required to make royalty payments on net sales of GVAX products sold by us, our affiliates and our sublicensees for the treatment of certain cancers, which are covered by purchased intellectual property rights or developed using purchased technology, at rates in the low-single digits. We are also required to pay milestone payments of up to $4.0 million for GVAX pancreas or prostate products in combination with *Listeria* or up to $12.0 million per product for other GVAX products upon the achievement of certain sales milestones. We are obligated to make royalty payments on a product-by-product and country-by-country basis until the later of (i) the expiration of the last to expire of the purchased patent rights covering the GVAX product or the regulatory exclusivity period and (ii) up to seven years from the first commercial sale of the product in such country depending on the level of net sales in such country after the expiration of the patent or regulatory exclusivity period. The royalties and milestone payments for GVAX products for the treatment of pancreas and prostate cancer, as well as the royalties and milestone payments for other cancer products, are each capped at specified maximum amounts. To the extent we enter into a sublicensing agreement relating to the GVAX pancreas or prostate cancer products in combination with *Listeria*, we are required to pay ANI a percentage of our sublicensing income, ranging from the low teens to the low thirties based on the indication, the stage of development of the GVAX products at the time the sublicense is granted and the amount of development costs expended by us at the time the sublicense is granted. The sublicensing payments owed under this ANI Agreement for pancreas and prostate cancer in combination with *Listeria* are each capped at specified maximum amounts.

JHU GVAX Agreement

In January 2013, we entered into a license agreement with JHU granting us an exclusive, worldwide, sublicensable license under certain GVAX-related patent rights and cell lines, and a non-exclusive, worldwide, sublicensable license to related know-how, in each case to make, have made, use, have used, sell, offer for sale, have sold, import, have imported, develop and commercialize products and services using or incorporating licensed patent rights, cell lines or

know-how for any use. Under the agreement, or the New License Agreement, we are obligated to use commercially reasonable efforts to develop and market licensed products and services, including using commercially reasonable efforts to achieve specified development milestones by specified dates.

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

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

GVAX RALA

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

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

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

CDN-Based Agreements

Karagen Agreement

In June 2012, we entered into a license agreement with Karagen Pharmaceuticals, Inc., or Karagen, pursuant to which Karagen granted us an exclusive, worldwide, sublicenseable license under certain patents and know-how related to CDNs 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 paid Karagen an upfront fee of $75,000 in 2012 and are required to make milestone payments totaling up to $900,000, in the aggregate, for the achievement of specified development and regulatory milestones as well as royalties based on net sales of products by us, our affiliates and sublicensees at rates ranging in the low single-digit percentages, determined by whether the disease field is an exclusive or non-exclusive disease field, subject to minimum annual royalties and standard reductions. In addition, we are required to pay Karagen a percentage of consideration received from any sublicensing arrangements ranging from the mid-single digits to the mid-teen digits determined by the current stage of development of the relevant licensed product at the time of the sublicense grant, or by whether we have exercised our option to add a designated field of use to its exclusive license, as applicable.

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

UCB Vance Agreement

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

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

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

MSK Agreement

In December 2014, we entered into a license agreement with Memorial Sloan Kettering Cancer Center, or MSK, The Rockefeller University, Rutgers, The State University of New Jersey, and University of Bonn, collectively the Licensors, pursuant to which we received an exclusive, worldwide, sublicensable license under certain patents related to CDNs 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.

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

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

Competition

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

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

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

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technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

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

Government Regulation and Product Approval

As a biopharmaceutical company that operates in the United States, we are subject to extensive regulation. Federal, state and local government authorities in the United States and in other countries extensively regulate, among other things, the research, development, testing, manufacturing, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of biological and pharmaceutical products such as those we are developing. Our product candidates must be approved by the FDA before they may be legally marketed in the United States and by the appropriate foreign regulatory agency before they may be legally marketed in foreign countries. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the United States, although there can be important differences. Additionally, some significant aspects of regulation in Europe are addressed in a centralized way, but country-specific regulation remains essential in many respects. The process for obtaining regulatory marketing approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

U.S. Product Development Process

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

- completion of nonclinical laboratory tests and animal studies according to good laboratory practices, or GLPs, and applicable requirements for the humane use of laboratory animals or other applicable regulations;

submission to the FDA of an Investigational New Drug Application, or IND, which must become effective before human clinical trials may begin;

performance of adequate and well-controlled human clinical trials according to the FDA s regulations commonly referred to as good clinical practices, or GCPs, and any additional

requirements for the protection of human research patients and their health information, to establish the safety and efficacy of the product candidate for its intended use;

submission to the FDA of a BLA for any biologic or an NDA for any drug we seek to market that includes substantive evidence of safety, purity, and potency, or safety and effectiveness from results of nonclinical testing and clinical trials;

satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the product is produced, to assess compliance with cGMP, to assure that the facilities, methods and controls are adequate to preserve the product s identity, strength, quality and purity, and, if applicable, the FDA s current good tissue practices, or GTPs, for the use of human cellular and tissue products;

potential FDA audit of the nonclinical study and clinical trial sites that generated the data in support of the BLA or NDA; and

FDA review and approval of the NDA, or licensure, of the BLA.

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

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

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

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

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

Phase 1. The biological product is initially introduced into healthy human patients and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.

Phase 2. The biological product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.

Phase 3. Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk to benefit ratio of the product and provide an adequate basis for product labeling.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA, the NIH and the investigators for serious and unexpected adverse events, 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 suspected adverse reaction within seven calendar days after the sponsor s initial receipt of the information. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research patients are being exposed to an unacceptable health risk, including risks inferred from other unrelated immuno-oncology trials. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB s requirements or if the biological

product has been associated with unexpected serious harm to patients.

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

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

U.S. Review and Approval Processes

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

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

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

Before approving a BLA or NDA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications.

For human tissue-based products, the FDA also will not approve the product if the manufacturer is not in compliance with the FDA s current good tissue practices, or GTPs, to the extent applicable. These are FDA regulations and guidance documents that govern the methods used in, and the

facilities and controls used for, the manufacture of human cells, tissues, and cellular and tissue based products, or HCT/Ps, which are human cells or tissue intended for implantation, transplant, infusion, or transfer into a human recipient. The primary intent of the GTP requirements is to ensure that cell and tissue based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable disease. FDA regulations also require tissue establishments to register and list their HCT/Ps with the FDA and, when applicable, to evaluate donors through screening and testing. Additionally, before approving a BLA or NDA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND trial requirements and GCP requirements. To assure cGMP, GTP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production and quality control.

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

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

Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. In addition, the FDA may require post marketing clinical trials, sometimes referred to as Phase 4 clinical trials, designed to further assess a biological product s safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

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

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does

not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

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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.

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

Expedited Development and Review Programs

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new products that meet certain criteria. Specifically, new products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. Unique to a Fast Track product, the FDA may consider for review sections of the BLA or NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA or NDA, the FDA agrees to accept sections of the BLA or NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA or NDA.

Any product, submitted to the FDA for approval, including a product with a Fast Track designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new product designated for priority review in an effort to facilitate the review. Additionally, a product may be eligible for accelerated approval. Products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug or biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical studies. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Fast Track designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

In 2012 the FDA established a Breakthrough Therapy designation which is intended to expedite the development and review of products that treat serious or life-threatening conditions. The designation is available for product candidates that are intended, alone or in combination with one or more other products, to treat serious

or life-threatening diseases or conditions and for which preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently available therapy on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the Fast Track program features, as well as more intensive FDA interaction and guidance. The Breakthrough Therapy designation is a distinct status from both Fast Track designation and priority review, which can also be granted to the same product if relevant criteria are met. If a product is designated as Breakthrough Therapy, FDA will expedite the development and review of such product.

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

Post-Approval Requirements

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

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

The FDA also may require post-marketing testing, known as Phase 4 testing, and surveillance to monitor the effects of an approved product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product s approved labeling, including the addition of new warnings and contraindications, and also may

require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA s policies may change, which could delay or prevent regulatory approval of our products under development.

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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 molecule as highly similar to an approved innovator biologic, among other requirements. The BPCIA, however, bars the FDA from approving biosimilar applications for 12 years after an innovator biological product receives initial marketing approval.

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

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

Other U.S. Healthcare Laws and Compliance Requirements

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

The federal Anti-Kickback Statute prohibits, among other things, any person or entity from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to

scrutiny if they do not qualify for an exception or safe harbor. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory

safe harbor, however, does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances.

Additionally, the intent standard under the Anti-Kickback Statute was amended by the Affordable Care Act to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act, as discussed below.

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

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

HIPAA created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

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

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

Additionally, the federal Physician Payments Sunshine Act under the Affordable Care Act, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children s Health Insurance Program, with certain exceptions, to report information related to certain payments or other transfers of value made or

distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members and payments or other transfers of value made to such physician owners. Failure to submit timely, accurately, and completely the required information may result in civil monetary penalties of up to an aggregate of $150,000 per year and up to an aggregate of $1 million per year for knowing failures). Manufacturers were required to begin collecting data on August 1, 2013 and submit reports on aggregate payment data to the government for the first reporting period of August 1, 2013 to December 31, 2013, by March 31, 2014, and to report detailed payment data for the first reporting period and submit legal attestation to the accuracy of such data by June 30, 2014. Thereafter, manufacturers must submit reports by the 90th day of each subsequent calendar year. CMS made all reported data publicly available on September 30, 2014. Certain states also mandate implementation of compliance programs, impose restrictions on pharmaceutical manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to healthcare providers and entities.

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

If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private qui tam actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to that third-party payors provide coverage, and establish adequate reimbursement levels for such products. In the United States, third-party payors include federal and state healthcare programs, private managed care providers, health insurers and other organizations. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. We may need to conduct

expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to

obtain the FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor s decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor s determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Different pricing and reimbursement schemes exist in other countries. In the EU, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

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

Healthcare Reform

In March 2010, President Obama enacted the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the Affordable Care Act, which has the potential to substantially change healthcare financing and delivery by both governmental and private insurers, and significantly impact the pharmaceutical and biotechnology industry. The Affordable Care Act will impact existing government healthcare programs and will result in the development of new programs.

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

- an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some government healthcare programs;

- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively and capped the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price, or AMP;

addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics, including our product candidates, that are inhaled, infused, instilled, implanted or injected;

extension of manufacturers Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;

expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility

categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers Medicaid rebate liability;

a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer s outpatient drugs to be covered under Medicare Part D;

expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program; and

a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

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

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. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. In addition, it is possible that there will be further legislation or regulation that could harm our business, financial condition and results of operations.

The Foreign Corrupt Practices Act

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

Additional Regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic

Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

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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.

Legal Proceedings

We are not currently subject to any material legal proceedings.

Facilities

We lease a 24,687 square foot facility in Berkeley, CA for research and development and administrative activities. The current lease agreement commenced on June 1, 2014 and has an initial term expiring on August 31, 2016. In February 2015, we entered into an addendum to the lease, which extends the term of the lease through December 31, 2018, with an option to extend until December 31, 2020. 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.

Employees

As of March 31, 2015, we had 53 full-time employees, 20 of whom hold Ph.D. degrees, 41 of whom were engaged in research and development activities and 12 of whom were engaged in finance, business development, facilities, human resources and administrative support. None of our employees are subject to a collective bargaining agreement.

We consider our relationship with our employees to be good.

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MANAGEMENT

Executive Officers and Directors

Our executive officers and directors, their respective positions and their respective ages at March 31, 2015 are as follows:

Name	Age	Position(s)
Executive Officers		
Stephen T. Isaacs	66	Chairman, Director, President and Chief Executive Officer
Gregory W. Schafer	50	Chief Operating Officer
Thomas W. Dubensky, Jr., Ph.D.	57	Chief Scientific Officer
Dirk G. Brockstedt, Ph.D.	46	Senior Vice President of Research and Development
Jennifer Lew	42	Senior Vice President of Finance
Non-Employee Directors		
Gerald Chan[3]	64	Director
William M. Greenman[1][3]	48	Director
Ross Haghighat[1][2]	51	Director
Frank McCormick, Ph.D.[3]	64	Director
Stephanie Monaghan O Brien[1][2]	56	Director

(1) Member of the audit committee.
(2) Member of the compensation committee.
(3) Member of the nominating and corporate governance committee.

Executive Officers

Stephen T. Isaacs has served as our Chairman, Director, President and Chief Executive Officer since 2008. Prior to Aduro, Mr. Isaacs founded Cerus Corporation, a biomedical products company commercializing the Intercept Blood Systems, in 1991. He served as President and Chief Executive Officer of Cerus from 1991 to 2004. Prior to Cerus, Mr. Isaacs founded and served as Chief Executive Officer and President of HRIS Associates and HRI Research, both biotechnology companies focusing on research and development. He held a non-teaching faculty position in the Department of Chemistry at the University of California Berkeley from 1978 to 1986. Mr. Isaacs has published over 20 peer-reviewed scientific articles and is an inventor on over 40 issued patents. Mr. Isaacs holds a B.A. degree in Biochemistry from University of California Berkeley, and had graduate training in organic chemistry in the Ph.D. program in the Department of Chemistry at Berkeley. Because of Mr. Isaacs biomedical expertise, extensive knowledge of our company and experience as founder and executive officer of biotechnology companies, we believe he is able to make valuable contributions to our board of directors.

Gregory W. Schafer has served as our Chief Operating Officer since July 2013. Prior to joining Aduro, he served as Chief Financial Officer of Jennerex, Inc, a private biotechnology company, from June 2010 until July 2013, where he was responsible for finance, accounting, planning, investor relations and treasury functions. Prior to Jennerex, he served as Chief Financial Officer of Onyx Pharmaceuticals, Inc., a public biotechnology company, from April 2006 until January 2009, where he was responsible for finance, accounting, risk management and strategic and operational planning. Before joining Onyx, he served as Chief Financial Officer and Vice President of finance for IntraBiotics

Pharmaceuticals and Cerus Corporation, both biotechnology companies. Prior to Cerus, Mr. Schafer worked as a management consultant for Deloitte & Touche LLP. Mr. Schafer also serves on the board of directors for Capricor, Inc., a public biotechnology company. He received his M.B.A. from the Anderson Graduate School of Management at the University of California, Los Angeles and a B.S.E. in mechanical engineering from the University of Pennsylvania.

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Thomas W. Dubensky, Jr., Ph.D. has served as our Chief Scientific Officer since September 2011. From 2009 to 2011, Dr. Dubensky served as Chief Scientific Officer of Immune Design Corp., a biotechnology company, where he was responsible for overseeing the development of immune therapies based on proprietary molecularly defined adjuvants and dendritic cell targeting vaccine platforms. He was a co-founder and Chief Scientific Officer of Anza Therapeutics, Inc., a biotechnology company which was spun out from Cerus Corporation in 2007, where he served as the Vice President of Research beginning in 2002. At Cerus and at Anza, he helped to develop vaccine platforms based on attenuated strains of *Listeria monocytogenes*, which serves as the technology basis for Aduro. Previously, Dr. Dubensky developed vaccine platforms based on alphaviruses, adenoviruses, retroviruses/lentiviruses and plasmid DNA in positions of increasing responsibility at Viagene Biotech, Inc., Chiron Corporation and Onyx Pharmaceuticals, Inc, all biotechnology companies. Dr. Dubensky has co-authored more than 60 scientific papers and is an inventor on more than 25 issued U.S. patents and multiple pending applications. Dr. Dubensky received his B.A. in Bacteriology and Immunology from the University of California, Berkeley; he earned his Ph.D. at the University of Colorado Health Sciences Center; and he was a post-doctoral fellow at Harvard Medical School in the Department of Pathology.

Dirk G. Brockstedt, Ph.D. joined Aduro in April 2009 and has served as our Senior Vice President of Research and Development since September 2011. Prior to joining Aduro, Dr. Brockstedt held various positions in the immunology department of Cerus Corporation since joining that company in 2002 and served as Cerus Corporation s Director, Immunology from 2006 to 2007. He was the third employee in the original Immunotherapy group at Cerus Corporation. Prior to Cerus Corporation, he was a scientist at Aventis in the Immunotherapy and Anti-Angiogenesis group from 1999 until 2002, developing novel therapies against cancer. Dr. Brockstedt has co-authored 36 scientific papers and is a named inventor on five issued patents and several pending applications. Dr. Brockstedt holds a Diploma/Masters of Science in Microbiology from the University of Kiel; he earned his Ph.D. from the University of Kiel and Stanford University, and he was a post-doctoral fellow at the Stanford School of Medicine in the department of Pathology.

Jennifer Lew joined Aduro in October 2013 and has served as our Senior Vice President of Finance since January 2015. Prior to joining Aduro, Ms. Lew held various roles at Dynavax Technologies Corporation, a biopharmaceutical company, from 2004 to October 2013, most recently as Vice President of Finance and Principal Accounting Officer, where she oversaw accounting and finance operations. Prior to joining Dynavax, Ms. Lew held positions as Assistant Controller and Director of Finance at QRS Corporation, a publicly-held technology company, from 2000 to 2004. Ms. Lew was a member of the audit practice at Ernst & Young from 1994 to 1999. She earned a B.A. in Economics/Accounting and Government from Claremont McKenna College and is a Certified Public Accountant (inactive status).

Board of Directors

Dr. Gerald Chan has served on our board of directors since 2014. Dr. Chan co-founded Morningside Venture (VI) Investments Limited, a private investment group with venture, private equity and property investments, in 1986. He has served as a member of the Global Advisory Council of the International Society for Stem Cell Research since 2008, the Global Advisory Council of Harvard University since 2012, the Dean s Board of Advisors of the Harvard School of Public Health since 2011, the advisory boards of the Cold Spring Harbor Conferences Asia since 2008, the Johns Hopkins Nanjing Center since 2004 and the Columbia University Center for Radiological Research since 2010. Dr. Chan also has been a member of the board of directors of Hang Lung Group Limited since 1986. Dr. Chan received his B.S. and M.S. degrees in engineering from the University of California, Los Angeles, and his Master s degree in medical radiological physics and Doctor of Science degree in radiation biology from Harvard University. He did his post-doctoral training at the Dana-Farber Cancer Institute as a fellow of the Leukemia Society of America. Because of his extensive experience in life science investments, we believe Dr. Chan will make valuable contributions

to our board of directors.

William M. Greenman has served as a member of our board of directors since 2010. Mr. Greenman is currently the President and Chief Executive Officer of Cerus Corporation, and has held several executive and management positions with Cerus since joining the company in 1995. Prior to Cerus, he worked in various

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marketing and business development positions in Baxter s Biotech Division from 1991 to 1995. Mr. Greenman holds undergraduate degrees in Biological Sciences and Economics from Stanford University. Because of his extensive experience holding executive positions and knowledge of the biomedical industry, we believe Mr. Greenman is able to make valuable contributions to our board of directors.

Ross Haghighat has served as a member of our board of directors since 2009. Mr. Haghighat is the founder, Chairman and Managing Partner of Triton Systems, Inc. Mr. Haghighat has served on the board of Triton Systems, Inc., a product venturing company, where he has also served as its Chief Executive Officer since 2009. Mr. Haghighat has served on the board of directors of Triton Systems, S12 Technologies and FRX Polymers since 2009. Mr. Haghighat holds a Bachelor s of Science and a Masters in Material Science, Organometallic Chemistry from Rutgers University and a Master of Business Administration from Boston College. Because of his extensive experience in the biotechnology field, we believe Mr. Haghighat will provide valuable contributions to our board of directors.

Frank McCormick, Ph.D., F.R.S., D.Sc. (Hon) has served as a member of our board of directors since 2010. Dr. McCormick has held the positions of Director of the University of California, San Francisco, or UCSF, Helen Diller Family Comprehensive Cancer Center, a multidisciplinary research and clinical care organization, since 1997, the position of Associate Dean of the UCSF School of Medicine since 1997 and has been a Fellow of the Royal Society, a society for science, since 1996. Prior to joining the UCSF faculty, Dr. McCormick pursued cancer-related work with several biotechnology firms, including Cetus Corporation as Director of Molecular Biology from 1981 to 1990 and Vice President of Research from 1990 to 1991, and Chiron Corporation as Vice President of Research from 1991 to 1992. In 1992, Dr. McCormick founded Onyx Pharmaceuticals and served as its Chief Scientific Officer until 1996. Dr. McCormick received his B.Sc. in biochemistry from the University of Birmingham, and his Ph.D. in biochemistry from the University of Cambridge and held postdoctoral fellowships in the U.S. at the State University of New York at Stony Brook and in London at the Imperial Cancer Research Fund. Because of Dr. McCormick s extensive experience in the biomedical industry, we believe Dr. McCormick is able to make valuable contributions to our board of directors.

Stephanie Monaghan O Brien has served as a member of our board of directors since 2011. Ms. O Brien has been a member of the investment team at Morningside since 1997. She has served as a director for numerous private nonclinical and clinical stage companies developing drugs across a broad spectrum of therapeutic focus, including oncology and immunotherapy, and has extensive experience providing operational and management oversight to venture-backed technology companies. She has also facilitated multiple financings for public and private companies such as Dendreon, BioVex, Stealth Biotherapeutics and Sohu.com. Prior to joining Morningside, Ms. O Brien spent nine years as a corporate lawyer with Hale and Dorr in the Boston and Washington, D.C. offices, working primarily on public offerings, venture capital finances and start-up companies. She previously worked at Chase Manhattan Bank, working in international portfolio analysis. She received her A.B., cum laude, from Harvard College and her J.D. from New York University School of Law. Because of Ms. O Brien s extensive experience serving on boards of directors and governing biotechnology companies, we believe she is able to make valuable contributions to our board of directors.

