
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, DC 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2015

OR

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

For the transition period from _____ to _____

Commission File Number: 001-37345

ADURO BIOTECH, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation or organization)

27-2366329
(I.R.S. Employer
Identification No.)

626 Bancroft Way, 3C
Berkeley, California 94710
(Address of principal executive offices including zip code)

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

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

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

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

Large accelerated filer ☐

Accelerated filer ☐

Non-accelerated filer ☒ (do not check if a smaller reporting company)

Smaller reporting company ☐

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

As of May 26, 2015, the registrant had 62,234,897 shares of common stock, \$0.0001 par value per share, outstanding.

Aduro Biotech, Inc.

Quarterly Report on Form 10-Q

For the Quarter Ended March 31, 2015

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In this Quarterly Report on Form 10-Q, “we,” “our,” “us,” “Aduro,” and “the Company” refer to Aduro Biotech, Inc. Aduro, Aduro Biotech, the Aduro logo and other trade names, trademarks or service marks of Aduro are the property of Aduro Biotech, Inc. This report contains references to our trademarks and to trademarks belonging to other entities. Trade names, trademarks and service marks of other companies appearing in this report are the property of their respective holders. We do not intend our use or display of other companies’ trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

PART I. – FINANCIAL INFORMATION
Item 1. Financial Statements

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

	March 31, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	\$ 132,984	\$ 119,456
Accounts receivable	531	3,153
Prepaid expenses and other current assets	3,446	2,612
Total current assets	136,961	125,221
Property and equipment, net	1,376	1,053
Other assets	428	188
Total assets	<u>\$ 138,765</u>	<u>\$ 126,462</u>
Liabilities, Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	\$ 3,680	\$ 5,030
Accrued clinical trial and manufacturing expenses	4,703	3,350
Accrued expenses and other liabilities	5,394	2,408
Deferred revenue	26,947	33,427
Total current liabilities	40,724	44,215
Deferred revenue	—	2,592
Convertible preferred stock warrant liability	1,096	100
Common stock warrant liability	9,235	889
Total liabilities	51,055	47,796
Commitments and contingencies (Note 6)		
Convertible preferred stock; \$0.0001 par value, 74,438,403 and 69,716,345 shares authorized at March 31, 2015 and December 31, 2014; 71,976,036 and 69,608,339 shares issued and outstanding at March 31, 2015 and December 31, 2014; aggregate liquidation value of \$170,261 and \$145,261 at March 31, 2015 and December 31, 2014, respectively	164,964	139,963
Stockholders' deficit:		
Common stock, \$0.0001 par value; 90,000,000 and 85,000,000 shares authorized at March 31, 2015 and December 31, 2014; 517,545 and 361,997 shares issued and outstanding at March 31, 2015 and December 31, 2014, respectively	—	—
Additional paid-in capital	1,005	346
Accumulated deficit	(78,259)	(61,643)
Total stockholders' deficit	(77,254)	(61,297)
Total liabilities, convertible preferred stock and stockholders' deficit	<u>\$ 138,765</u>	<u>\$ 126,462</u>

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

ADURO BIOTECH, INC.
Condensed Consolidated Statements of Operations
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended March 31,	
	2015	2014
Revenue:		
Collaboration and license revenue	\$ 9,238	\$ —
Grant revenue	336	25
Total revenue	9,574	25
Operating expenses:		
Research and development	10,646	4,729
General and administrative	6,210	1,384
Total operating expenses	16,856	6,113
Loss from operations	(7,282)	(6,088)
Interest expense	—	(1,354)
Other expense, net	(9,334)	(342)
Net loss	\$ (16,616)	\$ (7,784)
Net loss per common share, basic and diluted	\$ (39.97)	\$ (26.34)
Weighted average common shares outstanding, basic and diluted	415,746	295,498

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

ADURO BIOTECH, INC.
Condensed Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit
(In thousands, except share amounts)
(Unaudited)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance at January 1, 2015	69,608,339	\$ 139,963	361,997	\$ —	\$ 346	\$ (61,643)	\$ (61,297)
Issuance of Series E convertible preferred stock for cash, net of issuance costs (Note 7)	2,361,029	24,992	—	—	—	—	—
Issuance of preferred stock upon exercise of preferred stock warrants	6,668	9	—	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	155,548	—	79	—	79
Stock-based compensation expense	—	—	—	—	580	—	580
Net loss	—	—	—	—	—	(16,616)	(16,616)
Balance at March 31, 2015	<u>71,976,036</u>	<u>\$ 164,964</u>	<u>517,545</u>	<u>\$ —</u>	<u>\$ 1,005</u>	<u>\$ (78,259)</u>	<u>\$ (77,254)</u>

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

ADURO BIOTECH, INC.
Condensed Consolidated Statement of Cash Flows
(In thousands)
(Unaudited)

	Three Months Ended March 31,	
	2015	2014
Cash Flows from Operating Activities		
Net loss	\$ (16,616)	\$ (7,784)
Adjustments to reconcile net loss to net cash (used in) operating activities:		
Depreciation and amortization	93	43
Stock-based compensation	580	109
Loss from changes in the fair value of warrants, net	9,342	346
Non-cash interest expense related to convertible promissory notes payable	—	1,354
Changes in operating assets and liabilities:		
Accounts receivable	2,622	337
Prepaid expenses and other assets	(776)	(579)
Accounts payable	1,018	219
Deferred revenue	(9,072)	—
Accrued clinical trial and manufacturing expenses	1,353	1,151
Accrued expenses and other liabilities	2,985	(170)
Net cash used in operating activities	(8,471)	(4,974)
Cash Flows from Investing Activities		
Purchase of property and equipment	(314)	(126)
Net cash used in investing activities	(314)	(126)
Cash Flows from Financing Activities		
Proceeds from issuance of convertible preferred stock, net of issuance costs	22,522	—
Proceeds from issuance of convertible promissory note payable to related parties	—	308
Deferred offering costs	(297)	—
Proceeds from exercise of stock options and warrants	88	—
Net cash provided by financing activities	22,313	308
Net increase (decrease) in cash and cash equivalents	13,528	(4,792)
Cash and cash equivalents at beginning of period	119,456	8,532
Cash and cash equivalents at end of period	<u>\$ 132,984</u>	<u>\$ 3,740</u>
Supplemental Disclosure of Non-Cash Investing and Financing Activities		
Accrued offering costs	<u>\$ 910</u>	<u>\$ —</u>
Purchase of property and equipment in accounts payable	<u>\$ 214</u>	<u>\$ —</u>

