

Immune Design Corp.  
Form 10-Q  
September 08, 2014  
Table of Contents

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, 2014  
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  
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

26-2007174  
(IRS Employer  
Identification No.)

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

Indicate by check mark whether the registrant has submitted electronically 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  Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company

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

As of September 4, 2014, the number of outstanding shares of the registrant's common stock was 16,860,637.



Table of Contents

## TABLE OF CONTENTS

	Page
<u>NOTE REGARDING FORWARD-LOOKING STATEMENTS</u>	<u>3</u>
<u>PART I. FINANCIAL INFORMATION</u>	<u>4</u>
Item 1. <u>Financial Statements (Unaudited)</u>	<u>4</u>
<u>Condensed Balance Sheets as of June 30, 2014 and December 31, 2013</u>	<u>4</u>
<u>Condensed Statements of Operations for the Three and Six Months Ended June 30, 2014 and 2013</u>	<u>5</u>
<u>Condensed Statements of Cash Flows for the Six Months Ended June 30, 2014 and 2013</u>	<u>6</u>
<u>Notes to Condensed Financial Statements</u>	<u>7</u>
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>18</u>
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>24</u>
Item 4. <u>Controls and Procedures</u>	<u>24</u>
<u>PART II. OTHER INFORMATION</u>	<u>26</u>
Item 1. <u>Legal Proceedings</u>	<u>26</u>
Item 1A. <u>Risk Factors</u>	<u>27</u>
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>52</u>
Item 3. <u>Defaults Upon Senior Securities</u>	<u>52</u>
Item 4. <u>Mine Safety Disclosures</u>	<u>52</u>
Item 5. <u>Other Information</u>	<u>52</u>
Item 6. <u>Exhibits</u>	<u>52</u>

In this report, unless otherwise stated or the context otherwise indicates, references to "Immune Design," "the Company," "we," "us," "our" and similar references refer to Immune Design Corp. The Immune Design logo, "IMDZVex," "ZVex," and "GLASS" are our unregistered trademarks. All other trademarks, registered trademarks and trade names appearing in this report are the property of their respective holders.

Table of Contents

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.

Table of Contents

## PART I. FINANCIAL INFORMATION

## Item 1. Financial Statements

## IMMUNE DESIGN CORP.

## BALANCE SHEETS

(in thousands, except share and per share amounts)

	June 30, 2014 (unaudited)	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	\$ 18,003	\$ 30,387
Accounts receivable	1,038	87
Inventory	19	17
Prepaid expenses	969	179
Total current assets	20,029	30,670
Property and equipment, net	290	295
Deferred offering costs	1,765	—
Total assets	\$ 22,084	\$ 30,965
Liabilities, convertible preferred stock, and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable	\$ 1,369	\$ 866
Accrued liabilities	1,452	1,082
Deferred rent, current	36	27
Total current liabilities	2,857	1,975
Deferred rent, noncurrent	76	94
Convertible preferred stock warrant liability	7,486	3,336
Commitments and contingencies:		
Convertible preferred stock, \$0.001 par value per share; 12,882,593 and 12,882,593 shares authorized at June 30, 2014 (unaudited) and December 31, 2013, respectively; 9,769,422 and 9,769,422 shares issued and outstanding at June 30, 2014 (unaudited) and December 31, 2013, respectively; liquidation preference of \$84,300 and \$84,300 at June 30, 2014 (unaudited) and December 31, 2013, respectively	81,394	81,394
Stockholders' (deficit) equity:		
Common stock, \$0.001 par value per share; 15,045,871 and 15,045,871 shares authorized at June 30, 2014 (unaudited) and December 31, 2013, respectively; 369,750 and 369,460 shares issued and outstanding at June 30, 2014 (unaudited) and December 31, 2013, respectively	3	3
Additional paid-in capital	1,229	775
Accumulated deficit	(70,961)	(56,612)
Total stockholders' (deficit) equity	(69,729)	(55,834)
Total liabilities, convertible preferred stock and stockholders' (deficit) equity	\$ 22,084	\$ 30,965

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



Table of Contents

## IMMUNE DESIGN CORP.

## STATEMENTS OF OPERATIONS

(in thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
	(unaudited)			
Revenues:				
Licensing revenue	\$1,000	\$514	\$1,000	\$704
Product sales	64	368	89	742
Other, net	—	—	—	—
Total revenues	1,064	882	1,089	1,446
Operating expenses:				
Cost of product sales	18	250	32	462
Research and development	3,883	3,356	7,961	5,899
General and administrative	1,850	914	3,296	1,695
Total operating expenses	5,751	4,520	11,289	8,056
Loss from operations	(4,687	) (3,638	) (10,200	) (6,610
Interest and other income	—	4	1	35
Change in fair value of convertible preferred stock warrant liability	(1,439	) —	(4,150	) —
Net loss attributable to common stockholders	\$(6,126	) \$(3,634	) \$(14,349	) \$(6,575
Basic and diluted net loss per share attributable to common stockholders	\$(16.57	) \$(9.84	) \$(38.81	) \$(17.99
Weighted-average shares used to compute basic and diluted net loss per share attributable to common stockholders	369,750	369,460	369,702	365,435