Board Composition

Certain members of our board of directors were elected pursuant to the provisions of our amended and restated voting agreement. Under this agreement, our stockholders that are party to the agreement have agreed to vote their shares to elect to our board of directors: (i) two directors designated by a majority of the outstanding shares Series B convertible preferred stock, one of whom small be designated by MVIL for so long as MVIL holds at least 50% of the shares of Series B convertible preferred stock originally purchase by MVIL; (ii) two directors designated by purchasers who invested at least 60% of the Series C convertible preferred stock investment amount and who shall be reasonably

acceptable to MVIL; (iii) the person serving as Chief Executive Officer; and (vi) two individuals to serve as independent directors. This agreement will terminate upon the completion of this offering.

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Our board may establish the authorized number of directors from time to time by resolution. Our board of directors currently consists of six members. In accordance with our amended and restated certificate of incorporation to be filed in connection with this offering, immediately after this offering, our board of directors will be divided into three classes with staggered three-year terms. At each annual general meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors will be divided among the three classes as follows:

- the Class I directors will be Stephen T. Isaacs and William M. Greenman, and their terms will expire at the annual general meeting of stockholders to be held in 2016;
- the Class II directors will be Ross Haghighat and Frank McCormick, and their terms will expire at the annual general meeting of stockholders to be held in 2017; and
- the Class III directors will be Gerald Chan and Stephanie Monaghan O Brien, and their terms will expire at the annual general meeting of stockholders to be held in 2018.

We expect that any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control.

Director Independence

Generally, under the listing requirements and rules of NASDAQ, independent directors must comprise a majority of a listed company s board of directors within one year of the closing of this offering. Our board of directors has undertaken a review of its composition, the composition of its committees and the independence of each director. Our board of directors has determined that, other than Stephen Isaacs by virtue of his position as Chief Executive Officer, none of our directors has a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each is independent as that term is defined under the listing requirements of NASDAQ. Accordingly, a majority of our directors is independent, as required under applicable NASDAQ rules. In making this determination, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director.

Lead Independent Director

Our board of directors has appointed Stephanie Monaghan O Brien to serve as our lead independent director. As lead independent director, Ms. O Brien presides over periodic meetings of our independent directors, serves as a liaison between our Chief Executive Officer and the independent directors and performs such additional duties as our board of directors may otherwise determine and delegate.

Board Committees

The standing committees of our board of directors consist of an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee. Each of the committees report to the board of directors as they deem appropriate and as the board may request. The composition, duties and responsibilities of the committees are set forth below.

Audit Committee

Our audit committee consists of William Greenman, Ross Haghighat and Stephanie Monaghan O Brien. Our board of directors has determined that William Greenman, Ross Haghighat and Stephanie Monaghan O Brien

are independent under NASDAQ listing standards and Rule 10A-3(b)(1) of the Exchange Act. The chair of our audit committee is William Greenman, who our board of directors has determined is an audit committee financial expert within the meaning of SEC regulations. Our board of directors has also determined that each member of our audit committee has the requisite financial expertise required under the applicable requirements of NASDAQ. In arriving at this determination, the board has examined each audit committee member s scope of experience and the nature of their employment in the corporate finance sector. The primary functions of this committee include:

- reviewing and approving the engagement of our independent registered public accounting firm to perform audit services and any permissible non-audit services;
- evaluating the performance of our independent registered public accounting firm and deciding whether to retain their services;
- monitoring the rotation of partners on our engagement team of our independent registered public accounting firm;
- reviewing our annual and quarterly financial statements and reports and discussing the statements and reports with our independent registered public accounting firm and management, including a review of disclosures under Management s Discussion and Analysis of Financial Condition and Results of Operations;
- considering and approving or disapproving all related party transactions;
- reviewing, with our independent registered public accounting firm and management, significant issues that may arise regarding accounting principles and financial statement presentation, as well as matters concerning the scope, adequacy and effectiveness of our financial controls;
- conducting an annual assessment of the performance of the audit committee and its members, and the adequacy of its charter; and
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding financial controls, accounting or auditing matters.

Compensation Committee

Our compensation committee consists of Ross Haghighat and Stephanie Monaghan O Brien. Our board of directors has determined that each of Ross Haghighat and Stephanie Monaghan O Brien is independent under NASDAQ listing standards and the rules and regulations of the SEC, is a non-employee director as defined in Rule 16b-3 promulgated under the Exchange Act and is an outside director as that term is defined in Section 162(m) of the Code. The chair of our compensation committee is Stephanie Monaghan O Brien. The functions of this committee include:

determining the compensation and other terms of employment of our chief executive officer and our other executive officers and reviewing and approving corporate performance goals and objectives relevant to such compensation;

reviewing and recommending to the full board of directors the compensation of our directors;

evaluating and administering the equity incentive plans, compensation plans and similar programs advisable for us, as well as reviewing and recommending to our board of directors the adoption, modification or termination of our plans and programs;

establishing policies with respect to equity compensation arrangements;

reviewing with management our disclosures under the caption Compensation Discussion and Analysis and recommending to the full board its inclusion in our periodic reports to be filed with the SEC; and

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reviewing and evaluating, at least annually, the performance of the compensation committee and the adequacy of its charter.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of Gerald Chan, William Greenman and Frank McCormick. Our board of directors has determined that Gerald Chan, William Greenman and Frank McCormick are independent under NASDAQ listing standards and the rules and regulations of the SEC. The chair of our nominating and corporate governance committee is Gerald Chan. The functions of this committee include:

reviewing periodically and evaluating director performance on our board of directors and its applicable committees, and recommending to our board of directors and management areas for improvement;

interviewing, evaluating, nominating and recommending individuals for membership on our board of directors;

reviewing and recommending to our board of directors any amendments to our corporate governance policies; and

reviewing and assessing, at least annually, the performance of the nominating and corporate governance committee and the adequacy of its charter.

Code of Business Conduct and Ethics

In connection with this offering, our board of directors has adopted a code of business conduct and ethics that applies to all of our employees, officers and directors, including those officers responsible for financial reporting. Upon completion of this offering, our code of business conduct and ethics will be available on our website at www.aduro.com. We intend to disclose any amendments to the code, or any waivers of its requirements, on our website to the extent required by the applicable rules and exchange requirements. The inclusion of our website address in this prospectus does not include or incorporate by reference into this prospectus the information on or accessible through our website.

Compensation Committee Interlocks and Insider Participation

None of the members of the compensation committee is currently or has been at any time one of our officers or employees. None of our executive officers currently serves, or has served during the last year, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of our board of directors or compensation committee.

Non-Employee Director Compensation

The table below shows all compensation earned by or paid to our non-employee directors during the year ended December 31, 2014.

Name	Fees Earned or Paid in Cash	Option Awards[1]	Total
Gerald Chan	$	$ 19,506	$ 19,506
William M. Greenman		10,802	10,802
Ross Haghighat		10,802	10,802
Frank McCormick, Ph.D.		10,802	10,802
Stephanie Monaghan O Brien		10,802	10,802

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(1) The amounts in the Option Awards column reflect the aggregate grant date fair value of stock options granted during the calendar year computed in accordance with the provisions of Accounting Standards Codification (ASC) 718, *Compensation Stock Compensation*. The assumptions that we used to calculate these amounts are discussed in the notes to our audited consolidated financial statements included elsewhere in this prospectus. These amounts do not reflect the actual economic value that will be realized by the named executive officer upon the vesting of the stock options, the exercise of the stock options, or the sale of the common stock underlying such stock options.

Future Director Compensation

Our board of directors has adopted a director compensation policy for non-employee directors to be effective upon the closing of this offering. Pursuant to this policy, non-employee directors will be compensated $35,000 annually for their services and will not receive any additional compensation for any board meetings attended. Our lead non-employee director will receive an additional annual retainer of $15,000. Non-employee directors will receive $7,500 annually for serving on the audit committee ($15,000 annually for the chairman), $5,000 annually for serving on the compensation committee ($10,000 annually for the chairman), and $4,000 annually for serving on the nominating and corporate governance committee ($8,000 annually for the chairman). Non-employee directors will also be reimbursed for their reasonable out-of-pocket expenses incurred in attending meetings of our board of directors and committees of our board of directors. Newly appointed directors will be granted an option to purchase 15,000 shares of our common stock. The shares of common stock subject to these options will vest over three years, with one-third of the shares subject to the option vesting after the first year, and with the remaining shares subject to the option to vest in eight equal quarterly installments thereafter. Each non-employee director will also be granted an option to purchase 13,000 shares of our common stock on the date of each annual meeting of stockholders. The shares of common stock subject to these options will vest quarterly over 12 months. All options granted to our non-employee directors under the policy will vest in full upon the completion of a change in control.

On the date of this offering, we intend to grant each of our non-employee directors an option to purchase shares of our common stock having an exercise price per share equal to the initial public offering price of our common stock in this offering. Ms. O Brien and Mr. Haghighat will each be granted an option to purchase 65,000 shares of our common stock, Mr. Greenman will be granted an option to purchase 40,000 shares of our common stock, Dr. McCormick will be granted an option to purchase 30,000 shares of our common stock and Mr. Chan will be granted an option to purchase 20,000 shares of our common stock. The shares underlying the options will vest monthly over one year and will vest in full upon the completion of a change in control.

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EXECUTIVE COMPENSATION

Summary Compensation Table

The following table sets forth information regarding the compensation awarded to or earned by our Chief Executive Officer and our two other highest paid executive officers during the years ended December 31, 2013 and 2014. Throughout this prospectus, these officers are referred to as our named executive officers.

Name and Principal Position	Year	Salary ($)	Bonus ($)[1]	Option Awards ($)[2]	All Other Compensation ($)	Total ($)
Stephen T. Isaacs	2014	402,500	484,100	609,380	6,146	1,502,126
Chairman, President and Chief Executive Officer	2013	372,501	110,441	26,174	6,657	515,773
Gregory W. Schafer[3]	2014	318,000	267,900	168,673	46	754,619
Chief Operating Officer	2013	150,000	39,759	154,920	276	344,955
Thomas W. Dubensky, Jr., Ph.D.	2014	319,545	265,350	119,043	3,391	707,329
Chief Scientific Officer	2013	312,885	69,812	6,804	3,897	393,398

(1) Includes discretionary annual cash bonuses based on a target percentage of salary and discretionary bonuses for extraordinary performance in 2014 as awarded by the board of directors.

(2) The amounts in the Option Awards column reflect the aggregate grant date fair value of stock options granted during the calendar year computed in accordance with the provisions of Accounting Standards Codification (ASC) 718, *Compensation Stock Compensation*. The assumptions that we used to calculate these amounts are discussed in the notes to our audited consolidated financial statements included elsewhere in this prospectus. These amounts do not reflect the actual economic value that will be realized by the named executive officer upon the vesting of the stock options, the exercise of the stock options, or the sale of the common stock underlying such stock options.

(3) Mr. Schafer became an employee in July 2013.

In March 2015, our compensation committee approved discretionary bonuses to certain of our executive officers, including a bonus of $400,000 to Mr. Isaacs, a bonus of $240,000 to Mr. Schafer and a bonus of $210,000 to Dr. Dubensky.

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Outstanding Equity Awards at December 31, 2014

The following table provides information regarding outstanding equity awards held by our named executive officers at December 31, 2014.

		Option Awards			
Name	Vesting Commencement Date	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Option Exercise Price	Option Expiration Date
Stephen T. Isaacs	5/15/2006	204		19.59	5/15/2016
	2/12/2007	7,158		19.59	2/12/2017
	2/12/2008	2,126		34.31	2/12/2018
	2/12/2008	1,063		68.45	2/12/2018
	4/15/2011	241,954		0.52	10/24/2021
	4/15/2011	305,222		0.52	10/24/2021
	4/15/2011[1]	411,898	37,446	0.52	10/24/2021
	11/9/2012	261,191		0.45	3/18/2020
	11/9/2012	19,672		0.45	3/18/2020
	11/9/2012	36,532		0.45	3/18/2020
	11/27/2013	51,843		0.82	11/26/2023
	7/31/2014[2]	93,831	806,959	1.00	7/30/2024
Gregory W. Schafer	7/1/2013[1]	99,686	181,781	0.82	11/26/2023
	7/31/2014[2]	26,023	223,815	1.00	7/30/2024
Thomas W. Dubensky, Jr., Ph.D.	9/1/2011[1]	178,434	41,177	0.52	10/23/2021
	9/1/2011[3]	98,542	19,710	0.52	10/23/2021
	11/9/2012	3,649		0.45	3/18/2020
	11/27/2013	13,474		0.82	11/26/2023

	7/31/2014(2)	18,367	157,960	1.00	7/30/2024

(1) Twenty-five percent of the shares subject to the option vested on the first anniversary of the vesting commencement date, and the remainder vests in 36 equal monthly installments thereafter.
(2) The option vests as to 1/48 of the shares in monthly installments measured from July 31, 2014.
(3) 9,856 shares subject to the option vested on December 31, 2011, 29,562 shares subject to the option vested on December 31, 2012, 2013 and 2014, and the remaining 19,710 shares subject to the option vest on December 31, 2015.

Employment and Severance Agreements

We entered into an employment agreement with Stephen Isaacs, our Chairman, President and Chief Executive Officer, in February 2010, which was subsequently amended in July 2014. Mr. Isaacs is employed at will, which means that he has no definitive term of employment. The employment agreement provides for an annual base salary, which for 2013 was set at $380,000 and provides that Mr. Isaacs will be eligible to participate in any bonus plans established by us. If Mr. Isaacs is terminated by us without just cause and not due to his permanent disability, or if he terminates his employment for good reason, he will receive a lump sum payment equal to one year of his base salary and a lump sum payment equal to the product of his target bonus for the year in which his termination occurs multiplied by a percentage equal to the quotient of the number of days that lapsed in the year of termination divided by 365 (366 if a leap year), we will pay all applicable COBRA payments for up to 12 months, and all of his unvested equity awards will immediately vest in full, subject to Mr. Isaacs timely execution and the effectiveness of a release of claims against us. Additionally, upon the occurrence of a change in control, any and all of Mr. Isaacs unvested equity awards will immediately vest in full. Mr. Isaacs also entered into our standard proprietary information and inventions agreement.

We entered into an offer letter agreement with Gregory Schafer, our Chief Operating Officer, in April 2013. Mr. Schafer is employed at will, which means that he has no definitive term of employment. The offer

agreement provides for an initial base salary of $300,000 and provides for an annual cash bonus with a target level of 30% of his base salary, subject to the achievement of performance metrics. Mr. Schafer s offer letter also provided certain severance benefits, which were replaced in July 2014, when we entered into a severance agreement with Mr. Schafer. The offer letter agreement was subject to execution of our standard proprietary information and inventions agreement. The severance agreement provides that if Mr. Schafer is terminated by us without cause, and not due to his death or disability, or terminates his employment for good reason, each a qualifying termination, he will continue to receive his base salary for a period of six months following the termination date, we will pay applicable COBRA payments for a period of up to six months following the termination date, he will receive a lump sum payment equal to the product of his target bonus for the year in which his termination occurs multiplied by a percentage equal to the quotient of the number of days that lapsed in the year of termination divided by 365 (366 if a leap year), and the unvested portion of all of his equity awards will become vested and exercisable on an accelerated basis as if the termination had occurred six months after the termination date, subject to Mr. Schafer s timely execution and the effectiveness of a release of all claims against us. If Mr. Schafer s qualifying termination occurs during the time period beginning on the closing date of a change in control and ending on the first anniversary of such change in control, then the unvested portion of all of his equity awards shall become vested and exercisable on the qualifying termination date.

We entered into an offer letter agreement with Thomas W. Dubensky, Jr., Ph.D., our Chief Scientific Officer, in September 2011. Dr. Dubensky is employed at will, which means that he has no definitive term of employment. The offer letter agreement provides for an annual base salary, which for 2013 was set at $315,180 and provides for an annual cash bonus with a target level of not less than 25% of his base salary, subject to the achievement of performance metrics. The offer letter agreement was subject to execution of our standard proprietary information and inventions agreement. In July 2014, we entered into a severance agreement with Dr. Dubensky. The severance agreement provides that if Dr. Dubensky is terminated by us without cause, and not due to his death or disability, or terminates his employment for good reason, each a qualifying termination, he will continue to receive his base salary for a period of six months following the termination date, we will pay applicable COBRA payments for a period of up to six months following the termination date, he will receive a lump sum payment equal to the product of his target bonus for the year in which his termination occurs multiplied by a percentage equal to the quotient of the number of days that lapsed in the year of termination divided by 365 (366 if a leap year), and the unvested portion of all of his equity awards will become vested and exercisable on an accelerated basis as if the termination had occurred six months after the termination date, subject to Dr. Dubensky s timely execution and the effectiveness of a release of all claims against us. If Dr. Dubensky s qualifying termination occurs during the time period beginning on the closing date of a change in control and ending on the first anniversary of such change in control, then the unvested portion of all of his equity awards shall become vested and exercisable on the qualifying termination date.

Employee Benefit Plans

The principal features of our equity incentive plans are summarized below. These summaries are qualified in their entirety by reference to the actual text of the plans, which are filed as exhibits to the registration statement of which this prospectus is a part.

Oncologic, Inc. 2000 Long-Term Incentive Plan

The board of directors of Oncologic, Inc. adopted the Oncologic, Inc. 2000 Long-Term Incentive Plan., or the 2000 Long-Term Incentive Plan, in December 2000. Since the adoption of our 2009 Stock Incentive Plan, our board of directors has not granted and will not grant any additional options under the 2000 Long-Term Incentive Plan. However, the 2000 Long-Term Incentive Plan continues to govern the terms and conditions of outstanding options previously granted under the plan.

The 2000 Long-Term Incentive Plan provided for the grant of incentive stock options to our employees, and for the grant of non-qualified stock options, stock appreciation rights, restricted stock, dividend equivalents

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and other incentive awards to our employees, directors and consultants. Our board of directors, or a committee thereof appointed by our board of directors, administers the 2000 Long-Term Incentive Plan and the stock awards granted thereunder. The administrator has the authority to determine the terms and conditions of stock awards granted under the plan.

In the event of a corporate transaction, including a reorganization, merger, consolidation or sale of all or substantially all of our assets, the board of directors may, without the consent or approval of any participant: (1) accelerate the vesting and the time at which stock awards may be exercised, in whole or in part, of the stock awards and provide for their termination if not exercised prior to the corporate transaction; (2) require the mandatory surrender of some or all outstanding stock awards as of a specified date, in which case our board of directors would cancel such awards prior to the corporate transaction in exchange for a cash payment; (3) make such adjustments to the stock awards so that such stock awards thereafter cover the number and class of shares of stock or other securities to which the holder of such stock awards would have been entitled pursuant to the terms of the corporate transaction had such holder been the holder of record of the number of shares covered by the stock award; or (4) in the event of a transaction in which our common stockholder receive shares in the acquiror, the conversion of the stock awards into awards to acquire shares of the acquiror, assumption, continuation or substitution of a stock award by a successor corporation.

Triton BioSystems, Inc. 2001 Equity Incentive Plan

The board of directors of Triton BioSystems, Inc. adopted, and its stockholders approved, the Triton BioSytems, Inc. 2001 Equity Incentive Plan, or the 2001 Equity Incentive Plan, in March 2001. Since the adoption of our 2009 Stock Incentive Plan, our board of directors has not granted and will not grant any additional options under the 2001 Equity Incentive Plan. However, the 2001 Equity Incentive Plan continues to govern the terms and conditions of outstanding options previously granted under the plan.

The 2001 Equity Incentive Plan provided for the grant of incentive stock options to our employees, and for the grant of non-qualified stock options and restricted shares to our employees, directors, consultants and other individuals who provide services to us. Our board of directors, or a committee thereof appointed by our board of directors, administers the 2001 Equity Incentive Plan and the stock awards granted thereunder. The administrator has the authority to determine the terms and conditions of the options and restricted shares granted under the plan.

In the event of a change in control, including a sale of more than 50% of the voting power of our stock or a sale of substantially all of our assets, the administrator will take any one or more of the following actions with respect to each outstanding stock award: (1) cause an option to become fully vested and exercisable, (2) cause restricted shares to become non-forfeitable, (3) cancel an option in exchange for an option to purchase common stock of any successor company, (4) substitute restricted shares in exchange for restricted stock of any successor company, (5) cancel an option in exchange for cash and/or other consideration with a value equal to the difference between the option exercise price and the fair market value per share on the date of the change in control, or (6) redeem restricted shares in exchange for cash and/or other consideration.

2009 Stock Incentive Plan

Our board of directors adopted our 2009 Stock Incentive Plan, or the 2009 Stock Incentive Plan, and our stockholders approved our 2009 Stock Incentive Plan in October 2009. The 2009 Stock Incentive Plan was subsequently amended in 2011. The 2009 Stock Incentive Plan provides for the grant of incentive stock options to our employees and nonstatutory stock options and stock purchase awards to our employees, directors and consultants. At December 31, 2014, options to purchase 5,970,382 shares of our common stock at a weighted-average exercise price per share of $0.80 were outstanding under the 2009 Stock Incentive Plan. No other awards have been granted under the 2009

Stock Incentive Plan. At December 31, 2014, 3,154,755 shares of our common stock were available for future issuance pursuant to awards granted under the 2009 Stock Incentive Plan.

Following the completion of this offering and in connection with the effectiveness of our 2015 Plan, the 2009 Stock Incentive Plan will terminate and no further awards will be granted under the 2009 Stock Incentive Plan. However, all outstanding awards will continue to be governed by their existing terms.

Our board of directors, or a committee thereof appointed by our board of directors, administers the 2009 Stock Incentive Plan and the stock awards granted thereunder. The administrator has the authority to determine the terms and conditions of the options and restricted shares granted under the plan.