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

ADURO BIOTECH, INC.
Notes to Unaudited Condensed Consolidated Financial Statements

1. 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. Basis of Presentation, Use of Estimates, and Recent Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP, and following the requirements of the Securities and Exchange Commission, or the SEC, for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. GAAP have been condensed or omitted, and accordingly the balance sheet as of December 31, 2014 has been derived from audited consolidated financial statements at that date but does not include all of the information required by U.S. GAAP for complete financial statements. These financial statements have been prepared on the same basis as our annual financial statements and, in the opinion of management, reflect all adjustments (consisting only of normal recurring adjustments) that are necessary for a fair presentation of our financial information. The results of operations for the three months ended March 31, 2015 are not necessarily indicative of the results to be expected for the year ending December 31, 2015 or for any other interim period or for any other future year.

The accompanying condensed consolidated financial statements and related financial information should be read in conjunction with the audited consolidated financial statements and the related notes thereto for the year ended December 31, 2014 included in our Registration Statement on Form S-1 filed with the SEC.

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 revenue and expenses in the financial statements and accompanying notes. On an ongoing basis, management evaluates its estimates, including those related to revenue recognition, clinical trial accruals, convertible preferred stock and related warrants, common stock and related warrants, income taxes and stock-based compensation. Management bases its estimates on historical experience and on various other market-specific and relevant assumptions that management believes to be reasonable under the circumstances. Actual results could differ from those estimates.

Deferred Offering Costs

At March 31, 2015 and December 31, 2014, \$2.3 million and \$1.4 million, respectively, of deferred offering costs were capitalized, which were included in prepaid and other assets in the accompanying condensed consolidated balance sheets. The deferred offering costs will be offset against proceeds from the initial public offering, or IPO, to be recorded in the quarter ended June 30, 2015.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, or FASB, issued Auditing Standards Update, or ASU, No. 2014-09, *Revenue from Contracts with Customers* (Topic 606). This ASU affects any entity that either enters into contracts with customers to transfer goods and services or enters into contracts for the transfer of nonfinancial assets. ASU 2014-09 will replace most existing revenue recognition guidance in 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

ADURO BIOTECH, INC.
Notes to Unaudited Condensed Consolidated Financial Statements

expects to be entitled in exchange for those goods or services. In doing so, companies will need to use more judgment and make more estimates than under the currently effective guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. In April 2015, the FASB voted to propose a deferral of the effective date of the ASU by one year. The new guidance would be effective for fiscal years beginning after December 15, 2017 instead of December 15, 2016, which for the Company means January 1, 2018. Entities are permitted to adopt in accordance with the original effective date if they choose. The Company is currently evaluating the impact of this guidance on its consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* (Subtopic 205-40). 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 will be material to its consolidated financial statements.

3. Fair Value Measurements

The carrying amounts of certain of the Company's financial instruments, including cash equivalents, accounts receivable, and accounts payable 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. The determination of the fair value of the warrants is discussed in Note 8. Increases or decreases in the fair value of the underlying convertible preferred stock or common stock are accounted for as other expense, net in the accompanying condensed consolidated financial statements.

ADURO BIOTECH, INC.
Notes to Unaudited Condensed Consolidated Financial Statements

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):

March 31, 2015				
	Level 1	Level 2	Level 3	Total
Financial Assets:				
Money market funds	\$ 121,006	\$ —	\$ —	\$ 121,006
Financial Liabilities:				
Convertible preferred stock warrant liability	\$ —	\$ —	\$ 1,096	\$ 1,096
Common stock warrant liability	—	—	9,235	9,235
Total	\$ —	\$ —	\$ 10,331	\$ 10,331

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
Balance at December 31, 2014	\$ 100	\$ 889
Net increase in fair value upon revaluation	996	8,346
Balance at March 31, 2015	\$ 1,096	\$ 9,235

4. Balance Sheet Components

Property and Equipment, Net

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

	March 31, 2015	December 31, 2014
Lab equipment	\$ 1,516	\$ 1,165
Computer and office equipment	560	520
Furniture and fixtures	98	87
Leasehold improvements	318	304
Total property and equipment	2,492	2,076
Less: accumulated depreciation and amortization	(1,116)	(1,023)
Property and equipment, net	\$ 1,376	\$ 1,053

Depreciation and amortization expense for the three months ended March 31, 2015 and 2014 was \$93,000 and \$43,000, respectively.

Accrued Expenses and Other Liabilities

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

	March 31, 2015	December 31, 2014
Compensation and related benefits	\$ 2,675	\$ 1,276
Professional and consulting services	2,664	961
Other	55	171
Total accrued expenses and other liabilities	<u>\$ 5,394</u>	<u>\$ 2,408</u>

5. Collaboration Agreements

Novartis Agreement

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

Under the Novartis Agreement, the Company received an upfront payment of \$200 million from Novartis in April 2015. 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 or 12 years after first commercial sale of the product in such country.

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

Janssen ADU-741 and GVAX Prostate Agreements

In May 2014, the Company entered into a Research and License Agreement, or Janssen ADU-741 Agreement, and a GVAX Prostate License Agreement, or Janssen GVAX Prostate Agreement, with Janssen Biotech, Inc., or Janssen, a wholly-owned subsidiary of Johnson & Johnson Development Corporation, to collaborate on the development of a drug for the treatment of prostate cancer. Under the terms of the Janssen ADU-741 Agreement, the Company granted Janssen an exclusive, worldwide license to research, develop, manufacture, use, sell and otherwise exploit products containing ADU-741 for any and all uses. The Company is responsible for certain research and development activities from the effective date of the agreement until approval of an investigational new drug, or IND. Since the inception of the Janssen ADU-741 Agreement, the Company received an upfront payment of \$12.0 million and non-substantive and substantive milestone payments of \$6.5 million upon completion of certain development activities. 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

ADURO BIOTECH, INC.
Notes to Unaudited Condensed Consolidated Financial Statements

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 mid-single digits to low teens based on aggregate annual net sales and based on the country of sale.

