

Edgar Filing: Immune Design Corp. - Form 10-Q

Immune Design Corp.  
Form 10-Q  
August 12, 2015

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 June 30, 2015  
or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_  
Commission File Number: 001-36561

Immune Design Corp.  
(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)  
1616 Eastlake Ave. E., Suite 310  
Seattle, Washington 98102  
(206) 682-0645

26-2007174  
(IRS Employer  
Identification No.)

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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. (Check one):

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input type="checkbox"/>

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

As of August 3, 2015, the number of outstanding shares of the registrant's common stock was 20,129,580.



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In this report, unless otherwise stated or as the context otherwise requires, references to “Immune Design,” “the Company,” “we,” “us,” “our” and similar references refer to Immune Design Corp. The Immune Design logo, “IMDZVex,” “ZVex” and “GLAAS” are our unregistered trademarks. This report also contains registered marks, trademarks and trade names of other companies. All other trademarks, registered marks and trade names appearing in this report are the property of their respective holders.

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NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements. In some cases you can identify these statements by forward-looking words such as “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “could,” “project,” “plan,” “expect,” or similar expressions, or the negative or plural of these words or expressions. These forward-looking statements include statements concerning the following:

- our estimates regarding our expenses, revenues, anticipated capital requirements and our needs for additional financing;
- the implementation of our business model and strategic plans for our business and technology;
- the timing of the commencement, progress and receipt of data from any of our preclinical and clinical trials;
- the expected results of any clinical trial and the impact on the likelihood or timing of any regulatory approval;
- the scope of protection we establish and maintain for intellectual property rights covering our technology;
- the timing or likelihood of regulatory filings and approvals;
- the outcome of any current or future litigation;
- developments relating to our competitors and our industry; and
- our expectations regarding licensing, acquisitions and strategic operations.

These statements are only current predictions and are subject to known and unknown risks, uncertainties, and other factors that may cause our or our industry’s actual results, levels of activity, performance or achievements to be materially different from those anticipated by the forward-looking statements. We discuss many of these risks in this report in greater detail under the heading “Risk Factors” and elsewhere in this report. You should not rely upon forward-looking statements as predictions of future events.

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

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## PART I. FINANCIAL INFORMATION

## Item 1. Financial Statements

## IMMUNE DESIGN CORP.

## BALANCE SHEETS

(in thousands, except share and per share amounts)

	June 30, 2015 (unaudited)	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	\$ 128,998	\$ 75,354
Accounts receivable	879	1,970
Inventory	434	25
Prepaid expenses	432	633
Other current assets	103	—
Total current assets	130,846	77,982
Property and equipment, net	496	401
Total assets	\$ 131,342	\$ 78,383
Liabilities, preferred stock, and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 2,016	\$ 6,903
Accrued liabilities	4,138	5,001
Deferred rent, current	49	43
Total current liabilities	6,203	11,947
Other noncurrent liabilities	61	90
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Common stock, \$0.001 par value; 100,000,000 shares authorized at June 30, 2015 (unaudited) and December 31, 2014; 20,115,869 and 16,878,817 shares issued and outstanding at June 30, 2015 (unaudited) and December 31, 2014, respectively	20	17
Preferred stock, \$0.001 par value; 10,000,000 shares authorized; no shares issued or outstanding	—	—
Additional paid-in capital	235,744	157,092
Accumulated deficit	(110,686)	(90,763)
Total stockholders' equity	125,078	66,346
Total liabilities, preferred stock and stockholders' equity	\$ 131,342	\$ 78,383

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

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## IMMUNE DESIGN CORP.

## STATEMENTS OF OPERATIONS

(in thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
	(unaudited)			
Revenues:				
Licensing revenue	\$—	\$1,000	\$—	\$1,000
Product sales	19	64	108	89
Other, net	1,761	—	3,610	—
Total revenues	1,780	1,064	3,718	1,089
Operating expenses:				
Cost of product sales	44	18	123	32
Research and development	8,483	3,883	15,946	7,961
General and administrative	3,778	1,850	7,580	3,296
Total operating expenses	12,305	5,751	23,649	11,289
Loss from operations	(10,525)	(4,687)	(19,931)	(10,200)
Interest and other income	8	—	8	1
Change in fair value of convertible preferred stock warrant liability	—	(1,439)	—	(4,150)
Net loss attributable to common stockholders	\$(10,517)	\$(6,126)	\$(19,923)	\$(14,349)
Basic and diluted net loss per share attributable to common stockholders	\$(0.54)	\$(16.57)	\$(1.10)	\$(38.81)
Weighted-average shares used to compute basic and diluted net loss per share attributable to common stockholders	19,356,404	369,750	18,174,611	369,702

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

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IMMUNE DESIGN CORP.  
STATEMENTS OF CASH FLOWS  
(in thousands)

	Six Months Ended June 30,	
	2015	2014
	(unaudited)	
Operating activities		
Net loss	\$(19,923)	\$(14,349)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	111	122
Stock-based compensation expense	3,044	454
Revaluation of convertible preferred stock warrant liability	—	4,150
Changes in operating assets and liabilities:		
Accounts receivable	1,091	(951)
Inventory	(409)	(2)
Prepaid expenses	201	(790)
Accounts payable	(4,887)	389
Accrued liabilities	(870)	87
Deferred rent	(16)	(9)
Net cash used in operating activities	(21,658)	(10,899)
Investing activities		
Purchases of property and equipment	(206)	(117)
Net cash used in investing activities	(206)	(117)
Financing activities		
Issuance of common stock in public offering, net of offering costs	75,359	—
Deferred offering costs	—	(1,368)
Proceeds from exercise of stock options and employee stock purchases	149	—
Net cash provided by (used in) financing activities	75,508	(1,368)
Net increase (decrease) in cash and cash equivalents	53,644	(12,384)
Cash and cash equivalents, beginning of period	75,354	30,387
Cash and cash equivalents, end of period	\$128,998	\$18,003
Supplemental cash flow information		
Accrual of offering costs	\$—	\$397
Stock option exercises receivable	\$103	\$—
The accompanying notes are an integral part of these unaudited financial statements.		

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IMMUNE DESIGN CORP.

NOTES TO FINANCIAL STATEMENTS

(Information as of June 30, 2015 and for the three and six months ended June 30, 2015 and 2014 is unaudited)

1. Description of the Business

Immune Design Corp. (we, us or our) is a clinical-stage immunotherapy company with next-generation in vivo approaches designed to enable the body's immune system to fight disease. We have engineered our technologies to activate the immune system's natural ability to create tumor-specific cytotoxic T cells (CTLs) to fight cancer. We are developing multiple product candidates from our two discovery platforms, ZVex™ and GLAAS™. Our product candidates, CMB305, LV305 and G100, utilize multiple immuno-oncology approaches and are in Phase 1 clinical trials. CMB305 is a prime-boost approach, in which LV305 from our ZVex platform is dosed sequentially with G305 from our GLAAS platform. Although we are focusing our development efforts on CMB305 and G100, we have commenced an expansion trial of LV305 alone at the highest dose studied in its dose-escalation Phase 1 trial. The expansion trial will treat patients with any of four solid tumor types and explore the use of LV305 with a checkpoint inhibitor in melanoma patients who have had an inadequate response to anti-PD1 therapy. We were incorporated in February 2008 in the State of Delaware. Our operations are headquartered in Seattle, Washington, and we have an additional facility in South San Francisco, California.

2. Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

The accompanying financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP). To conform with GAAP, the preparation of our financial statements requires management to make judgments, assumptions, and estimates that affect the amounts reported in our financial statements and accompanying notes. Estimates are used for, but not limited to, accruals for clinical trial activity, other accrued liabilities, and assumptions used in determining stock-based compensation expenses and convertible preferred stock warrant liability. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable. Actual results could differ materially from those estimates.

Unaudited Interim Financial Information

The accompanying unaudited financial statements as of June 30, 2015 and for the three and six months ended June 30, 2015 and 2014 and the related interim information contained within the notes to the financial statements are unaudited. The unaudited interim financial statements have been prepared on the same basis as the audited financial statements and in the opinion of management, reflect all normal recurring adjustments necessary for a fair statement of our financial position for the interim periods presented. The results of operations for the three and six months ended June 30, 2015 are not necessarily indicative of the results to be expected for the year ended December 31, 2015 or for other future interim periods or years.

The accompanying unaudited financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 2014 included in our Annual Report on Form 10-K for the year ended December 31, 2014, filed with the Securities and Exchange Commission (SEC).

Segments

We operate in one segment and use cash flow as the primary measure to manage our business and do not segment the business for internal reporting or decision-making purposes.

Reverse Stock Split

On July 14, 2014, we filed an amendment to our amended and restated certificate of incorporation, effecting a 1-for-8.175 reverse stock split. All issued and outstanding stock and per share amounts contained in our financial statements have been retroactively adjusted to reflect this reverse stock split for all periods presented.

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IMMUNE DESIGN CORP.

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

(Information as of June 30, 2015 and for the three months ended June 30, 2015 and 2014 is unaudited)

Follow-On Public Offering

In April 2015, we closed an underwritten public offering of 3,000,000 shares of our common stock at a price of \$26.50 per share. In May 2015, we sold an additional 47,409 shares directly to our underwriters when they exercised a portion of their option to purchase additional shares at \$26.50 per share. We received net proceeds of \$75.4 million (inclusive of the exercise of a portion of the underwriters' option to purchase additional shares), after underwriting discounts and commissions and offering expenses totaling \$5.4 million.

Offering Costs

Offering costs represent legal, accounting and other direct costs related to our efforts to raise capital through our follow-on public offering in April 2015 and for our initial public offering (IPO) in July 2014. These costs were deferred until completion of the follow-on public offering and IPO, respectively, at which time they were reclassified to additional paid-in capital as a reduction of the proceeds.

Comprehensive Loss

Comprehensive loss is comprised of net loss and certain changes in equity that are excluded from net loss. There was no difference between comprehensive loss and net loss for the three and six months ended June 30, 2015 and 2014.

Revenue Recognition

We derive our revenue from collaboration and licensing agreements and the sale of products associated with material transfer, collaboration and supply agreements.

Licensing fees are recognized when the amounts are earned and determinable during the applicable period. We recognize up-front nonrefundable license fees when due under contractual agreements and when we do not have a continuing obligation to provide services related to the agreement. Revenue associated with nonrefundable up-front license fees under arrangements where the license fees and research and development activities cannot be accounted for as separate units of accounting is deferred and recognized as revenue on a straight-line basis over the expected term of our continued involvement in the research and development process. Revenues from the achievement of research and development milestones, if deemed substantive, are recognized as revenue when the milestones are achieved, and the milestone payments are due and collectible. If not deemed substantive, we recognize such milestones as revenue on a straight-line basis over the remaining expected term of continued involvement in the research and development process.

Milestones are considered substantive if all of the following conditions are met: (1) the milestone is nonrefundable, (2) achievement of the milestone was not reasonably assured at the inception of the arrangement, (3) substantive effort is involved to achieve the milestone, and (4) the amount of the milestone appears reasonable in relation to the effort expended, the other milestones in the arrangement and the related risk associated with the achievement of the milestone and any ongoing research and development or other services are priced at fair value. Payments received in advance of work performed are recorded as unearned revenue.

Certain agreements from which we derive our revenue include multiple deliverables. We recognize the revenue for each deliverable at fair value determined to be the estimated selling price in cases when neither vendor specific objective evidence nor third-party evidence is available.

Revenue is recognized when all of the following criteria are met: (1) persuasive evidence of an arrangement exists, (2) delivery has occurred or services have been rendered, (3) the price to the customer is fixed or determinable and (4) collectability is reasonably assured. The evaluation of these revenue recognition criteria requires significant management judgment. For instance, we use judgment to assess collectability based on factors such as the customer's creditworthiness and past collection history, if applicable. If we determine that collection of a payment is not reasonably assured, revenue recognition is deferred until receipt of payment. We also use judgment to assess

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IMMUNE DESIGN CORP.

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

(Information as of June 30, 2015 and for the three months ended June 30, 2015 and 2014 is unaudited)

whether a price is fixed or determinable including, but not limited to, reviewing contractual terms and conditions related to payment terms.

Revenue from product sales of glucopyranosyl lipid A (GLA), a product from our GLAAS platforms, is recognized when the risk of loss has passed to the customer or deferred until such time that risk of loss has passed. All revenues associated from the sale of GLA products supplied by us are reported under product sales with the applicable costs reported under cost of product sales. Product sales consist of the direct costs associated with the manufacture and formulation of GLA, including costs to purchase raw materials, third-party contract manufacturing costs, assay testing and ongoing product stability testing.

## Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB), issued Accounting Standards Update (ASU) No. 2014-09, related to the recognition of revenue. ASU 2014-09 requires entities to recognize revenue through the application of a five step model, which includes identification of the contract, identification of the performance obligations, determination of the transaction price, allocation of the transaction price to the performance obligations, and recognition of revenue as the entity satisfies the performance obligations. ASU 2014-09 is effective retrospectively for annual or interim reporting periods beginning after December 15, 2017, with early application permitted for annual reporting periods beginning after December 15, 2016. Early adoption prior to that dates is not permitted. We are evaluating the guidance to determine the potential impact on our results of operations, financial condition, cash flows, and financial statement disclosures.

## 3. Net Loss Per Share

Basic net loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period. Because of net losses recognized in each period, potential common shares issuable upon the exercise of outstanding stock options and warrants and the conversion of preferred shares in the IPO into common shares have not been reflected in the calculation of diluted net loss per share due to the anti-dilutive effect. Diluted net loss per share, therefore, does not differ from basic net loss per share.

The common stock equivalents issuable upon the conversion or exercise of the following dilutive securities has been excluded from the computation of diluted net loss per share attributable to common stockholders calculation because their effect would have been antidilutive for the periods presented:

	June 30, 2015 (unaudited)	2014
Convertible preferred stock	—	9,769,422
Options to purchase common stock	2,301,813	1,802,626
Warrants to purchase convertible preferred stock	—	1,975,532
Total outstanding shares of common stock equivalents	2,301,813	13,547,580

## 4. Fair Value of Financial Instruments

We measure and record cash and cash equivalents and convertible preferred stock warrant liabilities at fair value in the accompanying financial statements. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability, or an exit price, in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value, is as follows:

Level 1: Quoted prices in active markets for identical assets or liabilities.

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IMMUNE DESIGN CORP.

## NOTES TO FINANCIAL STATEMENTS (CONTINUED)

(Information as of June 30, 2015 and for the three months ended June 30, 2015 and 2014 is unaudited)

Level 2: Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, quoted prices 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 assets or liabilities.

Level 3: Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Level 1 securities consist of highly liquid money market funds. The fair value of Level 1 assets has been determined using quoted prices in active markets for identical assets.