In the event of a change of control, including a reorganization, merger, consolidation or sale of all or substantially all of our assets, the board of directors may: (1) accelerate the vesting, in whole or in part, of the stock awards and provide for the cancellation of the awards with notice to the holders at least three days prior to the change in control, and its termination of the Stock Incentive Plan prior to the change in control; (2) cancel or arrange for the cancellation of the plan and all outstanding stock awards with notice to the holders at least three days prior to the change in control without the payment of any consideration; (3) the assumption of the 2009 Stock Incentive Plan and all outstanding stock awards by the successor corporation or its parent; (4) the substitution by the successor corporation or its parent of options in the successor corporation or its parent with substantially the same terms for the outstanding options; or (5) the settlement for full value of all outstanding options under the 2009 Stock Incentive Plan determined as the number of shares to which the options relate multiplied by the difference between the fair market value of a share of our common stock on the date of the change in control and the exercise price.

2015 Equity Incentive Plan

Our board of directors adopted our 2015 Plan in March 2015 and our stockholders approved our 2015 Plan in April 2015. Our 2015 Plan, which becomes effective upon the pricing of this offering, is the successor to and continuation of the Stock Incentive Plan. Our 2015 Plan provides for the grant of incentive stock options, or ISOs, to our employees and for the grant of nonstatutory stock options, or NSOs, stock appreciation rights, restricted stock awards, RSU awards, performance stock awards, performance cash awards, and other forms of stock awards to our employees, directors, and consultants.

Authorized shares. The maximum number of shares of our common stock that may be issued pursuant to stock awards under our 2015 Plan is equal to 6,134,292, which number of shares will be increased by any shares subject to stock options or other stock awards granted under the 2009 Stock Incentive Plan that would have otherwise returned to our 2009 Stock Incentive Plan (such as upon the expiration or termination of a stock option prior to vesting), not to exceed 8,995,064. Additionally, the number of shares of our common stock reserved for issuance pursuant to stock awards under our 2015 Plan will automatically increase on January 1 of each year for a period of up to ten years, beginning on January 1, 2016 and ending on 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. The maximum number of shares of our common stock that may be issued upon the exercise of ISOs under our 2015 Plan is 30,671,460.

Shares subject to stock awards granted under our 2015 Plan that expire or terminate without being exercised in full, or that are paid out in cash rather than in shares, do not reduce the number of shares available for issuance under our 2015 Plan. Additionally, shares issued pursuant to stock awards under our 2015 Plan that we repurchase or that are forfeited, as well as shares used to pay the exercise price of a stock award or to satisfy the tax withholding obligations related to a stock award, become available for future grant under our 2015 Plan.

Plan administration. Our board of directors, or a duly authorized committee of our board of directors, will administer our 2015 Plan. Our board of directors may also delegate to one or more of our officers the authority to (1) designate

employees (other than officers) to receive specified stock awards, and (2) determine the number of shares subject to such stock awards. Subject to the terms of our 2015 Plan, the board of directors has the authority to determine the terms of awards, including recipients, the exercise, purchase or strike price of stock

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awards, if any, the number of shares subject to each stock award, the fair market value of a share of our common stock, the vesting schedule applicable to the awards, together with any vesting acceleration, and the form of consideration, if any, payable upon exercise or settlement of the award and the terms of the award agreements for use under our 2015 Plan.

The board of directors has the power to modify outstanding awards under our 2015 Plan. The board of directors has the authority to reprice any outstanding option or stock appreciation right, cancel any outstanding stock award in exchange for new stock awards, cash or other consideration or take any other action that is treated as a repricing under GAAP, with the consent of any adversely affected participant.

Section 162(m) limits. At such time as necessary for compliance with Section 162(m) of the Code, no participant may be granted stock awards that are intended to comply with Section 162(m) of the Code covering more than 2,000,000 shares of our common stock under our 2015 Plan during any calendar year pursuant to stock options, stock appreciation rights and other stock awards whose value is determined by reference to an increase over an exercise price or strike price of at least 100% of the fair market value of our common stock on the date of grant. Additionally, no participant may be granted in a calendar year a performance stock award covering more than 2,000,000 shares of our common stock or a performance cash award having a maximum value in excess of $5,000,000 under our 2015 Plan. These limitations are intended to give us the flexibility to grant compensation that will not be subject to the $1,000,000 annual limitation on the income tax deductibility imposed by Section 162(m) of the Code.

Performance awards. We believe our 2015 Plan permits the grant of performance-based stock and cash awards that may qualify as performance-based compensation that is not subject to the $1,000,000 limitation on the income tax deductibility imposed by Section 162(m) of the Code. Our compensation committee may structure awards so that the stock or cash will be issued or paid only following the achievement of certain pre-established performance goals during a designated performance period.

Our compensation committee may establish performance goals by selecting from one or more of the following performance criteria: (1) profit before tax; (2) billings; (3) revenues; (4) net revenues; (5) earnings (which may include earnings before interest and taxes, earnings before taxes, and net earnings); (6) operating income; (7) operating margin; (8) operating profit; (9) controllable operating profit, or net operating profit; (10) net profit; (11) gross margin; (12) operating expenses or operating expenses as a percentage of revenue; (13) net income; (14) earnings per share; (15) total stockholder return; (16) market share; (17) return on assets or net assets; (18) our stock price; (19) growth in stockholder value relative to a pre-determined index; (20) return on equity; (21) return on invested capital; (22) cash flow (including free cash flow or operating cash flows); (23) cash conversion cycle; (24) economic value added; (25) individual confidential business objectives; (26) contract awards or backlog; (27) overhead or other expense reduction; (28) credit rating; (29) strategic plan development and implementation; (30) succession plan development and implementation; (31) improvement in workforce diversity; (32) customer indicators; (33) new product invention or innovation; (34) attainment of research and development milestones; (35) improvements in productivity; (36) bookings; (37) initiation of phases of clinical trials and/or studies by specified dates; (38) regulatory body approval with respect to products, studies and/or trials; (39) patient enrollment dates; (40) commercial launch of products; and (41) to the extent that an award is not intended to comply with Section 162(m) of the Code, other measures of performance selected by our board of directors or compensation committee.

Our compensation committee may establish performance goals on a company-wide basis, with respect to one or more business units, divisions, affiliates, or business segments, and in either absolute terms or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless otherwise specified by our board of directors (i) in the award agreement at the time the award is granted or (ii) in such other document setting forth the performance goals at the time the performance goals are established, our compensation committee will

appropriately make adjustments in the method of calculating the attainment of the performance goals as follows: (1) to exclude restructuring and/or other nonrecurring charges;

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(2) to exclude exchange rate effects; (3) to exclude the effects of changes to GAAP; (4) to exclude the effects of any statutory adjustments to corporate tax rates; (5) to exclude the effects of any extraordinary items as determined under GAAP; (6) to exclude the dilutive effects of acquisitions or joint ventures; (7) to assume that any business divested by our company achieved performance objectives at targeted levels during the balance of a performance period following such divestiture; (8) to exclude the effect of any change in the outstanding shares of our common stock by reason of any stock dividend or split, stock repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination or exchange of shares or other similar corporate change, or any distributions to common stockholders other than regular cash dividends; (9) to exclude the effects of stock based compensation and the award of bonuses under our bonus plans; (10) to exclude costs incurred in connection with potential acquisitions or divestitures that are required to be expensed under GAAP; (11) to exclude the goodwill and intangible asset impairment charges that are required to be recorded under GAAP; (12) to exclude the effect of any other unusual, non-recurring gain or loss or other extraordinary item; (13) to exclude the effects of the timing of acceptance for review and/or approval of submissions to the FDA or any other regulatory body; and (14) to exclude the effects of entering into or achieving milestones involved in licensing joint ventures.

Changes to Capital Structure. In the event there is a specified type of change in our capital structure, such as a stock split, reverse stock split or recapitalization, appropriate adjustments will be made to: (1) the class and maximum number of shares reserved for issuance under our 2015 Plan; (2) the class and maximum number of shares by which the share reserve may increase automatically each year; (3) the class and maximum number of shares that may be issued upon the exercise of incentive stock options; (4) the class and maximum number of shares subject to stock awards that can be granted in a calendar year (as established under our 2015 Plan pursuant to Section 162(m) of the Code); and (5) the class and maximum number of shares and exercise price, strike price or purchase price, if applicable, of all outstanding stock awards.

Corporate transactions. Our 2015 Plan provides that in the event of certain specified significant corporate transactions, as defined under our 2015 Plan, each outstanding award will be treated as the administrator determines. The administrator may (1) arrange for the assumption, continuation or substitution of a stock award by a successor corporation; (2) arrange for the assignment of any reacquisition or repurchase rights held by us to a successor corporation; (3) accelerate the vesting, in whole or in part, of the stock award and provide for its termination prior to the transaction; (4) arrange for the lapse, in whole or in part, of any reacquisition or repurchase rights held by us; (5) cancel or arrange for the cancellation of the stock award prior to the transaction in exchange for a cash payment, if any, determined by the board of directors; or (6) cancel or arrange for the cancellation of the stock award prior to the transaction in exchange for a payment, in such form as may be determined by our board of directors equal to the excess, if any, of the value of the property the participant would have received upon the exercise of the stock award immediately prior to the transaction over any exercise price payable by such holder in connection with such exercise. The plan administrator is not obligated to treat all stock awards or portions of stock awards, even those that are of the same type, in the same manner.

Plan amendment or termination. Our board of directors has the authority to amend, suspend, or terminate our 2015 Plan, provided that such action does not materially impair the existing rights of any participant without such participant s written consent. No ISOs may be granted after the tenth anniversary of the date our board of directors adopted our 2015 Plan. No stock awards may be granted under our 2015 Plan while it is suspended or after it is terminated.

2015 Employee Stock Purchase Plan

Our board of directors adopted our ESPP in March 2015 and our stockholders approved our ESPP in April 2015. Our ESPP, which becomes effective upon the pricing of this offering, is intended to qualify as an employee stock purchase

plan under Section 423 of the Code. The first offering period under our ESPP will begin and end upon a date to be approved by our board of directors or the compensation committee.

Authorized shares.The maximum aggregate number of shares of our common stock that may be issued under our ESPP is 720,000 shares. Additionally, the number of shares of our common stock reserved for issuance

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under our ESPP will increase automatically each year for a period of up to ten years, beginning on January 1, 2016 and continuing through and including January 1, 2025, by the lesser of (1) 1% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year; (2) 1,080,000 shares of common stock; or (3) such lesser number as determined by our board of directors. The stock purchasable under our ESPP will be shares of authorized but unissued or reacquired common stock, including shares repurchased by us in the open market. Shares subject to purchase rights granted under our ESPP that terminate without having been exercised in full will be available for grant under our ESPP.

ESPP administration. Our board of directors will administer our ESPP. Our board of directors may delegate authority to administer our ESPP to our compensation committee. The administrator may approve offerings with a duration of not more than 27 months, and may specify one or more shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of our common stock will be purchased for the employees who are participating in the offering. The administrator, in its discretion, will determine the terms of offerings under our ESPP including determining which of our designated affiliates will be eligible to participate in the 423 component of our ESPP and which of our designated affiliates will be eligible to participate in the non-423 component of our ESPP.

Eligibility. Our employees, including executive officers, may have to satisfy one or more of the following service requirements before participating in our ESPP, as determined by the administrator: (1) customary employment for more than 20 hours per week and more than five months per calendar year, or (2) continuous employment for a minimum period of time, not to exceed two years. An employee may not be granted rights to purchase stock under our ESPP if such employee (a) immediately after the grant would own stock possessing 5% or more of the total combined voting power or value of our common stock; or (b) holds rights to purchase stock under our ESPP that would accrue at a rate that exceeds $25,000 worth of our stock for each calendar year that the rights remain outstanding.

Purchase rights and purchase price. Our ESPP permits participants to purchase shares of our common stock through payroll deductions or other methods with up to 15% of their earnings, as defined in the ESPP. The purchase price of the shares will be not less than 85% of the lower of the fair market value of our common stock on the first day of an offering or on the date of purchase.

Corporate transactions. In the event of certain specified corporate transactions, as defined in our ESPP, a successor corporation may assume, continue or substitute each outstanding purchase right. If the successor corporation does not assume, continue or substitute for the outstanding purchase rights, the offering in progress may be shortened and a new exercise date will be set, so that the participants purchase rights can be exercised and terminate immediately thereafter.

Changes to Capital Structure. In the event there occurs a change in our capital structure through such actions as a stock split, merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or similar transaction, the board of director will make appropriate adjustments to: (1) the number of shares reserved under our ESPP; (2) the maximum number of shares by which the shares reserve may increase automatically each year; (3) the number of shares and purchase price of all outstanding purchase rights; and (4) the number of shares that are subject to purchase limits under ongoing offerings.

ESPP amendment or termination. Our board of directors has the authority to amend, suspend or terminate our ESPP, at any time and for any reason. Any benefits, privileges, entitlements and obligations under any outstanding purchase rights granted before an amendment, suspension or termination of our ESPP will not be materially impaired except (1) with the participant s consent; (2) to comply with any laws, listing requirements or regulations; or (3) to obtain or maintain favorable tax, listing or regulatory treatment.

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401(k) Plan

We maintain a tax-qualified retirement plan that provides eligible U.S. employees with an opportunity to save for retirement on a tax advantaged basis. Eligible employees may defer eligible compensation subject to applicable annual Code limits. The 401(k) plan permits participants to make both pre-tax and certain after-tax (Roth) deferral contributions. These contributions are allocated to each participant s individual account and are then invested in selected investment alternatives according to the participant s directions. Employees are immediately and fully vested in their contributions. Currently, we do not make matching contributions or discretionary contributions to the 401(k) plan. The 401(k) plan is intended to be qualified under Section 401(a) of the Code with the 401(k) plan s related trust intended to be exempt under Section 501(a) of the Code. As a tax-qualified retirement plan, contributions to the 401(k) plan and earnings on those contributions are not taxable to the employees until distributed from the 401(k) plan.

Limitation on Liability and Indemnification Matters

Our amended and restated certificate of incorporation and restated bylaws, each to be effective immediately following the completion of this offering, will provide that we will indemnify our directors and officers, and may indemnify our employees and other agents, to the fullest extent permitted by the Delaware General Corporation Law. However, Delaware law prohibits our amended and restated certificate of incorporation from limiting the liability of our directors for the following:

- any breach of a director s duty of loyalty to us or to our stockholders;
- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or unlawful stock repurchases or redemptions; and
- any transaction from which a director derived an improper personal benefit.

If Delaware law is amended to authorize corporate action further eliminating or limiting the personal liability of a director, then the liability of our directors will be eliminated or limited to the fullest extent permitted by Delaware law, as so amended. Our amended and restated certificate of incorporation does not eliminate a director s duty of care and, in appropriate circumstances, equitable remedies, such as injunctive or other forms of non-monetary relief, remain available under Delaware law. It also does not affect a director s responsibilities under any other laws, such as the federal securities laws or other state or federal laws. Under our amended and restated bylaws, we will also be empowered to enter into indemnification agreements with our directors, officers, employees and other agents and to purchase insurance on behalf of any person whom we are required or permitted to indemnify.

In addition to the indemnification required in our amended and restated certificate of incorporation and amended and restated bylaws, we have entered into indemnification agreements with each of our current directors and executive officers. These agreements provide for the indemnification of such persons for all reasonable expenses and liabilities incurred in connection with any action or proceeding brought against them by reason of the fact that they are or were serving in such capacity. We believe that these certificate of incorporation and bylaws provisions and indemnification agreements are necessary to attract and retain qualified persons as directors, officers and employees. Furthermore, we

have obtained director and officer liability insurance to cover liabilities our directors and officers may incur in connection with their services to us and expect to increase the level upon completion of this offering.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. A

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stockholder s investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, or the Securities Act, may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable. There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

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CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

The following is a description of transactions since January 1, 2011 to which we have been a party, in which the amount involved exceeded or will exceed $120,000, and in which any of our executive officers, directors, promoters or holders of more than 5% of any class of our voting securities, or an affiliate or immediate family member thereof, had or will have a direct or indirect material interest, other than compensation, termination and change in control arrangements, which are described under Executive Compensation. We believe the terms obtained or consideration that we paid or received, as applicable, in connection with the transactions described below were comparable to terms available or the amounts that would be paid or received, as applicable, in arm s-length transactions with unrelated third parties.

Convertible Note Financing

In August 2013, September 2013, October 2013, December 2013 and January 2014 we issued and sold to investors, including an executive officer and holders of more than 5% of our capital stock, convertible promissory notes, or the notes, in the aggregate principal amount of $13.0 million, which we refer to as our bridge notes. The bridge notes issued carried an interest rate of 5.0% per annum.

The participants in these loan arrangements included the following holders of more than 5% of our capital stock or entities affiliated with them. The following table presents the aggregate principal amount of convertible promissory notes issued to these related parties for more than $120,000.

	Aggregate Principal Amount of Notes	
Morningside Venture (VI) Investments Limited[1]	$	8,000,000
John E. and Lois A. Rogers	$	3,116,000

(1) Dr. Chan and Ms. O Brien are members of our board of directors who have been designated by MVIL. Additionally, pursuant to the Series B purchase agreement, as defined below, we issued and sold to MVIL convertible promissory notes in the aggregate principal amount of $9.0 million. The notes carried no interest.

Series B Preferred Stock Financing

In April 2011, we entered into a Series B convertible preferred stock purchase agreement, or the Series B purchase agreement, pursuant to which we issued and sold an aggregate of 12,716,523 shares of our Series B convertible preferred stock for $1.19 per share, warrants exercisable for 615,669 shares of our common stock and warrants exercisable for 83,771 shares of Series B Preferred Stock for aggregate consideration of approximately $15.1 million. In addition during 2011, the aggregate amount of $1.1 million of convertible notes converted into 1,185,806 shares of Series B convertible preferred stock at a conversion price equal to approximately $0.95 per share, a 20% discount to the purchase price, and approximately $9.0 million of convertible notes converted during 2013 and 2014 into 7,539,380 shares of Series B convertible preferred stock at a conversion price equal to $1.19 per share. The table below sets forth the number of shares of Series B convertible preferred stock issued to our stockholders who held more than 5% of any class of our voting securities and their affiliates, to the extent they were issued more than $120,000 of our Series B convertible preferred stock. For each share of preferred stock set forth in the table below, the holder will receive, upon conversion, 0.72 of a share of our common stock upon the closing of this offering.

	Number of Shares of Series B Convertible Preferred Stock	Number of Common Stock Warrant Shares	Number of Series B Preferred Stock Warrant Shares	Aggregate Purchase Price
Morningside Venture (VI) Investments Limited[1]	15,497,614	452,363	61,410	$ 18,500,000[2]
John E. and Lois A. Rogers	3,046,477	68,558	11,815	$ 3,559,341[3]

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(1) Dr. Chan and Ms. O Brien are members of our board of directors who have been designated by MVIL.
(2) Includes the conversion of an aggregate principal amount of $9.0 million of convertible notes into 7,539,380 shares of Series B convertible preferred stock.
(3) Includes the conversion of an aggregate principal and interest amount of $0.3 million of convertible notes into 323,924 shares of Series B convertible preferred stock.

Series C Preferred Stock Financing

In May 2014, we entered into a Series C convertible preferred stock purchase agreement, or the Series C purchase agreement, pursuant to which we issued and sold an aggregate of 19,423,965 shares of our Series C convertible preferred stock for approximately $2.17 per share, for aggregate consideration of approximately $42.2 million. In addition, the aggregate amount of approximately $13.5 million of the bridge notes converted into 6,199,217 shares of Series C convertible preferred stock at a conversion price equal to approximately $2.17 per share. The table below sets forth the number of shares of Series C convertible preferred stock issued to stockholders who held more than 5% of any class of our voting securities and their affiliates, to the extent they were issued more than $120,000 of our Series C convertible preferred stock. For each share of preferred stock set forth in the table below, the holder will receive, upon conversion, 0.72 of a share of our common stock upon the closing of this offering.

	Number of Shares of Series C Convertible Preferred Stock	Aggregate Purchase Price
Morningside Venture (VI) Investments Limited[1]	15,345,433	$ 33,299,588[3]
Johnson & Johnson Innovation-JJDC, Inc.	4,608,295	$ 10,000,000
John E. and Lois A. Rogers[2]	4,244,750	$ 9,211,107[4]

(1) Dr. Chan and Ms. O Brien are members of our board of directors who have been designated by MVIL.
(2) Consists of (a) 3,955,243 purchased by John E. Rogers and Lois A. Rogers, JTWROS, (b) 52,637 purchased by the Buchholz Rogers Family Living Trust 2012, (c) 52,637 purchased by the Phan Rogers Trust, (d) 26,319 shares purchased by Christopher Hagerman, (e) 26,319 shares purchased by Joseph Rogers, (f) 26,319 shares purchased by Lisa M. Rogers, (g) 26,319 shares purchased by Michael J. Rogers, (h) 26,319 shares purchased by Molly Rogers, (i) 26,319 shares purchased by Peter Rogers and (j) 26,319 shares purchased by Sara Rogers, over which John E. Rogers exercises voting control.
(3) Includes the conversion of an aggregate principal and interest amount of $8.3 million of convertible notes into 3,824,695 shares of Series C convertible preferred stock.
(4) Includes the conversion of an aggregate principal and interest amount of $3.2 million of convertible notes into 1,479,773 shares of Series C convertible preferred stock.

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Series D Preferred Stock Financing

In December 2014, we entered into a Series D convertible preferred stock purchase agreement, or the Series D purchase agreement, pursuant to which we issued and sold an aggregate of 19,012,173 shares of our Series D convertible preferred stock for approximately $2.70 per share, for aggregate consideration of approximately $51.4 million. The table below sets forth the number of shares of Series D convertible preferred stock issued to stockholders who held more than 5% of any class of our voting securities and their affiliates, to the extent they were issued more than $120,000 of our Series D convertible preferred stock. For each share of preferred stock set forth in the table below, the holder will receive, upon conversion, 0.72 of a share of our common stock upon the closing of this offering.