Under the Janssen GVAX Prostate Agreement, the Company granted Janssen an exclusive worldwide license to research, develop, manufacture, use, sell and otherwise exploit products containing GVAX Prostate for any and all uses. The Company received an upfront payment of \$500,000 in May 2014 and 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 for the Janssen ADU-741 Agreement and Janssen GVAX Prostate Agreement as one arrangement and has identified the deliverables within the arrangement as a license to the technology and research and development activities through IND 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, the Company entered into a Research and License Agreement with Janssen, or Janssen ADU-214 Agreement, to develop a drug for the treatment of lung cancer. Under the terms of the Janssen ADU-214 Agreement, the Company granted Janssen an exclusive, worldwide license to research, develop, manufacture, use, sell and otherwise exploit products containing ADU-214 for any and all uses. 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 \$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 any net sales of licensed products by Janssen, its affiliates and sublicensees at a rate ranging from high-single digits to low teens based on the aggregate annual net sales of licensed products worldwide and based on the country of sale.

For the three months ended March 31, 2015, the Company recognized revenue from its Janssen ADU-741 Agreement and Janssen ADU-214 Agreement totaling \$9.2 million related to amortization of the upfront fees and development-related substantive and non-substantive milestones. The remaining balance of the payments received of \$26.9 million is included in deferred revenue at March 31, 2015.

6. Commitments and Contingencies

Leases

The Company leases its office and research and development facility in Berkeley, California, under a non-cancelable operating lease. In February 2015, the Company amended its office lease agreement to increase the total square footage to approximately 25,000 square feet and extended the term of the lease to expire on December 31, 2018. The lease also contains an option to extend the lease for an additional two years. Rent expense was \$110,000 and \$72,000 during the three months ended March 31, 2015 and 2014, respectively.

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, officers and key employees that may require the Company to indemnify such individuals against liabilities that may arise by reason of their status or service as directors, officers or key employees 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.

7. Convertible Preferred Stock

Novartis Stock Purchase

Concurrent with the March 2015 entry into the Novartis Agreement (See Note 5), 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 Convertible Preferred Stock (or 1,699,940 shares of common stock on an as-converted basis) for \$25.0 million. Under the stock purchase agreement, NIBR purchased an additional \$25.0 million of the Company's common stock concurrent with the completion of the Company's April 2015 IPO at the initial price per share offered to the public.

8. Warrants

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 March 31, 2015 and December 31, 2014 (in thousands, except share data):

	Shares at		Fair Value at	
	March 31, 2015	December 31, 2014	March 31, 2015	December 31, 2014
Classified as warrant liability:				
Series A-1	24,235	24,235	\$ 289	\$ 25
Series B	83,771	83,771	807	75
Total convertible preferred stock warrants	108,006	108,006	1,096	100
Common	615,658	615,658	9,235	889
Total classified as warrant liability	723,664	723,664	\$ 10,331	\$ 989

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.

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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.

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 \$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 by April 15, 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 condensed consolidated balance sheet, as the warrants are subject to performance conditions which may result in the issuance of a variable number of shares.

The change in fair value of warrants recorded as liabilities has been included in Other Expense, net in the accompanying condensed consolidated financial statements.

The key assumptions used in the Black-Scholes option-pricing model for the valuation of the convertible preferred stock warrants were as follows:

	Three Months Ended March 31,	
	2015	2014
Expected term (in years)	1.04 - 6.04	2.04 - 7.04
Fair value of underlying shares	\$10.80	\$0.67 - \$1.56
Volatility	80.9% - 108.9%	63.1% - 80.8%
Risk-free interest rate	0.26% - 1.54%	0.44% - 2.30%
Dividend yield	—%	—%

The key assumptions used in the Black-Scholes option-pricing model for the valuation of the common stock warrants were as follows:

	Three Months Ended March 31,	
	2015	2014
Expected term (in years)	6.04 - 6.58	7.04 - 9.79
Fair value of underlying shares	\$15.00	\$1.07
Volatility	82.6%	77.3% - 80.4%
Risk-free interest rate	0.36% - 1.63%	2.30% - 2.73%
Dividend yield	—%	—%

9. 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.

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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, 2014	3,154,755	5,970,382	\$ 0.80	
Authorized	360,000	—		
Granted	(3,195,247)	3,195,247	\$ 1.82	
Exercised	—	(155,548)	\$ 0.52	
Canceled	55,070	(55,070)	\$ 1.35	
Balance – March 31, 2015	<u>374,578</u>	<u>8,955,011</u>	\$ 1.17	\$ 124,114
Options exercisable – March 31, 2015		<u>3,751,658</u>	\$ 0.74	\$ 53,729
Options vested and expected to vest – March 31, 2015		<u>8,506,800</u>	\$ 1.15	\$ 118,034

Stock-based Compensation Expense

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

	Three Months Ended March 31,	
	2015	2014
Research and development	\$ 145	\$ 44
General and administrative	435	65
Total stock-based compensation expense	<u>\$ 580</u>	<u>\$ 109</u>

In determining the fair value of the stock-based awards, the Company uses the Black-Scholes option-pricing model. The fair value of stock option awards granted to employees during the three months ended March 31, 2015 was estimated at the date of grant using the following assumptions:

	Three Months Ended March 31, 2015
Expected term (in years)	5.6 - 6.1
Volatility	79.2% - 82.8%
Risk-free interest rate	1.54% - 1.78%
Dividend yield	—%

No options were granted to employees during the three months ended March 31, 2014.