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

Table of Contents

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

	Six Months Ended	
	June 30,	
	2014	2013
	(unaudited)	
Operating activities		
Net loss	\$(14,349	) \$(6,575
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	122	221
Compensation related to stock option grants	454	84
Revaluation of convertible preferred stock warrant liability	4,150	—
Other non-cash losses/(gains)	—	(32
Changes in operating assets and liabilities:		
Accounts receivable	(951	) (432
Inventory	(2	) 83
Prepaid expenses	(790	) (219
Accounts payable	389	(21
Accrued liabilities	87	(1,041
Deferred rent	(9	) 68
Net cash used in operating activities	(10,899	) (7,864
Investing activities		
Purchases of property and equipment	(117	) (119
Proceeds from the sale of property and equipment	—	43
Net cash used in investing activities	(117	) (76
Financing activities		
Issuance of common stock	—	6
Deferred offering costs	(1,368	) —
Net cash provided (used in) by financing activities	(1,368	) 6
Net decrease in cash and cash equivalents	(12,384	) (7,934
Cash and cash equivalents, beginning of period	30,387	12,762
Cash and cash equivalents, end of period	\$18,003	\$4,828
Supplemental schedule of noncash financing activities:		
Accrued offering costs	\$397	\$—

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



Table of Contents

IMMUNE DESIGN CORP.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

(Information as of June 30, 2014 and for the three and six months ended June 30, 2014 and 2013 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, or CTLs, to fight cancer. We are developing multiple product candidates from our two discovery platforms, IMDZVex™ or "ZVex™" for short (previously known as DCVex) and GLAAS™, which we believe have the potential to treat a broad patient population. Our product candidates, LV305, CMB305 and G100, utilize multiple immuno-oncology approaches and, we believe, address the shortcomings of existing therapies. LV305 and G100 are in Phase 1 clinical trials and we expect to initiate a Phase 1 clinical trial for CMB305 by the end of the year. CMB305 combines our two platforms in a prime-boost approach that we believe should be more effective than either LV305 or G305 alone. Although we plan to focus our development efforts on CMB305 and G100, we plan to conduct a small exploratory trial to compare LV305 and CMB305 in the same tumor types. After reviewing those data, we may elect to separately develop LV305.

We were incorporated in February 2008 in the State of Delaware. Our operations are headquartered in Seattle, Washington with additional facilities 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 condensed financial statements as of June 30, 2014 and for the three and six months ended June 30, 2014 and 2013 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 as of June 30, 2014 and the results of operations and cash flows for the three and six months ended June 30, 2014 and 2013. The results of operations for the three and six months ended June 30, 2014 are not necessarily indicative of the results to be expected for the year ended December 31, 2014 or for other future interim periods or years.

The accompanying unaudited condensed financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 2013 included in our prospectus, dated July 23, 2014, filed with the Securities and Exchange Commission (SEC) pursuant to Rule 424(b)(4) of the Securities Act of 1933, as amended.

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.

Initial Public Offering

In July 2014, we completed our initial public offering of shares of our common stock (IPO), pursuant to which we issued 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-

7

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Table of Contents

IMMUNE DESIGN CORP.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (CONTINUED)

(Information as of June 30, 2014 and for the three and six months ended June 30, 2014 and 2013 is unaudited)

allotment at \$12.00 per share. We received net proceeds of \$60.4 million (inclusive of the exercise of the over-allotment) after deducting underwriting discounts and commissions and offering expenses from the IPO. In connection with the closing of the IPO, all of our 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 were cash exercised for \$8.1 million 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 increase in shares outstanding in July 2014 is expected to impact the year-over-year comparability of our net loss per share calculations over the next year.

Deferred Offering Costs

Deferred offering costs represent legal, accounting and other direct costs related to our efforts to raise capital through our IPO of our common stock. These costs were deferred through the completion of the IPO and on the completion of the IPO will be 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, 2014 and 2013.