	Number of Shares of Series D Convertible Preferred Stock		Aggregate Purchase Price
Morningside Venture (VI) Investments Limited(1)	2,774,798	$	7,500,001.51
John E. and Lois A. Rogers	731,072	$	1,976,014.51
Entities affiliated with Fidelity Investments(2)	5,549,595	$	15,000,000.32

(1) Dr. Chan and Ms. O Brien are members of our board of directors who have been designated by MVIL.
(2) Consists of (a) 2,692,455 shares purchased by Fidelity Securities Fund: Fidelity OTC Portfolio. (b) 2,376,915 shares purchased by Fidelity Select Portfolios: Biotechnology Portfolio and (c) 480,225 shares purchased by Fidelity Advisors Series VII: Fidelity Advisor Biotechnology Fund.

Amended and Restated Voting Agreement

We have entered into an amended and restated voting agreement with certain holders of our common stock and preferred stock, including certain of our named executive officers and directors and entities with which certain of our directors are affiliated, with respect to the election of our directors and certain other matters. All of our current directors were elected pursuant to the terms of this agreement. The amended and restated voting agreement will terminate upon the closing of this offering. For more information, see Management Board Composition.

Amended and Restated Right of First Refusal and Co-Sale Agreement

We have entered into an amended and rested right of first refusal and co-sale agreement with certain holders of our common stock and preferred stock, including certain of our named executive officers and directors and entities with which certain of our directors are affiliated. This agreement provides the holders of preferred stock a right of purchase and a right of co-sale in respect of sales of securities by certain holders of our common stock and preferred stock. These rights of purchase and co-sale will terminate upon the closing of this offering.

Amended and Restated Investors Rights Agreement

We have entered into an amended and restated investors rights agreement with certain holders of our preferred stock, including certain of our directors and entities with which certain of our directors are affiliated. This agreement provides that the holders of common stock issuable upon conversion of our preferred stock have the right to demand

that we file a registration statement or request that their shares of common stock be covered by a registration statement that we are otherwise filing. With respect to this offering, the registration rights have been validly waived. In addition to the registration rights, the second amended and restated investors rights agreement provides for certain information rights and a right of first offer. The provisions of the second amended and restated investors rights agreement, other than those relating to registration rights, will terminate upon the closing of this offering. For more information regarding this agreement, see Description of Capital Stock Registration Rights.

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Indemnification Agreements

We have entered into indemnification agreements with each of our directors and executive officers. For more information regarding these agreements, see Executive Compensation Limitation on Liability and Indemnification Matters.

Insider Participation

JJDC, an existing stockholder, has agreed to purchase approximately $10.0 million of shares of our common stock in this offering at the initial public offering price. Certain other of our existing stockholders, including stockholders affiliated with our directors, have agreed to purchase an additional approximately $12.5 million of shares of our common stock in this offering at the initial public offering price.

Policies and Procedures for Transactions with Related Persons

We have adopted a policy that our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of any class of our common stock and any members of the immediate family of any of the foregoing persons are not permitted to enter into a related person transaction with us without the prior consent of our audit committee. Any request for us to enter into a transaction with an executive officer, director, nominee for election as a director, beneficial owner of more than 5% of any class of our voting securities or any member of the immediate family of any of the foregoing persons, in which the amount involved exceeds $120,000 and such person would have a direct or indirect interest, must first be presented to our audit committee for review, consideration and approval. In approving or rejecting any such proposal, our audit committee is to consider the material facts of the transaction, including, but not limited to, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related person s interest in the transaction. All of the transactions described above were entered into prior to the adoption of such policy, but after presentation, consideration and approval by our board of directors.

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PRINCIPAL STOCKHOLDERS

The following table sets forth, at March 31, 2015, information regarding beneficial ownership of our capital stock by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock;
- each of our named executive officers;
- each of our directors; and
- all of our current executive officers and directors as a group.

Beneficial ownership is determined according to the rules of the SEC and generally means that a person has beneficial ownership of a security if he, she or it possesses sole or shared voting or investment power of that security, including options and warrants that are currently exercisable within 60 days of March 31, 2015. Except as indicated by the footnotes below, we believe, based on the information furnished to us, that the persons named in the table below have sole voting and investment power with respect to all shares of common stock shown that they beneficially own, subject to community property laws where applicable. The information does not necessarily indicate beneficial ownership for any other purpose, including for purposes of Sections 13(d) and 13(g) of the Securities Act.

Our calculation of the percentage of beneficial ownership prior to this offering is based on 52,340,204 shares of our common stock (including preferred stock on an as-converted to common stock basis) outstanding at March 31, 2015. We have based our calculation of the percentage of beneficial ownership after this offering on 60,810,792 shares of our common stock outstanding immediately after the closing of this offering and the concurrent private placement (assuming no exercise of the underwriters option to purchase additional shares of common stock).

JJDC, an existing stockholder, has agreed to purchase approximately $10.0 million of shares of our common stock in this offering at the initial public offering price. Certain other of our existing stockholders, including stockholders affiliated with our directors, have agreed to purchase an additional approximately $12.5 million of shares of our common stock in this offering at the initial public offering price. The information set forth in the table below reflects the purchase of all of these shares in this offering by such stockholders, with each such stockholder purchasing the respective number of shares indicated in the footnotes to the table.

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Unless otherwise indicated, the address of each beneficial owner listed in the table below is c/o Aduro Biotech, Inc., 626 Bancroft Way, 3C, Berkeley, California 94710.

Name of beneficial owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned Before Offering	Percentage of Shares Beneficially Owned After Offering
5% Stockholders:			
Morningside Venture (VI) Investments Limited and Ultimate Keen Limited[1]	24,966,855	47.0%	41.3%
John E. and Lois A. Rogers[2]	6,365,717	12.1%	10.7%
Entities affiliated with Fidelity Investments[3]	3,995,707	7.6%	6.6%
Johnson & Johnson Innovation-JJDC, Inc.[4]	3,317,972	6.3%	6.4%
Executive Officers and Directors:			
Stephen T. Isaacs[5]	1,786,764	3.3%	2.9%
Gregory W. Schafer[6]	241,169	*	*
Thomas W. Dubensky, Jr.[7]	384,089	*	*
Gerald Chan[8]	4,799	*	*
Stephanie Monaghan O Brien[9]	40,154	*	*
William M. Greenman[10]	40,152	*	*
Ross Haghighat[11]	1,260,153	2.4%	2.1%
Frank McCormick[12]	49,536	*	*
All executive officers and directors as a group (10 persons)[13]	4,354,993	7.9%	6.8%

* Represents beneficial ownership of less than 1% of the outstanding common stock.

(1) Consists of (a) 18,602,342 shares and 762,014 shares issuable upon the exercise of warrants held by Morningside Venture (VI) Investments Limited, or MVIL, and (b) 5,602,499 shares held by Ultimate Keen Limited, or UKL, which were acquired from MVIL. In addition, the percentage of shares beneficially owned after the offering reflects that MVIL has purchased 441,176 shares of our common stock in this offering at the initial public offering price. MIVL and UKL have voted together in the past with respect to our voting securities and plan to continue to act together with respect to our voting securities. Yuk Lan Wong and Louise Mary Garbarino, the directors of MVIL, share voting and dispositive control over the shares held by MVIL. The address of MVIL is 2nd Floor, Le Prince de Galles, 3-5 Avenue des Citronniers, MC 98000, Monaco. Raymond Long Sing Tang and Jill Marie Franklin, the directors of Ultimate Keen Limited, or UKL, share voting and dispositive control over the shares held by UKL. The address of UKL is P.O. Box 957, Offshore Incorporations Centre, Road Town, Tortola, British Virgin Islands.

(2) Consists of (a) 5,844,701 shares and 212,953 shares issuable upon the exercise of warrants held by John E. Rogers and Lois A. Rogers, JTWROS, (b) 52,298 shares and 3,716 shares issuable upon the exercise of warrants held by the Buchholz Rogers Family Living Trust 2012, (c) 52,298 shares and 3,716 shares issuable upon the exercise of warrants held by the Phan Rogers Trust, (d) 26,149 shares and 1,856 shares issuable upon the exercise of warrants held by Christopher Hagerman, (e) 26,149 shares and 1,856 shares issuable upon the exercise of warrants held by Joseph Rogers, (f) 26,149 shares and 1,856 shares issuable upon the exercise of warrants held by Lisa M. Rogers, (g) 26,149 shares and 1,856 shares issuable upon the exercise of warrants held by Michael J. Rogers, (h) 26,149 shares and 1,856 shares issuable upon the exercise of warrants held by Molly Rogers, (i) 26,149 shares and 1,856 shares issuable upon the exercise of warrants held by Peter Rogers and (j) 26,149

shares and 1,856 shares issuable upon the exercise of warrants held by Sara Rogers, over which John E. Rogers exercises voting control. The address for John E. and Lois A. Rogers is 5110 North 40th Street, Suite 234, Phoenix, Arizona 85018. In addition, the percentage of shares beneficially owned after the offering reflects that John E. Rogers and Lois A. Rogers, JTWROS, have purchased 147,058 shares of our common stock in this offering at the initial public offering price.

(3) Consists of (a) 1,938,567 shares held by Fidelity Securities Fund: Fidelity OTC Portfolio, (b) 1,711,378 shares held by Fidelity Select Portfolios: Biotechnology Portfolio and (c) 345,762 shares held by Fidelity Advisor Series VII: Fidelity Advisor Biotechnolgy Fund. These accounts are managed by direct or indirect subsidiaries of FMR LLC. Edward C. Johnson 3d is a Director and the Chairman of FMR LLC and Abigail P. Johnson is a Director, the Vice Chairman and the President of FMR LLC. Members of the family of

Edward C. Johnson 3d, including Abigail P. Johnson, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other Series B shareholders have entered into a shareholders voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR LLC. Neither FMR LLC nor Edward C. Johnson 3d nor Abigail P. Johnson has the sole power to vote or direct the voting of the shares owned directly by the various investment companies registered under the Investment Company Act, or the Fidelity Funds, advised by Fidelity Management & Research Company, a wholly owned subsidiary of FMR LLC, which power resides with the Fidelity Funds Boards of Trustees. Fidelity Management & Research Company carries out the voting of the shares under written guidelines established by the Fidelity Funds Boards of Trustees. The address for FMR LLC is 245 Summer Street, Boston, MA 02210.

(4) The board of directors of Johnson & Johnson Innovation-JJDC, Inc., or JJDC, Linda M. Vogel, Manager, Operations of JJDC, exercises voting and dispositive control over the shares held by JJDC. The address of JJDC is 410 George Street, New Brunswick, NJ 08901. In addition, the percentage of share beneficially owned after the offering reflects that JJDC has purchased 588,235 shares of our common stock in this offering at the initial public offering price.

(5) Includes (a) 1,632,077 shares issuable pursuant to stock options exercisable within 60 days of March 31, 2015, (b) 11,916 shares issuable upon the exercise of warrants.

(6) Includes (a) 203,573 shares issuable pursuant to stock options exercisable within 60 days of March 31, 2015, and (b) 3,317 shares issuable upon the exercise of a warrant.

(7) Consists of 384,089 shares issuable pursuant to stock options exercisable within 60 days of March 31, 2015.

(8) Consists of 4,799 shares issuable pursuant to stock options exercisable within 60 days of March 31, 2015.

(9) Consists of 40,154 shares issuable pursuant to stock options exercisable within 60 days of March 31, 2015.

(10) Consists of 40,152 shares issuable pursuant to stock options exercisable within 60 days of March 31, 2015.

(11) Consists of (a) 14,762 shares and 50,904 shares issuable pursuant to stock options exercisable within 60 days of March 31, 2015 held by Ross Haghighat, (b) 373,407 shares and 6,636 shares issuable upon the exercise of warrants held by Triton Holdings LLC, (c) 745,463 shares and 56,819 shares issuable upon the exercise of warrants held by Triton Systems, Inc. and (d) 12,162 shares held by Turnpike Properties, LLC, over which Ross Haghighat exercises voting and dispositive control.

(12) Consists of 49,536 shares issuable pursuant to stock options exercisable within 60 days of March 31, 2015.

(13) Includes 2,953,466 shares issuable pursuant to stock options exercisable within 60 days of March 31, 2015 and 78,688 shares issuable upon the exercise of warrants held by the directors and executive officers.

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DESCRIPTION OF CAPITAL STOCK

General

The following description of our capital stock summarizes the most important terms of our capital stock as they are expected to be in effect upon the closing of this offering. The descriptions of our capital stock and certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws are summaries and are qualified by reference to the amended and restated certificate of incorporation and the amended and restated bylaws that will be in effect immediately following the closing of this offering. Copies of these documents will be filed with the SEC as exhibits to our registration statement, of which this prospectus forms a part.

Our amended and restated certificate of incorporation provides for common stock and undesignated preferred stock, the rights, preferences and privileges of which may be designated from time to time by our board of directors.

Immediately following the closing of this offering, our authorized capital stock will consist of 310,000,000 shares, all with a par value of $0.0001 per share, of which 300,000,000 shares will be designated as common stock and 10,000,000 shares will be designated as preferred stock.

At December 31, 2014, we had outstanding 50,479,916 shares of common stock, which assumes the conversion of all shares of preferred stock outstanding at December 31, 2014 into 50,117,919 shares of common stock upon the closing of this offering. Our outstanding capital stock was held by approximately 244 stockholders of record at December 31, 2014. In addition, at December 31, 2014, there were outstanding options to acquire 5,970,382 shares of our common stock.

Common Stock

The holders of our common stock are entitled to one vote per share on all matters submitted to a vote of our stockholders. Subject to preferences that may be applicable to any preferred stock outstanding at the time, the holders of outstanding shares of common stock are entitled to receive ratably any dividends declared by our board of directors out of assets legally available therefor. In the event that we liquidate, dissolve or wind up, holders of our common stock are entitled to share ratably in all assets remaining after payment of liabilities and the liquidation preference of any then outstanding shares of preferred stock. Holders of common stock have no preemptive or conversion rights or other subscription rights. There are no redemption or sinking fund provisions applicable to the common stock. All outstanding shares of common stock are, and all shares of common stock to be outstanding upon completion of this offering will be, fully paid and nonassessable.

Preferred Stock

At December 31, 2014, there were 69,608,339 shares of our preferred stock outstanding, which will convert into 50,117,919 shares of our common stock upon the closing of this offering.

Upon the closing of this offering, our board of directors may, without further action by our stockholders, fix the rights, preferences, privileges and restrictions of up to an aggregate of 10,000,000 shares of preferred stock in one or more series and authorize their issuance, subject to the approval rights of the common stock described above. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of our common stock or common stock. The issuance of our preferred stock could adversely affect the voting power of holders of our common stock or common stock and the

likelihood that such holders will receive dividend payments and payments upon liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change of control or other corporate action. Upon the closing of this offering, no shares of preferred stock will be outstanding, and we have no present plan to issue any shares of preferred stock.

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Registration Rights

We are party to an amended and restated investors rights agreement that provides that holders of our preferred 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 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 five years following the completion of this 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

The holders of an aggregate of 47,691,942 shares of common stock outstanding at December 31, 2014, including shares issuable upon conversion of outstanding preferred stock, giving effect to the company conversion as if it occurred on such date, will be entitled to certain demand registration rights. At any time beginning after the earlier of December 19, 2016 or six months following the date of this prospectus, the holders of at least (a) a majority of our common stock issued or issuable upon conversion of our Series C preferred stock and Series D preferred stock, voting together as a single class, or (b) a majority of our common stock issued or issuable upon conversion of our Series B preferred stock, on not more than two occasions, request that we register all or a portion of their shares, subject to certain specified exceptions. Such request for registration must cover such number of shares such that the anticipated aggregate offering price, net of the underwriting discount, would equal or exceed $5.0 million.

Piggyback Registration Rights

In connection with this offering, the holders of an aggregate of 47,701,554 shares of common stock outstanding at December 31, 2014, including shares issuable upon conversion of outstanding preferred stock, giving effect to the company conversion as if it occurred on such date, were entitled to, and the necessary percentage of holders waived, their rights to notice of this offering and to include their shares of registrable securities in this offering. In the event that we propose to register any of our securities under the Securities Act in another offering, either for our own account or for the account of other security holders, the holders of these shares 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 an aggregate of 47,691,942 shares of common stock outstanding at December 31, 2014, including shares issuable upon conversion of outstanding preferred stock, giving effect to the company conversion as if it occurred on such date, will be entitled to certain Form S-3 registration rights. Any holder or holders of these shares can make a request that we register their shares on Form S-3 if we are qualified to file a registration statement on

Form S-3, subject to certain specified exceptions. 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.

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Anti-Takeover Provisions

Certificate of Incorporation and Bylaws to be in Effect Immediately Following the Closing of this Offering

Because our stockholders do not have cumulative voting rights, our stockholders holding a majority of the outstanding shares of common stock outstanding will be able to elect all of our directors. Our amended and restated certificate of incorporation and amended and restated bylaws to be effective immediately following the closing of this offering will 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 holders of a majority of our common stock and common stock, voting together as a single class, or by the majority of our whole board of directors, or our chief executive officer.

As described above in Management Board Composition, in accordance with our amended and restated certificate of incorporation to be filed in connection with this offering, immediately after this offering, our board of directors will be divided into three classes with staggered three-year terms.

The foregoing provisions will 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 change our control.

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 others from making tender offers for our shares and may have the effect of deterring hostile takeovers or delaying changes in our control or management. 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, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder 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 stockholder;

upon closing 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 by (i) persons who are directors and also officers and (ii) 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; or

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.

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In general, Section 203 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; or
- the receipt by the interested stockholder of the benefit of any loss, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines an interested stockholder as an entity or person who, together with the person s affiliates and associates, beneficially owns, or 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 discourage or prevent mergers or other takeover or change of control attempts of our company.

Choice of Forum

Our amended and restated certificate of incorporation will provide 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 amended and restated certificate of incorporation or our bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine.

Limitations of Liability and Indemnification

See Executive Compensation Limitation on Liability and Indemnification Matters.

Listing

Our common stock has been approved for listing on the NASDAQ Global Select Market under the symbol ADRO.

Transfer Agent and Registrar

Upon the closing of this offering, the transfer agent and registrar for our common stock will be Computershare Trust Company, N.A. The transfer agent and registrar s address is 250 Royall Street, Canton, Massachusetts 02021.

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SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our capital stock. Future sales of our common stock in the public market, or the availability of such shares for sale in the public market, could adversely affect market prices prevailing from time to time. As described below, only a limited number of shares will be available for sale shortly after this offering due to contractual and legal restrictions on resale. Nevertheless, sales of our common stock in the public market after such restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price at such time and our ability to raise equity capital in the future.

Based on the number of shares outstanding at December 31, 2014, upon the closing of this offering, 58,950,504 shares of common stock will be outstanding, assuming no exercise of the underwriters option to purchase additional shares of common stock and no exercise of outstanding options. Of the outstanding shares, all of the shares sold in this offering will be freely tradable, except that any shares held by our affiliates, as that term is defined in Rule 144 under the Securities Act, may only be sold in compliance with the limitations described below.

The remaining shares of our common stock outstanding after this offering are restricted securities as such term is defined in Rule 144 under the Securities Act and are subject to lock-up agreements with us as described below. Following the expiration of the lock-up period, restricted securities may be sold in the public market only if registered or if they qualify for an exemption from registration under Rule 144 or 701 promulgated under the Securities Act, described in greater detail below.

Rule 144

In general, a person who has beneficially owned restricted shares of our common stock for at least six months would be entitled to sell their securities provided that (i) such person is not deemed to have been one of our affiliates at the time of, or at any time during the 90 days preceding, a sale and (ii) we are subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Persons who have beneficially owned restricted shares of our common stock for at least six months but who are our affiliates at the time of, or any time during the 90 days preceding, a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three-month period only a number of securities that does not exceed the greater of either of the following:

- 1% of the number of shares of our common stock outstanding after this offering, which will equal 571,466 shares assuming no exercise of the underwriters option to purchase additional shares of common stock; or
- the average weekly trading volume of our common stock on the NASDAQ Global Select Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale;

provided, in each case, that we are subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Such sales both by affiliates and by non-affiliates must also comply with the manner of sale, current public information and notice provisions of Rule 144.

Rule 701

Rule 701 under the Securities Act, as in effect on the date of this prospectus, permits re-sales of shares in reliance upon Rule 144 but without compliance with certain restrictions of Rule 144, including the holding period requirement.

Most of our employees, executive officers, directors or consultants who purchased shares under a written compensatory plan or contract may be entitled to rely on the resale provisions of Rule 701, but all holders of Rule 701 shares are required to wait until 90 days after the date of this prospectus before selling their shares. However, substantially all Rule 701 shares are subject to lock-up agreements as described below and under Underwriting and will become eligible for sale at the expiration of those agreements.

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Lock-Up Agreements

We, our directors and executive officers, and substantially all of our stockholders have agreed with the underwriters that for a period of 180 days following the date of this prospectus, subject to certain exceptions, we and they will not, directly or indirectly, offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale or otherwise dispose of or hedge any of our shares of common stock, any options or warrants to purchase shares of our common stock, or any securities convertible into, or exchangeable for or that represent the right to receive shares of our common stock. Merrill, Lynch, Pierce, Fenner & Smith Incorporated and Leerink Partners LLC may, in their sole discretion, at any time, release all or any portion of the shares from the restrictions in such agreement.

Employees can only sell vested shares. Employees who do not hold vested shares, including shares subject to options, upon expiration of these selling restrictions will not be able to sell shares until they vest.

Registration Rights

On the date beginning 181 days after the date of this prospectus, the holders of approximately 47,701,554 shares of our common stock, or their transferees, will be entitled to certain rights with respect to the registration of those shares under the Securities Act. For a description of these registration rights, see Description of Capital Stock Registration Rights. If these shares are registered, they will be freely tradable without restriction under the Securities Act.