10. Income Taxes

The Company did not record a provision or benefit for income taxes during the three months ended March 31, 2015 and 2014. The Company continues to maintain a valuation allowance for its U.S. federal and state deferred tax assets.

The Company accounts for uncertain tax positions in accordance with FASB's Accounting Standards Codification, or ASC, 740, *Accounting for Income Taxes*. As of March 31, 2015 and 2014, the total amount of unrecognized tax benefits was \$0.5 million and \$0.3 million, respectively. As of March 31, 2015 and 2014, no amount of the unrecognized tax benefits, if recognized, would reduce the Company's annual effective tax rate because the benefits are in the form of deferred tax assets for which a full valuation allowance has been recorded.

The Company's policy is to recognize interest and penalties related to unrecognized tax benefits in income tax expense. As of March 31, 2015 and 2014, the Company accrued no interest and penalties in the statement of financial position. Total interest and penalties included in the statements of operations for the quarters ended March 31, 2015 and 2014 are each zero. The Company does not expect the amount of existing unrecognized tax benefits to change significantly within the next 12 months.

ADURO BIOTECH, INC.
Notes to Unaudited Condensed Consolidated Financial Statements

The Company is subject to taxation for federal and the state of California purposes only. The Company's federal and California tax returns are open by statute for tax years 2011 and 2010 forward, respectively, and could be subject to examination by the tax authorities.

11. Net Loss per Common Share

Since the Company was in a loss position for all periods presented, basic net loss per common share is the same as diluted net loss per common share for all periods presented as the inclusion of all potential common shares outstanding would have been anti-dilutive. Potentially dilutive securities that were not included in the diluted per common share calculations because they would be anti-dilutive were as follows:

	March 31,	
	2015	2014
Convertible preferred stock	71,976,036	22,041,002
Options to purchase common stock	8,955,011	4,029,202
Convertible preferred stock warrants	108,006	108,006
Common stock warrants	1,154,270	1,154,270
Convertible notes	—	9,951,981
Total	<u>82,193,323</u>	<u>37,284,461</u>

12. Subsequent Events

Initial Public Offering

On April 14, 2015, the Company's registration statements on Form S-1 (File No. 333-202667) relating to its IPO of common stock became effective. The IPO closed on April 20, 2015 at which time the Company issued 8,050,000 shares of its common stock at a price of \$17.00 per share, which included 1,050,000 shares sold pursuant to the exercise of the underwriters' option to purchase additional shares. The Company received \$127.3 million, net of underwriting discounts and commission, but before offering expenses. The Company also sold to NIBR in a concurrent private placement 1,470,588 shares of common stock at a price of \$17.00 per share for proceeds of \$25.0 million. In addition, upon the Company's IPO, all outstanding shares of convertible preferred stock converted by their terms into approximately 51,823,000 shares of common stock.

Reverse Stock Split

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

2015 Equity Incentive Plan

In March 2015, the Company's board of directors adopted and in April 2015 the Company's stockholders approved the 2015 Equity Incentive Plan, or the 2015 Plan, which became effective upon the IPO and provides for the granting of incentive stock options, nonstatutory stock options, and other forms of stock awards to its employees, directors, and consultants.

ADURO BIOTECH, INC.
Notes to Unaudited Condensed Consolidated Financial Statements

2015 Employee Stock Purchase Plan

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

Item 2. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our unaudited condensed consolidated financial statements and related notes included in Part I, Item 1 of this report and with our audited financial statements and related notes thereto for the year ended December 31, 2014, included in our prospectus dated April 14, 2015, filed with the Securities and Exchange Commission pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, or the Prospectus. This discussion and other parts of this report contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section of this report titled “Risk factors.”

Forward-Looking Statements

This discussion contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements are identified by words such as “believe,” “will,” “may,” “estimate,” “continue,” “anticipate,” “intend,” “should,” “plan,” “expect,” “predict,” “could,” “potentially” or the negative of these terms or similar expressions. You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other “forward-looking” information. These statements relate to our future plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in this report in Part II, Item 1A — “Risk Factors,” and elsewhere in this report. Forward-looking statements are based on our management’s beliefs and assumptions and on information currently available to our management. These statements, like all statements in this report, speak only as of their date, and we undertake no obligation to update or revise these statements in light of future developments. We caution investors that our business and financial performance are subject to substantial risks and uncertainties.

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. 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, and 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. 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, in March 2015 for CDN product candidates in oncology.

Recent Developments

In April 2015, we completed our initial public offering, or IPO, of our common stock pursuant to which we issued 8,050,000 shares of our common stock at a price of \$17.00 per share, which included 1,050,000 shares sold pursuant to the exercise of the underwriters’ option to purchase additional shares. We received \$127.3 million, net of underwriting discounts and commission, but before offering expenses. We concurrently closed a private placement of 1,470,588 shares of common stock at a price of \$17.00 per share, for proceeds of an additional \$25.0 million.

Also in April 2015, in connection with our collaboration and license agreement, we received an upfront payment of \$200 million from Novartis.

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. In addition, we established a collaboration and license agreement with Novartis in March 2015. 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 collaboration 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 collaboration with Novartis, 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.

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 and manufacturing 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 collaboration with Novartis and 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.

Other Expense, Net

Other 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 convertible promissory note warrants, and interest income earned on our cash and cash equivalents.

Results of Operations

Comparison of the Three Months Ended March 31, 2015 and 2014

	Three Months Ended March 31,		Change
	2015	2014	\$
(in thousands)			
Revenue:			
Collaboration and license revenue	\$ 9,238	\$ —	\$ 9,238
Grant revenue	336	25	311
Total revenue	9,574	25	9,549
Operating expenses:			
Research and development	10,646	4,729	5,917
General and administrative	6,210	1,384	4,826
Total operating expenses	16,856	6,113	10,743
Loss from operations	(7,282)	(6,088)	(1,194)
Interest expense	—	(1,354)	1,354
Other expense, net	(9,334)	(342)	(8,992)
Net loss	\$ (16,616)	\$ (7,784)	\$ (8,832)

Revenue

Collaboration and license revenue was \$9.2 million for the three months ended March 31, 2015, due to recognition of a portion of the upfront fees and non-substantive development-related milestones achieved under the May 2014 and October 2014 Janssen agreements.