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 deferred 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 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 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), 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

8

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Table of Contents

IMMUNE DESIGN CORP.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (CONTINUED)

(Information as of June 30, 2014 and for the three and six months ended June 30, 2014 and 2013 is unaudited)

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. The standard 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, 2016, with early application 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

We compute net loss per share attributable to common stockholders using the two-class method required for participating securities. We consider all series of our convertible preferred stock to be participating securities. In accordance with the two-class method, earnings allocated to these participating securities, which include participation rights in undistributed earnings, are subtracted from net income to determine total undistributed earnings to be allocated to common stockholders.

Basic net loss per share attributable to common stockholders is computed by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period. All participating securities are excluded from basic weighted-average common shares outstanding. In computing diluted net loss per share attributable to common stockholders, undistributed earnings are re-allocated to reflect the potential impact of dilutive securities, including stock options and warrants. Diluted net loss per share attributable to common stockholders is computed by dividing net loss attributable to common stockholders by the weighted-average number of common equivalent shares outstanding for the period. Diluted net loss per share attributable to common stockholders includes any dilutive effect from outstanding stock options and warrants using the treasury stock method. The common stock issuable upon the conversion or exercise of the following dilutive securities has been excluded from the diluted net loss per share attributable to common stockholders calculation because their effect would have been antidilutive for the periods presented:

	Three Months Ended June 30,	
	2014	2013
	(unaudited)	
Convertible preferred stock	9,769,422	5,818,356
Options to purchase common stock	1,802,626	732,445
Warrants to purchase convertible preferred stock	1,975,532	—
	13,547,580	6,550,801

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.

9

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Table of Contents

IMMUNE DESIGN CORP.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (CONTINUED)

(Information as of June 30, 2014 and for the three and six months ended June 30, 2014 and 2013 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.

In certain cases where there is limited activity or less transparency around inputs to valuation, securities are classified as Level 3 within the valuation hierarchy. The Level 3 liability that is measured at estimated fair value on a recurring basis consists of the convertible preferred stock warrant liability. The estimated fair value of the outstanding convertible preferred stock warrant liability is measured using the income method approach in combination with a Monte Carlo simulation. Inputs used to determine estimated fair value include the estimated fair value of the underlying stock at the valuation measurement date, the multiple scenarios outlining probabilities and the remaining contractual term of the warrants, risk-free interest rates, expected dividends, and the expected volatility of the price of the underlying stock.

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

	June 30, 2014 (unaudited)			
	LEVEL 1	LEVEL 2	LEVEL 3	TOTAL
Assets:				
Money market funds	\$17,716	\$—	\$—	\$17,716
Liabilities:				
Convertible preferred stock warrant liability	\$—	\$—	\$7,486	\$7,486

  

	December 31, 2013			
	LEVEL 1	LEVEL 2	LEVEL 3	TOTAL
Assets:				
Money market funds	\$30,030	\$—	\$—	\$30,030
Liabilities:				
Convertible preferred stock warrant liability	\$—	\$—	\$3,336	\$3,336

We classify the convertible preferred stock warrant liability within Level 3 because the warrant liability is valued using valuation models with significant unobservable inputs. The estimated fair value of warrants accounted for as liabilities was determined on the issuance date and are subsequently remeasured to fair value at each reporting date. The change in fair value of the 2013 warrants is recorded in the statements of operations as a non-operating gain or loss by using a Monte Carlo option pricing model with the following assumptions:

Upon the issuance in October 2013 of our Series C convertible preferred stock, we used the following assumptions to estimate fair value: equity value of the entity, different conversion prices for different scenarios, time to maturity of 1.7 to 2.0 years under the different exercise scenarios, volatility of 82% and risk free rate of 0.3%.

For December 31, 2013, we used the following assumptions to estimate fair value: equity value of the entity, different conversion prices for different scenarios, time to maturity of 1.2 to 1.7 years under the different exercise scenarios, volatility of 82% and risk free rate of 0.3%.



Table of Contents

IMMUNE DESIGN CORP.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (CONTINUED)

(Information as of June 30, 2014 and for the three and six months ended June 30, 2014 and 2013 is unaudited)

For June 30, 2014, we used the following assumptions to estimate fair value: equity value of the entity, different conversion prices for different scenarios, time to maturity of 0.1 to 1.3 years under the different exercise scenarios, volatility of 102.3% and risk free rate of 0.2%.

The table below shows the reconciliation of the convertible preferred stock warrant liability measured and recorded at fair value on a recurring basis, using significant unobservable inputs (Level 3) (in thousands):

	Estimated Fair Value
Balance as of December 31, 2013	\$3,336
Change in fair value of convertible preferred stock warrant liability (unaudited)	4,150
Balance as of June 30, 2014 (unaudited)	\$7,486

Warrants were issued in October 2013 and, as such, there was no convertible preferred stock warrant liability as of June 30, 2013.