Equity Incentive Plans

As soon as practicable after the closing of this offering, we intend to file a Form S-8 registration statement under the Securities Act to register shares of our common stock issued or reserved for issuance under our equity compensation plans and agreements. This registration statement will become effective immediately upon filing, and shares covered by this registration statement will thereupon be eligible for sale in the public markets, subject to vesting restrictions, the lock-up agreements described above and Rule 144 limitations applicable to affiliates. For a more complete discussion of our equity compensation plans, see Executive Compensation Employee Benefit Plans.

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MATERIAL U.S. FEDERAL INCOME AND ESTATE TAX CONSEQUENCES TO NON-U.S. HOLDERS OF OUR COMMON STOCK

The following is a summary of the material U.S. federal income and estate tax consequences to non-U.S. holders (as defined below) of the acquisition, ownership and disposition of our common stock issued pursuant to this offering. This discussion is not a complete analysis of all potential U.S. federal income tax consequences relating thereto, does not address the potential application of the Medicare contribution tax and does not address any gift tax consequences or any tax consequences arising under any state, local or foreign tax laws, or any other U.S. federal tax laws. This discussion is based on the Code, Treasury Regulations promulgated thereunder, judicial decisions and published rulings and administrative pronouncements of the Internal Revenue Service, or IRS, all as in effect as of the date of this prospectus. These authorities may change, possibly retroactively, resulting in U.S. federal income tax consequences different from those discussed below. We have not requested a ruling from the IRS with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS will agree with such statements and conclusions.

This discussion is limited to non-U.S. holders who purchase our common stock issued pursuant to this offering and who hold our common stock as a capital asset within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all of the U.S. federal income tax consequences that may be relevant to a particular holder in light of such holder s particular circumstances. This discussion also does not consider any specific facts or circumstances that may be relevant to holders subject to special rules under the U.S. federal income tax laws, including, without limitation, certain former citizens or long-term residents of the United States, partnerships or other pass-through entities, controlled foreign corporations, passive foreign investment companies, corporations that accumulate earnings to avoid U.S. federal income tax, banks, financial institutions, investment funds, insurance companies, brokers, dealers or traders in securities, tax-exempt organizations, tax-qualified retirement plans, persons subject to the alternative minimum tax, persons that own, or have owned, actually or constructively, more than 5% of our common stock and persons holding our common stock as part of a hedging or conversion transaction or straddle, or a constructive sale, or other risk reduction strategy.

If an entity or arrangement that is classified as a partnership for U.S. federal income tax purposes holds our common stock, the U.S. federal income tax treatment of a partner will generally depend on the status of the partner and the activities of the partnership. Partnerships holding our common stock and the partners in such partnerships are urged to consult their tax advisors as to particular U.S. federal income tax consequences to them of holding and disposing of our common stock.

PROSPECTIVE INVESTORS SHOULD CONSULT THEIR TAX ADVISORS REGARDING THE PARTICULAR U.S. FEDERAL INCOME TAX CONSEQUENCES TO THEM OF ACQUIRING, OWNING AND DISPOSING OF OUR COMMON STOCK, AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL OR FOREIGN TAX LAWS, ANY OTHER U.S. FEDERAL TAX LAWS OR ANY APPLICABLE TAX TREATY.

Definition of Non-U.S. Holder

For purposes of this discussion, a non-U.S. holder is any beneficial owner of our common stock that is not a U.S. person or a partnership (including any entity or arrangement treated as a partnership) for U.S. federal income tax purposes. A U.S. person is any of the following:

an individual citizen or resident of the United States;

a corporation (or other entity treated as a corporation for U.S. federal income tax purposes) created or organized under the laws of the United States, any state thereof or the District of Columbia;

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an estate, the income of which is subject to U.S. federal income tax regardless of its source; or

a trust (1) whose administration is subject to the primary supervision of a U.S. court and which has one or more U.S. persons who have the authority to control all substantial decisions of the trust, or (2) that has a valid election in effect under applicable Treasury Regulations to be treated as a U.S. person.

Distributions on our Common Stock

As described in the section entitled Dividend Policy, we do not anticipate paying any cash dividends in the foreseeable future. However, if we make cash or other property distributions on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and will first be applied against and reduce a holder s tax basis in our common stock, but not below zero. Any excess will be treated as gain realized on the sale or other disposition of our common stock and will be treated as described under the section of this prospectus titled Gain on Disposition of our Common Stock below.

Dividends (out of earnings and profits) paid to a non-U.S. holder of our common stock generally will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends, or such lower rate specified by an applicable income tax treaty. To receive the benefit of a reduced treaty rate, a non-U.S. holder must furnish to us or our paying agent a valid IRS Form W-8BEN (in the case of an individual), IRS Form W-8BEN-E (in the case of an entity) or applicable successor form, including a U.S. taxpayer identification number and certifying such holder s qualification for the reduced rate. This certification must be provided to us or our paying agent prior to the payment of dividends and must be updated periodically. If the non-U.S. holder holds the stock through a financial institution or other agent acting on the non-U.S. holder s behalf, the non-U.S. holder will be required to provide appropriate documentation to the agent, which then will be required to provide certification to us or our paying agent, either directly or through other intermediaries.

Non-U.S. holders that do not timely provide the required certification, but that qualify for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS.

If a non-U.S. holder holds our common stock in connection with the conduct of a trade or business in the United States, and dividends paid on our common stock are effectively connected with such holder s U.S. trade or business (and are attributable to such holder s permanent establishment in the United States if required by an applicable tax treaty), the non-U.S. holder will be exempt from U.S. federal withholding tax. To claim the exemption, the non-U.S. holder must generally furnish a properly executed IRS Form W-8ECI (or applicable successor form).

Any dividends paid on our common stock that are effectively connected with a non-U.S. holder s U.S. trade or business (and if required by an applicable income tax treaty, are attributable to a permanent establishment maintained by the non-U.S. holder in the United States) generally will be subject to U.S. federal income tax on a net income basis at the regular graduated U.S. federal income tax rates in the same manner as if such holder were a resident of the United States. A non-U.S. holder that is a foreign corporation also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year, as adjusted for certain items. Non-U.S. holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

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Gain on Disposition of our Common Stock

Subject to the discussion below regarding backup withholding and FATCA, a non-U.S. holder generally will not be subject to U.S. federal income tax on any gain realized upon the sale or other disposition of our common stock, unless:

- the gain is effectively connected with the non-U.S. holder s conduct of a trade or business in the United States, and if required by an applicable income tax treaty, is attributable to a permanent establishment maintained by the non-U.S. holder in the United States;
- the non-U.S. holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition, and certain other requirements are met; or
- our common stock constitutes a United States real property interest by reason of our status as a United States real property holding corporation, or USRPHC, for U.S. federal income tax purposes at any time within the shorter of the five-year period preceding the disposition and the non-U.S. holder s holding period for our common stock, and our common stock is not regularly traded on an established securities market during the calendar year in which the sale or other disposition occurs.

The determination of whether we are a USRPHC depends on the fair market value of our U.S. real property interests relative to the fair market value of our other trade or business assets and our foreign real property interests. We believe we are not currently and do not anticipate becoming a USRPHC for U.S. federal income tax purposes.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular graduated U.S. federal income tax rates in the same manner as if such holder were a resident of the United States. A non-U.S. holder that is a foreign corporation may also be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year, as adjusted for certain items. Non-U.S. holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

Gain described in the second bullet point above will be subject to U.S. federal income tax at a flat 30% rate (or such lower rate specified by an applicable income tax treaty), but may be offset by certain U.S.-source capital losses (even though the individual is not considered a resident of the United States), provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses.

Information Reporting and Backup Withholding

We must report annually to the IRS and to each non-U.S. holder the amount of dividends on our common stock paid to such holder and the amount of any tax withheld with respect to those dividends. These information reporting requirements apply even if no withholding was required because the dividends were effectively connected with the holder s conduct of a U.S. trade or business, or withholding was reduced or eliminated by an applicable income tax treaty. This information also may be made available under a specific treaty or agreement with the tax authorities in the country in which the non-U.S. holder resides or is established. Backup withholding, currently at a 28% rate, generally will not apply to payments to a non-U.S. holder of dividends on or the gross proceeds of a disposition of our common stock provided the non-U.S. holder furnishes the required certification as to its non-U.S. status, such as by providing a valid IRS Form W-8BEN, IRS Form W-8BEN-E or IRS Form W-8ECI, or certain other requirements are met.

Notwithstanding the foregoing, backup withholding may apply if the payor has actual knowledge, or reason to know, that the holder is a U.S. person who is not an exempt recipient.

Backup withholding is not an additional tax. If any amount is withheld under the backup withholding rules, the non-U.S. holder should consult with a U.S. tax advisor regarding the possibility of and procedure for obtaining a refund or a credit against the non-U.S. holder s U.S. federal income tax liability, if any.

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Foreign Accounts

Sections 1471 through 1474 of the Code (commonly referred to as FATCA) will impose a U.S. federal withholding tax of 30% on certain payments, including dividends on and the gross proceeds of a disposition of our common stock, made to a foreign financial institution (as specially defined under these rules) unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners) or an exemption applies. FATCA also generally will impose a U.S. federal withholding tax of 30% on certain payments, including dividends on and the gross proceeds of a disposition of our common stock, made to a non-financial foreign entity unless such entity provides the withholding agent a certification identifying the direct and indirect U.S. owners of the entity or an exemption applies. An intergovernmental agreement between the United States and an applicable foreign country may modify these requirements. Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such taxes. These withholding taxes currently may be imposed on dividends paid on our common stock. These withholding taxes may also be imposed on gross proceeds from sales or other dispositions of our common stock after December 31, 2016.

Prospective investors are encouraged to consult with their own tax advisors regarding the possible implications of these rules on their investment in our common stock.

Estate Tax

Individual non-U.S. holders and entities whose property is potentially includible in such an individual s gross estate for U.S. federal estate tax purposes (for example, a trust funded by such an individual and with respect to which the individual has retained certain interests or powers), should note that, absent an applicable treaty benefit, our common stock generally will be treated as U.S. situs property subject to U.S. federal estate tax.

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UNDERWRITING

Merrill Lynch, Pierce, Fenner & Smith Incorporated and Leerink Partners LLC are acting as representatives of each of the underwriters named below. Subject to the terms and conditions set forth in an underwriting agreement among us and the underwriters, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of shares of common stock set forth opposite its name below.

Underwriter	Number of Shares
Merrill Lynch, Pierce, Fenner & Smith Incorporated	2,800,000
Leerink Partners LLC	2,275,000
William Blair & Company, L.L.C.	1,225,000
Canaccord Genuity Inc.	700,000
Total	7,000,000

Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, including the validity of the shares, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officer s certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Commissions and Discounts

The representatives have advised us that the underwriters propose initially to offer the shares to the public at the public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of $.71 per share. After the initial offering, the public offering price, concession or any other term of the offering may be changed.

The following table shows the public offering price, underwriting discount and proceeds before expenses to us. The information assumes either no exercise or full exercise by the underwriters of their option to purchase additional shares.

	Per Share	Without Option	With Option

Public offering price	$ 17.00	$ 119,000,000	$ 136,850,000
Underwriting discount	$1.19	$8,330,000	$9,579,500
Proceeds, before expenses, to Aduro Biotech, Inc.	$ 15.81	$ 110,670,000	$ 127,270,500

The expenses of the offering, not including the underwriting discount, are estimated at $3.0 million and are payable by us. We have also agreed to reimburse the underwriters for certain expenses in an amount up to $37,500.

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JJDC, an existing stockholder, has agreed to purchase approximately $10.0 million of shares of our common stock in this offering at the initial public offering price. Certain other of our existing stockholders, including stockholders affiliated with our directors, have agreed to purchase an additional approximately $12.5 million of shares of our common stock in this offering at the initial public offering price.

Option to Purchase Additional Shares

We have granted an option to the underwriters, exercisable for 30 days after the date of this prospectus, to purchase up to 1,050,000 additional shares at the public offering price, less the underwriting discount. If the underwriters exercise this option, each will be obligated, subject to conditions contained in the underwriting agreement, to purchase a number of additional shares proportionate to that underwriter s initial amount reflected in the above table.

Reserved Shares

At our request, the underwriters have reserved for sale, at the initial public offering price, up to 350,000 shares offered by this prospectus for sale to certain of our directors, officers, employees, business associates and related persons through a Reserved Share Program. If these persons purchase reserved shares, this will reduce the number of shares available for sale to the general public. Any reserved shares that are not so purchased will be offered by the underwriters to the general public on the same terms as the other shares offered by this prospectus.

No Sales of Similar Securities

We, our executive officers and directors and our other existing security holders have agreed not to sell or transfer any common stock or securities convertible into, exchangeable for, exercisable for, or repayable with common stock, for 180 days after the date of this prospectus without first obtaining the written consent of Merrill Lynch, Pierce, Fenner & Smith Incorporated and Leerink Partners LLC. Specifically, we and these other persons have agreed, with certain limited exceptions, not to directly or indirectly

offer, pledge, sell or contract to sell any common stock,

sell any option or contract to purchase any common stock,

purchase any option or contract to sell any common stock,

grant any option, right or warrant for the sale of any common stock,

lend or otherwise dispose of or transfer any common stock,

request or demand that we file a registration statement related to the common stock, or

enter into any swap or other agreement that transfers, in whole or in part, the economic consequence of ownership of any common stock whether any such swap or transaction is to be settled by delivery of shares or other securities, in cash or otherwise.

This lock-up provision applies to common stock and to securities convertible into or exchangeable or exercisable for or repayable with common stock. It also applies to common stock owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition.

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NASDAQ Global Select Market Listing

Our common stock has been approved for listing on the NASDAQ Global Select Market under the symbol ADRO.

Before this offering, there has been no public market for our common stock. The initial public offering price will be determined through negotiations between us and the representatives. In addition to prevailing market conditions, the factors to be considered in determining the initial public offering price are

- the valuation multiples of publicly traded companies that the representatives believe to be comparable to us,
- our financial information,
- the history of, and the prospects for, our company and the industry in which we compete,
- an assessment of our management, its past and present operations, and the prospects for, and timing of, our future revenues,
- the present state of our development and
- the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

An active trading market for the shares may not develop. It is also possible that after the offering the shares will not trade in the public market at or above the initial public offering price.

The underwriters do not expect to sell more than 5% of the shares in the aggregate to accounts over which they exercise discretionary authority.

Price Stabilization, Short Positions and Penalty Bids

Until the distribution of the shares is completed, SEC rules may limit underwriters and selling group members from bidding for and purchasing our common stock. However, the representatives may engage in transactions that stabilize the price of the common stock, such as bids or purchases to peg, fix or maintain that price.

In connection with the offering, the underwriters may purchase and sell our common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering. Covered short sales are sales made in an amount not greater than the underwriters option to purchase additional shares described above. The underwriters may close out any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price

of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option granted to them. Naked short sales are sales in excess of such option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of shares of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

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Similar to other purchase transactions, the underwriters purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. The underwriters may conduct these transactions on the NASDAQ Global Select Market, in the over-the-counter market or otherwise.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor any of the underwriters make any representation that the representatives will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

Electronic Distribution

In connection with the offering, certain of the underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail.

Other Relationships

Some of the underwriters and their affiliates have engaged in, and may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. They have received, or may in the future receive, customary fees and commissions for these transactions.

In addition, in the ordinary course of their business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Notice to Prospective Investors in the European Economic Area

In relation to each Member State of the European Economic Area, each a Relevant Member State, no offer of shares may be made to the public in that Relevant Member State other than:

(a) to any legal entity which is a qualified investor as defined in the Prospectus Directive;

(b) to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives; or

(c) in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of shares shall require us or the representatives to publish a prospectus pursuant to Article 3 of the

Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive. Each person in a Relevant Member State who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed that it is a qualified investor within the meaning of the law in that Relevant Member State implementing Article 2(1)(e) of the Prospectus Directive. In the case of any shares being offered to a financial intermediary as that term is used in Article 3(2) of the Prospectus Directive, each such financial intermediary will be deemed to have represented, acknowledged and agreed that

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the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any shares to the public other than their offer or resale in a Relevant Member State to qualified investors as so defined or in circumstances in which the prior consent of the representatives has been obtained to each such proposed offer or resale.

We, the representatives and their affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgements and agreements.

This prospectus has been prepared on the basis that any offer of shares in any Relevant Member State will be made pursuant to an exemption under the Prospectus Directive from the requirement to publish a prospectus for offers of shares. Accordingly any person making or intending to make an offer in that Relevant Member State of shares which are the subject of the offering contemplated in this prospectus may only do so in circumstances in which no obligation arises for us or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Directive in relation to such offer. Neither we nor the underwriters have authorized, nor do they authorize, the making of any offer of shares in circumstances in which an obligation arises for us or the underwriters to publish a prospectus for such offer.

For the purpose of the above provisions, the expression an offer to the public in relation to any shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the shares to be offered so as to enable an investor to decide to purchase or subscribe the shares, as the same may be varied in the Relevant Member State by any measure implementing the Prospectus Directive in the Relevant Member State and the expression Prospectus Directive means Directive 2003/71/EC (including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member States) and includes any relevant implementing measure in the Relevant Member State and the expression 2010 PD Amending Directive means Directive 2010/73/EU.

Notice to Prospective Investors in the United Kingdom

In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are qualified investors (as defined in the Prospectus Directive) (i) who have professional experience in matters relating to investments falling within Article 19 (5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, or the Order, and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as relevant persons). This document must not be acted on or relied on in the United Kingdom by persons who are not relevant persons. In the United Kingdom, any investment or investment activity to which this document relates is only available to, and will be engaged in with, relevant persons.

Notice to Prospective Investors in Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, us, the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory

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Authority FINMA, or FINMA, and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

Notice to Prospective Investors in the Dubai International Financial Centre

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority, or DFSA. This prospectus is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The shares to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

Notice to Prospective Investors in Australia

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission, or ASIC, in relation to the offering. This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001, or the Corporations Act, and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the shares may only be made to persons, or the Exempt Investors, who are sophisticated investors (within the meaning of section 708(8) of the Corporations Act), professional investors (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the shares without disclosure to investors under Chapter 6D of the Corporations Act.

The shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

Notice to Prospective Investors in Hong Kong

The shares have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to professional investors as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or (b) in other circumstances which do not result in the document being a prospectus as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance. No advertisement, invitation or document relating to the shares has been

or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are

likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to professional investors as defined in the Securities and Futures Ordinance and any rules made under that Ordinance.

Notice to Prospective Investors in Japan

The shares have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) and, accordingly, will not be offered or sold, directly or indirectly, in Japan, or for the benefit of any Japanese Person or to others for re-offering or resale, directly or indirectly, in Japan or to any Japanese Person, except in compliance with all applicable laws, regulations and ministerial guidelines promulgated by relevant Japanese governmental or regulatory authorities in effect at the relevant time. For the purposes of this paragraph, Japanese Person shall mean any person resident in Japan, including any corporation or other entity organized under the laws of Japan.

Notice to Prospective Investors in Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275, of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

(a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

(b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:

(a) to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;

(b) where no consideration is or will be given for the transfer;

(c) where the transfer is by operation of law;

(d) as specified in Section 276(7) of the SFA; or

(e) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

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LEGAL MATTERS

Cooley LLP of Palo Alto, California will pass upon the validity of the shares of common stock offered hereby. The underwriters are being represented by Latham & Watkins LLP of Menlo Park, California in connection with the offering.

EXPERTS

The financial statements included in this prospectus have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report appearing herein and elsewhere in the registration statement of which this prospectus forms a part. Such financial statements are included in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to this offering of our common stock. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement, some items of which are contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. For further information with respect to us and our common stock, we refer you to the registration statement, including the exhibits and the financial statements and notes filed as a part of the registration statement. Statements contained in this prospectus concerning the contents of any contract or any other document are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. The exhibits to the registration statement should be referenced for the complete contents of these contracts and documents. A copy of the registration statement and the exhibits filed therewith may be inspected without charge at the public reference room of the SEC, located at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You may obtain information on the operation of the public reference rooms by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet website that contains reports, proxy statements and other information about issuers, like us, that file electronically with the SEC. The address of that website is www.sec.gov.

As a result of this offering, we will become subject to the information and reporting requirements of the Exchange Act and, in accordance with this law, will file periodic reports, proxy statements and other information with the SEC. These periodic reports, proxy statements and other information will be available for inspection and copying at the SEC s public reference facilities and the website of the SEC referred to above. We also maintain a website at http://www.aduro.com. After the closing of this offering, you may access our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act with the SEC free of charge at our website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is not part of this prospectus.

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ADURO BIOTECH, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 31, 2013 and 2014

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors

Aduro Biotech, Inc.

Berkeley, California

We have audited the accompanying consolidated balance sheets of Aduro Biotech, Inc. and its subsidiary (the Company) as of December 31, 2013 and 2014, and the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders deficit, and cash flows for each of the years then ended. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of Aduro Biotech, Inc. and its subsidiary as of December 31, 2013 and 2014, and the results of their operations and their cash flows for each of the years then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ Deloitte & Touche LLP

San Francisco, California

March 2, 2015 (April 3, 2015 as to the effects of the reverse stock split and subsequent event described in Note 17)

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ADURO BIOTECH, INC.