Grant revenue was \$0.3 million for the three months ended March 31, 2015, an increase of \$0.3 million compared to the three months ended March 31, 2014, primarily due to an increase in grant-related research and development.

Research and Development Expenses

The following table summarizes our research and development expenses incurred during the three months ended March 31, 2015 and 2014:

	Three Months Ended March 31,		Change
	2015	2014	\$
(in thousands)			
Compensation and related personnel costs	\$ 3,896	\$ 1,106	\$ 2,790
Clinical development	2,985	1,584	1,401
Other research and development costs	1,911	598	1,313
Contract manufacturing	1,596	1,126	470
Facility costs	92	58	34
Licensing fees	166	257	(91)
Total research and development	\$ 10,646	\$ 4,729	\$ 5,917

Research and development expenses were \$10.6 million for the three months ended March 31, 2015, an increase of \$5.9 million, compared to the three months ended March 31, 2014. The increase was primarily attributed to \$2.8 million of incremental compensation and related personnel expenses associated with additional research and development headcount; a \$1.4 million increase in clinical development expenses mainly associated with ongoing trials for our lead indication in pancreatic cancer; a \$1.3 million increase in other research and development costs primarily for our CDN program; and a \$0.5 million increase in contract manufacturing costs of our clinical product candidates.

General and Administrative Expenses

The following table summarizes our general and administrative expenses incurred during the three months ended March 31, 2015 and 2014:

	Three Months Ended March 31,		Change
	2015	2014	\$
	(in thousands)		
Outside professional services	\$ 2,677	\$ 445	\$ 2,232
Compensation and related personnel costs.	3,063	709	2,354
Other general and administrative	243	103	140
Facility costs	227	127	100
Total general and administrative	<u>\$ 6,210</u>	<u>\$ 1,384</u>	<u>\$ 4,826</u>

General and administrative expenses were \$6.2 million for the three months ended March 31, 2015, an increase of \$4.8 million, compared to the three months ended March 31, 2014. The increase was primarily due to \$2.2 million of incremental legal, consulting and other professional services fees related to our collaboration agreement, general corporate matters and accounting support, as well as a \$2.4 million increase in compensation and related personnel expenses primarily related to additional general and administrative headcount.

Interest Expense

We did not have any interest expense during the three months ended March 31, 2015. Interest expense for the three months ended March 31, 2014 was due to the amortization of debt discount associated with convertible promissory note warrants, issuance of the equity component of a convertible promissory note and beneficial conversion features attributable to certain promissory notes, as well as stated interest costs associated with our borrowings.

Other Expense, Net

Other expense, net increased by \$9.0 million for the three months ended March 31, 2015, compared to the three months ended March 31, 2014. The increase was primarily due to the remeasurement of the fair value of liability classified preferred and common stock warrants.

Liquidity and Capital Resources

To date, 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 March 31, 2015, we had cash and cash equivalents of \$133.0 million.

In April 2015, we completed our IPO pursuant to which we issued 8,050,000 shares of our common stock at a price of \$17.00 per share, which included 1,050,000 shares sold pursuant to the exercise of the underwriters' option to purchase additional shares. We received \$127.3 million, net of underwriting discounts and commission, but before offering expenses. We concurrently closed a private placement of 1,470,588 shares of common stock at a price of \$17.00 per share, for proceeds of an additional \$25.0 million.

In March 2015, the Company established a worldwide collaboration with Novartis for the development and commercialization of products containing an agonist of the molecular target known as STING in the field of oncology, including immuno-oncology and cancer vaccines. Under the Novartis Agreement, we received an upfront payment of \$200 million in April 2015. 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. Concurrent with the entry into the Novartis Agreement, we and Novartis Institutes of BioMedical Research, Inc., or NIBR, entered into a stock purchase agreement to purchase 2,361,029 shares of our Series E Preferred Stock (which converted into 1,699,940 shares of common stock at the completion of the IPO), for \$25.0 million.

Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, third-party clinical, manufacturing, and other research and development services, laboratory and related supplies, and legal and other professional services. Cash used to fund operating expenses is impacted by the timing of when we pay expenses, as reflected in the change in our outstanding accounts payable and accrued expenses. We expect to incur substantial expenditures in the foreseeable future for the development and potential commercialization of our product candidates. Specifically, 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.

Cash Flows

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

	Three Months Ended March 31,	
	2015	2014
	(in thousands)	
Net cash provided by (used in):		
Operating activities	\$ (8,471)	\$ (4,974)
Investing activities	(314)	(126)
Financing activities	22,313	308
Net change in cash and cash equivalents	<u>\$ 13,528</u>	<u>\$ (4,792)</u>

Operating Activities

Net cash used in operating activities was \$8.5 million for the three months ended March 31, 2015, compared to net cash used in operating activities of \$5.0 million for the three months ended March 31, 2014. The increase in net cash used was primarily due to a \$8.8 million increase in net loss primarily due to increased research and development and general and administrative expenses, partially offset by the \$3.0 million milestone payment received from the research and license agreement with Janssen.

Investing Activities

Net cash used in investing activities was \$0.3 million for the three months ended March 31, 2015, compared to \$0.1 million for the three months ended March 31, 2014. 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 \$22.3 million for the three months ended March 31, 2015, compared to \$0.3 million for the three months ended March 31, 2014. The increase was primarily related to \$25.0 million in gross proceeds from the issuance of Series E convertible preferred stock, partially offset by \$2.8 million of stock issuance costs and payments related to preparing to become a public company.

Contractual Obligations and Other Commitments

During the three months ended March 31, 2015, there were no material changes to our contractual obligations and commitments described under the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" in the Prospectus.

Off-Balance Sheet Arrangements

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

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Management believes there have been no material changes to our quantitative and qualitative disclosures about market risks during the three months ended March 31, 2015, compared to those discussed in our prospectus dated April 14, 2015 filed with the SEC on April 15, 2015 pursuant to Rule 424(b) under the Securities Act.