The following table summarizes our financial assets and liabilities measured at fair value on a recurring basis (in thousands):

	June 30, 2015 (unaudited)			
Assets:	LEVEL 1	LEVEL 2	LEVEL 3	TOTAL
Money market funds	\$128,015	\$—	\$—	\$128,015

	December 31, 2014			
Assets:	LEVEL 1	LEVEL 2	LEVEL 3	TOTAL
Money market funds	\$73,098	\$—	\$—	\$73,098

## 5. Inventory

Inventory consists of the following (in thousands):

	June 30, 2015 (unaudited)	December 31, 2014
Work in process	\$429	\$—
Finished goods	5	25
Total inventory	\$434	\$25

## 6. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	June 30, 2015 (unaudited)	December 31, 2014
Research and development services	\$2,496	\$1,845
Legal and professional services	125	1,253
Employee compensation	1,099	1,379
Unearned revenue	418	524
Total accrued liabilities	\$4,138	\$5,001

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IMMUNE DESIGN CORP.

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

(Information as of June 30, 2015 and for the three months ended June 30, 2015 and 2014 is unaudited)

7. Commitments and Contingencies

Operating Leases

We lease our lab and office space under an operating lease in Seattle, Washington. The lease commenced in February 2013 and continues through November 2016, with an option to extend the term for an additional month.

We also lease office space under an operating lease in South San Francisco, California. The lease commenced in January 2015 and continues through January 2020, with an option to extend for an additional five years. In connection with the lease, we were required to provide a \$121,000 letter of credit as a security deposit. As of June 30, 2015, no funds had been drawn on the letter of credit.

The terms of these leases provide for rental payments on a monthly basis and on a graduated scale. We recognize rent expense on a straight-line basis over the lease periods and accrue for rent expense incurred but not paid. As of June 30, 2015, the remaining aggregate non-cancelable rent payable under our leases is \$2.2 million.

Contingencies

In June 2015, we entered into a clinical supply agreement with NanoPass Technologies LTD (NanoPass) for the use of their intradermal delivery device in certain of our clinical trials. In connection with the execution of the agreement, we committed to pay an upfront fee of \$600,000 for access and rights to use their device. The upfront fee was paid in July 2015. In addition, we agreed to pay certain future milestone fees up to an aggregate of \$4.5 million upon the achievement of certain clinical milestones.

We are also contingently obligated to pay any potential future milestone payments to third parties as part of certain collaboration and licensing agreements, which could total up to \$2.4 million in aggregate payments for the first licensed GLA product we develop, up to \$1.3 million in aggregate payments for each subsequent licensed GLA product we develop and up to \$1.9 million in aggregate payments for the ZVex products we develop. We also have potential future royalty payments we may be required to make under our licensing agreements as described in Note 9. Payments under these agreements are uncertain due to the occurrence of the events requiring payment under these agreements, including our share of potential future milestone and royalty payments. These payments generally become due and payable only upon achievement of certain clinical development, regulatory or commercial milestones.

8. Series C Convertible Preferred Stock Warrant Liability

In October 2013, in connection with the issuance of our Series C convertible preferred stock, we issued fully exercisable warrants for the purchase of 1,975,532 shares of our Series C convertible preferred stock at an exercise price of \$8.175 per share. In July 2014, immediately prior to the closing of the IPO, warrants representing 996,940 shares of common stock were exercised for \$8.1 million in cash, and warrants representing 978,592 shares of common stock were automatically net exercised for a total of 311,923 shares of common stock. Upon exercise of the warrants, the convertible preferred stock warrant liability was reclassified to stockholders' equity. For the three and six months ended June 30, 2014, respectively, we recorded a \$1.4 million and \$4.2 million non-operating loss on our statement of operations related to the change in fair value of the preferred stock warrant liability. As of June 30, 2015 there were no warrants outstanding.

9. License and Collaboration Agreements

Licenses Granted

In August 2014, we entered into an agreement with Sanofi under which we granted Sanofi an exclusive license for use of our GLAAS platform to discover, develop and commercialize products to treat a selected food allergy. Upon execution of the agreement, we received a \$3.5 million upfront payment, recognized as revenue during the third quarter of 2014. The agreement provides for additional payments of up to \$168.0 million based upon the attainment

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IMMUNE DESIGN CORP.

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

(Information as of June 30, 2015 and for the three months ended June 30, 2015 and 2014 is unaudited)

of certain development and commercialization milestones, and tiered royalties on sales of approved products. Sanofi may terminate the agreement at any time upon six months' written notice.

In October 2010, we entered into three separate license agreements with MedImmune, LLC (MedImmune) pursuant to which we granted MedImmune a worldwide, sublicensable, exclusive license to use GLA to develop and sell vaccines in three different infectious disease indications. Two of the three agreements remain in full force and effect, and the rights granted under the third have returned to us. Under the license agreements, MedImmune is obligated to use commercially reasonable efforts to develop and obtain regulatory approval for a licensed product in certain markets, and to market and sell licensed products in any country where it obtains regulatory approval. In 2010, MedImmune paid us upfront payments under the license agreements. Under each license agreement, MedImmune is obligated to make additional payments based on achievement of certain development, regulatory, and commercial milestones for the licensed indication. MedImmune is also obligated to pay us a low double-digit percentage share of non-royalty payments that it receives from sublicensees and a mid single-digit percentage royalty payment on net sales of licensed products, which royalty is subject to reduction under certain circumstances. Through June 30, 2015, MedImmune has paid us an aggregate of \$5.5 million under the license agreements. Under each license agreement, MedImmune is obligated to make additional aggregate payments of \$62.9 million to \$75.0 million, depending on the infectious disease indication, and the achievement of certain development, regulatory and commercial milestones for the licensed indication.

**Licenses Acquired**

In July 2008, we licensed certain rights to research, develop, and commercialize GLA from the Infectious Disease Research Institute (IDRI) and amended the agreement in 2010. We paid an upfront fee and issued shares of our common stock valued at \$59,000 for the license. We recorded the upfront cash payment and the fair value of the common stock as research and development expense in 2008, as the licensed rights had no alternative future use. In addition, we agreed to pay certain fees in the future if we should elect to continue development of the applicable technologies, including payments upon achievement of certain development and commercialization milestones and royalty payments of a single-digit percentage of net sales, if and when commercialized; however, we may terminate our development program at any time without obligation to IDRI. Under our license agreement with IDRI, we are obligated to share with IDRI a percentage of payments received from third-party licensees.

Through June 30, 2015, we have paid IDRI an aggregate of \$1.9 million in upfront fees, milestone payments and sublicense revenue related to our sublicensees. We expensed these amounts to research and development expense, as the rights had no alternative future use. We are obligated to pay IDRI up to \$2.4 million in additional payments based on the achievement of certain developmental and regulatory milestones for the first GLA product, and up to \$1.3 million in additional payments based on the achievement of certain developmental and regulatory milestones for each subsequent GLA product.

In 2009, we licensed certain patent rights directed to the production of dendritic cell-targeted therapeutic and prophylactic immunization strategies from the California Institute of Technology (Caltech) in exchange for shares of our common stock valued at \$25,000. We make annual minimum royalty payments under the license. In addition, we agreed to pay certain fees in the future, including milestone payments upon achievement of certain development and commercialization milestones and royalty payments on net sales in the low single-digit percentage, if and when commercialized, if we should elect to continue development of the related technology; however, we may terminate our development program at any time without further obligation to Caltech. In addition, we are required to pay Caltech up to an aggregate of \$1.6 million in additional payments upon the achievement of certain regulatory and sales milestones.

In June 2015, we entered into a clinical supply agreement with NanoPass for the use of their intradermal delivery device in certain of our clinical trials. See Note 7 for additional information.

**Collaborations**



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## IMMUNE DESIGN CORP.

## NOTES TO FINANCIAL STATEMENTS (CONTINUED)

(Information as of June 30, 2015 and for the three months ended June 30, 2015 and 2014 is unaudited)

In October 2014, we entered into a collaboration with Sanofi Pasteur for the development of a Herpes Simplex Virus immune therapy. Sanofi Pasteur and Immune Design will each contribute product candidates to the collaboration: Sanofi Pasteur will contribute HSV-529, a clinical-stage replication-defective HSV vaccine product candidate, and Immune Design will contribute G103, our preclinical trivalent vaccine product candidate. The collaboration will explore the potential of various combinations of agents, including leveraging Immune Design's GLAAS platform, with the goal to select the best potential immune therapy for patients. Each company will develop the products jointly through Phase 2 clinical trials, at which point Sanofi Pasteur intends to continue development of the most promising candidate and be responsible for commercialization. Sanofi Pasteur will bear the costs of all preclinical and clinical development, with Immune Design providing a specific formulation of GLA from the GLAAS platform at its cost through Phase 2 studies. Immune Design will be eligible to receive future milestone and royalty payments on any product developed from the collaboration. We recognize funding from collaborative research and development efforts as revenue as we perform or deliver the related services in accordance with contract terms as long as we will receive payment for such services upon standard payment terms. The costs of the related services performed are recorded as research and development expenses on the statement of operations. For the three and six months ended June 30, 2015, we recognized \$1.8 million and \$3.6 million in revenue under this collaboration arrangement. As of June 30, 2015, we have an outstanding receivable of \$835,000.

## 10. Stockholders' Equity

## Preferred Stock

Our board of directors has the authority to fix and determine and to amend the number of shares of any series of preferred stock that is wholly unissued or to be established and to fix and determine and to amend the designation, preferences, voting powers and limitations, and the relative, participating, optional or other rights, of any series of shares of preferred stock that is wholly unissued or to be established. There was no preferred stock issued and outstanding as of June 30, 2015 or December 31, 2014.

## Common Stock

We had 20,115,869 and 16,878,817 shares of common stock outstanding as of June 30, 2015 and December 31, 2014, respectively. Shares of common stock reserved for future issuance were as follows:

	June 30, 2015 (unaudited)	December 31, 2014
Shares to be issued under the employee stock purchase plan	321,309	155,220
Shares to be issued upon exercise of outstanding stock options	2,301,813	1,907,091
Shares available for future stock option grants	1,367,553	1,274,067
Shares of common stock reserved for future issuance	3,990,675	3,336,378

## Equity Incentive Plans

In April 2014, our board of directors adopted, and in July 2014 our stockholders approved, the 2014 Employee Stock Purchase Plan (2014 ESPP). Upon the approval of the 2014 ESPP, 155,220 shares of our common stock were reserved for issuance. The initial offering period was from April 1, 2015 through June 30, 2015. As of June 30, 2015, 2,699 shares have been purchased under the 2014 Plan.

The total number of shares of common stock available for issuance under the 2014 ESPP will automatically increase annually on January 1 by (i) the lesser of 1% of the total number of shares of our common stock issued and outstanding as of December 31 of the immediately preceding year or (ii) 200,000 shares. On January 1, 2015, in accordance with the 2014 ESPP annual increase provisions, the authorized shares increased by 168,788 shares.

In 2008, we adopted the 2008 Equity Incentive Plan (2008 Plan) for eligible employees, officers, directors, and consultants, which provides for the grant of incentive and non-statutory stock options, restricted stock awards, restructured stock unit awards grant, and stock appreciation rights. The terms of the stock awards, including vesting

requirements, are determined by the board of directors, subject to the provisions of the 2008 Plan.

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IMMUNE DESIGN CORP.

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

(Information as of June 30, 2015 and for the three months ended June 30, 2015 and 2014 is unaudited)

In April 2014, our board of directors adopted, and in July 2014 our stockholders approved, the 2014 Omnibus Incentive Plan (2014 Plan) which provides for the granting of certain awards to eligible employees, officers, directors and consultants. Upon approval of the 2014 Plan by the stockholders in July 2014, 1,400,000 shares of our common stock were reserved for issuance under the 2014 Plan and we ceased granting stock awards under the 2008 Plan. All shares of common stock subject to awards under the 2008 Plan that expire, terminate, or are otherwise surrendered, canceled, forfeited or repurchased without having been fully exercised or resulting in the issuance of common stock become available for issuance under the 2014 Plan.

The total number of shares of common stock available for issuance under the 2014 Plan will automatically increase annually on January 1 by 4% of the total number of shares of our common stock issued and outstanding as of December 31 of the immediately preceding year. On January 1, 2015, in accordance with the 2014 Plan and annual increase provisions, the authorized shares increased by 675,152 shares.

Stock options granted under the 2008 Plan and 2014 Plan generally vest over four years and vested options are exercisable until ten years after the date of grant. Vesting of certain employee options may be accelerated in the event of a change in control of our company. We grant stock options under the 2014 Plan with exercise prices equal to the fair value of our common stock on the date of grant. There were a total of 2,084,913 shares of common stock authorized under the 2014 Plan as of June 30, 2015.

## Stock Option Activity

Summary stock option information is as follows:

	OPTIONS OUTSTANDING	WEIGHTED- AVERAGE EXERCISE PRICE	WEIGHTED- AVERAGE REMAINING CONTRACT TERM (in years)	AGGREGATE INTRINSIC VALUE (in thousands)
Outstanding at December 31, 2014	1,907,091	\$4.16	8.16	\$50,847
Granted (unaudited)	670,394	\$28.08		
Exercised (unaudited)	(186,944)	) \$1.10		
Forfeited (unaudited)	(88,728)	) \$18.11		
Outstanding at June 30, 2015 (unaudited)	2,301,813	\$10.80	8.28	\$28,362
Vested and expected to vest after June 30, 2015 (unaudited)	2,151,367	\$10.37	8.22	\$27,189
Exercisable as of June 30, 2015 (unaudited)	891,275	\$2.57	7.09	\$16,205

As of June 30, 2015, there was \$15.4 million of total unrecognized stock-based compensation expense related to nonvested stock options that is expected to be recognized over a weighted-average period of 3.1 years. The total intrinsic value of options exercised during the six months ended June 30, 2015 and 2014 was \$4.4 million and \$0, respectively.

## Stock-Based Compensation Expense

Employee stock-based compensation expense recognized was calculated based on awards ultimately expected to vest and has been reduced for estimated forfeitures. Forfeitures are estimated at the time of grant and revised, as necessary, in subsequent periods if actual forfeitures differ from those estimates. Total stock-based compensation expense recognized in our statement of operations is as follows (in thousands):



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## IMMUNE DESIGN CORP.

## NOTES TO FINANCIAL STATEMENTS (CONTINUED)

(Information as of June 30, 2015 and for the three months ended June 30, 2015 and 2014 is unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
	(unaudited)			
Employee:				
Research and development	\$487	\$92	\$889	\$143
General and administrative	1,151	143	1,945	229
Non-Employee:				
Research and development	61	32	96	82
General and administrative	114	—	114	—
Total stock-based compensation expense	\$1,813	\$267	\$3,044	\$454

We use the Black-Scholes option pricing model to estimate the fair value of stock options at the grant date. The Black-Scholes option pricing model requires us to make certain estimates and assumptions, including assumptions related to the expected price volatility of our stock, the period during which the options will be outstanding, the rate of return on risk-free investments and the expected dividend yield of our stock.

To estimate the fair value of our common stock prior to our IPO, our board of directors periodically determined the per share fair value of our common stock at various dates using valuations performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants Practice Aid, Valuation of Privately-Held Company Equity Securities Issued as Compensation. We performed these valuations contemporaneously as of December 31, 2012, October 16, 2013 and March 31, 2014. For financial reporting purposes, we also performed a retrospective valuation on December 31, 2013. Upon the completion of our IPO, the fair value of our common stock has been determined by the trading value of our common stock on NASDAQ.