Consolidated Balance Sheets

(In thousands, except share and per share amounts)

	December 31,		Pro Forma at December 31, 2014 (unaudited)
	2013	2014	
Assets			
Current assets:			
Cash and cash equivalents	$ 8,532	$ 119,456	$ 119,456
Accounts receivable	357	3,153	3,153
Prepaid expenses and other current assets	467	2,612	2,612
Total current assets	9,356	125,221	125,221
Property and equipment, net	399	1,053	1,053
Other assets	125	188	188
Total assets	$ 9,880	$ 126,462	$ 126,462
Liabilities, Convertible Preferred Stock and Stockholders (Deficit) Equity			
Current liabilities:			
Accounts payable	$ 763	$ 5,030	$ 5,030
Accrued clinical trial and manufacturing expenses	890	3,350	3,350
Accrued expenses and other liabilities	1,138	2,408	2,408
Deferred revenue	57	33,427	33,427
Note payable to related party	200		
Convertible promissory notes payable to related parties, net	11,383		
Total current liabilities	14,431	44,215	44,215
Deferred revenue		2,592	2,592
Convertible promissory note payable to related party, net	1,406		
Convertible preferred stock warrant liability	72	100	
Common stock warrant liability	505	889	889
Total liabilities	16,414	47,796	47,696
Commitments and contingencies (Note 9)			
Convertible preferred stock; $0.0001 par value, 25,555,508 and 69,716,345 shares authorized at December 31, 2013 and 2014;	32,224	139,963	

22,041,003 and 69,608,339 shares issued and outstanding at December 31, 2013 and 2014; no shares issued and outstanding, pro forma (unaudited); aggregate liquidation value of $145,261 at December 31, 2014			
Stockholders (deficit) equity:			
Common stock, $0.0001 par value; 32,000,000 and 85,000,000 shares authorized; and 295,498 and 361,997 shares issued and outstanding at December 31, 2013 and 2014, respectively; 50,479,916 shares issued and outstanding, pro forma (unaudited)			5
Additional paid-in capital	5,871	346	140,404
Accumulated deficit	(44,629)	(61,643)	(61,643)
Total stockholders (deficit) equity	(38,758)	(61,297)	78,766
Total liabilities, convertible preferred stock and stockholders (deficit) equity	$ 9,880	$ 126,462	$ 126,462

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

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ADURO BIOTECH, INC.

Consolidated Statements of Operations and Comprehensive Loss

(In thousands, except share and per share amounts)

	Year Ended December 31,	
	2013	**2014**
Revenue:		
Collaboration and license revenue	$	$ 13,038
Grant revenue	828	351
Total revenue	828	13,389
Operating expenses:		
Research and development	10,687	23,513
General and administrative	4,677	8,994
Total operating expenses	15,364	32,507
Loss from operations	(14,536)	(19,118)
Interest expense	(1,371)	(2,395)
Gain on extinguishment of convertible promissory notes		3,553
Other (expense) income, net	(147)	946
Net loss and comprehensive loss	$ (16,054)	$ (17,014)
Net loss per common share, basic and diluted	$ (55.80)	$ (53.06)
Shares used in computing net loss per common share, basic and diluted	287,711	320,686
Pro forma net loss per common share, basic and diluted (unaudited)		$ (0.70)
Shares used in computing pro forma net loss per common share, basic and diluted (unaudited)		28,042,827

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

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ADURO BIOTECH, INC.

Consolidated Statements of Convertible Preferred Stock and Stockholders Deficit

(In thousands, except share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Total Stockholders
	Shares	Amount	Shares	Amount	Capital	Deficit	Deficit
Balance at January 1, 2013	14,839,965	$ 23,693	262,827	$	$ 866	$ (28,575)	$ (27,709)
Issuance of Series B convertible preferred stock for cash, net of $65 of issuance costs	2,593,639	3,031					
Issuance of Series B convertible preferred stock upon conversion of convertible promissory notes	4,607,399	5,500					
Convertible promissory notes beneficial conversion feature (Note 5)					2,339		2,339
Recognition of equity component of Series B convertible promissory note (Note 5)					2,241		2,241
Issuance of common stock upon exercise of stock options			32,671		16		16
Stock-based compensation expense					409		409
Net loss						(16,054)	(16,054)
Balance at December 31, 2013	22,041,003	32,224	295,498		5,871	(44,629)	(38,758)
Issuance of Series C convertible preferred stock for cash, net of $262 of issuance costs (Note 10)	19,423,965	41,888					
Issuance of Series C convertible preferred stock upon conversion of convertible promissory notes (Note 5)	6,199,217	13,452					

Effects of Series C convertible preferred stock tranche (Note 10)		(1,475)					
Issuance of Series B convertible preferred stock upon conversion of Series B convertible promissory notes (Note 5)	2,931,981	4,956					
Issuance of Series D convertible preferred stock for cash, net of $2,470 of issuance costs (Note 10)	19,012,173	48,918					
Reclassification of common stock warrants (Note 12)					784		784
Convertible promissory notes beneficial conversion feature					57		57
Reacquisition of equity component of Series B convertible promissory note					(3,432)		(3,432)
Reacquisition of convertible promissory notes beneficial conversion feature					(3,553)		(3,553)
Issuance of common stock upon exercise of stock options			66,499		49		49
Stock-based compensation expense					570		570
Net loss						(17,014)	(17,014)
Balance at December 31, 2014	69,608,339	$ 139,963	361,997	$	$ 346	$ (61,643)	$ (61,297)

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

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ADURO BIOTECH, INC.

Consolidated Statement of Cash Flows

(In thousands)

	Year Ended December 31,	
	2013	**2014**
Cash Flows from Operating Activities		
Net loss	$ (16,054)	$ (17,014)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation and amortization	129	240
Stock-based compensation	409	570
Loss from changes in the fair value of warrants, net	162	566
Gain from changes in the fair value of preferred stock derivative liability		(1,475)
Gain on extinguishment of convertible promissory notes		(3,553)
Non-cash interest expense related to convertible promissory notes payable	1,367	2,380
Changes in operating assets and liabilities:		
Accounts receivable	(315)	(2,796)
Prepaid expenses and other assets	(382)	(1,117)
Accounts payable	(670)	1,681
Deferred revenue		35,962
Accrued clinical trial and manufacturing expenses	711	2,460
Accrued expenses and other liabilities	411	1,461
Net cash (used in) provided by operating activities	(14,232)	19,365
Cash Flows from Investing Activities		
Purchase of property and equipment	(170)	(782)
Net cash used in investing activities	(170)	(782)
Cash Flows from Financing Activities		
Proceeds from issuance of convertible promissory note payable to related parties	16,192	308
Repayment of note payable to related party		(200)
Proceeds from issuance of convertible preferred stock, net of issuance costs	3,031	93,276
Deferred offering costs		(1,092)
Proceeds from exercise of stock options	16	49
Net cash provided by financing activities	19,239	92,341
Net increase in cash and cash equivalents	4,837	110,924
Cash and cash equivalents at beginning of period	3,695	8,532

Cash and cash equivalents at end of period	$ 8,532	$ 119,456
Supplemental Disclosure		
Cash paid for interest	$ 32	$ 18
Supplemental Disclosure of Non-Cash Investing and Financing Activities		
Issuance of Series C convertible preferred stock to a related party and other investors in connection with conversion of convertible promissory notes and accrued interest	$	$ 13,452
Issuance of Series B convertible preferred stock to a related party in connection with conversion of convertible promissory notes	$ 5,500	$ 4,956

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

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ADURO BIOTECH, INC.

Notes to Consolidated Financial Statements

1. Nature of Business and Management s Plans

Nature of Business

Aduro Biotech, Inc., or the Company, is a clinical-stage immuno-oncology company located in Berkeley, California. The Company was founded in 2000 under the name Oncologic, Inc., later merged with Triton BioSystems, Inc. in 2008, and subsequently changed its name to Aduro Biotech, Inc. in 2009. The Company is focused on the development of technology platforms designed to stimulate robust and durable immune responses against cancer. The Company operates in one business segment.

The Company s more advanced technology platform is its proprietary Live, Attenuated, Double- Deleted, or LADD, method of engineering *Listeria monocytogenes* bacteria into therapeutic agents that stimulate both an immediate innate immune response and a targeted adaptive immune response to specific tumor antigens. The Company s earlier-stage technology platform is based on cyclic dinucleotides, or CDNs, novel small molecules that activate the intracellular Stimulator of Interferon Genes, or STING, receptor, a central mediator of the innate immune response. The Company s pipeline of product candidates has the potential to be applicable to a variety of cancers and to be combinable with a range of conventional and emerging cancer therapies, including cellular vaccines, chemotherapy, radiotherapy and checkpoint inhibitors, among others.

2. Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America and include the accounts of Aduro Biotech, Inc. and its wholly owned subsidiary, Aduro GVAX, Inc. All intercompany transactions and balances have been eliminated.

Unaudited Pro Forma Stockholders Equity

On December 16, 2014, the Company s board of directors authorized management of the Company to file a registration statement with the Securities and Exchange Commission for the Company to sell shares of its common stock to the public. The unaudited pro forma stockholders equity at December 31, 2014 presents the Company s stockholders equity as though all the Company s outstanding convertible preferred stock had converted into shares of common stock upon the completion of an initial public offering, or IPO, of the Company s common stock. In addition, the pro forma stockholders equity assumes the reclassification of the convertible preferred stock warrant liability and deferred offering costs to stockholders equity upon completion of an IPO of the Company s common stock.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America 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 expenses in the financial statements and accompanying notes. On an ongoing basis, management evaluates its estimates, including those related to revenue recognition, clinical trial accruals, convertible preferred stock and related warrants, common stock and

related warrants, income taxes and stock-based compensation. Management bases its estimates on historical experience and on various other market-specific and relevant assumptions that management believes to be reasonable under the circumstances. Actual results could differ from those estimates.

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ADURO BIOTECH, INC.

Notes to Consolidated Financial Statements (continued)

Revenue Recognition

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

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

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

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

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

The Company recognizes revenue from research and development grants when the related research expenses are incurred and the Company s specific performance obligations under the terms of the respective contracts are satisfied. Revenue recognized in the accompanying financial statements is not subject to repayment.

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, 2013 and 2014, cash and cash equivalents consisted of

cash in bank deposits and money market accounts held at financial institutions. The recorded carrying amount of cash equivalents approximates their fair value.

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ADURO BIOTECH, INC.

Notes to Consolidated Financial Statements (continued)

Deferred Offering Costs

Deferred offering costs, consisting primarily of legal, accounting and filing fees related to the IPO, are capitalized. The deferred offering costs will be offset against proceeds from the IPO upon the effectiveness of the offering. In the event the offering is terminated, all capitalized deferred offering costs will be expensed. At December 31, 2014, $1.4 million of deferred offering costs were capitalized, which were included in prepaid and other assets in the accompanying consolidated balance sheets. No amounts were deferred at December 31, 2013.

Preferred Stock Derivative Liability

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

Concentration of Credit Risk

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

Accounts receivable consist of amounts due from a company related to a milestone payment and grant proceeds for services under an agreement with the United States government. The Company s management believes these receivables are fully collectible.

Property and Equipment

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

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

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

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ADURO BIOTECH, INC.

Notes to Consolidated Financial Statements (continued)

Impairment of Long-Lived Assets

The Company reviews its 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. The Company has not recorded an impairment of long-lived assets since inception.

Accrued Research and Development Costs

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

Convertible Preferred Stock

The Company has classified the convertible preferred stock as temporary equity in the balance sheets due to certain change in control events that are outside the Company s control, including liquidation, sale or transfer of the Company, as holders of the convertible preferred stock can cause redemption of the shares. The Company has not adjusted the carrying values of the convertible preferred stock to the liquidation preferences of such shares because it is uncertain whether or when an event would occur that would obligate the Company to pay the liquidation preferences to holders of shares of convertible preferred stock. Subsequent adjustments to the carrying values to the liquidation preferences will be made only when it becomes probable that such a redemption event will occur.

Convertible Preferred Stock and Common Stock Warrant Liability

Warrants for shares that are contingently redeemable are classified as liabilities in the balance sheets. Certain common stock warrants are subject to performance conditions which may result in the issuance of a variable number of shares. At initial recognition, the Company classified these warrants as liabilities on the balance sheets at their estimated fair value. The warrants are subject to remeasurement at each balance sheet date, with changes in fair value recognized as a component of other income (expense), net. The Company will continue to adjust the liability for changes in fair value until the earlier of the conversion to common stock warrants, performance conditions met, expiration or exercise

of the warrants.

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

ADURO BIOTECH, INC.

Notes to Consolidated Financial Statements (continued)

conduct certain research and development activities on the Company s behalf and allocations of facilities-related costs. Nonrefundable advance payments for goods or services to be rendered in the future for use in research and development activities are deferred and capitalized as prepaid expenses until the related goods are delivered or the services are performed.

Stock-Based Compensation

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

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

Income Taxes

The Company accounts for income taxes using the asset and liability method. Under this method, deferred income tax assets and liabilities are recorded based on the estimated future tax effects of differences between the financial reporting and the tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Deferred income taxes are classified as current or non-current, based on the classifications of the related assets and liabilities giving rise to the temporary differences. 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 Company follows the authoritative guidance under Accounting Standards Codification Topic, or ASC 740, which clarifies the accounting for uncertainty in tax positions recognized in the financial statements. ASC 740 provides that a tax benefit from an uncertain tax position may be recognized when it is more likely that not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on the technical merits.

Recent Accounting Pronouncements

In May 2014, the FASB issued ASU 2014-09 (ASC 606), *Revenue from Contracts with Customers*. This ASU affects any entity that either enters into contracts with customers to transfer goods and services or enters into contracts for the transfer of nonfinancial assets. ASU 2014-09 will replace most existing revenue recognition guidance in GAAP when it becomes effective. The standard s core principle is that a company will recognize revenue when it transfers promised

goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In doing so, companies will need to use more judgment and make more estimates than under the currently effective guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. ASU 2014-09 is effective for annual periods beginning after December 15, 2016, including interim periods within that period. Early adoption is not permitted. The Company is currently evaluating the impact of this guidance on its consolidated financial statements.

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ADURO BIOTECH, INC.

Notes to Consolidated Financial Statements (continued)

In June 2014, the FASB issued ASU 2014-10, *Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation.* ASU 2014-10 simplifies the accounting guidance by removing all incremental financial reporting requirements for development stage entities. The amendments related to the elimination of the inception-to-date information and other disclosure requirement of Topic 915 should be applied retrospectively and are effective for annual reporting periods beginning after December 15, 2014 and interim periods therein. The Company has elected to early adopt this guidance and, accordingly, there is no inception to date information presented in these consolidated financial statements.

In August 2014, the FASB issued ASU 2014-15, *Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern*. ASU 2014-15 requires management to evaluate whether there is substantial doubt about an entity s ability to continue as a going concern and to provide related footnote disclosures. In doing so, companies will have reduced diversity in the timing and content of footnote disclosures than under today s guidance. ASU 2014-15 is effective for the Company in the first quarter of 2016 with early adoption permitted. The Company does not believe the impact of adopting ASU 2014-15 on its consolidated financial statements will be material.

3. Fair Value Measurements

The carrying amounts of certain of the Company s financial instruments, including cash equivalents, accounts receivable, accounts payable and convertible promissory notes payable approximated 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 to sell 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 financial instruments consist of Level 1 assets and Level 3 liabilities. Where quoted prices are available in an active market, securities are classified as Level 1. Level 1 assets consist of highly liquid money market funds that are included in cash equivalents.

In certain cases where there is limited activity or less transparency around the inputs to valuation, securities are classified as Level 3. Level 3 liabilities consist of common and preferred stock warrant liabilities,

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ADURO BIOTECH, INC.

Notes to Consolidated Financial Statements (continued)

convertible promissory note warrant liabilities and preferred stock derivative liability. The determination of the fair value of the warrants is discussed in Note 12. Generally, increases or decreases in the fair value of the underlying convertible preferred stock or common stock would result in a directionally similar impact in the fair value measurement of the associated warrant 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, 2013			
	Level 1	Level 2	Level 3	Total
Financial Assets:				
Money market funds	$ 633	$	$	$ 633
Financial Liabilities:				
Convertible preferred stock warrant liability	$	$	$ 72	$ 72
Common stock warrant liability			505	505
Convertible promissory note warrants[1]			617	617
Total	$	$	$ 1,194	$ 1,194

[1] Convertible promissory note warrants are classified as part of convertible promissory notes payable.

	December 31, 2014			
	Level 1	Level 2	Level 3	Total
Financial Assets:				
Money market funds	$ 110,001	$	$	$ 110,001
Financial Liabilities:				
Convertible preferred stock warrant liability	$	$	$ 100	$ 100
Common stock warrant liability			889	889
Total	$	$	$ 989	$ 989

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

	Preferred Stock Warrant Liability	Common Stock Warrant Liability	Preferred Stock Derivative Liability	Convertible Promissory Note Warrants
Balance at December 31, 2012	$ 81	$ 334	$	$
Issuance of convertible promissory note warrants				617
Net increase (decrease) in fair value upon revaluation	(9)	171		
Balance at December 31, 2013	72	505		617
Issuance of convertible promissory note warrants				15
Initial recognition of preferred stock derivative liability			3,018	
Issuance of preferred stock			(1,543)	
Net increase (decrease) in fair value upon revaluation	28	384	(1,475)	152
Reclassification to additional paid-in capital				(784)
Balance at December 31, 2014	$ 100	$ 889	$	$

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ADURO BIOTECH, INC.

Notes to Consolidated Financial Statements (continued)

4. Balance Sheet Components

Property and Equipment, Net

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

	December 31,	
	2013	**2014**
Lab equipment	$ 569	$ 1,165
Computer and office equipment	439	520
Furniture and fixtures	24	87
Leasehold improvements	150	304
Total property and equipment	1,182	2,076
Less: accumulated depreciation and amortization	(783)	(1,023)
Property and equipment, net	$ 399	$ 1,053

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

Accrued Expenses and Other Liabilities

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

	December 31,	
	2013	**2014**
Compensation and related benefits	$ 786	$ 1,276
Professional and consulting services	135	961
Interest payable	190	
Other	27	171
Total accrued expenses and other liabilities	$ 1,138	$ 2,408

5. Related Party Convertible Promissory Notes

Convertible Promissory Notes Payable to Related Parties, Short-Term

In August 2013, the Company entered into a note and warrant purchase agreement with related parties to raise up to $13.0 million via the issuance of convertible promissory notes, or the Notes, and warrants to purchase common stock. The Notes bear interest at 5% per annum and automatically convert into equity shares upon the earlier of the closing of a convertible preferred stock financing with proceeds of at least $35.0 million, or Next Financing Event, or the merger or sale of the Company, or Sale Event, or the maturity of the notes on May 30, 2014. If the Notes are converted due to a Next Financing Event, the conversion price shall be equal to the issue price of the equity financing, with investors receiving a variable number of shares. If the Notes are converted due to a Sale Event or their maturity, the conversion price shall be based on the Series B convertible preferred stock issue price of $1.1937322 per share, with the investors receiving a fixed number of shares, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series B convertible preferred stock. The Company determined that the automatic conversion feature upon occurrence of the Next Financing Event represented a redemption feature embedded within the

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ADURO BIOTECH, INC.

Notes to Consolidated Financial Statements (continued)

Notes. The Company also determined that the provisions whereby the Notes automatically convert upon a Sale Event or on the original maturity date of the Notes of May 30, 2014 were considered to be conversion options within the Notes.

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

Each Note was also issued with warrants to purchase common stock with the number of warrants being equal to 10% of the outstanding principal balance of the Notes (or $1.3 million) divided by the issuance price per share of the shares into which the Notes convert. The warrants can be exercised at any time into a variable number of shares of common stock at an exercise price of $0.02 per share for a period of 10 years from the date of issuance. See Note 12. In May 2014, a total of 431,316 warrant shares were issued when the Notes and accrued interest were converted into Series C convertible preferred stock. At the time the warrants were issued, the Company recognized the fair value of the warrants of $0.6 million as a discount on the related Notes. Prior to the Series C convertible preferred stock financing in May of 2014, such warrants were determined to be embedded derivatives and classified together with the Notes on the consolidated balance sheet.

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

At the time of the Series C convertible preferred stock offering in May 2014, the Notes were redeemed under the Next Financing Event redemption feature whereby the aggregate of the outstanding principal and accrued interest balance of the Notes of $13.4 million was converted into 6,199,217 shares of Series C convertible preferred stock based on the Series C convertible preferred stock fair value. The redemption of the Notes was accounted for as a debt extinguishment. Additionally, the Notes contained a beneficial conversion feature which was reacquired and a portion of the reacquisition price allocated to the beneficial conversion feature. The amount allocated to reacquire the beneficial conversion feature was measured using the intrinsic value of the conversion option at the extinguishment date and reflected as a reduction to equity of $3.6 million. As a result, the amount allocated to reacquire the Notes was less than the carrying value of the Notes which resulted in a gain on extinguishment of $3.6 million.

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

Convertible Promissory Notes Payable to Related Party, Long-Term

As part of the Series B convertible preferred stock financing, the Company entered into various unsecured convertible promissory notes and warrants with an investor. The notes are noninterest-bearing, convertible into Series B preferred stock at a price of $1.1937322 per share upon the closing of a convertible preferred stock financing with proceeds of at least $2.0 million and mature on April 15, 2021. Convertible promissory notes in the amounts of $2.5 million, $3.0 million and $3.5 million were issued in October

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ADURO BIOTECH, INC.

Notes to Consolidated Financial Statements (continued)

2011, August 2012 and January 2013, respectively. In January 2013, the $2.5 million and $3.0 million notes were converted into 4,607,399 shares of Series B convertible preferred stock. In May and November 2014 $1.6 million and $1.9 million of the convertible promissory notes, respectively, were converted into 1,373,843 and 1,558,138 shares of Series B convertible preferred stock, respectively. See Note 10.

As part of the Series B preferred stock financing, the Company also issued warrants to the investor as follows: (a) in April 2011, warrants to purchase 61,410 shares of Series B convertible preferred stock and 60,315 shares of common stock; (b) in June 2011, warrants to purchase 241,260 shares of common stock; and (c) in October 2011, warrants to purchase 150,787 shares of common stock. See Note 12 for information regarding the terms of the warrants.

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

The outstanding carrying balance of the long-term convertible promissory note payable to related party, net of the unamortized debt discount was $1.4 million at December 31, 2013. There was no balance outstanding at December 31, 2014.