Item 4. Controls and Procedures

Evaluation of disclosure controls and procedures.

Our management, with the participation of our President and Chief Executive Officer and our Chief Operating Officer, our principal financial officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) prior to the filing of this quarterly report. Based on that evaluation, our President and Chief Executive Officer and our Chief Operating Officer have concluded that, as of the end of the period covered by this quarterly report, our disclosure controls and procedures were, in design and operation, effective.

Changes in internal control over financial reporting.

There were no changes in our internal control over financial reporting during the quarter ended March 31, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent limitation on the effectiveness of internal control.

The effectiveness of any system of internal control over financial reporting, including ours, is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating, and evaluating the controls and procedures, and the inability to eliminate misconduct completely. Accordingly, any system of internal control over financial reporting, including ours, no matter how well designed and operated, can only provide reasonable, not absolute assurances. In addition, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. We intend to continue to monitor and upgrade our internal controls as necessary or appropriate for our business, but cannot assure you that such improvements will be sufficient to provide us with effective internal control over financial reporting.

PART II. – OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may become involved in legal proceedings relating to claims arising from the ordinary course of business. Our management believes that there are currently no claims or actions pending against us, the ultimate disposition of which could have a material adverse effect on our results of operations, financial condition or cash flows.

Item 1A. Risk Factors

You should carefully consider the following risk factors, in addition to the other information contained in this quarterly report on Form 10-Q, including the section of this report titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our financial statements and related notes. If any of the events described in the following risk factors and the risks described elsewhere in this report occurs, our business, operating results and financial condition could be seriously harmed. This quarterly report on Form 10-Q also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this report. The risks relating to our business set forth in our prospectus dated April 14, 2015 that forms a part of the Company’s Registration Statement on Form S-1, filed with the SEC, are set forth below and are unchanged substantively as of March 31, 2015, except for those risks designated by an asterisk ().*

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, and for the three month period ended March 31, 2015, we reported a net loss of \$16.1 million, \$17.0 million and \$16.6 million, respectively. At March 31, 2015, we had an accumulated deficit of \$78.3 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 March 31, 2015, our cash and cash equivalents were \$133.0 million. We expect to continue to spend substantial amounts to continue the clinical development of our product candidates. If we are able to gain regulatory approval for any of our product candidates, we will require significant additional amounts of cash in order to launch and commercialize any such product candidates. In addition, other unanticipated costs may arise. Because the design and outcome of our planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates.

Our future capital requirements depend on many factors, including:

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

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

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

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

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

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions 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 their actual performance. If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive cash compensation in connection with such services. We also give grants to investigators' institutions from time to time. If certain of these relationships exceed specific financial thresholds, they must be reported to the FDA. If these relationships and any related compensation paid results in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected interpretation of the study, the integrity of the data generated at the

applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay in approval, or rejection, of our marketing applications by the FDA. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

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

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

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

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

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

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;
- FDA could require a Risk and Evaluation Medication Strategy or REMS which could require the creation and management of a medication guide, communication plan or other elements to ensure safe use;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

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

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

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

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to study sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

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

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

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

Human clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Because our product candidates are based on new technologies 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. FDA can also rescind the Breakthrough Therapy designation in the event that the program no longer meets the criteria for eligibility. This could occur if a new therapy is approved and the existing data no longer show substantial improvement over the new therapy. We have obtained Breakthrough Therapy designation for our CRS-207 and GVAX Pancreas combination. Despite the potential advantages of Breakthrough Therapy designation, we may fail to obtain regulatory approval of CRS-207 and GVAX Pancreas, and if we do obtain approval, we may fail to do so on an accelerated basis. In addition, while we intend to seek Breakthrough Therapy designation for other product candidates, we may never receive such designation.

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

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

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

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

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

- The manufacturing of drug products is susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment or vendor or operator error. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If foreign microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our products are made, these manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.
- The manufacturing facilities in which our product candidates are made could be adversely affected by equipment failures, labor shortages, natural disasters, power failures and numerous other factors.
- We and our contract manufacturers must comply with the FDA's 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 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, market access, and manufacturing organizations and well-established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products. We believe the key competitive factors that will affect the development and commercial success of our product candidates are efficacy, safety, tolerability, reliability, convenience of use, price and reimbursement.

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

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

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

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

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

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

At 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.

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

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

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

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

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

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

- decreased demand for our product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;

- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate; and
- a decline in our share price.

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

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

Risks Related to Our Reliance on Third Parties

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

Because we have limited resources, we may seek to enter into collaboration agreements with other pharmaceutical or biotechnology companies. Any failure by our partners to perform their obligations or any decision by our partners to terminate these agreements could negatively impact our ability to successfully develop, obtain regulatory approvals for and commercialize our product candidates. In the event we grant exclusive rights to such partners, we would be precluded from potential commercialization of our product candidates within the territories in which we have a partner. For example, we have entered into exclusive research and license agreements with Janssen for the development and commercialization of ADU-741, GVAX for prostate cancer and ADU-214. Under these agreements, we have granted Janssen exclusive rights to develop and commercialize LADD product candidates for prostate and lung cancers. In addition, we have granted Janssen exclusive rights to develop and commercialize LADD product candidates with certain antigens and antigen combinations implicated in lung and other cancers for all fields of use. We have also entered into a collaboration and license agreement with Novartis for the development and commercialization of 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, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

Risks Related to Government Regulation

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

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

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

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;

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

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

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

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

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

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

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

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or the conditions of approval, or contain requirements for potentially costly post-market testing and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a risk evaluation and mitigation strategy, or REMS, as a condition of approval of our product candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. Later discovery of previously

unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

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

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

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

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

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

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

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

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

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

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific, clinical and cost-effectiveness data and support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be

obtained. We intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the EU, the pricing of biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate.