The fair values of stock options granted to employees were calculated using the following assumptions:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
	(unaudited)			
Weighted-average estimated fair value	\$15.97	\$6.33	\$21.80	6.33
Risk-free interest rate (1)	1.56% - 1.72%	1.76% - 2.16%	1.50% - 1.72%	1.76% - 2.16%
Expected term of options (in years) (2)	6.08	5.50 - 6.75	5.50 - 6.08	5.50 - 6.75
Expected stock price volatility (3)	86%	90%	82% - 91%	90%
Expected dividend yield (4)	—	—	—	—

(1) The risk-free interest rate assumption was based on zero-coupon U.S. Treasury instruments that had terms consistent with the expected term of our stock option grants.

We used the “simplified method” for options to determine the expected term of our stock option grants. Under this (2) approach, the weighted-average expected life is presumed to be the average of the vesting term and the contractual term of the option.

Volatility is a measure of the amount by which a financial variable, such as share price, has fluctuated or is (3) expected to fluctuate during a period. We analyzed the stock price volatility of companies at a similar stage of development to estimate expected volatility of our stock price.

(4) We have never declared or paid cash dividends and do not presently plan to pay cash dividends in the foreseeable future.

## 11. Legal Proceedings

TheraVectys SA v. Immune Design Corp.



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IMMUNE DESIGN CORP.

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

(Information as of June 30, 2015 and for the three months ended June 30, 2015 and 2014 is unaudited)

In October 2013, TheraVectys SA, or TVS, a French biotechnology company, filed a complaint against us in the United States District Court for the District of Delaware. TVS alleged that it had entered into a contractual relationship with Henogen SA, or Henogen, in 2010 with respect to the production of lentiviral vector vaccines for TVS. Henogen is a contract manufacturing organization with which we contracted for the manufacture of our LV305 product candidate. TVS alleged that its contractual relationship with Henogen contained an exclusivity provision limiting Henogen's ability to participate in the manufacturing process of a vaccine based on lentiviral DNA vectors for third parties, as well as a provision preventing Henogen from sharing or using certain TVS confidential technology for manufacturing processes developed by TVS with or for the benefit of others. TVS alleged that we entered into a contractual relationship with Henogen in 2012 to manufacture lentiviral vectors for vaccines, which TVS contends interfered with its contract with Henogen and resulted in the use of certain TVS confidential information and trade secrets. The complaint asserted three counts for relief: tortious interference with contractual relationship, unfair competition and misappropriation of trade secrets. TVS did not specify its claimed damages, other than to assert that they exceed \$75,000. TVS also requested in its complaint injunctive relief enjoining us from importing, receiving, possessing or using lentiviral vector vaccines developed or produced by Henogen, but never filed a motion seeking injunctive relief. The parties entered into several stipulations extending the deadline for us to respond to the complaint. On or about April 7, 2014, TVS filed a Notice of Voluntary Dismissal without prejudice of this lawsuit. On or about July 24, 2014, shortly after our Registration Statement on Form S-1 was declared effective by the SEC for our initial public offering, TVS filed a new complaint against us in the Chancery Court of the State of Delaware, alleging facts substantially similar to the prior complaint. In addition, the complaint further alleges that we obtained shipments of lentiviral vectors for vaccines from Henogen and are conducting clinical trials with these lentiviral vectors. The complaint asserts four counts for relief: tortious interference with contractual relationship, unfair competition, misappropriation of trade secrets, and unjust enrichment; claimed damages were not specified. The complaint also requested injunctive relief enjoining us from using lentiviral vectors developed or produced by Henogen, using any other materials or information obtained by Henogen, and citing to the FDA or otherwise relying on any clinical trials using lentiviral vector vaccines developed or produced by Henogen.

On or about July 24, 2014, TVS also filed a motion for expedited proceedings in support of an anticipated motion for preliminary injunction. On August 8, 2014 the court granted TVS' motion for expedited proceedings and set a hearing date in mid-November 2014 for TVS' anticipated motion for preliminary injunction. In September 2014, TVS filed a motion to postpone the hearing date and delay the proceedings it previously sought to expedite. The court granted the motion and set a new date for the hearing. On or about December 15, 2014, TVS filed a motion for a preliminary injunction seeking, among other things, to enjoin us from making any use of lentiviral vectors pending final resolution of the litigation. A hearing was held on TVS's motion in January 2015.

By order dated March 9, 2015, the Chancery Court denied TVS' motion for a preliminary injunction. The court has not yet made any final determination on the merits of the lawsuit, which will be determined at a full trial. A trial date has not yet been set. We intend to continue to vigorously defend this lawsuit.

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### Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following management's discussion and analysis of financial condition and results of operations in conjunction with our unaudited financial statements and notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q and with our audited financial statements and related notes thereto for the year ended December 31, 2014, included in our Annual Report on Form 10-K, filed with the Securities and Exchange Commission (SEC).

#### Overview

Immune Design Corp. (we, us or our) is a clinical-stage immunotherapy company with next-generation in vivo approaches designed to enable the body's immune system to fight disease. We have engineered our technologies to activate the immune system's natural ability to create tumor-specific cytotoxic T cells (CTLs) to fight cancer. We are developing multiple product candidates from our two discovery platforms, ZVex™ and GLAAS™, which we believe have the potential to treat a broad cancer patient population. Our primary product candidates, CMB305 and G100, are in Phase 1 clinical trials, utilize multiple immuno-oncology approaches and, we believe, address the shortcomings of existing therapies. CMB305 is a prime-boost approach, in which an agent called LV305 from our ZVex platform is dosed sequentially with an agent from our GLAAS platform, G305. Although we currently intend to focus our ZVex-based development efforts on CMB305, we have an ongoing expansion trial of LV305 at the highest dose studied in its dose-escalation Phase 1 trial. The expansion trial is designed to study four tumor types and will explore the use of LV305 with a checkpoint inhibitor in melanoma patients who have an inadequate response to anti-PD1 therapy alone. Because of the mechanism of action of both approaches, we believe the combination of our product candidates with a checkpoint inhibitor should increase the clinical benefit to patients, as compared to either approach alone. To that end, we recently established clinical collaborations with each of Merck and Genentech covering three of our clinical trials. In the first case, Merck will contribute KEYTRUDA® (pembrolizumab), its anti-PD-1 therapy, to both our planned G100 Phase 1 clinical trial in patients with Non-Hodgkin's Lymphoma, as well as the LV305 Phase 1 expansion arm in melanoma patients who have an inadequate response to anti-PD1 therapy. Genentech, in contrast, is providing atezolizumab, its investigational anti-PD-L1 therapy, to our planned randomized Phase 2 clinical trial for patients with selected soft tissue sarcomas. We are the sponsor of these three clinical trials, and none of the parties to these arrangements have transferred any rights to their products to the other.

We have devoted substantially all of our resources since inception to our drug development efforts, including undertaking clinical trials of our product candidates, development of our ZVex and GLAAS discovery platforms, conducting preclinical studies, protecting our intellectual property and providing general and administrative support to our product development activities. To date, we have funded our operations primarily through proceeds from the issuance of our stock, payments received under license and collaboration agreements and GLA product sales.

Our net loss was \$10.5 million and \$19.9 million for the three and six months ended June 30, 2015, respectively, compared to \$6.1 million and \$14.3 million for the three and six months ended June 30, 2014, respectively. As of June 30, 2015, we had an accumulated deficit of \$110.7 million. We have incurred net losses to date and we expect to continue to incur significant expenses and increasing operating losses for at least the next several years.

Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will significantly increase as we:

- complete our current and planned Phase 1 clinical trials;
- advance clinical development of CMB305 and G100 into Phase 2 clinical studies;
- perform additional process development for our product candidates, including initial commercial scale up efforts;
- seek regulatory approvals for our product candidates, if any, that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize and market products for which we obtain regulatory approval;
- maintain, expand and protect our intellectual property portfolio;

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- continue research and development efforts to build our pipeline beyond the current product candidates;
- hire additional clinical, quality control, scientific and management personnel; and
- add operational and financial personnel to support our product development efforts and operational support applicable to operating as a public company.

We do not expect to generate significant revenue unless and until we successfully complete development of, obtain marketing approval for and commercialize our product candidates, either alone or in collaboration with third parties. We expect these activities will take a number of years and our success in these efforts is subject to significant uncertainty. Accordingly, we will need to raise additional capital prior to the regulatory approval and commercialization of any of our product candidates. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our operating activities through public or private equity or debt financings, collaborations or licenses, capital lease transactions or other available financing transactions. However, we may be unable to raise additional funds through these or other means when needed, on favorable terms or at all.

Management's discussion and analysis of financial condition and results of operations is based upon the unaudited financial statements included in this Quarterly Report on Form 10-Q, which we prepared in accordance with generally accepted accounting principles in the United States of America (GAAP) for interim periods and with Regulation S-X promulgated under the Securities and Exchange Act of 1934, as amended.

### Second Quarter 2015 and Other Recent Highlights

In August 2015, we announced the establishment of clinical collaborations with each of Merck and Genentech covering three of our clinical trials. In the first case, Merck will contribute KEYTRUDA® (pembrolizumab), its anti-PD-1 therapy, to both our planned G100 Phase 1 clinical trial in patients with Non-Hodgkin's Lymphoma, as well as the LV305 Phase 1 expansion arm in melanoma patients who have an inadequate response to anti-PD1 therapy. Genentech, in contrast, is providing atezolizumab, its investigational anti-PD-L1 therapy, to our planned randomized Phase 2 trial for patients with selected soft tissue sarcomas. We are the sponsor of these three clinical trials, and none of the parties to these arrangements have transferred any rights to their products to the other.

In May 2015, we announced the presentation of positive clinical data from three immuno-oncology Phase 1 studies at the 2015 American Society of Clinical Oncology (ASCO) Annual Meeting. The three trials provide first-in-human clinical data with our immuno-oncology cancer agents, LV305, G305, and G100, which are designed to generate anti-tumor immunity. LV305 and G305 are individually active agents that we administer in sequence to form the product candidate called CMB305, the company's prime-boost approach targeting the tumor-associated antigen, NY-ESO-1. G100, in contrast, is a potent toll-like receptor-4 (TLR4) agonist that is being administered intratumorally to activate local and systemic immunity.

In April 2015, we closed an underwritten public offering of 3,000,000 shares of our common stock at a price of \$26.50 per share. In May 2015, we sold an additional 47,409 shares directly to our underwriters when they exercised a portion of their option to purchase additional shares at \$26.50 per share. We received net proceeds of \$75.4 million (inclusive of the exercise of a portion of the underwriters' option to purchase additional shares), after underwriting discounts and commissions and offering expenses totaling \$5.4 million.

### Financial Overview

#### Revenue

#### Collaboration and Licensing Revenue

We derive our revenue from collaboration and licensing agreements and the sale of products associated with material transfer, collaboration and GLA supply agreements. We have recognized \$1.8 million and \$3.7 million in total revenue during the three and six months ended June 30, 2015, respectively. This compares to \$1.1 million and \$1.1 million for the three and six months ended June 30, 2014, respectively. We may generate revenue in the future from payments from future license or collaboration agreements, product sales or government contracts and grants. We expect that any revenue we generate will fluctuate from quarter to quarter.

#### GLA Product Sales



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We sell formulations of GLA to selected companies for use in ongoing preclinical studies and clinical trials. All revenues associated with the sale of GLA supplied by us are reported as GLA product sales with the applicable costs reported under cost of product sales. For the three and six months ended June 30, 2015, we recognized approximately \$19,000 and \$108,000 in product revenues, respectively, and \$44,000 and \$123,000 in cost of GLA product sales, respectively, through these arrangements. This compares to approximately \$64,000 and \$89,000 in product revenues, respectively, and \$18,000 and \$32,000 in cost of GLA product sales, respectively, for the three and six months ended June 30, 2014.

**Research and Development Expenses**

We focus our resources on our internal and collaborative research and development activities, including the conduct of preclinical studies, product development, activities related to regulatory filings for our product candidates and clinical trials. We recognize our research and development expenses as they are incurred. Research and development costs consist of salaries and benefits, including associated stock-based compensation, lab supplies and facility costs, as well as fees paid to other entities that conduct certain research and development activities, including clinical studies and manufacturing, on our behalf.

We are conducting research and development activities on several oncology disease targets and account for research and development costs on a program-by-program basis.

The table below summarizes our direct research and development expenses for the periods indicated. Our direct research and development expenses consist principally of external costs, such as fees paid to contract manufacturing organizations (CMOs), clinical research organizations (CROs), consultants, clinical trial sites and for contract research services. We typically use our employee and infrastructure resources across multiple research and development programs, and therefore do not allocate salaries, stock-based compensation, employee benefit or other indirect costs related to our research and development to specific product candidates. Those expenses are included in "Indirect research and development expense by type" in the table below:

	Three Months Ended June 30, 2015		Six Months Ended June 30, 2015	
	2014		2014	
	(in thousands)			
	(unaudited)			
Direct research and development expense by platform:				
ZVex	\$3,493	\$1,849	\$6,801	\$3,892
GLAAS	688	490	1,091	1,049
G103	1,744	—	3,421	—
Other	—	28	—	30
Total direct research and development program expense	5,925	2,367	11,313	4,971
Indirect research and development expense by type:				
Personnel related costs	2,192	1,107	3,917	2,254
Research and development supplies and services	119	202	267	360
Allocated facility, equipment, travel and other expense	247	207	449	376
Total indirect research and development expense	2,558	1,516	4,633	2,990
Total research and development expense	\$8,483	\$3,883	\$15,946	\$7,961

We plan to increase our research and development expenses for the foreseeable future as we continue to develop our product candidates. At this time, we cannot reasonably estimate the nature, timing or costs of the efforts that will be necessary to complete the remainder of the development of any of our product candidates or the period in which material net cash, if any, from these product candidates may commence. This is due to the numerous risks and

uncertainties associated with developing drugs, including the uncertainty of:

- the scope, rate of progress, expense and results of our ongoing and additional clinical trials that we may conduct;
- the scope, rate of progress and expense of process development;
- other research activities; and
- the timing of regulatory approvals.

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General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for employees in executive, finance, information technology and human resources functions. Other significant general and administrative expenses include professional fees for accounting and legal services, expenses associated with obtaining and maintaining patents and other intellectual property and allocation of facilities costs.

We expect that our general and administrative expenses will increase as we continue to expand infrastructure to support operating as a public company. These increases will likely include increased costs for director and officer liability insurance, costs related to the hiring of additional personnel and increased fees for directors, outside consultants, lawyers and accountants. We also expect to incur significant costs to comply with corporate governance, internal controls and similar requirements applicable to public companies.

Interest and Other Income (Expense)

Interest and other income consists of interest income earned on our cash and cash equivalents and marketable securities and the gain or loss on the disposal of property and equipment, if any, and foreign currency gain or loss.