6. Note Payable to Related Party

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

7. Collaboration Agreements

Janssen ADU-741 and GVAX Prostate Agreements

In May 2014, the Company entered into a Research and License Agreement, or Janssen ADU-741 Agreement, and a GVAX Prostate License Agreement, or Janssen GVAX Prostate Agreement, with Janssen Biotech, Inc., or Janssen, a

wholly-owned subsidiary of Johnson & Johnson Development Corporation, to collaborate in the development of a drug for the treatment of prostate cancer. Under the terms of the Janssen ADU-741 Agreement, the Company granted Janssen exclusive, worldwide license under intellectual property rights controlled by the Company to research, develop, manufacture, use, sell and otherwise exploit products containing ADU-741 for any and all uses. The Company is responsible for certain research and development

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ADURO BIOTECH, INC.

Notes to Consolidated Financial Statements (continued)

activities from the effective date of the agreement until approval of an investigational new drug, or IND. During 2014, the Company received an upfront payment of $12.0 million and non-substantive milestone payments of $3.5 million upon completion of certain development activities. In December 2014, the Company completed a substantive milestone resulting in recognition of collaboration and license revenue of $3.0 million. The Company received the $3.0 million payment in January 2015. Under the terms of the Janssen ADU-741 Agreement, the Company may receive future nonrefundable milestone payments up to a total of $1.0 million after completion of various stages of the research and development activities, and the Company is eligible to receive future contingent payments up to a total of $345.5 million comprised of development milestones through completion of all Phase 3 clinical trials, as well as launch, commercialization and sales milestones. The contingent payments are triggered upon the activities expected to be undertaken by Janssen. The Company is eligible to receive royalties on net sales of licensed products by Janssen, its affiliates and sublicensees at a rate ranging from the mid-single digits to low teens based on the aggregate annual net sales and based on the country of sale.

Under the Janssen GVAX Prostate Agreement, the Company granted Janssen an exclusive worldwide license under intellectual property rights controlled by the Company to research, develop, manufacture, use, sell and otherwise exploit products containing GVAX Prostate for any and all uses. The Company received an upfront payment of $500,000 in June 2014 and may receive an additional $2.0 million on the achievement of a specified commercial milestone. In addition, the Company is eligible to receive royalties in the high single digits based on net sales of the product.

The development activities being conducted by the Company are based on a combination of the technology licensed under both agreements. Accordingly, the Company has accounted the Janssen ADU-741 Agreement and Janssen GVAX Prostate Agreement as one arrangement and has identified the deliverables within the arrangement as a license to the technology and research and development activities through IND regulatory approval. The Company has determined that the licenses and development services under the license and research agreements represent a single unit of accounting. The licenses do not have stand-alone value to Janssen, separable from the development services to be performed under the agreement, as Janssen is unable to use the licenses for their intended purpose without the Company s performance of the research and development services. As a result, the Company recognizes revenue from the upfront payments ratably over the term of its estimated period of performance under the agreement. Changes in the estimated period of performance will be accounted for prospectively as a change in estimate. The upfront fees received totaling $12.5 million are being recognized on a straight-line basis from the effective date of the agreements to September 2015, the Company s estimated performance period. The Company will recognize non-substantive milestone payments on a straight-line basis through September 2015, the Company s estimated performance period.

Janssen ADU-214 Agreement

In November 2014, a Research and License Agreement with Janssen, or Janssen ADU-214 Agreement, became effective to develop a drug for the treatment of lung cancer. Under the terms of the Janssen ADU-214 Agreement, the Company granted Janssen an exclusive, worldwide license under intellectual property rights controlled by the Company to research, develop, manufacture, use, sell and otherwise exploit products containing ADU-214 for any and all uses. The Company is responsible for certain research and development activities from the effective date of the agreement until IND regulatory approval. In November 2014, the Company received an upfront license fee of $30.0

million, which is being recognized as revenue on a straight-line basis from the effective date of the Janssen ADU-214 Agreement to February 2016, the Company s estimated performance period. Changes in the estimated period of performance will be accounted for prospectively as a change in estimate. Under the terms of the Janssen ADU-214 Agreement, the Company may receive future nonrefundable milestone payments up to a total of $11.0 million after completion of various stages of the research and development activities, and the Company is eligible to receive future contingent payments up to a total of

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ADURO BIOTECH, INC.

Notes to Consolidated Financial Statements (continued)

$776.0 million comprised of development milestones through completion of all Phase 3 clinical trials, as well as regulatory and commercial milestones. The contingent payments are triggered upon the activities expected to be undertaken by Janssen. The Company is eligible to receive royalties on net sales of licensed products by Janssen, its affiliates and sublicensees at a rate ranging from the high-single digits to the low teens based on the aggregate annual net sales of licensed products worldwide and based on the country of sale.

For the year ended December 31, 2014, the Company recognized revenue totaling $13.0 million related to amortization of the upfront fees and development-related substantive and non-substantive milestones. The remaining balance of the payments received of $36.0 million is included in deferred revenue at December 31, 2014.

8. Research and Development and License Agreements

Listeria-Based Agreements

JHU Listeria Agreement

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

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

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

UCB Listeria Agreement

In March 2012, the Company entered into a license agreement with the Regents of the University of California on behalf of its Berkeley campus, or UCB, granting the Company an exclusive, worldwide, sublicensable license to certain patent rights covering the use of the *Listeria monocytogenes* phage integration vector which accelerates the

genetic engineering of *Listeria* to express more than one antigen to make, use, import, and commercialize products and to provide services for all fields of use. Under this agreement, or the UCB *Listeria* Agreement, the Company is obligated to use commercially reasonable efforts to develop, manufacture and sell licensed products and services and the Company is obligated to achieve specified development and regulatory milestones by specified dates.

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ADURO BIOTECH, INC.

Notes to Consolidated Financial Statements (continued)

Under the UCB *Listeria* Agreement, the Company is required to make future milestone payments totaling up to $350,000 upon achievement of certain development and regulatory milestones. The Company is required to pay an annual license maintenance fee until its first sale of a product covered by the licensed patent rights. Under the UCB *Listeria* Agreement, the Company is obligated to pay UCB royalties based on net sales of licensed products and services sold by the Company and its sublicensees at a rate in the low single digits, subject to minimum annual royalties and customary reductions, and a percentage of certain of the Company s sublicensing revenues in the low-single digits to low thirties depending on how the product covered by the licensed patent rights is used.

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

The Company made payments of $30,000 and $845,000 in milestone, annual maintenance fees and sublicensing fees related to this agreement during the years ended December 31, 2013 and 2014, respectively, which were recorded in research and development expense.

Cerus Corporation Agreement

On November 3, 2009, the Company entered into a license agreement with Cerus Corporation, or Cerus. Under the terms of this license agreement, Cerus granted the Company a worldwide exclusive license under certain of Cerus patents and technology to make, have made, use, import, offer for sale and sell therapeutics for the treatment or prevention of any human or animal diseases involving a vaccine or immunotherapy.

The Company is required to pay Cerus royalties based on a percentage of net sales in the low single digits, including net sales by sublicensees, of products incorporating the licensed technology and from the provision of any services based upon the licensed technology. If the products or services are bundled with any other products or services, the portion of the net sales allocated to the licensed technology would be used in determining the royalty payments.

GVAX-Based Agreements

ANI Agreement

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

Under the ANI Agreement, the Company paid ANI cash consideration of $1.0 million and will be required to make royalty payments on net sales of GVAX products sold by the Company, its affiliates and its sublicensees for the treatment of certain cancers, which are covered by purchased intellectual property rights or developed using purchased

technology, at rates in the low single digits. The Company is also required to pay milestone payments up to $4.0 million for GVAX pancreas or prostate products in combination with *Listeria* or up to $12.0 million per product for other GVAX products upon the achievement of certain sales milestones. The Company is obligated to make royalty payments on a product-by-product and country-by-country basis until the later of (i) the expiration of the last to expire of the purchased patent rights covering the GVAX product or the

ADURO BIOTECH, INC.

Notes to Consolidated Financial Statements (continued)

regulatory exclusivity period and (ii) up to seven years from the first commercial sale of the product in such country depending on the level of net sales in such country after the expiration of the patent or regulatory exclusivity period. The royalties and milestone payments for GVAX products for the treatment of pancreas and prostate cancer, as well as the royalties and milestone payments for other cancer products, are each capped at specified maximum amounts. To the extent the Company enters into a sublicensing agreement relating to the GVAX pancreas or prostate cancer products in combination with *Listeria*, the Company is required to pay ANI a percentage of the Company s sublicensing income, ranging from the low teens to the low thirties based on the indication, the stage of development of the GVAX products at the time the sublicense is granted and the amount of development costs expended by the Company at the time the sublicense is granted. The sublicensing payments owed under this ANI Agreement for pancreas and prostate cancer products in combination with *Listeria* are each capped at specified maximum amounts.

In 2013, the Company recorded the $1.0 million payment for the purchase of the assets as research and development expense because the Company determined that there was no alternative future use. During 2014, the Company made a payment of $0.1 million for sublicensing fees, which was recorded in research and development expense.

JHU GVAX Agreement

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

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

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

the Company may terminate the New License Agreement at will upon 90 days prior written notice to JHU.

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ADURO BIOTECH, INC.

Notes to Consolidated Financial Statements (continued)

CDN-Based Agreements

Karagen Agreement

In June 2012, the Company entered into a license agreement with Karagen Pharmaceuticals, Inc., or Karagen, pursuant to which Karagen granted the Company an exclusive, worldwide, sublicenseable license under certain patents and know-how related to CDNs 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 totaling up to $900,000, in the 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 UCB, granting the Company an exclusive, worldwide, sublicenseable license under certain patent rights covering the use of the CDN 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 paid UCB an upfront fee of $50,000 in 2014, which was recorded in research and development expenses, and 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 our 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.

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Notes to Consolidated Financial Statements (continued)

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 CDNs and a non-exclusive, worldwide, sublicensable license under specified know-how, in each case to develop, make, have made, use, have used, import, sell, and otherwise commercialize licensed products for use in therapeutic and/or prophylactic treatments in humans. Under this agreement, or the MSK Agreement, the Company is obligated to use commercially reasonable efforts to develop and commercialize a licensed product, including achieving specified development and regulatory milestones by specified dates.

Under the MSK Agreement, the Company paid MSK an up-front fee of $50,000 in January 2015, which was recorded in research and development expenses in 2014, and is required to make future milestone payments totaling up to $3.3 million upon achievement of certain development, regulatory and commercialization milestones. Under the MSK Agreement, the Company is also obligated to pay MSK royalties based on net sales of licensed products by the Company and our sublicensees at a rate in the low single digits, subject to minimum annual royalties and a percentage of certain of the Company s sublicensing revenues ranging from ten to mid-twenties.

The MSK Agreement will continue in effect until the expiration of our royalty obligations. The Company or the Licensors may terminate the agreement for uncured material breach upon 90 days prior written notice and the Company may terminate the agreement at will upon 30 days prior written notice to the Licensors.

9. Commitments and Contingencies

Leases

The Company leases their office and research and development facility in Berkeley, California, under a non-cancelable operating lease which expires in August 2016. In April 2014, the Company amended its office lease agreement to increase the square footage by 3,990 square feet of rentable space resulting in an $8,000 increase in the monthly rent payment effected on June 1, 2014.

Rent expense was $281,000 and $344,000 for the years ended December 31, 2013 and 2014, respectively. Under the terms of the lease agreement, the Company is also responsible for certain insurance, property tax and maintenance expenses. Future minimum payments under the lease at December 31, 2014 are as follows (in thousands):

Year ending December 31,	Amounts
2015	$ 392
2016	261
Total	$ 653

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ADURO BIOTECH, INC.

Notes to Consolidated Financial Statements (continued)

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 parties for losses suffered or incurred by the indemnified party. Some of the provisions will limit losses to those arising from third party actions. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments the Company could be required to make under these provisions is not determinable. The Company has never incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. The Company has also entered into indemnification agreements with its directors and officers that may require the Company to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers to the fullest extent permitted by Delaware corporate law. The Company currently has directors and officers insurance.

Legal

During the normal course of business, the Company may be a party to legal claims that may not be covered by insurance. Management does not believe that any such claims would have a material impact on the Company s financial statements.

Other Commitments

The Company has various manufacturing, clinical, research and other contracts with vendors in the conduct of the normal course of its business. All contracts are terminable, with varying provisions regarding termination. If a contract with a specific vendor were to be terminated, the Company would only be obligated for the products or services that the Company had received at the time the termination became effective as well as non-cancelable and non-refundable payment obligations incurred by the vendor for products or services before the termination became effective. In the case of terminating a clinical trial agreement at a particular site, the Company would also be obligated to provide continued support for appropriate medical procedures at that site until completion or termination.

10. Convertible Preferred Stock

In January 2013, the Company issued 2,593,639 shares of Series B convertible preferred stock to related parties for net cash proceeds of $3.0 million and 4,607,399 shares as settlement of outstanding convertible promissory notes issued in October 2011 and August 2012, in the amount of $5.5 million. In May and November 2014, the Company issued 1,373,843 and 1,558,138 shares, respectively, of Series B convertible preferred stock to the related party as settlement of a convertible promissory note issued in January 2013. See Note 5.

On May 30, 2014, the Company entered into the Series C Preferred Stock Purchase Agreement with existing as well as new investors for the issuance of up to 31,544,844 shares of Series C convertible preferred stock at a purchase price of $2.17 per share. Upon the execution of the agreement, the Company issued 17,119,818 shares of Series C convertible preferred stock for net cash proceeds of $36.9 million and 6,199,217 shares as settlement of outstanding convertible promissory notes, including accrued interest, in the amount of $13.4 million. On December 15, 2014, the

Company issued 2,304,148 additional shares of Series C convertible preferred stock to the related party for cash proceeds of $5.0 million.

In May 2014, the Company recorded a preferred stock derivative liability in the amount of $3.0 million, as a related party received the right to purchase from the Company, on the same terms, additional shares of Series

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ADURO BIOTECH, INC.

Notes to Consolidated Financial Statements (continued)

C convertible preferred stock, in a second and third tranche. As the related party holds a majority of the board seats, the decision to complete these tranches was deemed to be outside the control of the Company. During the year ended December 31, 2014, the Company recognized a $1.5 million gain related to changes in fair value of the preferred stock derivative liability. At the time of the second and third tranche funding, the Company remeasured the preferred stock derivative liability, with the change in fair value recognized as a component of other income (expense), net. At the date of derecognition of the preferred stock derivative liability, the Company reclassified the remaining value associated with the liability of $1.5 million to Series C convertible preferred stock.

The key assumptions used in the valuation of the preferred stock derivative liability were as follows:

	Year Ended December 31, 2014
Expected term (in years)	0 0.55
Fair value of underlying shares	$2.17 $2.46
Volatility	80.0%
Risk-free interest rate	0.02% 0.07%
Dividend yield	%

On December 19, 2014, the Company entered into the Series D Preferred Stock Purchase Agreement with existing as well as new investors for the issuance of up to 19,012,173 shares of Series D convertible preferred stock at a purchase price of $2.70 per share. Upon the execution of the agreement, the Company issued 19,012,173 shares of Series D convertible preferred stock for net cash proceeds of $48.9 million.

At December 31, 2013, convertible preferred stock consisted of the following (in thousands, except share data):

	Shares Authorized	Shares Outstanding	Net Carrying Value	Liquidation Preference
Series A	161,844	161,844	$ 8,092	$ 8,092
Series A-1	3,396,666	3,369,431	4,582	4,582
Series B	22,000,000	18,509,728	19,550	22,096
Total	25,555,508	22,041,003	$ 32,224	$ 34,770

At December 31, 2014, convertible preferred stock consisted of the following (in thousands, except share data):

	Shares Authorized	Shares Outstanding	Net Carrying Value	Liquidation Preference
Series A	161,843	161,843	$ 8,092	$ 8,092
Series A-1	3,393,666	3,369,431	4,582	4,582
Series B	21,525,480	21,441,709	24,505	25,596
Series C	25,623,183	25,623,183	53,866	55,603
Series D	19,012,173	19,012,173	48,918	51,388
Total	69,716,345	69,608,339	$ 139,963	$ 145,261

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ADURO BIOTECH, INC.

Notes to Consolidated Financial Statements (continued)

Significant provisions of the convertible preferred stock are as follows:

Dividends The holders of preferred stock are entitled to receive, on a pari passu basis, non-cumulative dividends, as adjusted for stock splits, dividends, reclassifications or the like, prior and in preference to any declaration or payment of any dividends to the holders of common stock, when and if declared by the Board of Directors, at a rate of 8% of the original issuance price per share for Series B, Series C, and Series D, or collectively, Senior Preferred, and 5% for Series A-1 and Series A, or collectively, Junior Preferred, per annum. No dividends have been declared by the Board of Directors or paid since inception.

Conversion At the option of the holder, each share of preferred stock is convertible into fully paid and nonassessable shares of common stock on a 0.72-for-1 basis, subject to stock splits, stock dividends and dilution. Each share of preferred stock automatically converts into the number of shares of common stock into which such shares are convertible at the then applicable conversion ratio upon (i) the closing of the sale of shares of common stock in a public offering resulting in at least $45.0 million of gross proceeds, or (ii) the consent of the majority of the holders of the then outstanding shares of Series B and Series C and at least 60% of the then outstanding shares of Series D, voting together as a single class on an as-converted basis.

Liquidation In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, holders of Senior Preferred are entitled to receive, prior and in preference to holders of Junior Preferred and common stock, an amount equal to their original issue price plus any declared and unpaid dividends. If upon occurrence of such an event, the assets and funds to be distributed among the holders of Senior Preferred are insufficient to permit the payment to such holders, the entire assets and funds of the Company legally available for distribution will be distributed ratably among the holders of Senior Preferred. Upon completion of the distribution to the holders of Senior Preferred, holders of Junior Preferred are entitled to receive prior and in preference to holders of common stock, an amount equal to their original issue price plus any declared but unpaid dividends. If upon occurrence of such an event, after payment in full of preferential amounts due to holders of Senior Preferred, the assets and funds to be distributed among the holders of Junior Preferred are insufficient to permit the payment to such holders, the entire remaining assets and funds of the Company legally available for distribution will be distributed ratably among the holders of Junior Preferred. All remaining legally available assets of the Company are to be distributed pro rata to the holders of Senior Preferred and common stock, on an as-converted basis. A liquidation may be deemed to be occasioned by or to include (unless waived by the written election of the majority of the outstanding shares of Series B and majority of Series C and Series D holders at least 10 days prior to the effective date of such event) (i) a consolidation or merger of the Company with or into any other corporation in which the Company s stockholders of record as constituted immediately prior to such transaction will, immediately after such transaction, fail to hold at least 50% of the voting power of the result of the surviving corporation; or (ii) a sale, conveyance or disposition of all or substantially all of the assets of the Company.

Voting Each holder of preferred stock is entitled to the number of votes equal to the number of shares of common stock into which each such shares of preferred stock could be converted on the record date for the vote or consent of the stockholders, except as otherwise required by law or other provisions of the Company s Certificate of Incorporation, and have voting rights and powers equal to the voting rights and powers of the common stockholders. The holders of Series B, voting as a separate class, are entitled to elect two member of the Board of Directors. The holders of Series

C, voting as a separate class, are entitled to elect two members of the Board of Directors. The holders of preferred stock and common stock, voting as a single class on an as-converted basis, are entitled to elect three members of the Board of Directors.

Protective Provisions The holders of Series D have certain protective provisions. As long as any shares of Series D are outstanding, the Company cannot, without the approval of the majority of the then

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ADURO BIOTECH, INC.

Notes to Consolidated Financial Statements (continued)

outstanding shares of Series D, voting as a separate class, take any actions that: (i) amends, alters or repeals any powers, preferences or rights of Series D preferred stock; (ii) increase or decrease the authorized number of shares of Series D; (iii) redeem, repurchase or make acquisitions of the Series C, Series B, Junior Preferred or common stock; or (iv) declare or pay any dividends or distributions on the Series C, Series B, Junior Preferred or common stock.

The holders of Series C and Series B have certain protective provisions. As long as any shares of Series C and Series B are outstanding, the Company cannot, without the approval of 60% of the then outstanding shares of Series C and a majority of the then outstanding shares of Series B, each voting as a separate class, take any actions that: (i) consummates a liquidation, dissolution or winding up of the Company; (ii) amends, alters or repeals any powers, preferences or rights of Series C or Series B preferred stock; (iii) results in issuance of any additional class or series of capital stock, unless the class ranks junior to Series C or Series B preferred stock with respect to liquidation preferences; (iv) increases or decreases the authorized number of members of the Board of Directors; (v) declare or pay any dividends or distributions on the preferred and common stock; or (vi) redeem, repurchase or make acquisitions of any securities of the Company.

The holders of Junior Preferred have certain protective provisions. As long as any shares of Junior Preferred are outstanding, the Company cannot, without the approval of the majority of the then outstanding shares of Junior Preferred, voting as a separate class, take any action that: (i) amends, alters or repeals any powers, preferences or rights of Junior Preferred; or (ii) increase the number of authorized shares of Junior Preferred.

11. Common Stock

The Company had reserved shares of common stock, on an as-converted basis, for future issuance as follows:

	December 31,	
	2013	**2014**
Convertible preferred stock outstanding	15,869,471	50,117,919
Options issued and outstanding	4,029,331	5,970,382
Shares available for future stock option grants	92,278	3,154,755
Series A-1 convertible preferred stock warrants	17,447	17,447
Series B convertible preferred stock warrants	60,308	60,308
Common stock warrants	1,154,270	1,154,270
Total	21,223,105	60,475,081

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ADURO BIOTECH, INC.