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

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

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

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

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

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

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

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, which may constrain the business or

financial arrangements and relationships through which we sell, market and distribute any drugs for which we obtain marketing approval. In addition, we may be subject to transparency laws and patient privacy regulation by the U.S. federal and state governments and by governments in foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other third-party payors that are false or fraudulent or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating these statutes without actual knowledge of the statutes or specific intent to violate them;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization;
- the federal Physician Payment Sunshine Act, created under the Affordable Care Act, and its implementing regulations, which require manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services, or HHS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members and payments or other "transfers of value" made to such physician owners;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our business activities could be subject to challenge under one or more of such laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time-and resource-consuming and can divert management's attention from the business. Additionally, as a result of these investigations, healthcare providers and entities

may have to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

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

Risks Related to Our Intellectual Property

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

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

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

With respect to patent rights, we do not know whether any of the pending patent applications for any of our compounds or biologic products will result in the issuance of patents that effectively protect our technology or products, or if any of our issued patents or if any of our or our licensors' issued patents will effectively prevent others from commercializing competitive technologies and products. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or in some cases not at all, until they are issued as a patent. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions.

Our pending applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, issued patents that we own or have licensed from third parties may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in the loss of patent protection, the narrowing of claims in such patents or the invalidity or unenforceability of such patents, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection for our technology and products. Protecting against the unauthorized use of our or our licensor's patented technology, trademarks and other intellectual property rights is expensive, difficult and may in some cases not be possible. In some cases, it may be difficult or impossible to detect third-party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult. For example, two of our patents, U.S. Patent Nos. 7,842,289 and 7,935,804, 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 *ex 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 *ex 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, ADU-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-741 and/or GVAX Prostate that may also be relevant to another product candidates that we may be developing and commercializing, we could be prevented from seeking extension of the same patent for our product. If we do not have the ability to control the strategy for patent term extension of any of our licensed patents, our business may be materially harmed.

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

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

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

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

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

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

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

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

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

The BPCIA established legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an existing brand product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

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

Additionally, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic

competition sooner than anticipated. The extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

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

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

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

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

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

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

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

Competitors may infringe our patents or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. Also, third parties may initiate legal proceedings against us or our licensors to challenge the validity or scope of intellectual property rights we own or control. These proceedings can be expensive and time consuming. Many of our current and potential competitors have the ability to dedicate substantially greater resources to defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. Litigation could

result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, in an infringement proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments in any such proceedings. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock.

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

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

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

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

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

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

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

us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. Our agreements with employees also provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our employees, consultants or contractors use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions.

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

Risks Related to our Financial Results

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

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

In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award as 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 our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly.

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

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

- future accounting pronouncements or changes in our accounting policies; and
- the changing and volatile global economic environment.

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

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.

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 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 Ownership of Our Common Stock

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

The trading price of our common stock has been, and is likely to 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 quarterly report on Form 10-Q, these factors include:

- the commencement, enrollment or results of the planned clinical trials of our product candidates or any future clinical trials we may conduct, or changes in the development status of our product candidates;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority’s review of such filings, including without limitation the FDA’s issuance of a “refusal to file” letter or a request for additional information;
- adverse results or delays in clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning our manufacturers;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- our inability to establish collaborations if needed;
- our failure to commercialize our product candidates;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- the size and growth of our initial cancer target markets;
- our ability to successfully treat additional types of cancers or at different stages;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or immuno-oncology in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;

- trading volume of our common stock;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

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

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

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

At March 31, 2015, we had \$133.0 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 March 31, 2015, we cannot assure you that further deterioration of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or our ability to meet our financing objectives. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

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

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

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

Our executive officers, directors, and 5% stockholders beneficially owned approximately 74.5% of our voting stock at March 31, 2015. 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. 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. Therefore, these stockholders have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

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 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, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) (a) December 31, 2020, (b) the last day of the fiscal year in which we have total annual gross revenue of at least \$1.0 billion or (c) the last day of the fiscal year 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 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. 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 lapse, the trading price of our common stock could decline. At May 15, 2015, we had outstanding a total of 61,869,356 shares of common stock. Of these shares, approximately 53.4 million shares of our common stock are currently restricted as a result of securities laws or lock-up agreements but will be able to be sold upon expiration of the lockup period in October 2015.

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.

The holders of 49,401,494 shares of our common stock at May 15, 2015 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. 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.

Pursuant to our 2015 Plan, 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.

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

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

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

- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential 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.

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

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

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

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

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Sales of Unregistered Securities

- (1) From January 1, 2015 to March 31, 2015, we granted stock options to purchase an aggregate of 3,195,247 shares of common stock at exercise prices ranging from \$1.45 to \$7.45 per share to a total of 57 employees and consultants under our 2009 Equity Incentive Plan. From January 1, 2015 to March 31, 2015, options to purchase an aggregate of 155,548 shares of common stock were exercised.
- (2) From January 1, 2015 to March 31, 2015, we issued 6,668 shares of Series A-1 convertible preferred stock (convertible into 4,800 shares of common stock) pursuant to the cash exercise of warrants to purchase shares of our Series A-1 convertible preferred stock at an exercise price of \$1.36 per share. We received cash proceeds of \$9,068 from the exercise of such warrants. These warrants were issued to two accredited investors.
- (3) In March 2015, we issued an aggregate of 2,361,029 shares of our Series E convertible preferred stock (convertible into 1,699,940 shares of common stock) to one accredited investor at a price per share of \$10.59.

The offers, sales and issuances of the securities described in paragraph (1) above were deemed to be exempt from registration under the Securities Act in reliance on Rule 701 thereunder as offers and sale of securities pursuant to certain compensatory benefit plans and contracts relating to compensation in compliance with Rule 701.

The offer, sale, and issuance of the securities described in paragraphs (2) and (3) above was deemed to be exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder as a transaction by an issuer not involving a public offering. The recipients of securities in these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in this transaction. The recipients of securities in these transactions were accredited investors and had adequate access, through employment, business or other relationships, to information about us.