Change in Fair Value of Convertible Preferred Stock Warrant Liability

In October 2013, in connection with the issuance of the Series C convertible preferred stock, we issued fully exercisable warrants for the purchase of 1,975,532 shares of our Series C convertible preferred stock at an exercise price of \$8.175 per share. The warrants were recorded at fair value at issuance, at each subsequent reporting date, and immediately prior to their exercise in July 2014. Immediately prior to the closing of our IPO, the preferred stock warrants were exercised in full and the preferred shares issued upon exercise were automatically converted to common stock upon the closing of our IPO; accordingly, we no longer record a related periodic fair value adjustment.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. We evaluate these estimates and judgments on an on-going basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are more fully described in Note 2 of the accompanying unaudited financial statements and in Note 2 to the audited financial statements contained in our Annual Report. There have been no significant or material changes in our critical accounting policies during the six months ended June 30, 2015, as compared to those disclosed in "Management's Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies and Use of Estimates" in our Annual Report.

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## Results of Operations

## Comparison of Three Months Ended June 30, 2015 and 2014

The following table summarizes our results of operations for the three months ended June 30, 2015 and 2014:

	Three Months Ended June 30,		Increase/ (Decrease)
	2015	2014	
	(in thousands)		
	(unaudited)		
Total revenues	\$1,780	\$1,064	\$716
Operating expenses:			
Cost of product sales	44	18	26
Research and development	8,483	3,883	4,600
General and administrative	3,778	1,850	1,928
Total operating expenses	12,305	5,751	6,554
Loss from operations	(10,525)	) (4,687	) (5,838 )
Interest and other income	8	—	8
Change in fair value of convertible preferred stock warrant liability	—	(1,439	) 1,439
Net loss attributable to common stockholders	\$(10,517	) \$(6,126	) \$(4,391 )

## Total Revenues and Cost of Product Sales

The \$0.7 million increase in total revenues was primarily attributable to the \$1.8 million of collaboration revenue recognized in the second quarter of 2015 associated with the Sanofi Pasteur G103 collaboration that was entered into in the fourth quarter of 2014. There was no such collaboration revenue recorded in the second quarter of 2014. This was offset by a \$1.0 million decrease in license revenue, as there were no such milestone or license revenue recognized during the second quarter of 2015 in addition to a slight decrease in product sales.

## Research and Development Expenses

The \$4.6 million increase in research and development expenses was primarily attributable to an increase of \$1.7 million to support research and development and contract manufacturing of G103, which is paid for under the Sanofi Pasteur G103 collaboration agreement, and an increase of \$1.3 million and \$400,000 primarily for contract manufacturing and clinical trials, respectively, for LV305 and CMB305. Additionally, there was an increase of \$1.1 million in personnel-related expenses, including stock-based compensation, as a result of growth in research and development headcount to support our advancing research and clinical pipeline.

## General and Administrative Expenses

The \$1.9 million increase was primarily attributable to a \$1.9 million increase in personnel-related expenses, including stock based compensation, primarily related to an increase in administrative headcount to support the growth and expansion of our business.

## Change in Fair Value of Convertible Preferred Stock Warrant Liability

Immediately prior to the closing of our initial public offering (IPO) in July 2014, all preferred stock warrants were exercised or net exercised in full and the preferred shares issued upon exercise or net exercise were automatically converted to common stock upon the closing of the IPO. Accordingly, no related periodic fair value adjustment was recorded during the three months ended June 30, 2015.

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## Comparison of Six Months Ended June 30, 2015 and 2014

The following table summarizes our results of operations for the six months ended June 30, 2015 and 2014:

	Six Months Ended June 30,		Increase/ (Decrease)
	2015	2014	
	(in thousands)		
	(unaudited)		
Total revenues	\$3,718	\$1,089	\$2,629
Operating expenses:			
Cost of product sales	123	32	91
Research and development	15,946	7,961	7,985
General and administrative	7,580	3,296	4,284
Total operating expenses	23,649	11,289	12,360
Loss from operations	(19,931)	(10,200)	(9,731)
Interest and other income	8	1	7
Change in fair value of convertible preferred stock warrant liability	—	(4,150)	4,150
Net loss attributable to common stockholders	\$(19,923)	\$(14,349)	\$(5,574)

## Total Revenues and Cost of Product Sales

The \$2.6 million increase in total revenues was attributable to the \$3.6 million of collaboration revenue recognized during the six month period ended June 30, 2015 associated with the Sanofi Pasteur G103 collaboration that was entered into in the fourth quarter of 2014. There was no such collaboration revenue recorded in the six month period ended June 30, 2014. This was offset by a decrease in license revenue of \$1.0 million compared to the same period in prior year, as there were no such milestone or license revenue recognized during the six month period ended June 30, 2015.

## Research and Development Expenses

The \$8.0 million increase in research and development expenses was primarily attributable to an increase of \$3.3 million to support research and development and contract manufacturing of G103, which is paid for under the Sanofi Pasteur G103 collaboration and an increase of \$2.1 million and \$900,000 primarily for contract manufacturing and clinical trials, respectively, for LV305 and CMB305. Additionally, there was an increase of \$1.7 million in personnel-related expenses, including stock based compensation as a result of growth in research and development headcount to support our advancing research and clinical pipeline.

## General and Administrative Expenses

The \$4.3 million increase was primarily attributable to a \$900,000 increase in professional service fees to support our operations as a public company and legal services to defend ongoing litigation, a \$2.9 million increase in personnel-related expenses, including stock based compensation, and a \$500,000 increase in facility and office costs, primarily related to an increase in administrative headcount to support the growth and expansion of our business.

## Change in Fair Value of Convertible Preferred Stock Warrant Liability

Immediately prior to the closing of our initial public offering (IPO) in July 2014, all preferred stock warrants were exercised or net exercised in full and the preferred shares issued upon exercise or net exercise were automatically converted to common stock upon the closing of the IPO. Accordingly, no related periodic fair value adjustment was recorded during the six months ended June 30, 2015.

## Liquidity and Capital Resources

In April 2015, we closed an underwritten public offering of 3,000,000 shares of our common stock at a price of \$26.50 per share. In May 2015, we sold an additional 47,409 shares directly to our underwriters when they exercised a portion of their option to purchase additional shares at \$26.50 per share. We received net proceeds of \$75.4 million (inclusive of the exercise of a portion of the underwriters' option to purchase additional shares), after underwriting discounts and commissions and offering expenses totaling \$5.4 million.



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In July 2014, we completed our IPO of 5,000,000 shares of our common stock at a price of \$12.00 per share. In August 2014, we sold an additional 410,564 shares of common stock directly to our underwriters when they exercised a portion of their over-allotment at \$12.00 per share. We received net proceeds of \$57.8 million (inclusive of the exercise of the over-allotment) after deducting underwriting discounts and commissions and offering expenses. In connection with the closing of the IPO, all outstanding shares of convertible preferred stock automatically converted into 9,769,422 shares of common stock. In July 2014, prior to the completion of the IPO, warrants to purchase 996,940 shares of common stock were exercised for \$8.1 million in cash and resulted in the issuance of an additional 996,940 shares of common stock. Immediately prior to the closing of the IPO, warrants to purchase 978,592 shares were automatically net exercised, resulting in an issuance of an additional 311,923 shares of common stock. The significant number of shares issued in July 2014 is expected to impact the year-over-year comparability of our net loss per share calculations through the third quarter of 2015.

As of June 30, 2015, we had cash and cash equivalents totaling \$129.0 million. In addition to our existing cash and cash equivalents, we are eligible to receive research and development funding and to earn milestone and other contingent payments for the achievement of defined collaboration objectives and certain development, regulatory and commercial milestones and royalty payments under our collaboration agreements. Our ability to earn these milestone and contingent payments and the timing of achieving these milestones is primarily dependent upon the outcome of our collaborators' research and development activities and is uncertain at this time.

### Funding Requirements

Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, third-party clinical and preclinical research and development services, including manufacturing, laboratory and related supplies, legal, patent and other regulatory expenses and general overhead costs. We believe our use of CROs and CMOs provides us with flexibility in managing our spending and limits our cost commitments.

Because our product candidates are in various stages of clinical and preclinical development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates or whether, or when, we may achieve profitability. Until such time, if ever, that we can generate substantial product revenues, we expect to finance our cash needs through equity or debt financings and, potentially, collaboration arrangements. Except for any obligations of our collaborators to reimburse us for research and development expenses or to make milestone or royalty payments under our agreements with them, we do not have any committed external source of liquidity. To the extent that we raise additional capital through the future sale of equity or debt, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders. If we raise additional funds through collaboration arrangements in the future, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Based on our research and development plans and our timing expectations related to the progress of our programs, we expect that our existing cash and cash equivalents as of June 30, 2015 will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we expect. Additionally, the process of developing products and testing them in clinical trials is costly, and the timing of progress and expenses in these trials is uncertain. Our future capital requirements will depend on many factors, including, among others:

- the scope, rate of progress, results and costs of our clinical trials, preclinical studies and other research and development activities;
- the scope, rate of progress and costs of our manufacturing development and commercial manufacturing activities;
- the cost, timing and outcomes of regulatory proceedings, including FDA review of any Biologics License Application, or BLA, we file;



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payments required with respect to development milestones we achieve under our in-licensing agreements;  
 the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims;  
 the costs associated with commercializing our product candidates, if they receive regulatory approval;  
 the cost and timing of developing our ability to establish sales and marketing capabilities;  
 the costs of current or future litigation or judgments;  
 competing technological efforts and market developments;  
 changes in our existing research relationships;  
 our ability to establish collaborative arrangements to the extent necessary;  
 revenues received from any existing or future products; and  
 payments received under any current or future strategic partnerships.

**Cash Flows**

The following is a summary of cash flows for the six months ended June 30, 2015 and 2014:

	Six Months Ended June 30,	
	2015	2014
	(in thousands)	
Net cash used in operating activities	\$(21,658)	\$(10,899)
Net cash used in investing activities	(206)	(117)
Net cash provided by (used in) financing activities	75,508	(1,368)
Net Cash Used in Operating Activities		

Net cash used in operating activities was \$21.7 million during the six months ended June 30, 2015 and consisted of our net loss of \$19.9 million offset by non-cash charges of \$3.0 million for stock-based compensation expense and the net change in operating assets and liabilities of \$4.8 million.

Net cash used in operating activities was \$10.9 million during the six months ended June 30, 2014 and consisted of our net loss of \$14.3 million offset by non-cash charges of \$0.5 million for stock-based compensation expense, and a \$4.2 million non-cash loss for the revaluation of convertible preferred stock warrant liabilities. The net change in operating assets and liabilities was \$1.3 million.

**Net Cash Used in Investing Activities**

Net cash used in investing activities was \$0.2 million and \$0.1 million for the six months ended June 30, 2015 and 2014, respectively, and primarily relates to the purchase of property and equipment, primarily lab equipment to support research and development efforts.

**Net Cash Provided by (Used in) Financing Activities**

Net cash provided by financing activities was \$75.5 million for the six months ended June 30, 2015, which consisted of \$75.4 million in net proceeds received from our secondary offering and cash received for the exercise of stock options and purchase of ESPP shares. Net cash used in financing activities was \$1.4 million for the six months ended June 30, 2014 and consisted of offering related expenses for our initial public offering.

**Contractual Obligations and Contingent Liabilities**

During the six months ended June 30, 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 our Annual Report on Form 10-K for the year ended December 31, 2014 except for the following:

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In June 2015, we entered into a clinical supply agreement with NanoPass Technologies LTD (NanoPass) for the use of their intradermal delivery device in certain of our clinical trials. In connection with the execution of the agreement, we committed to pay an upfront fee of \$600,000 for access and rights to use their device. The upfront fee was paid in July 2015. In addition, we agreed to pay milestone fees up to an aggregate of \$4.5 million upon the achievement of certain future clinical milestones.

### 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.

### JOBS Act

On April 5, 2012, the Jumpstart Our Business Startups Act of 2012 (JOBS Act) was enacted. Section 107 of the JOBS Act provides that an “emerging growth company” can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, for complying with new or revised accounting standards. In other words, an “emerging growth company” can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period; and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

We are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, as an “emerging growth company,” we intend to rely on certain of these exemptions, including without limitation, (i) providing an auditor’s attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an “emerging growth company” until the earliest of (a) the last day of the fiscal year in which we have total annual gross revenues of \$1.0 billion or more, (b) the last day of our fiscal year following the fifth anniversary of the completion of the our IPO in July 2014, (c) the date on which we have issued more than \$1.0 billion in nonconvertible debt during the previous three years or (d) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

### Item 3. Quantitative and Qualitative Disclosures about Market Risk

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates and concentration of credit risk. As of June 30, 2015, we had cash and cash equivalents of \$129.0 million consisting of bank deposits and interest-bearing money market accounts. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term maturities of our cash equivalents and the low risk profile of our securities, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents and marketable securities. Additionally, our cash balances deposited in a bank in the United States may be in excess of insured levels.

We contract with contract manufacturers internationally. Transactions with these providers are predominantly settled in U.S. dollars and, therefore, we believe that we have only minimal exposure to foreign currency exchange risks. We do not hedge against foreign currency risks.

### Item 4. Controls and Procedures

Evaluation of disclosure controls and procedures. Management, including our President and Chief Executive Officer and Vice President, Finance and Administration, evaluated the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)), as of the end of the period covered by this report. Based upon the evaluation, the President and Chief Executive Officer and Vice President, Finance and Administration concluded that the disclosure controls and procedures were effective to ensure that information required to be disclosed in the reports we file and submit under the Securities Exchange Act of 1934, as amended, is



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(i) recorded, processed, summarized and reported as and when required and (ii) accumulated and communicated to our management, including the President and Chief Executive Officer and Vice President, Finance and Administration, as appropriate to allow timely discussion regarding required disclosure.

Changes in internal control over financial reporting. There have been no significant changes in our internal control over financial reporting during our most recent fiscal quarter that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II: OTHER INFORMATION

Item 1. Legal Proceedings

There have been no material changes to the Legal Proceedings disclosed in our quarterly report on Form 10-Q for the three-month period ended March 31, 2015.

Item 1A. Risk Factors

This Quarterly Report on Form 10-Q contains forward-looking information based on our current expectations. Because our business is subject to many risks and our actual results may differ materially from any forward-looking statements made by or on behalf of us, this section includes a discussion of important factors that could affect our business, operating results, financial condition and the trading price of our common stock. You should carefully consider these risk factors, together with all of the other information included in this Quarterly Report on Form 10-Q as well as our other publicly available filings with the SEC.

Risks Related to Our Financial Position and Capital Needs

We have incurred net losses since our inception and anticipate that we will continue to incur net losses for the foreseeable future.

We are a clinical-stage biotechnology company with a limited operating history. Investment in biotechnology 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 efficacy or an acceptable safety profile, obtain regulatory approval or become commercially viable. We have no products approved for commercial sale and have generated only limited revenue to date. We continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not and have never been profitable and have incurred losses in each period since our inception in 2008. For the three and six months ended June 30, 2015, we reported net losses of \$10.5 million and \$19.9 million, respectively, compared with a net losses of \$6.1 million and \$14.3 million for three and six months ended June 30, 2014, respectively. As of June 30, 2015, we had an accumulated deficit of \$110.7 million.

We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates. We may also 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 revenues, if any. 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 currently have limited revenues and may never achieve or maintain profitability.