Notes to Consolidated Financial Statements (continued)

12. Warrants

The Company had issued and outstanding warrants that are not subject to remeasurement as follows:

	Warrants Outstanding			Exercise	
	December 31, 2013	December 31, 2014	Issuance Date	Price per Share	Terms (Years)
Type of Security:					
Common	1,152	1,152	November 2008	$ 34.73	10.0
Common	720	720	January 2009	$ 34.73	10.8
Common	288	288	February 2009	$ 34.73	10.0
Common	360	360	March 2009	$ 34.73	10.0
Common	144	144	April 2009	$ 34.73	10.0
Common	66,176	66,176	July 2009	$ 1.89	10.0
Common	21,176	21,176	September 2009	$ 1.89	10.0
Common	17,280	17,280	April 2011	$ 0.70	10.0
Common	N/A	232,258[(1)]	August 2013	$ 0.02	10.0
Common	N/A	132,715[(1)]	September 2013	$ 0.02	10.0
Common	N/A	56,131[(1)]	December 2013	$ 0.02	10.0
Common	N/A	10,212[(1)]	January 2014	$ 0.02	10.0
Total	107,296	538,612			

(1) In connection with the issuance of convertible promissory notes to related parties, warrants to purchase common stock were issued in August 2013, September 2013, December 2013 and January 2014. These warrants were classified together with convertible promissory notes payable at issuance. At December 31, 2013, the number of warrants issued was subject to adjustment pending the occurrence of the next round of financing. On May 30, 2014, outstanding principal and accrued interest of the convertible promissory notes in the amount of $13.5 million was converted into Series C convertible preferred stock and issued 431,316 common stock warrants. See Note 5. At the conversion date, warrants at the then fair value were reclassified into additional paid-in capital in the amount of $0.8 million.

The Company had issued and outstanding warrants that are subject to remeasurement as follows:

	Warrants Outstanding		Exercise

	December 31, 2013	December 31, 2014	Issuance Date	Price per Share	Terms (Years)
Type of Security:					
Series A-1	10,002	10,002	April 2011	$ 1.36	10.0
Series A-1	14,233	14,233	April 2011	$ 1.23	10.0
Series B	83,771	83,771	April 2011	$ 1.19	5.0
Common	197,638	197,638	April 2011	$ 0.01	10.0
Common	241,260	241,260	June 2011	$ 0.01	9.8
Common	176,760	176,760	October 2011	$ 0.01	9.5
Common	(2)	N/A	August 2013	$ 0.02	10.0
Common	(2)	N/A	September 2013	$ 0.02	10.0
Common	(2)	N/A	December 2013	$ 0.02	10.0
Total	723,664	723,664			

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Notes to Consolidated Financial Statements (continued)

(2) In connection with the issuance of convertible promissory notes to related parties, warrants to purchase common stock were issued in August 2013, September 2013, and December 2013. At December 31, 2013, the number of warrants issued was subject to adjustment pending the occurrence of the next round of financing. On May 30, 2014, outstanding principal and accrued interest of the convertible promissory notes in the amount of $13.5 million was converted into Series C convertible preferred stock and issued 431,316 common stock warrants. See Note 5.

The following is a summary of the outstanding warrants to purchase common stock and warrants to purchase convertible preferred stock that are subject to remeasurement and their fair values at December 31, 2013 and 2014 (in thousands, except share data):

	Shares at December 31,		Fair Value at	
	December 31, 2013	2014	December 31, 2013	December 31, 2014
Classified as warrant liability:				
Series A-1	24,235	24,235	$ 13	$ 25
Series B	83,771	83,771	59	75
Total convertible preferred stock warrants	108,006	108,006	72	100
Common	615,658	615,658	505	889
Total classified as warrant liability	723,664	723,664	$ 577	$ 989
Classified within convertible promissory notes payable:				
Common(3)			617	
Total classified within convertible promissory notes payable			$ 617	$

(3) In connection with the issuance of convertible promissory notes to related parties, warrants to purchase common stock were issued in August 2013, September 2013 and December 2013. At December 31, 2013, the number of warrants issued is subject to adjustment should the Next Financing Event occur. See Note 5.

In April 2011, the Company issued warrants to purchase 24,235 shares of Series A-1 convertible preferred stock as consideration for services provided, with a weighted-average exercise price of $1.28 per share. The warrants are immediately exercisable and expire, if not exercised, in April 2021. As the shares into which the warrants are

exercisable are contingently redeemable, the Company has recognized a liability for the fair value of these warrants on the consolidated balance sheets. The Company determined the fair value of the warrants to be $16,000 on the date of grant using the Black-Scholes option pricing model. The fair value of the warrants was $13,000 and $25,000 at December 31, 2013 and December 31, 2014, respectively.

In April 2011, in connection with the Series B convertible preferred stock financing, the Company issued warrants to purchase 83,771 shares of Series B convertible preferred stock, with an exercise price of $1.19 per share. The warrants are immediately exercisable and expire, if not exercised, in April 2016. As the shares into which the warrants are exercisable are contingently redeemable, the Company has recognized a liability for the fair value of these warrants on the consolidated balance sheets. The Company determined the fair value of the warrants to be $70,000 on the date of grant using the Black-Scholes option pricing model. The fair value of the warrants was $59,000 and $75,000 at December 31, 2013 and December 31, 2014, respectively.

In April, June, and October 2011, as part of the Series B convertible preferred stock financing, the Company issued warrants to purchase an aggregate of 615,658 shares of common stock, with an exercise price of

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ADURO BIOTECH, INC.

Notes to Consolidated Financial Statements (continued)

$0.01 per share. The warrants are exercisable beginning in April 2015 and may terminate, in whole or part, if the Company obtains certain levels of government grant funds before April 2015. The warrants expire, if not exercised, in April 2021. The Company estimated that it is more likely than not that the minimum level of grant funds will not be achieved and has recognized a liability for the fair value of these warrants on the consolidated balance sheet, as the warrants are subject to performance conditions which may result in the issuance of a variable number of shares. The Company determined the fair value of the warrants to be $393,000 on the date of grant using a Black-Scholes option pricing model. The fair value of the warrants was $0.5 million and $0.9 million at December 31, 2013 and December 31, 2014, respectively.

In August 2013, September 2013, December 2013 and January 2014, in connection with the issuance of the convertible promissory notes payable to related parties, the Company issued warrants to purchase shares of common stock equal to 10% of the outstanding principal balance of the convertible promissory notes (or $1.3 million) divided by the issuance price per share of the shares into which the convertible promissory notes convert. The warrants are immediately exercisable at $0.02 per share and expire, if not exercised, 10 years from the date of issuance. The warrants are recorded at fair value as a bifurcated embedded derivative instrument subject to remeasurement at the end of each reporting period in other income (expense), net in the consolidated statements of operations and comprehensive loss. The fair value of the derivative liability was $0.6 million at December 31, 2013 and is presented on a combined basis with the underlying convertible promissory notes on the consolidated balance sheets. In May 2014, the fair value of derivative liability of $0.8 million was reclassified to additional paid-in capital.

Convertible Preferred Stock Warrants

The key assumptions used in the Black-Scholes option-pricing model for the valuation of the convertible preferred stock warrants were as follows:

	Year Ended December 31,			
	2013		2014	
Expected term (in years)	2.29	8.04	1.29	7.04
Fair value of underlying shares	$0.79	$1.41	$0.67	$1.98
Volatility	80.0%		53.9%	80.8%
Risk-free interest rate	0.37%	2.51%	0.23%	2.30%
Dividend yield	%		%	

Common Stock Warrants and Convertible Promissory Note Warrants

The key assumptions used in the Black-Sholes option-pricing model for the valuation of the common stock warrants were as follows:

	Year Ended December 31,

	2013		2014	
Expected term (in years)	7.29	9.83	6.29	9.79
Fair value of underlying shares	$0.82		$1.02	$1.45
Volatility	80.0%		75.7%	80.4%
Risk-free interest rate	1.46%	3.04%	1.84%	2.73%
Dividend yield	%		%	

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Notes to Consolidated Financial Statements (continued)

13. Stock Option Plan

In October 2009, the Company adopted the 2009 Stock Incentive Plan, or the Plan. The Plan provides for the granting of stock-based awards to employees, directors and consultants under terms and provisions established by the Board of Directors.

Under the Plan, the Board of Directors may grant incentive stock options or nonqualified stock options. Incentive stock options may only be granted to Company employees. 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. The Board of Directors determined the fair value of common stock using valuations prepared by an unrelated third-party valuation firm. Options expire after 10 years (five years for stockholders owning greater than 10% of the voting stock). The Board of Directors determines the period over which the options vest and become exercisable. Shares issued upon exercise of unvested options shall be subject to the Company s right to repurchase at their purchase price.

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, 2012	582,610	3,105,901	$ 0.74	
Authorized	468,000			
Granted	(964,888)	964,888	$ 0.82	
Exercised		(32,671)	$ 0.48	
Canceled	6,556[1]	(8,787)	$ 17.15	
Balance December 31, 2013	92,278	4,029,331	$ 0.72	$ 985
Authorized	5,071,079			
Granted	(2,019,598)	2,019,598	$ 1.00	
Exercised		(66,499)	$ 0.74	
Canceled	10,996[1]	(12,048)	$ 9.33	
Balance December 31, 2014	3,154,755	5,970,382	$ 0.80	$ 4,335
Options exercisable December 31, 2014		3,538,966	$ 0.71	$ 3,090

Options vested and expected to vest	December 31, 2014	5,753,383	$	0.80	$	4,220

(1) The amount excludes 2,231 and 1,052 canceled options for the years ended December 31, 2013 and 2014, respectively, initially granted from the legacy stock option plans. As these plans have been terminated, any options canceled are not added back to the existing option plan pool.

The aggregate intrinsic values of options outstanding, exercisable, vested and expected to vest were calculated as the difference between the exercise price of the options and the estimated fair value of the Company s common stock, as determined by the Board of Directors, at December 31, 2014.

The aggregate intrinsic value of options exercised under the Plan was zero and $17,000 for the years ended December 31, 2013 and December 31, 2014, respectively.

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ADURO BIOTECH, INC.

Notes to Consolidated Financial Statements (continued)

The total fair value of options that vested during the years ended December 31, 2013 and 2014 were $0.3 million and $0.5 million, respectively.

The weighted-average grant date fair value of employee options granted during the years ended December 31, 2013 and 2014 were $0.55 and $0.67 per share, respectively.

At December 31, 2014, the weighted-average remaining contractual life was 6.9 years and 7.8 years for exercisable options and vested and expected to vest options, respectively. The weighted-average remaining contractual life of options outstanding was 8.0 years and 7.9 years at December 31, 2013 and 2014, respectively.

Stock-based Compensation Expense

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

	Year Ended December 31,	
	2013	**2014**
Research and development	$ 194	$ 202
General and administrative	215	368
Total stock-based compensation expense	$ 409	$ 570

At December 31, 2014, the total unrecognized compensation expense related to unvested options, net of estimated forfeitures, was $1.4 million, which the Company expects to recognize over an estimated weighted- average period of 3.2 years.

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

Expected Term The Company s expected term represents the period that the Company s stock-based awards are expected to be outstanding and is determined using the simplified method (based on the mid- point between the vesting date and the end of the contractual term).

Expected Volatility Since the Company is not yet a public company and does not have any 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.

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Notes to Consolidated Financial Statements (continued)

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,			
	2013		2014	
Expected term (in years)	5.0	6.0	5.3	6.1
Volatility	75.7	78.6%	70.2	77.3%
Risk-free interest rate	1.36	1.73%	1.85	2.0%
Dividend yield		%		%

For the years ended December 31, 2013 and 2014, the Company recognized $0.4 million and $0.5 million, respectively, of stock-based compensation related to options granted to employees. The compensation expense is allocated on a departmental basis, based on the classification of the option holder. No income tax benefits have been recognized in the statements of operations for stock-based compensation arrangements and no stock-based compensation costs have been capitalized as property and equipment as of December 31, 2014.

The Company uses the fair value method to value options granted to non-employees. In 2013 and 2014, the Company recognized stock-based compensation of $50,000 and $85,000, respectively, related to options granted to non-employees.

The fair value of stock option awards granted to non-employees was estimated at the date of grant using a Black-Scholes option-pricing model with the following assumptions:

	Year Ended December 31,			
	2013		2014	
Expected term (in years)	10.0		9.3	9.7
Volatility	78.4%		78.0	78.1%
Risk-free interest rate	2.72%		2.19	2.39%
Dividend yield		%		%

14. Income Taxes

For both the years ended December 31, 2013 and 2014, the Company recorded no provision for income taxes due to losses incurred.

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

	Year Ended December 31,	
	2013	**2014**
U.S. federal taxes at statutory rate	(34.0%)	(34.0%)
U.S. research credits	(1.3)	(1.0)
Warrants	3.8	2.1
Other permanent items	0.2	1.0
Change in valuation allowance	31.3	31.9
Total	%	%

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Notes to Consolidated Financial Statements (continued)

The tax effects of temporary differences and carryforwards that give rise to significant portions of the deferred tax assets are as follows (in thousands):

	December 31,	
	2013	2014
Deferred tax assets:		
Net operating loss carryforwards	$ 16,823	$ 17,746
Research and development credits	1,394	870
Stock-based compensation	100	124
Accruals and reserves	291	488
Gross deferred tax assets	18,608	19,228
Valuation allowance	(18,600)	(19,212)
Total deferred tax assets	8	16
Deferred tax liabilities:		
Tangible assets	(8)	(16)
Total deferred tax liabilities	(8)	(16)
Net deferred tax assets	$	$

The Company is required to reduce its deferred tax assets by a valuation allowance if it is more likely than not that some or all of its deferred tax assets will not be realized. Management must use judgment in assessing the potential need for a valuation allowance, which requires an evaluation of both negative and positive evidence. The weight given to the potential effect of negative and positive evidence should be commensurate with the extent to which it can be objectively verified. In determining the need for and amount of the valuation allowance, if any, the Company assesses the likelihood that it will be able to recover its deferred tax assets using historical levels of income, estimates of future income and tax planning strategies. As a result of historical cumulative losses, the Company determined that, based on all available evidence, there was substantial uncertainty as to whether it will recover recorded net deferred taxes in future periods. Accordingly, the Company recorded a valuation allowance against all of its net deferred tax assets at December 31, 2013 and 2014. The net valuation allowance increased by $5.7 million and $0.6 million in 2013 and 2014, respectively.

At December 31, 2014, the Company generated net operating loss, or NOL, carryforwards (before tax effects) for federal and state income tax purposes of $51.2 million and $6.0 million, respectively. These federal and state NOL carryforwards will begin to expire in 2027 and 2017, respectively, if not utilized. In addition, the Company generated federal and state research and development tax credit carryforwards of $0.3 million and $0.9 million, respectively, to

offset future income tax liabilities. The federal research and development tax credits can be carried forward for 20 years and will start to expire in 2034, if not utilized, while the state research and development tax credit can be carried forward indefinitely.

Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, the Company s ability to utilize NOL carryforwards or other tax attributes, such as research tax credits, in any taxable year may be limited if the Company has experienced an ownership change. Generally, a Section 382 ownership change occurs if one or more stockholders or groups of stockholders who owns at least 5% of a corporation s stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a specified testing period. Similar rules may apply under state tax laws. The Company performed a Section 382 analysis and believes that it experienced multiple ownership changes under Section 382 of the Code. As a result of the ownership changes, the Company estimates that the utilization of $42.4 million and $5.0 million of federal and state NOLs, respectively, is subject to annual limitations under Section 382. Future changes in the

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Notes to Consolidated Financial Statements (continued)

Company s stock ownership, some of which are outside of the Company s control, could result in additional ownership changes under Section 382 of the Code and result in additional limitations. All of the Company s federal tax credits generated prior to 2014 will expire unutilized subject to limitation while the state credit carryforwards will not expire as they are carried forward indefinitely. The Company has recorded a full valuation allowance related to its NOLs, tax credits and other net deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets. The Company s NOLs may expire unutilized or underutilized, which would prevent the Company from offsetting future taxable income.

Uncertain Tax Positions

A reconciliation of the Company s unrecognized tax benefits for the years ended December 31, 2013 and 2014 is as follows (in thousands):

	December 31,	
	2013	**2014**
Balance at beginning of year	$ 587	$ 695
Reductions based on tax positions related to prior year		(412)
Additions based on tax positions related to current year	108	225
Balance at end of year	$ 695	$ 508

There were no unrecognized tax benefits included in the balance sheet that would, if recognized, affect the effective tax rate.

The Company does not foresee material changes to its gross uncertain income tax position liability within the next 12 months.

The Company files income tax returns in the United States and state jurisdictions. 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, 2010 through December 31, 2013. 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.

The Company will recognize accrued interest and penalties related to unrecognized tax benefits as income tax expense in its statements of operations. At December 31, 2014, the amount of interest and penalties the Company has recorded was zero.

15. Employee Benefit Plan

The Company sponsors a 401(k) plan. All employees are eligible to participate in the 401(k) plan after meeting certain eligibility requirements. Participants may elect to have a portion of their salary deferred and contributed to the 401(k) plan up to the limit allowed under the Internal Revenue Code. The Company has made no contributions to the 401(k) plan since inception.

16. Net Loss per Common Share and Pro Forma Net Loss per Common Share (Unaudited)

Net Loss per Common Share

Since the Company was in a loss position for all periods presented, basic net loss per common share is the same as diluted net loss per common share for all periods presented as the inclusion of all potential common

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Notes to Consolidated Financial Statements (continued)

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,	
	2013	**2014**
Convertible preferred stock	22,041,003	69,608,339
Options to purchase common stock	4,029,331	5,970,382
Convertible preferred stock warrants	108,006	108,006
Common stock warrants	722,954	1,154,270
Convertible notes	9,766,261	
Total	36,667,555	76,840,997

Pro Forma Net Loss per Common Share (Unaudited)

The Company has presented pro forma basic and diluted net loss per common share, which has been computed to give effect to the conversion of all shares of convertible preferred stock into shares of common stock as if such conversion had occurred as of the beginning of the period presented or the original date of issuance, if later. The following table sets forth the computation of the Company s pro forma basic and diluted net loss per common share (in thousands, except share and per share amounts):

	Year Ended December 31, 2014
Net loss	$ (17,014)
Change in fair value of convertible preferred stock warrant liability	28
Interest expense associated with convertible promissory notes payable to related parties	266
Interest expense associated with beneficial conversion feature and warrants related to convertible promissory notes payable to related parties	1,998
Gain from preferred stock derivative liability revaluation	(1,475)
Gain on extinguishment of convertible promissory notes	(3,553)
Net loss used in computing pro forma net loss per common share, basic and diluted	$ (19,750)
Shares used in computing net loss per common share, basic and diluted	320,686
Pro forma adjustments to reflect assumed conversion of convertible preferred stock and convertible promissory notes to related parties	27,722,141

Shares used in computing pro forma net loss per common share, basic and diluted		28,042,827
Pro forma net loss per common share, basic and diluted	$	(0.70)

17. Subsequent Events

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 commercialization of products containing an agonist of the molecular target known as Stimulator of Interferon Genes, or 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

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ADURO BIOTECH, INC.

Notes to Consolidated Financial Statements (continued)

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 million from Novartis. The Company is also eligible to receive up to an additional $250 million in development milestones and up to an additional $250 million in regulatory approval milestones.

The Company is responsible for 38% of the joint development costs worldwide and Novartis is responsible for the remaining 62% of the joint development costs worldwide. The Company will also receive 50% of all profits for any products commercialized pursuant to this collaboration in the United States and 45% of all profits for specified European countries and Japan. For each of these profit share countries, each party will be responsible for its respective commercial sharing percentage of all joint commercialization costs incurred in that country. For all other countries where 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 and 12 years after first commercial sale of the product in such country.

With respect to the United States, specified European countries and/or Japan, the Company may elect for such region to either reduce by 50% or to eliminate in full the Company s development 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 net sales of product for such region, as described above.

Novartis Stock Purchase

Concurrent with the entry into the Novartis Agreement, the Company and Novartis Institutes for BioMedical Research, Inc., or NIBR, entered into a stock purchase agreement to purchase 2,361,029 shares of the Company s Series E Preferred Stock (or 1,699,940 shares of common stock on an as-converted basis), representing 2.7% of the Company s then-outstanding equity and convertible securities, for $25.0 million. Under the stock purchase agreement, NIBR is committed to purchase an additional $25.0 million of the Company s common stock concurrent with the completion of this offering at the initial price per share offered to the public. If this offering is not completed by December 15, 2015, NIBR will purchase 2,361,029 shares of the Company s Series E Preferred Stock (or 1,699,940 shares of common stock on an as-converted basis) for $25.0 million.

Reverse Stock Split

On April 1, 2015, the Company effected a 0.72-for-1 reverse split of its common stock. Upon the effectiveness of the reverse stock split, (i) every 1 share of outstanding common stock was combined into 0.72 of a share of common

stock, (ii) the number of shares of common stock for which each outstanding option or warrant to purchase common stock is exercisable was proportionally decreased on a 0.72-for-1 basis, (iii) the exercise price of each outstanding option or warrant to purchase common stock was proportionately increased on a 0.72-for-1 basis, and (iv) the conversion ratio for each share of preferred stock which is convertible into the Company s common stock was proportionately reduced on a 0.72-for-1 basis. All of the outstanding common

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Notes to Consolidated Financial Statements (continued)

stock share numbers (including shares of common stock which the Company s outstanding preferred stock shares are convertible into), warrants, share prices, exercise prices and per share amounts have been adjusted in this prospectus, on a retroactive basis, to reflect this 0.72-for-1 reverse stock split for all periods presented. The par value per share and the authorized number of shares of common stock and preferred stock were not adjusted as a result of the reverse stock split.

Subsequent events have been evaluated through April 3, 2015 which is the date the financial statements were available to be issued.

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Through and including May 9, 2015 (the 25th day after the date of this prospectus), all dealers effecting transactions in the Common Stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to a dealer s obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

7,000,000 Shares

Common Stock

PROSPECTUS

BofA Merrill Lynch

Leerink Partners

William Blair

Canaccord Genuity

April 14, 2015