## 5. Inventory

Inventory consists of the following (in thousands):

	June 30, 2014 (unaudited)	December 31, 2013
Raw materials	\$13	\$13
Work in process	4	—
Finished goods	2	4
Total inventory	\$19	\$17

## 6. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	June 30, 2014 (unaudited)	December 31, 2013
Accrued research and development and professional services	\$1,237	\$405
Employee compensation	197	649
Unearned revenue	18	28
Total accrued liabilities	\$1,452	\$1,082

## 7. Series C Convertible Preferred Stock Warrant Liability

In October 2013, pursuant to 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. The warrants will expire at the earlier of two years from issuance, upon certain clinical milestones or upon a liquidation event.

All warrants were unexercised as of December 31, 2013 and June 30, 2014. The estimated fair value for the warrants as of December 31, 2013 and June 30, 2014 was \$3,336,000 and \$7,486,000, respectively. The fair value of the warrants was determined using the income method valuation model in combination with a Monte Carlo simulation in consideration of multiple early exercise triggers associated with the warrants.

In April 2014, we amended the warrants to provide for their automatic net exercise if the per share price in the IPO exceeds the exercise price of the warrants, immediately prior to the closing of the IPO. In July 2014, prior to the completion of the IPO, 996,940 of the warrants were cash exercised for \$8.1 million in cash and 978,592 of the

warrants were automatically net exercised for a total of 311,923 shares of common stock. Upon exercise of the warrants, the preferred stock liability was reclassified from liabilities to stockholders' (deficit) equity.

## 8. Commitments and Contingencies

### Operating Leases

In December 2013, we entered into a new operating lease agreement for office space in South San Francisco, California. The lease commenced in January 2014 and continues through January 2018, with an option to extend for an additional three years. The terms of the office lease 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 period and accrue for rent expense incurred but not paid. The lease also requires us to pay additional amounts for operating and maintenance expenses beginning January 2015. With the execution of this lease, we were required to provide a \$36,000 letter of credit as a security deposit. As of June 30, 2014, no funds had been drawn down on the letter of credit.

### Contingencies

We have 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.

These payments have not been recorded as liabilities due to the uncertainty of 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.

## 9. License and Collaboration Agreements

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. 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 royalty payments on net sales of licensed products, which royalty is subject to reduction under certain circumstances. Through June 30, 2014, MedImmune has paid us an aggregate of \$4.5 million in payments under the license agreements. Under each license agreement, MedImmune is obligated to make additional aggregate payments of \$62.9 million to \$76.0 million, depending on the infectious disease indication, based on achievement of certain development, regulatory and commercial milestones for the licensed indication. For the three-months ended June 30, 2014 we recognized \$1.0 million for the achievement of development milestones under these license agreements.

In May 2013, we entered into a nonexclusive license agreement granting Medicago, Inc. (Medicago) a right to research, develop, and commercialize GLA in the field of pandemic influenza. Medicago paid an upfront payment of \$0.5 million under the license agreement, which was fully recognized in 2013, and is also obligated to make additional payments of up to \$9.5 million based on achievement of certain development and government contract milestones for the licensed indication. Medicago is also obligated to pay us a mid single-digit royalty on net sales of licensed products, which royalty is subject to reduction under license expiration.

Under our license agreement with the Infectious Disease Research Institute (IDRI), we are obligated to share with IDRI a percentage of payments received from third party licensees.

In July 2008, we licensed certain rights to research, develop, and commercialize GLA from 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. In addition, we agreed to pay certain fees in the future if we should elect to continue development of the applicable technologies, including milestone payments upon achievement of certain development and commercialization milestones and royalty payments of single-digit percentage of net sales, if and when commercialized; however, we may terminate our development programs at any time without obligation to IDRI.



Table of Contents

IMMUNE DESIGN CORP.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (CONTINUED)

(Information as of June 30, 2014 and for the three and six months ended June 30, 2014 and 2013 is unaudited)

Through June 30, 2014, we have paid an aggregate of \$1.4 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. In 2013, we paid \$140,000 in license-related milestone payments which were expensed in research and development expenses. 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 January 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 2009, we issued shares of our common stock valued at \$25,000 for this license. We have made annual minimum royalty payments under the license annually through January 2014. In addition, we agreed to pay certain fees in the future if we should elect to continue development of the related technology, including milestone payments upon achievement of certain development and commercialization milestones and royalty payments on net sales, if and when commercialized, in the low single digit percentage; 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.