To date, we have only generated limited revenues from sales of GLA and such revenues have not been sufficient to cover our operating expenses. Our ability to generate significant product revenue and become profitable depends upon our ability to successfully commercialize our current product candidates or any other future product candidates. We do not anticipate generating revenue from the sale of our current or future product candidates for the foreseeable future.

Our ability to generate significant product revenue from our current or future product candidates also depends on a number of additional factors, including but not limited to our ability to:

- successfully complete the research and clinical development of and receive regulatory approval for current and future product candidates, including those of our licensees for the use of GLA in specific indications; launch, commercialize and achieve market acceptance of our current and future product candidates for which we obtain marketing approval, if any, and if launched independently, successfully establish a sales, marketing and distribution infrastructure;
- establish and maintain supplier and manufacturing relationships with third parties, and ensure adequate and legally compliant manufacturing of bulk drug substances and drug products to maintain that supply;

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- obtain coverage and adequate product reimbursement from third-party payors, including government payors;

- establish, maintain and protect our intellectual property rights; and

- attract, hire and retain qualified personnel.

In addition, because of the numerous risks and uncertainties associated with biotechnology product development, including that our product candidates may not achieve the clinical endpoints of applicable trials, we are unable to predict the timing or amount of increased expenses and if or when we will achieve or maintain profitability. In addition, our expenses could increase beyond expectations if we decide to or are required by the U.S. Food and Drug Administration, or FDA, or foreign regulatory authorities to perform additional studies or trials in addition to those that we currently anticipate. Even if we complete the development and regulatory processes described above, we anticipate incurring significant costs associated with launching and commercializing these products.

Even if we generate revenues from the sale of any of our product candidates that may be approved, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable and subsequently do not sustain profitability on a continuing basis, we may be unable to continue our operations at planned levels and be forced to reduce our operations or even shut down.

We will require additional capital to finance our operations, which may not be available to us on acceptable terms, if at all. As a result, we may not complete the development and commercialization of our product candidates or develop new product candidates.

Development of our product candidates will require substantial additional funds to conduct research, development and clinical trials necessary to bring such product candidates to market and to establish manufacturing, marketing and distribution capabilities. Our future capital requirements will depend on many factors, including, among others:

- the scope, rate of progress, results and costs of our clinical trials, preclinical studies and other research and development activities;

- the scope, rate of progress and costs of our manufacturing development and commercial manufacturing activities;

- the cost, timing and outcomes of regulatory proceedings, including FDA review of any Biologics License Application, or BLA, we file;

- payments required with respect to development milestones we achieve under our in-licensing agreements;

- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims;

- the costs associated with commercializing our product candidates, if they receive regulatory approval;

- the cost and timing of developing our ability to establish sales and marketing capabilities;

- the costs of current or future litigation or judgments;

- competing technological efforts and market developments;

- changes in our existing research relationships;

- our ability to establish collaborative arrangements to the extent necessary;

- revenues received from any existing or future products; and

- payments received under any current or future strategic partnerships.

We anticipate that we will continue to generate significant losses for the next several years as we incur expenses to complete our clinical trial programs for our product candidates, build commercial capabilities, develop our product pipeline and expand our corporate infrastructure. We believe that our existing cash and cash equivalents will allow us to fund our operating plan for at least the next 12 months. However, our operating plan may change as a result of factors currently unknown to us.

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There can be no assurance that our revenue and expense forecasts will prove to be accurate, and any change in the foregoing assumptions could require us to obtain additional financing earlier than anticipated. Actual research and development costs could substantially exceed budgeted amounts.

We may never be able to generate a sufficient amount of product revenue to cover our expenses. To finance our operations, we expect to seek additional funding through public or private equity or debt financings, collaborations or licenses, capital lease transactions or other available financing transactions. However, we cannot be certain that additional financing will be available on acceptable terms, if at all. Moreover, in the event that additional funds are obtained through arrangements with collaborative partners, such arrangements may require us to relinquish rights to certain of our technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves. Our failure to obtain adequate financing when needed and on acceptable terms could force us to delay, reduce the scope of or eliminate one or more of our research or development programs.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies.

Until we can generate a sufficient amount of revenue from our product candidates, if ever, we expect to finance future cash needs through public or private equity or debt offerings or from other sources. Additional capital may not be available on reasonable terms, if at all. If we raise additional funds through the issuance of additional debt or equity securities, it could result in dilution to our existing stockholders and increased fixed payment obligations.

Furthermore, these securities may have rights senior to those of our common stock and could contain covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects.

We plan to use potential future operating losses and our federal and state net operating loss, or NOL, carryforwards to offset taxable income from revenue generated from operations or corporate collaborations. However, our ability to use NOL carryforwards could be limited as a result of issuance of equity securities.

We plan to use our current year operating losses to offset taxable income from any revenue generated from operations or corporate collaborations. To the extent that our taxable income exceeds any current year operating losses, we plan to use our NOL carryforwards to offset income that would otherwise be taxable. However, under the Tax Reform Act of 1986, the amount of benefits from our NOL carryforwards may be impaired or limited if we incur a cumulative ownership change of more than 50%, as interpreted by the U.S. Internal Revenue Service, over a three-year period. As a result, our use of federal NOL carryforwards could be limited by the provisions of Section 382 of the U.S. Internal Revenue Code of 1986, as amended, depending upon the timing and amount of additional equity securities that we issue. In addition, we have not performed an analysis of limitations, and we may have experienced an ownership change under Section 382 as a result of past financings. State NOL carryforwards may be similarly limited. Any such disallowances may result in greater tax liabilities than we would incur in the absence of such a limitation and any increased liabilities could adversely affect our business, results of operations, financial condition and cash flow.

### **Risks Related to Our Business and Industry**

We are subject to litigation that could interrupt the supply of our drug candidates, delay our clinical trials and future clinical development and materially harm our business.

In September 2013, Henogen, the manufacturer of some of our lentiviral vectors, was sued in Belgium by one of its customers, TheraVectys SA, or TVS, who claimed that the manufacturer had breached its exclusive contract with TVS by producing lentiviral vectors for us. While we were not named in the suit in Belgium, we voluntarily intervened in that proceeding to protect our rights. In addition, TVS subsequently filed a complaint against us in the United States District Court for the District of Delaware, alleging tortious interference, unfair competition and misappropriation of trade secrets. In April 2014, TVS filed a Notice of Voluntary Dismissal without prejudice in the lawsuit filed in the District of Delaware. As a result of the action in Belgium, Henogen was temporarily enjoined

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from producing or delivering the lentiviral vectors we need for our ZVex platform-based product candidates. This injunction was lifted by the Belgian court in October 2013.

In October 2013, Henogen filed an action in the Commercial Court of Paris against TVS. We were not a party to this action. In April 2014, the Commercial Court of Paris rendered a decision in which it dismissed all claims asserted by Henogen, determined that Henogen had breached the agreement with TVS and, among other things, ordered Henogen to comply with the exclusivity provision of that agreement. It is our understanding that Henogen and TVS have reached a settlement agreement pertaining to this matter.

On or about July 24, 2014, shortly after our Registration Statement on Form S-1 was declared effective by the SEC for our initial public offering, TVS filed a new complaint against us in the Chancery Court of the State of Delaware, alleging facts substantially similar to the prior complaint filed in the District of Delaware. In addition, the complaint further alleges that we obtained shipments of lentiviral vectors for vaccines from Henogen and are conducting clinical trials with these lentiviral vectors. The complaint asserts four counts for relief: tortious interference with contractual relationship, unfair competition, misappropriation of trade secrets, and unjust enrichment. The complaint does not specify the amount of alleged damages. The complaint also requests injunctive relief enjoining us from using lentiviral vectors developed or produced by Henogen, using any other materials or information obtained by Henogen, and citing to the FDA or otherwise relying on any clinical trials using lentiviral vector vaccines developed or produced by Henogen.

On or about July 24, 2014, TVS also filed a motion for expedited proceedings in support of an anticipated motion for preliminary injunction. On August 8, 2014, the court granted TVS' motion for expedited proceedings and set a hearing date in mid-November 2014 for TVS' anticipated motion for preliminary injunction. In September 2014, TVS filed a motion to postpone the hearing date and delay the proceedings it previously sought to expedite. The court granted the motion and set a new date for the hearing. On or about December 15, 2014, TVS filed a motion for a preliminary injunction seeking, among other things, to enjoin us from making any use of lentiviral vectors pending final resolution of the litigation. A hearing was held on TVS's motion in January 2015.

By order dated March 9, 2015, the Chancery Court denied TVS' motion for a preliminary injunction. The court has not yet made any final determination on the merits of the lawsuit, which will be determined at a full trial. A trial date has not yet been set. We cannot predict the outcome of any trial on the merits. The Chancery Court ruled that TVS had not established a reasonable probability of success on the merits of most, but not all, of its claims. If we receive an adverse judgment, we could be subject to the payment of damages, which could have a material adverse effect on our financial position and results of operations. In addition, the Chancery Court could enter injunctive or other equitable relief of unknown scope, which could delay or prevent further development of CMB305, LV305 or other product candidates from our ZVex platform.

We have transitioned the manufacture of our lentiviral vectors to a new manufacturer to mitigate the risk of future supply interruptions. However, in the event we are unable to use any lentiviral vectors manufactured from our current manufacturer or any future manufacturer or the clinical data from the ongoing clinical trials of CMB305, LV305, prevented from conducting any new clinical trials using lentiviral vectors or otherwise prevented from developing, using or producing products using lentiviral vectors as a result of an injunction ordered by the Delaware Chancery Court after a trial on the merits or any other legal proceeding, the development of LV305 or any other product candidates from our ZVex platform could be substantially delayed and our business could be harmed. We also cannot be certain that TVS will not bring separate actions against us or our current or any future contract manufacturer which we may use to produce lentiviral vectors. Any such litigation could lead to delays in manufacturing doses of, or developing, CMB305, LV305 or other products candidates from our ZVex platform.

Ongoing legal proceedings with TheraVectys SA are time consuming and expensive and constitute a significant distraction to management, which could adversely affect our ability to execute on our business plan and have a material adverse effect on our business.

TVS is simultaneously pursuing its legal proceeding against us in the Chancery Court of the State of Delaware and a separate patent opposition proceeding at the EPO. While we did not initiate these proceedings, we are obligated to vigorously defend the company and protect our intellectual property. Litigation is expensive, particularly given the



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multiple jurisdictions and actions brought by TVS. The costs of defending these actions and protecting our rights have a material adverse effect on our results of operations through at least 2015. In addition, managing these actions is time consuming and results in significant distraction of management and operational resources, which could have a material adverse effect on our ability to execute on our business plan.

Our product candidates are in early stages of development. We cannot predict if we will receive regulatory approval to commercialize our product candidates.

All of our product candidates are in early stages of development, including product candidates that are in Phase 1 clinical development, and they will require extensive preclinical and clinical testing. We cannot predict with any certainty if or when we might submit a BLA for regulatory approval for any of our product candidates or whether any such BLA will be accepted for review by FDA, or whether any BLA will be approved upon review.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support our proposed indications. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and preclinical testing. If our clinical results are not successful, we may terminate the clinical trials for a product candidate and abandon any further research or testing of the product candidate. Any delay in, or termination of, our clinical trials will delay and possibly preclude the filing of any BLAs with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues.

If our product candidates fail to meet safety and efficacy endpoints in clinical trials, they will not receive regulatory approval, and we will be unable to market them.

Our product candidates may not prove to be safe and efficacious in clinical trials and may not meet all of the applicable regulatory requirements needed to receive regulatory approval. For example, while we have observed a complete response in a patient with a loco-regional Merkel cell tumor treated with G100 in an ongoing Phase 1 clinical trial, the results from our Phase 1 clinical trial are not yet final, and we cannot assure you that G100 will be efficacious in clinical trials, that the complete response was a result of being treated with G100 or that any response will be durable.

As part of the regulatory process, we must conduct clinical trials for each product candidate to demonstrate safety and efficacy to the satisfaction of the FDA and other regulatory authorities abroad. The number and design of clinical trials that will be required may vary depending on factors such as the product candidate, the condition being evaluated, results of the previous trial and regulations or guidance applicable to any particular product candidate. The design of our clinical trials is based on many assumptions about the expected effect of our product candidates, and if those assumptions prove incorrect, the clinical trials may not demonstrate the safety or efficacy of our product candidates. Preliminary results may not be confirmed upon full analysis of the detailed results of a trial, and prior clinical trial program designs and results may not be predictive of future clinical trial designs or results. Product candidates in later stage clinical trials may fail to show the desired safety and efficacy despite having progressed through initial clinical trials with acceptable endpoints. If our product candidates fail to meet the necessary safety or efficacy endpoints, we may not be able to receive regulatory approval.

If we experience delays in clinical testing, we will be delayed in commercializing our product candidates, our costs may increase and our business may be harmed.

We have not completed all the clinical trials necessary to support an application with the FDA for approval to market any of our product candidates. Our current and future clinical trials may be delayed or terminated as a result of many factors, including:

- efforts by TVS or others to slow down our clinical development, including through the entry of a permanent injunction or other equitable relief by the Chancery Court of Delaware after a trial on the merits in our ongoing litigation with TVS;

- delays in, or failure to obtain, approval from institutional review boards, or IRBs, or ethics committees, or ECs, or institutional biosafety committees, to begin clinical trials at study sites;

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imposition of a clinical hold by the FDA or other regulatory authorities, or a decision by the FDA, other regulatory authorities, IRBs, ECs, or recommendation by a data safety monitoring board, to suspend or terminate clinical trials at any time for safety issues or for any other reason;

- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites;
- deviations from the trial protocol by clinical trial sites and investigators, or failure to conduct the trial in accordance with regulatory requirements;
- failure of third parties, such as CROs, to satisfy their contractual duties or meet expected deadlines;
- delays in the testing, validation, manufacturing and delivery of the product candidates to the clinical sites;
  - for clinical trials in selected patient populations, delays in identification and auditing of central or other laboratories and the transfer and validation of assays or tests to be used to identify selected patients;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- delays caused by patients dropping out of a trial due to side effects, disease progression or other reasons;
- slow patient enrollment because of the perceived risk of contracting HIV because the viral vector we use in LV305 and CMB305 was constructed from genetic sequences, some of which were derived from HIV;
- withdrawal of clinical trial sites from our clinical trials as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials; or
- changes in government regulations or administrative actions or lack of adequate funding to continue the clinical trials.

Any inability of us or our partners to timely complete clinical development could result in additional costs to us or impair our ability to generate product revenues or development, regulatory, commercialization and sales milestone payments and royalties on product sales.

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

We may not be able to enroll a sufficient number of patients, or those with required or desired characteristics to complete our clinical trials in a timely manner. Patient enrollment is affected by factors including:

- the nature and size of the patient population;
  - the number and location of clinical sites we enroll;
  - competition with other companies for clinical sites or patients;
  - design of the trial protocol;
  - eligibility criteria for the study in question;
  - slow patient enrollment because of the perceived risk of contracting HIV because the viral vector we use in LV305 and CMB305 was constructed from genetic sequences, some of which were derived from HIV;
  - ability to obtain and maintain patient consents; and
  - clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.
- If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay or terminate ongoing or planned clinical trials, either of which would have an adverse effect on our business.