Use of Proceeds from our Public Offering of Common Stock

On April 14, 2015, our registration statements on Form S-1 (File No. 333-202667) relating to our IPO of common stock became effective. The IPO closed on April 20, 2015 at which time we issued 8,050,000 shares of our common stock at an initial offering price of \$17.00 per share. We received net proceeds from the IPO of approximately \$124.3 million, after deducting underwriting discounts of approximately \$9.6 million and expenses of approximately \$3.0 million. None of the expenses associated with the IPO were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to their associates, or to our affiliates. Merrill, Lynch, Pierce, Fenner & Smith Incorporated and Leerink Partners LLC acted as joint book-running managers and William Blair & Company, L.L.C. and Canaccord Genuity Inc. acted as co-managers for the offering.

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

There has been no material change in the planned use of proceeds from our IPO from that described in the prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on April 15, 2015.

Repurchases of Shares or of Company Equity Securities

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits

Number	Description
3.1	Amended and Restated Certificate of Incorporation of Aduro Biotech, Inc. (1)
3.2	Amended and Restated Bylaws of Aduro Biotech, Inc. (2)
4.1	Form of common stock certificate (3)
4.2	Amended and Restated Investor Rights Agreement, by and among Aduro Biotech, Inc. and the stockholders named therein, dated December 19, 2014. (4)
10.1+	2015 Equity Incentive Plan. (5)
10.2+	Forms of Stock Option Agreement and Notice of Grant of Stock Option under the 2015 Equity Incentive Plan. (6)
10.3+	2015 Employee Stock Purchase Plan. (7)
10.4	Form of Indemnification Agreement made by and between Aduro Biotech, Inc. and each of its directors and executive officers. (8)
10.30	Fourth Addendum to Office Lease, dated February 20, 2015, by and between the Company and Bancroft Way, LLC. (9)
10.31†	Amendment No. 1 to Exclusive License between Aduro Biotech, Inc. and the Regents of the University of California, dated March 6, 2015. (10)
10.32+	Aduro Biotech, Inc. Severance Plan and Summary Plan Description. (11)
10.33+	Aduro Biotech, Inc. Non-Employee Director Compensation Policy. (12)
10.34†	Collaboration and License Agreement between Aduro Biotech, Inc. and Novartis Pharmaceuticals Corporation, dated March 12, 2015; and the related letter agreement dated March 19, 2015. (13)
10.35	Series E Preferred Stock Purchase Agreement between Aduro Biotech, Inc. and Novartis Institutes for BioMedical Research, Inc., dated March 12, 2015. (14)
10.36	Common Stock Purchase Agreement between Aduro Biotech, Inc. and Novartis Institutes for BioMedical Research, Inc., dated March 12, 2015. (15)
31.1	Certifications of Principal Executive Officer pursuant to Rule 13a-14(a).
31.2	Certifications of Principal Financial Officer pursuant to Rule 13a-14(a).
32.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

- (1) Incorporated herein by reference to the same numbered exhibit of our current report on Form 8-K (File No. 001-37345) filed with the SEC on April 20, 2015.
- (2) Incorporated herein by reference to Exhibit 3.5 of our registration statement on Form S-1, as amended (File No. 333-202667), filed with the SEC on April 6, 2015.
- (3) Incorporated herein by reference to the same numbered exhibit of our registration statement on Form S-1, as amended (File No. 333-202667), as filed with the SEC on April 6, 2015.

- (4) Incorporated herein by reference to the same numbered exhibit of our registration statement on Form S-1 (File No. 333-202667), as filed with the SEC on March 11, 2015.
- (5) Incorporated herein by reference to Exhibit 10.7 of our registration statement on Form S-1, as amended (File No. 333-202667), filed with the SEC on April 6, 2015.
- (6) Incorporated herein by reference to Exhibit 10.8 of our registration statement on Form S-1, as amended (File No. 333-202667), filed with the SEC on April 6, 2015.
- (7) Incorporated herein by reference to Exhibit 10.9 of our registration statement on Form S-1, as amended (File No. 333-202667), filed with the SEC on April 6, 2015.
- (8) Incorporated herein by reference to Exhibit 10.10 of our registration statement on Form S-1, as amended (File No. 333-202667), filed with the SEC on April 6, 2015.
- (9) Incorporated herein by reference to Exhibit 10.31 of our registration statement on Form S-1 (File No. 333-202667), filed with the SEC on March 11, 2015.
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- + Indicates management contract or compensatory plan.
- † Certain portions of this exhibit are subject to a confidential treatment order.
- * The Certifications attached as Exhibits 32.1 and 32.2 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Aduro Biotech, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-Q, irrespective of any general incorporation language contained in such filing.

SIGNATURES

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

Aduro Biotech, Inc.

Date: May 28, 2015

By: /s/ Stephen T. Isaacs

Stephen T. Isaacs

Chairman, President and Chief Executive Officer

(Principal Executive Officer)

Aduro Biotech, Inc.

Date: May 28, 2015

By: /s/ Gregory W. Schafer

Gregory W. Schafer

Chief Operating Officer

(Principal Financial Officer)

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- * The Certifications attached as Exhibits 32.1 and 32.2 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Aduro Biotech, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-Q, irrespective of any general incorporation language contained in such filing.

CERTIFICATIONS

I, Stephen T. Isaacs, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Aduro Biotech, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - c) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 28, 2015

/s/ Stephen T. Isaacs

Stephen T. Isaacs

Chairman, President and Chief Executive Officer

CERTIFICATIONS

I, Gregory W. Schafer, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Aduro Biotech, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - c) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 28, 2015

/s/ Gregory W. Schafer

Gregory W. Schafer

Chief Operating Officer

ADURO BIOTECH, INC.
CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Aduro Biotech, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2015, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Stephen T. Isaacs, Chairman, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Stephen T. Isaacs

Stephen T. Isaacs

Chairman, President and Chief Executive Officer

May 28, 2015

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

ADURO BIOTECH, INC.
CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Aduro Biotech, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2015, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Gregory W. Schafer, Chief Operating Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Gregory W. Schafer

Gregory W. Schafer

Chief Operating Officer

May 28, 2015

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