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Our product candidates may cause undesirable side effects or have other properties that could prevent their regulatory approval, limit the commercial scope of their approved uses, or result in significant negative consequences following any marketing approval.

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 other comparable foreign regulatory authorities. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. In such an event, 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. Drug-related side effects could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. 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 any such products, a number of potentially significant negative consequences could result, including:

- we may suspend marketing of, or withdraw or recall, such product;
- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- the FDA or other regulatory authorities may issue safety alerts, “Dear Healthcare Provider” letters, press releases or other communications containing warnings about such product;
- the FDA may require the establishment or modification of a Risk Evaluation and Mitigation Strategy, or REMS, or a comparable foreign regulatory authority may require the establishment or modification of a similar strategy that may, for instance, restrict distribution of our products and impose other implementation requirements on us;
- regulatory authorities may require that we conduct post-marketing studies;
- we could be sued and held liable for harm caused to subjects or patients; and
- our reputation may suffer.

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

We may be required to suspend, repeat, redesign or terminate our clinical trials if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive or the trials are not well designed. Clinical trials must be conducted in accordance with the FDA’s current Good Clinical Practices, or cGCP, or other applicable foreign government guidelines. Clinical trials are subject to oversight by the FDA, other foreign governmental agencies, IRBs and ECs at the study sites where the clinical trials are conducted. In addition, clinical trials must be conducted with product candidates produced in accordance with applicable current Good Manufacturing Practices, or cGMP. Clinical trials may be suspended by the FDA, other foreign governmental agencies, or us for various reasons, including:

- deficiencies in the conduct of the clinical trials, including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols;
- deficiencies in the clinical trial operations or trial sites;
- the product candidate may have unforeseen adverse side effects;
- deficiencies in the trial design necessary to demonstrate efficacy;
- fatalities or other adverse events arising during a clinical trial due to medical problems that may not be related to clinical trial treatments;
- the product candidate may not appear to be more effective than current therapies; or

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the quality or stability of the product candidate may fall below acceptable standards.

Our ZVex platform is novel, which may raise new regulatory issues that could delay or make regulatory approval of our product ZVex candidates more difficult.

The process of obtaining required FDA and other regulatory approvals, including foreign approvals, is expensive, often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. Because our ZVex platform is novel, regulatory agencies lack experience with product candidates such as LV305 and CMB305, which may lengthen the regulatory review process, increase our development costs and delay or prevent commercialization of our ZVex product candidates.

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. Our inability to obtain regulatory approval for our product candidates would substantially harm our business.

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any future product candidates will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval from the FDA or a comparable foreign regulatory authority for many reasons, including:

- disagreement with the design or implementation of our clinical trials;
- failure to demonstrate that a product candidate is safe and effective for its proposed indication;
- failure of clinical trials' endpoints to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- the insufficiency of data collected from clinical trials of our product candidates to support the submission and filing of a BLA or other submission or to obtain regulatory approval;
- failure to obtain approval of the manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies; or
- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval.

The FDA or a comparable foreign regulatory authority may require more information, including additional preclinical or clinical data to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. 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 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.

Regulatory authorities' assessment of the data and results required to demonstrate safety and efficacy can change over time and can be affected by many factors, such as the emergence of new information, including on other products, changing policies and agency funding, staffing and leadership.

Our failure to obtain regulatory approval in international jurisdictions would prevent us from marketing our product candidates outside the United States.

In order to market and sell our products in other jurisdictions, we must obtain separate marketing approvals for those jurisdictions and comply with their numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States

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generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, we must secure product reimbursement approvals before regulatory authorities will approve the product for sale in that country. 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. Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not ensure approval in any other country, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. Also, if regulatory approval for any of our product candidates is granted, it may be later withdrawn. If we fail to comply with the regulatory requirements in international markets and 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 and our business will be adversely affected. We may not obtain foreign regulatory approvals on a timely basis, if at all. Our failure to obtain approval of any of our product candidates by regulatory authorities in countries outside of the United States may significantly diminish the commercial prospects of that product candidate and our business prospects could decline.

Even if our product candidates receive regulatory approval, they may still face future development and regulatory difficulties.

Even if we obtain regulatory approval for a product candidate, it will be subject to ongoing regulation by the FDA and comparable foreign regulatory authorities, including requirements governing the manufacture, quality control, further development, labeling, packaging, tracking, storage, distribution, safety surveillance, import, export, advertising, promotion, record-keeping and reporting of safety and other post-market information. The FDA and comparable foreign regulatory authorities continue to closely monitor the safety profile of any product even after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of any of our product candidates, they may, among other measures, require labeling changes or establishment of a REMS or similar strategy, impose significant restrictions on a product's indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we or the manufacturing facilities for our product candidates, if approved, fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
  - mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
  - impose a consent decree, which can include various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
  - seek an injunction or other court actions to impose civil or criminal penalties or monetary fines;
  - suspend or withdraw regulatory approval;
  - suspend any ongoing clinical trials;
  - refuse to approve pending applications or supplements to applications filed by us;
  - suspend or impose restrictions on operations, including costly new manufacturing requirements; or
  - seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall.
- The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenue.

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Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the Department of Justice, the Department of Health and Human Services' Office of Inspector General, state attorneys general, members of Congress and the public. Violations, including promotion of our products for unapproved, or off-label, uses, may be subject to enforcement letters, inquiries and investigations, as well as civil and criminal sanctions. Additionally, comparable foreign regulatory authorities will heavily scrutinize advertising and promotion of any product candidate that obtains approval in their respective jurisdictions.

In the United States, engaging in the impermissible promotion of our products for off-label uses can also subject us to false claims litigation under federal and state statutes, which can lead to administrative, civil and criminal penalties, damages, monetary fines, disgorgement, individual imprisonment, exclusion from participation in Medicare, Medicaid and other federal healthcare programs, curtailment or restructuring of our operations and agreements that materially restrict the manner in which a company promotes or distributes drug products. These false claims statutes include, but are not limited to, the federal civil False Claims Act, which allows any individual to bring a lawsuit against an individual or entity, including a pharmaceutical or biopharmaceutical company on behalf of the federal government alleging the knowing submission of false or fraudulent claims, or causing to present such false or fraudulent claims, for payment or approval by a federal program such as Medicare or Medicaid. If the government decides to intervene and prevails in the lawsuit, the individual initiating the lawsuit will share in any fines or settlement funds. These False Claims Act lawsuits against pharmaceutical and biopharmaceutical companies have increased significantly in number and breadth, leading to several substantial civil and criminal settlements regarding certain sales practices, including promoting off-label drug uses involving fines in excess of \$1.0 billion. This growth in litigation has increased the risk that a pharmaceutical or biopharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations, and be excluded from Medicare, Medicaid and other federal and state healthcare programs. If we do not lawfully promote our approved products, we may become subject to such litigation, which have a material adverse effect on our business, financial condition and results of operations. Promotion prior to marketing approval or for off-label uses may also give rise to criminal prosecution in the European Union.

The FDA's and other applicable government agencies' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval, and thus the sale and promotion, of our product candidates. 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, which would adversely affect our business, prospects and ability to achieve or sustain profitability. Our product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

Even if our product candidates receive regulatory approval, they may not gain adequate market acceptance among physicians, patients, healthcare payors and others in the medical community. Our commercial success also depends on coverage and adequate reimbursement and pricing of our product candidates by third-party payors, including government payors, which may be difficult or time-consuming to obtain, may be limited in scope and may not be obtained in all jurisdictions in which we may seek to market our products. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including:

- the efficacy and safety profile as demonstrated in clinical trials;
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which the product candidate is approved;
- acceptance of the product candidate as a safe and effective treatment by physicians, clinics and patients;
- the potential and perceived advantages of product candidates over alternative treatments;
- the perceived risk of contracting HIV because the viral vector we use in LV305 and CMB305 was constructed from genetic sequences, some of which were derived from HIV;
- the cost of treatment in relation to alternative treatments;



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- the availability of coverage and adequate reimbursement and pricing by third-party payors, including government payors and the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors;
- the willingness of the target patient population to try new therapies based on new technologies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- relative convenience, frequency and ease of administration;
- the frequency and severity of adverse events;
- the effectiveness of sales and marketing efforts; and
- unfavorable publicity relating to the product candidate.

Our competitors may develop and market products that are less expensive, more effective, safer or reach the market sooner than our product candidates, which may diminish or eliminate the commercial success of any products we may commercialize.

The biotechnology industry is intensely competitive and subject to rapid and significant technological change. We face competition with respect to our current product candidates and will face competition with respect to any future product candidates from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Many of our competitors have significantly greater financial, technical and human resources. Smaller and early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our competitors may obtain regulatory approval of their product candidates more rapidly than we may or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products and these competitors may also be more successful than us in manufacturing and marketing their products.

Our competitors will also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Although there are only a few approved in vivo immuno-oncology therapies, there are numerous currently approved therapies to treat cancer. Many of these approved drugs are well-established therapies or products and are widely accepted by physicians, patients and third-party payors. Some of these drugs are branded and subject to patent protection, and others are available on a generic basis. Insurers and other third-party payors may also encourage the use of generic products or specific branded products. We expect that if our product candidates are approved, they will be priced at a significant premium over competitive generic, including branded generic, products. It may be difficult for us to differentiate our products from currently approved therapies, which may adversely impact our business strategy. In addition, many companies are developing new therapeutics, and we cannot predict what the standard of care will be as our product candidates progress through clinical development.

We believe that our ability to successfully compete will depend on, among other things:

- the efficacy and safety profile of our product candidates, including relative to marketed products and product candidates in development by third parties;
- the time it takes for our product candidates to complete clinical development and receive marketing approval;
  - the ability to commercialize any of our product candidates that receive regulatory approval;
- the price of our products, including in comparison to branded or generic competitors;
- whether coverage and adequate levels of reimbursement are available under private and governmental health insurance plans, including Medicare;

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the ability to establish, maintain and protect intellectual property rights related to our product candidates;  
the ability to manufacture commercial quantities of any of our product candidates that receive regulatory approval;  
and

acceptance of any of our product candidates that receive regulatory approval by physicians and other healthcare providers.

If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate or derive sufficient revenue from that product candidate and may not become or remain profitable.

We may encounter delays in our clinical enrollment or other unforeseen challenges because the viral vector used in LV305 and CMB305 was constructed from genetic sequences, some of which were derived from HIV.

The viral vector in our LV305 and CMB305 product candidates was constructed from many genetic sequences, some of which were derived from HIV. While the vector will not cause an HIV infection, patients may test positive for HIV under certain screening tests and perceive the use of our product candidates as putting themselves at risk of contracting HIV. We disclose the origination of the vector in the consent forms used in our trial enrollments, which may cause patients to be deterred from enrolling in our trials resulting in delays in the enrollment for our clinical trials. Furthermore, we may encounter other difficulties, such as lack of market adoption of any commercialized product candidate, due to the public's negative perception of the risk of contracting HIV.

We will need to develop or acquire additional capabilities in order to commercialize any product candidates that obtain regulatory approval, and we may encounter unexpected costs or difficulties in doing so.

We will need to acquire additional capabilities and effectively manage our operations and facilities to successfully pursue and complete future research, development and commercialization efforts. Currently, we have no experience in preparing applications for marketing approval, commercial-scale manufacturing, managing of large-scale information technology systems or managing a large-scale distribution system. We will need to add personnel and expand our capabilities, which may strain our existing managerial, operational, regulatory compliance, financial and other resources. To do this effectively, we must:

- train, manage and motivate a growing employee base;

- accurately forecast demand for our products; and

- expand existing operational, financial and management information systems.

We plan to conduct process development activities to support late stage development and commercialization activities and seek approval of our product candidates. Should we not receive timely approval of our production process, our ability to produce the immunotherapy products following regulatory approval for sale could be delayed, which would further delay the period of time when we would be able to generate revenues from the sale of such products, if we are even able to generate revenues at all.

We have no internal sales or marketing capability and may rely on alliances with others possessing such capabilities to commercialize our products successfully.

We intend to market our product candidates, if and when such product candidates are approved by the FDA or comparable foreign regulatory authorities, either directly or through other strategic alliances and distribution arrangements with third parties. There can be no assurance that we will be able to enter into third-party marketing or distribution arrangements on advantageous terms or at all. To the extent that we do enter into such arrangements, we will be dependent on our marketing and distribution partners. In entering into third-party marketing or distribution arrangements, we expect to incur significant additional expense. If we are unable to enter into such arrangements on acceptable terms, or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval. Depending on the nature of the third party relationship, we may have little control over such third parties, and any of these third parties may fail to devote the necessary resources and attention to sell, market and distribute our products effectively. If we are not successful in commercializing our product candidates,

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either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

We depend on key personnel for our continued operations and future success and a loss of certain key personnel could significantly hinder our ability to move forward with our business plan.

To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, technical and management personnel and we face significant competition for experienced personnel. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. In particular, the loss of one or more of our executive officers could be detrimental to us if we cannot recruit suitable replacements in a timely manner. The competition for qualified personnel in the immuno-oncology field is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary for the development of our business or to recruit suitable replacement personnel.

Many of the other biopharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover and develop product candidates and our business will be limited.

Even if we commercialize a product candidate, it or any other product candidates that we develop may become subject to unfavorable pricing regulations, third-party coverage or reimbursement practices or healthcare reform initiatives, which could harm our business.

Our ability to commercialize any product candidates successfully will depend in part on the extent to which coverage and adequate reimbursement for our product candidates will be available from government health administration authorities, private health insurers and other organizations. The laws that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval.

Current and future legislation may increase the difficulty and cost for us to commercialize our drug candidates and affect the prices we may obtain.

In the United States and many foreign jurisdictions, the legislative landscape continues to evolve. There have been a number of enacted or proposed legislative and regulatory changes affecting the healthcare system and pharmaceutical and biopharmaceutical industries that could, among other things, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidate for which we obtain marketing approval.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or, collectively, the Affordable Care Act. Among other things, the Affordable Care Act expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs, effective the first quarter of 2010 and revising the definition of "average manufacturer price," or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices. This could increase the amount of Medicaid drug rebates manufacturers are required to pay to states. The Affordable Care Act further created a separate AMP for certain categories of drugs generally provided in non-retail outpatient settings. The legislation also extended Medicaid drug rebates, previously due only on fee-for-service utilization, to Medicaid managed care utilization, and created an alternative rebate formula for certain new formulations of certain existing products that is intended to increase the amount of rebates due on those drugs. Also effective in 2010, the Affordable Care Act expanded the types of entities eligible to receive discounted 340B pricing, although, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs used in orphan indications.



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In addition, because 340B pricing is determined based on AMP and Medicaid drug rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discounts to increase. The Affordable Care Act also imposes a significant annual fee on companies that manufacture or import branded prescription drug products. Furthermore, as of 2011, this law changed the Medicare Part D coverage gap discount program by requiring manufacturers to provide a 50% point-of-sale-discount off the negotiated price of applicable brand drugs to certain eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D. Additionally, the Affordable Care Act created a new licensure framework for follow-on biologic products. The Affordable Care Act also created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with providing funding for such research. Additionally, the Affordable Care Act created the Independent Payment Advisory Board, which has the authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs and those recommendations could have the effect of law, even if Congress does not act on the recommendation. Furthermore, the Affordable Care Act established a Center for Medicare & Medicaid Innovation at the Centers for Medicare & Medicaid Services to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending. Substantial new provisions affecting compliance have also been enacted, which may affect our business practices with healthcare practitioners, as described in more detail below. Notably, a significant number of provisions are not yet, or have only recently become, effective.

Many of the details regarding the implementation of the Affordable Care Act are yet to be determined, and at this time, it remains unclear the full effect that the Affordable Care Act would have on our business. In particular, there is uncertainty surrounding the applicability of the biosimilars provisions under the Affordable Care Act to our product candidates. FDA's implementation of the biosimilars provisions is at an early stage. Depending on how FDA's regulation of biosimilars evolves, we may be required to change our current strategies.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least \$1.2 trillion for fiscal years 2012 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2%, starting in 2013. The Bipartisan Budget Act of 2013, enacted on December 26, 2013, and Public Law 113-82, enacted on February 15, 2014, expanded sequestration through fiscal year 2024. These cuts will occur unless Congress repeals or amends the reductions in future legislation. Continuation of sequestration or enactment of other reductions in Medicare reimbursement for drugs could affect our ability to achieve a profit on any candidate products that are approved for marketing. Moreover, the recently enacted Drug Supply Chain Security Act imposes new obligations on manufacturers of pharmaceutical products, related to product tracking and tracing. Among the requirements of this new legislation, manufacturers will be required to provide certain information regarding drug products to individuals and entities to which product ownership is transferred, label drug product with a product identifier, and keep certain records regarding the drug product. The transfer of information to subsequent product owners by manufacturers will eventually be required to be done electronically. Manufacturers will also be required to verify that purchasers of the manufacturers' products are appropriately licensed. Further, manufacturers will have drug product investigation, quarantine, disposition, and notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products, as well as products that are the subject of fraudulent transactions or that are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death. In the European Union, the Falsified Medicines Directive imposes similar requirements which are expected to add materially to product costs.

In addition to federal reforms, individual states have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and designed to encourage importation from other countries and bulk purchasing.



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Legally-mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce ultimate demand for our products or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

In addition, given recent federal and state government initiatives directed at lowering the total cost of healthcare, Congress and state legislatures will likely continue to focus on healthcare reform, the cost of prescription drugs and biologics and the reform of the Medicare and Medicaid programs. While we cannot predict the full outcome of any such legislation, it may result in decreased reimbursement for drugs and biologics, which may further exacerbate industry-wide pressure to reduce prescription drug prices. This could harm our ability to generate revenues. In addition, legislation has been introduced that, if enacted, would permit more widespread importation or re-importation of pharmaceutical products from foreign countries into the United States, including from countries where the products are sold at lower prices than in the United States. Such legislation, or similar regulatory changes, could put competitive pressure on our ability to profitably price our products, which, in turn, could adversely affect our business, results of operations, financial condition and prospects. Alternatively, in response to legislation such as this, we might elect not to seek approval for or market our products in foreign jurisdictions in order to minimize the risk of re-importation, which could also reduce the revenue we generate from our product sales.

We expect that the Affordable Care Act, as well as other healthcare reform measures that have and may be adopted in the future, may result in more rigorous coverage criteria and exert downward pressure on the price that we receive for any approved product, and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate sufficient revenue, attain profitability or successfully commercialize our products. The full impact of these new laws, as well as laws and other reform measures that may be proposed and adopted in the future, remains uncertain, but may continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs, which could have a material adverse effect on our business operations.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of our product candidates.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human trials and may face greater risk if we commercialize any products that we develop. Product liability claims may be brought against us by subjects enrolled in our trials, patients, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against such claims, we could incur substantial liabilities.

Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our products;
- termination of clinical trial sites or entire trial programs;
- injury to our reputation and significant negative media attention;
- withdrawal of trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial subjects or patients;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize any products that we may develop.

While we currently hold \$5.0 million in trial liability insurance coverage, this may not adequately cover all liabilities that we may incur. We also may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise in the future. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain marketing approval for our product candidates, but we may be unable to obtain commercially reasonable product liability insurance. A successful product liability



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claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business and financial condition.

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse, transparency 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 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 that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include, but are not limited to, the following:

- the federal Anti-Kickback Statute prohibits persons from, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, the referral of an individual for the furnishing or arranging for the furnishing, or the purchase, lease or order, or arranging for or recommending purchase, lease or order, any good or service for which payment may be made under a federal healthcare program such as Medicare and Medicaid;

- the federal false claims laws impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to 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, imposes criminal liability for knowingly and willfully executing a scheme to defraud any healthcare benefit program, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense, or knowingly and willfully making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and its implementing regulations, also imposes obligations on certain covered entity health care providers, health plans, and health care clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the Physician Payment Sunshine Act (federal Open Payments program), created under Section 6002 of the Affordable Care Act and its implementing regulations, requires manufacturers of drugs, devices, biologics 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 U.S. Department of Health and Human Services information related to "payments or other transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to the U.S. Department of Health and Human Services ownership and investment interests held by physicians (as defined above) and their immediate family members;

- 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

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state and foreign laws that govern 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.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, that person or entity may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

### **Risks Related to our Dependence on Third Parties**

We rely on the assistance of third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties, comply with budgets and other financial obligations or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates in a timely or cost-effective manner.

We rely, and expect to continue to rely, on the assistance of third-party CROs to conduct our clinical trials. Because we do not conduct our own clinical trials, we must rely on the efforts of others and cannot always control or accurately predict the timing of such trials, the costs associated with such trials or the procedures that are followed for such trials. We do not anticipate significantly increasing our personnel in the foreseeable future and therefore, expect to continue to rely on the assistance of third parties to conduct our future clinical trials. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they do not carry out the trials in accordance with budgeted amounts, if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or for other reasons, or if they fail to maintain compliance with applicable government regulations and standards, our clinical trials may be extended, delayed or terminated or may become prohibitively expensive, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.

We currently depend on third parties for the development and commercialization of our non-cancer treatment product candidates.

We have entered into exclusive licenses and development agreements with MedImmune pursuant to which we have granted MedImmune exclusive licenses to develop and commercialize product candidates relating to certain infectious diseases. We also have entered into an exclusive license agreement with Sanofi for use of our GLAAS discovery platform to develop therapeutic agents to treat a selected food allergy and a collaboration agreement with Sanofi Pasteur for the development of a herpes simplex virus immune therapy. We cannot control whether or not these partners will devote sufficient time and resources to the ongoing clinical and preclinical programs or whether these partners will fulfill their obligations under the agreements. The product candidates developed pursuant to these agreements may not be scientifically, medically or commercially successful.

In addition, we could be adversely affected by:

- our partners' failure to timely perform their obligations under our agreements;
- our partners' failure to timely or fully develop or effectively commercialize the product candidates; and
- a material contractual dispute between us and our partners.

Any of the foregoing could adversely impact the likelihood and timing of any milestone or royalty payments we are eligible to receive from MedImmune, Sanofi or Sanofi Pasteur, and could result in a material adverse effect on our business, results of operations and prospects and would likely cause our stock price to decline.

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We may not succeed in establishing and maintaining additional development collaborations, which could adversely affect our ability to develop and commercialize product candidates.

In addition to our current agreements with MedImmune, Sanofi and Sanofi Pasteur, a part of our strategy is to enter into additional product development collaborations in the future, including collaborations with major biotechnology or pharmaceutical companies. We face significant competition in seeking appropriate development partners and the negotiation process is time-consuming and complex. Moreover, we may not succeed in our efforts to establish a development collaboration or other alternative arrangements for any of our other existing or future product candidates and programs because our research and development pipeline may be insufficient, our product candidates and programs may be deemed to be at too early a stage of development for collaborative effort and third parties may not view our product candidates and programs as having the requisite potential to demonstrate safety and efficacy. Even if we are successful in our efforts to establish new development collaborations, the terms that we agree upon may not be favorable to us and we may not be able to maintain such development collaborations if, for example, development or approval of a product candidate is delayed or sales of an approved product candidate are disappointing.

Moreover, if we fail to establish and maintain additional development collaborations related to our product candidates: the development of certain of our current or future product candidates may be impaired or delayed;

- our cash expenditures related to development of certain of our current or future product candidates would increase significantly and we may need to seek additional financing;
- we may be required to hire additional employees or otherwise develop expertise, such as sales and marketing expertise, for which we have not budgeted; and
- we will bear all of the risk related to the development of any such product candidates.

If we enter into one or more collaborations, we may be required to relinquish important rights to and control over the development of our product candidates or otherwise be subject to unfavorable terms.

Any future collaborations we enter into could subject us to a number of risks, including:

- we may not be able to control the amount and timing of resources that our collaborators devote to the development or commercialization of our product candidates;
- collaborators may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new version of a product candidate for clinical testing;
- collaborators may not pursue further development and commercialization of products resulting from the strategic partnering arrangement or may elect to discontinue research and development programs;
- collaborators may not commit adequate resources to the marketing and distribution of our product candidates, limiting our potential revenues from these products;
- disputes may arise between us and our collaborators that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and consumes resources;
- collaborators may experience financial difficulties;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- business combinations or significant changes in a collaborator's business strategy may also adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;
- collaborators could decide to move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- collaborators could terminate the arrangement or allow it to expire, which would delay the development and may increase the cost of developing our product candidates.

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We have no internal manufacturing capacity and anticipate continued reliance on third-party manufacturers for the development and commercialization of our products.

We do not currently operate manufacturing facilities for clinical or commercial production of our product candidates. We have limited experience in manufacturing our product candidates, and we lack the resources and the capabilities to do so on a clinical or commercial scale. We do not intend to develop facilities for the manufacture of products for clinical trials or commercial purposes in the foreseeable future. We rely on third-party contract manufacturing organizations, or CMOs, to produce bulk drug substance and formulated drug products as well as fill/finish required for our clinical trials. We plan to continue to rely upon CMOs and, potentially, collaboration partners, to manufacture commercial quantities of our product candidates. We do not have a long-term commercial supply arrangement in place with any of our contract manufacturers. If we need to identify additional manufacturers, we may experience delay and additional cost. We have not secured commercial supply agreements with any contract manufacturers and can give no assurance that we will enter commercial supply agreements with any contract manufacturers on favorable terms or at all.

Our contract manufacturers' failure to achieve and maintain high manufacturing standards, in accordance with applicable regulatory requirements, or the incidence of manufacturing errors, could result in patient injury or death, product shortages, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously harm our business. Contract manufacturers often encounter difficulties involving production yields, quality control and quality assurance, as well as shortages of qualified personnel. Our existing manufacturers and any future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business. In the event of a natural disaster, business failure, strike or other difficulty, we may be unable to replace a third-party manufacturer in a timely manner and the production of our product candidates would be interrupted, resulting in delays and additional costs.

Manufacturers have limited or no experience producing our product candidates and may not produce our vectors and product candidates at the quality, quantities and timing needed to support clinical trials or commercialization.

The components of our product candidates are difficult to make and require technical expertise. No manufacturer currently has the experience or ability to produce our vectors and product candidates at commercial levels. Our CMOs may encounter technical or scientific issues related to manufacturing or process development that we may be unable to resolve in a timely manner or with available funds, which could delay our clinical trials.

We currently obtain several components of our product candidates, such as the full length NY-ESO-1 protein in CMB305, from a single source. The loss of our current CMO could result in manufacturing delays for the component substitution, and we may need to accept changes in terms or price from our existing supplier in order to avoid such delays. If we utilize an alternative source, we may be required to demonstrate comparability of the drug product before releasing the product for clinical use.

### **Risks Related to Intellectual Property**

If we are unable to obtain or protect intellectual property rights, we may not be able to compete effectively in our market.

Our success depends in significant part on our and our licensor's and licensees' ability to establish, maintain and protect patents and other intellectual property rights and operate without infringing the intellectual property rights of others.

We have filed patent applications both in the United States and in foreign jurisdictions to obtain patent rights to inventions we have discovered. We have also licensed from third parties rights to patent portfolios. Some of these licenses give us the right to prepare, file and prosecute patent applications and maintain and enforce patents we have licensed, and other licenses may not give us such rights.

The patent prosecution process is expensive and time-consuming, and we and our current or future licensors and licensees may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our licensors or licensees will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to

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obtain patent protection on them. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and are reliant on our licensors or licensees. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. If our current or future licensors or licensees fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our licensors or licensees are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors' or licensees' patent rights are highly uncertain. Our and our licensors' or licensees' pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. The patent examination process may require us or our licensors or licensees to narrow the scope of the claims of our or our licensors' or licensees' pending and future patent applications, which may limit the scope of patent protection that may be obtained. We may be required to disclaim part or all of the term of certain patents or part or all of the term of certain patent applications.

There are no assurances that our patent counsel, lawyers or advisors have given us correct advice or counsel. Opinions from such patent counsel or lawyers may not be correct or based on incomplete facts. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. Even if patents do successfully issue and even if such patents cover our product candidates, third parties may challenge their validity, enforceability or scope. No assurance can be given that if challenged, our patents would be declared by a court to be valid or enforceable or that even if found valid and enforceable, a competitor's technology or product would be found by a court to infringe our patents. The possibility exists that others will develop products which have the same effect as our products on an independent basis which do not infringe our or our licensor's patents or other intellectual property rights, or will design around the claims of patents that we have had issued that cover our products. We may analyze patents or patent applications of our competitors that we believe are relevant to our activities, and consider that we are free to operate in relation to our product candidates, but our competitors may achieve issued claims, including in patents we consider to be unrelated, which block our efforts or may potentially result in our product candidates or our activities infringing such claims. Our and our licensors' or licensees' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover the technology. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

In addition, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from biosimilar or generic products. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. We expect to seek extensions of patent terms where these are available in any countries where we are prosecuting patents. However, the applicable authorities, including the U.S. Patent and Trademark Office, or USPTO, and FDA 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 take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.



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

Filing, prosecuting, enforcing and defending patents on product candidates in all countries throughout the world is prohibitively expensive, and our or our current or future licensors' intellectual property rights in some countries outside the United States can be less extensive than those in the United States. Moreover, the standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology patents. In addition, even where patent protection is obtained, third-party competitors may challenge our patent claims in the various patent offices. For example, in February 2013, a third party filed an opposition at the European Patent Office, or EPO, requesting revocation of European Patent No. 2068918 directed to GLA formulations and uses. This patent is licensed to us by the Infectious Disease Research Institute, or IDRI, and is an important part of our proprietary position for GLA in Europe. We are vigorously defending the grant of this patent, however the final outcome of the proceedings is uncertain and will likely not be known for several years. We cannot be certain that this patent will be maintained by the EPO. Moreover, it is possible that the patent will be maintained, but in a limited scope, and we cannot predict if such a scope would adequately cover our products. Revocation of this patent, or maintenance of an amended patent with inadequate coverage could impair our ability to prevent competition from third parties in Europe, which could have an adverse impact on our business.

The laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. For example, some of our patents relate to treatment methods or dosing regimens that are not considered patentable subject matter in some foreign countries. Consequently, we and our licensors may not be able to prevent third parties from practicing our and our licensors' inventions in 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 and our licensors' 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 and our licensors have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates and our and our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in 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 and our licensors to stop the infringement of our and our licensors' patents or marketing of competing products in violation of our and our licensors' proprietary rights generally. Proceedings to enforce our and our licensors' patent rights in foreign jurisdictions could result in substantial costs and divert our 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 requirements for patentability may differ in certain countries, particularly developing countries. Furthermore, generic drug 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 drug manufacturers may develop, seek approval for, and launch generic versions of our products. Certain countries in Europe and developing countries, including China, have compulsory licensing laws under which a patent owner may be compelled 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.

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Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve technological and legal complexity, and obtaining and enforcing biopharmaceutical patents is costly, time-consuming, and inherently uncertain. The 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 may weaken our and our licensors' ability to obtain new patents or to enforce existing patents and patents we and our licensors or collaborators may obtain in the future.

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. On September 16, 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 are prosecuted and may also affect patent litigation. The USPTO recently developed new 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, only became effective on 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 or our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents, all of which could have a material adverse effect on our business and financial condition.

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

Periodic maintenance and annuity 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. Non-compliance events that could result in abandonment or lapse of a patent or patent application include 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 or collaborators fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which would have a material adverse effect on our business.

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.

Third parties may infringe our or our licensors' or collaborators' patents or misappropriate or otherwise violate our or our licensors' or collaborators' intellectual property rights. In the future, we or our licensors or collaborators may initiate legal proceedings to enforce or defend our or our licensors' or collaborators' intellectual property rights, to protect our or our licensors' or collaborators' trade secrets or to determine the validity or scope of intellectual property rights we own or control. Also, third parties may initiate legal proceedings against us or our licensors or collaborators to challenge the validity or scope of intellectual property rights we own or control. The proceedings can be expensive and time-consuming and many of our or our licensors' or collaborators' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors or collaborators can. Accordingly, despite our or our licensors' or collaborators' efforts, we or our licensors or collaborators may not prevent third parties from infringing upon or misappropriating intellectual



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property rights we own or control, particularly in countries where the laws may not protect those rights as fully as in the United States. 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 for various reasons, including on the grounds that our or our licensors' or collaborators' patents do not cover the technology in question. An adverse result in any litigation proceeding could result in one or more of our or our licensors' or collaborators' patents being invalidated, held unenforceable or interpreted narrowly.

Third-party preissuance submission of prior art to the USPTO, or opposition, derivation, reexamination, inter partes review or interference proceedings, or other preissuance or post-grant proceedings in the United States or other jurisdictions provoked by third parties or brought by us or our licensors or collaborators may be instituted with respect to our or our licensors' or collaborators' patents or patent applications. An unfavorable outcome of a third-party challenge to our owned or licensed patents or patent applications could include a determination of unpatentability, invalidity or a narrowing amendment to our patents. An unfavorable outcome in an interference proceeding that awards our patent claims to a third party could require us or our licensors or collaborators to cease using related technology. Our business could be harmed if the prevailing party does not offer us or our licensors or collaborators a license on commercially reasonable terms or at all. Even if we or our licensors or collaborators obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors or collaborators. In addition, if the breadth or strength of protection provided by our or our licensors' or collaborators' patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Even if we successfully defend such litigation or proceeding, we may incur substantial costs and it may distract our management and other employees. We could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent.

For example, in February 2013, a third party filed an opposition at the EPO, requesting revocation of European Patent No. 2068918 directed to GLA formulations and uses. We licensed this patent from IDRI. We are vigorously defending the grant of this patent. This patent is an important part of our proprietary position for GLA in Europe. The final outcome of the proceedings is uncertain and will likely not be known for several years.

An unfavorable outcome could require us or our licensors, collaborators or suppliers to cease using the related technology or developing or commercializing our product candidates, or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our licensors, collaborators or suppliers a license on commercially reasonable terms or at all. Even if we or our licensors, collaborators or suppliers obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors, collaborators or suppliers. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our drug candidates or force us to cease some of our business operations, which could materially harm our business.

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. 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.

If we breach the agreements under which third parties have licensed intellectual property rights to us, we could lose the ability to use certain of our technologies or continue the development and commercialization of our product candidates.

Our commercial success depends upon our ability to identify, test, develop, manufacture, market and sell product candidates and use our and our licensors' or collaborators' proprietary technologies without infringing the proprietary rights of third parties. Pursuant to the license agreement with IDRI, we obtained licensing rights to certain GLA technologies, which we utilize in the development of our GLA product candidates. Similarly, under our licenses with Caltech and UNC Chapel Hill, we obtained rights to certain patents which we utilize in the



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development of our ZVex based product candidates. If we fail to comply with the obligations under the license agreements, including a material breach by us, certain insolvency events or failure to diligently pursue the development of products, the other party may have the right to terminate the license agreements. In addition, IDRI may terminate our licenses in the event we challenge the validity, enforceability or scope of any patent licensed to us by IDRI. In the event one of these licenses is terminated, we will not be able to develop, manufacture, market or sell any product candidate that is covered by the license agreement. Such an occurrence would adversely affect our ability to continue to develop our current product candidates as well as potential future product candidates. Termination of any of these licenses or reduction or elimination of our rights under any license agreement may result in our having to negotiate a new or reinstated agreement, which may not be available to us on equally favorable terms, or at all, or cause us to lose our rights under the license agreement, including our rights to intellectual property or technology important to our development programs.

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

Many of our 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 executed proprietary rights, non-disclosure and non-competition 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 confidential information or intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defending against claims of misappropriation of trade secrets could be costly and time consuming, regardless of the outcome. If we fail in prosecuting or 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 successfully prosecute or defend against such claims, litigation could result in substantial costs and distract management. For example, we are currently defending against a lawsuit initiated by TVS claiming, among other things, that we misappropriated TVS' trade secrets. While we intend to vigorously defend against these claims and we believe TVS has not established a reasonable likelihood of success on the merits with respect to these claims, we cannot guarantee the outcome in a trial on the merits.

Our inability to protect our confidential information and trade secrets would harm our business and competitive position.

In addition to seeking patents for some of our technology and products, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts both within and outside the United States may be less willing or unwilling to protect trade secrets. If a competitor lawfully obtained or independently developed any of our trade secrets, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position.

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### Risks Related to Ownership of Our Common Stock

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

The trading price of our common stock has been and is likely to continue to be highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. In addition to the factors discussed in this “Risk Factors” section and elsewhere in this report, these factors include:

- the success of competitive products or technologies;
- regulatory actions with respect to our products or our competitors’ products;
- actual or anticipated changes in our growth rate relative to our competitors;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- results of clinical trials of our product candidates or those of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to in-license or acquire additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our officers, directors, or their affiliated funds or our other stockholders;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- rumors or new announcements by third parties, including competitors; and
- general economic, industry and market conditions.

In addition, the stock market in general, and The NASDAQ Global Market, or NASDAQ, and biotechnology 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. The realization of any of the above risks or any of a broad range of other risks, including those described in this “Risk Factors” section, could have a dramatic and material adverse impact on the market price of our common 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.

As of June 30, 2015, our executive officers, directors and holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 60% of our voting stock. These stockholders may have the ability to control us through this ownership position and be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests

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and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

We are an “emerging growth company” as defined in the JOBS Act and will be able to avail ourselves of reduced disclosure requirements applicable to emerging growth companies, which could make our common stock less attractive to investors and adversely affect the market price of our common stock.

For so long as we remain an “emerging growth company” as defined in the JOBS Act, we may take advantage of certain exemptions from various requirements applicable to public companies that are not “emerging growth companies” including:

- the provisions of Section 404(b) of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, requiring that our independent registered public accounting firm provide an attestation report on the effectiveness of our internal control over financial reporting;

- the “say on pay” provisions (requiring a non-binding shareholder vote to approve compensation of certain executive officers) and the “say on golden parachute” provisions (requiring a non-binding shareholder vote to approve golden parachute arrangements for certain executive officers in connection with mergers and certain other business combinations) of the Dodd-Frank Wall Street Reform and Protection Act, or Dodd-Frank Act, and some of the disclosure requirements of the Dodd-Frank Act relating to compensation of our chief executive officer;

- the requirement to provide detailed compensation discussion and analysis in proxy statements and reports filed under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and instead provide a reduced level of disclosure concerning executive compensation; and

- any rules that the Public Company Accounting Oversight Board may adopt requiring mandatory audit firm rotation or a supplement to the auditor’s report on the financial statements.

We may take advantage of these exemptions until we are no longer an “emerging growth company.” We would cease to be an “emerging growth company” upon the earliest of: (i) the first fiscal year following the fifth anniversary of our initial public offering in July 2014; (ii) the first fiscal year after our annual gross revenues are \$1.0 billion or more; (iii) the date on which we have, during the previous three-year period, issued more than \$1.0 billion in non-convertible debt securities; or (iv) as of the end of any fiscal year in which the market value of our common stock held by non-affiliates exceeded \$700.0 million as of the end of the second quarter of that fiscal year.

We currently take advantage of some, but not all, of the reduced regulatory and reporting requirements that will be available to us so long as we qualify as an “emerging growth company.” For example, we have irrevocably elected not to take advantage of the extension of time to comply with new or revised financial accounting standards available under Section 102(b) of the JOBS Act. Our independent registered public accounting firm will not be required to provide an attestation report on the effectiveness of our internal control over financial reporting so long as we qualify as an “emerging growth company,” which may increase the risk that material weaknesses or significant deficiencies in our internal control over financial reporting go undetected. Likewise, so long as we qualify as an “emerging growth company,” we may elect not to provide you with certain information, including certain financial information and certain information regarding compensation of our executive officers, that we would otherwise have been required to provide in filings we make with the SEC which may make it more difficult for investors and securities analysts to evaluate our company. 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 and may decline.

We incur significant increased costs as a result of operating as a public company, and our management devotes substantial time to meet compliance obligations.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act as well as rules subsequently implemented by the SEC and NASDAQ, that impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in

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corporate governance practices. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and financial condition. In addition, on July 21, 2010, 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. The requirements of these rules and regulations will increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and may also place undue strain on our personnel, systems and resources. Our management and other personnel will need to devote a substantial amount of time to these new compliance initiatives.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall. Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock. Certain of our existing stockholders are subject to lockup agreements with the underwriters of our follow-on public offering, which we closed in April 2015. At the close of trading on July 14, 2015, approximately 7,981,214 shares, which were subject to lock-up agreements, became eligible for sale.

Our common stock is thinly traded and in the future, may continue to be thinly traded, and our stockholders may be unable to sell at or near asking prices or at all if they need to sell their shares to raise money or otherwise desire to liquidate such shares.

To date, we have a low volume of daily trades in our common stock on NASDAQ. For example, the average daily trading volume in our common stock on NASDAQ during the six months ended June 30, 2015 was approximately 100,000 shares per day. Our stockholders may be unable to sell their common stock at or near their asking prices or at all, which may result in substantial losses to our stockholders.

The market for our common stock may be characterized by significant price volatility when compared to seasoned issuers, and we expect that our share price will be more volatile than a seasoned issuer for the indefinite future. As noted above, our common stock may be sporadically and/or thinly traded. As a consequence of this lack of liquidity, the trading of relatively small quantities of shares by our stockholders may disproportionately influence the price of those shares in either direction. The price for our shares could, for example, decline significantly in the event that a large number of our common stock are sold on the market without commensurate demand, as compared to a seasoned issuer that could better absorb those sales without adverse impact on its share price.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would benefit our stockholders and may prevent attempts by our stockholders to replace or remove our current management.

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Provisions in our amended and restated certificate of incorporation and amended and restated bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders, or remove our current management. These provisions include:

- authorizing the issuance of “blank check” preferred stock, the terms of which we may establish and shares of which we may issue without stockholder approval;
- prohibiting cumulative voting in the election of directors, which would otherwise allow for less than a majority of stockholders to elect director candidates;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, who are responsible for appointing the members of our management. Because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or the DGCL, which may discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our stockholders. Under the DGCL, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other things, the board of directors has approved the transaction. Any provision of our amended and restated certificate of incorporation or amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change of control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

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

Use of Proceeds

On July 23, 2014, our registration statement on Form S-1 (File No. 333-196979) relating to the IPO was declared effective by the SEC, pursuant to which we registered an aggregate of 5,750,000 shares of our common stock for an aggregate offering amount of \$74.9 million. On July 29, 2014, we issued and sold 5,000,000 shares of our common stock at an initial public offering price of \$12.00 per share. In August 2014, we sold an additional 410,564 shares of our common stock directly to the underwriters when they partially exercised their over-allotment option at \$12.00 per share. We sold an aggregate of 5,410,564 shares of our common stock in the IPO and received net proceeds of \$57.8 million, after deducting underwriting discounts and commissions of \$4.5 million and expenses of \$2.6 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. On August 26, 2014, we completed the IPO. Jefferies LLC and Leerink Partners LLC acted as joint book-running managers and Wells Fargo Securities, LLC acted as lead manager for the IPO.

We expect to use the net proceeds from the IPO: (i) to fund Phase 2 clinical trials of CMB305, including completion of a randomized, clinical trial in a high-incidence tumor; (ii) to fund an exploratory trial of LV305 with a checkpoint inhibitor in melanoma patients who have had an inadequate response to anti-PD1 therapy; (iii) to fund an additional Phase 1 clinical trial of G100 in a second indication; and (iv) for working capital and general corporate purposes. There has been no material change in the planned use of proceeds from the IPO as described in our Annual Report on Form 10-K for the year ended December 31, 2014.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which is incorporated herein by reference.

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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.

Immune Design Corp.  
(Registrant)

Date: August 12, 2015

/s/ Carlos Paya, M.D., Ph.D.  
Carlos Paya, M.D., Ph.D.  
President and Chief Executive Officer  
(Principal Executive Officer)

Date: August 12, 2015

/s/ Stephen Brady  
Stephen Brady  
Executive Vice President, Strategy & Finance  
(Principal Accounting Officer and Principal Financial Officer)

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EXHIBIT INDEX

Exhibit

No.	Description
3.1	Amended and Restated Certificate of Incorporation of the Company (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the SEC on July 29, 2014).
3.2	Amended and Restated Bylaws of the Company (incorporated herein by reference to Exhibit 3.4 to the Company's Registration Statement on Form S-1 (File No. 333-196979), as filed with the SEC on June 23, 2014).
4.1	Specimen Common Stock Certificate of the Company (incorporated herein by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1 (File No. 333-196979), as filed with the SEC on June 23, 2014).
10.1	Separation and Consulting Agreement, between the Company and J. Paul Rickey, dated May 31, 2015.
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
32.1*	Certifications of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certifications of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	Financial statements from the Quarterly Report on Form 10-Q of Immune Design Corp. for the quarter ended June 30, 2015, formatted in XBRL (eXtensible Business Reporting Language): (i) the Balance Sheets, (ii) the Statements of Comprehensive Loss, (iii) the Statements of Stockholders' Deficit, (iv) the Statements of Cash Flow and (v) Notes to Financial Statements.
Furnished herewith and not deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act.	