## 10. Stockholders' Deficit

## Common Stock

We had 369,750 and 369,460 shares of common stock outstanding as of June 30, 2014 and December 31, 2013 respectively. Shares of common stock reserved for future issuance were as follows:

	June 30, 2014 (unaudited)	December 31, 2013
Shares to be issued upon conversion of convertible preferred stock	9,769,422	9,769,422
Shares to be issued upon exercise of convertible preferred stock warrants and conversion of convertible preferred stock	1,975,532	1,975,532
Shares to be issued upon exercise of outstanding stock options	1,802,626	1,463,747
Shares available for future stock option grants	77,240	122,829
Shares of common stock reserved for future issuance	13,624,820	13,331,530

## Equity Incentive Plan

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.

Stock options granted under the 2008 Plan generally vest within four years and vested options are exercisable from the grant date 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 to employees with exercise prices equal to the fair value of our common stock on the date of grant. The term of incentive stock options may not exceed ten years from the date of grant. In May 2014, an additional 293,576 shares of common stock were authorized for future grants under the 2008 Plan. There were 1,951,514 shares of common stock authorized under the 2008 Plan as of June 30, 2014. 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, we ceased granting stock awards under the 2008 Plan, and any 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 any common stock being issued will become available for issuance under the 2014 Plan.

Table of Contents

IMMUNE DESIGN CORP.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (CONTINUED)

(Information as of June 30, 2014 and for the three and six months ended June 30, 2014 and 2013 is unaudited)

## 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, 2013	1,463,747	\$ 1.20	8.67	\$2,552
Granted (unaudited)	370,604	\$8.49		
Exercised (unaudited)	(290	) \$1.31		
Canceled/forfeited (unaudited)	(31,435	) \$1.82		
Outstanding at June 30, 2014 (unaudited)	1,802,626	\$2.69	8.51	\$11,215
Vested and expected to vest after June 30, 2014 (unaudited)	1,460,814	\$2.40	8.27	\$9,505
Exercisable as of June 30, 2014 (unaudited)	551,028	\$1.11	6.56	\$4,300

As of June 30, 2014, there was \$2.7 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 3.2 years.

## 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 accompanying statements of operations is as follows (in thousands):

	Three Months Ended June 30, 2014		Six Months Ended June 30, 2014	
	2014	2013	2014	2013
	(unaudited)			
Employee:				
Research and development	\$92	\$8	\$143	\$16
General and administrative	143	26	229	49
Non-Employee:				
Research and development	32	(3	) 82	1
General and administrative	—	7	—	18
Total stock-based compensation expense	\$267	\$38	\$454	\$84

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



Table of Contents

IMMUNE DESIGN CORP.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (CONTINUED)

(Information as of June 30, 2014 and for the three and six months ended June 30, 2014 and 2013 is unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
	(unaudited)			
Weighted-average estimated fair value	\$6.33	\$1.09	\$6.33	1.08
Risk-free interest rate	1.76% - 2.16%	1.16% - 1.22%	1.76% - 2.16%	0.97% - 1.22%
Expected term of options (in years)	5.50 - 6.75	5.97 - 6.01	5.50 - 6.75	5.45 - 6.08
Expected stock price volatility	90%	90%	90%	90%
Expected dividend yield	—%	—%	—%	—%

We used the “simplified method” for options to determine the expected term of our stock option grants. Under this 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 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. 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 have never declared or paid any cash dividends and do not presently plan to pay cash dividends in the foreseeable.

## 11. Legal Proceedings

## TheraVectys

## TheraVectys SA v. Henogen SA

In September 2013, TheraVectys SA, or (TVS), a French biotechnology company, filed an action in the Commercial Court of Charleroi in Belgium against Henogen SA (Henogen). Henogen is a contract manufacturing organization with which we contracted for the manufacture of our LV305 product candidate. We were not named as a defendant in the action. In this action, TVS alleged that Henogen was preparing to transfer TVS’s proprietary and to us by dispatching batches of our lentiviral vector and was acting in breach of an alleged exclusivity obligation towards TVS. On September 11, 2013, Henogen was served with an ex parte order of the Commercial Court of Charleroi temporarily enjoining Henogen from manufacturing, dispatching, delivering or communicating about batches of lentiviral vectors to any company or individual other than TVS. On September 18, 2013, Henogen filed an opposition to the ex parte order, and, in a hearing on September 19, 2013, requested the annulment of the ex parte order. We filed an application to intervene and our counsel appeared at the hearing in support of Henogen’s request to annul the ex parte order. On October 7, 2013, the Commercial Court of Charleroi issued an order extending the temporary injunction by an additional 15-day period starting on the date of the serving of the judgment by the most diligent party but allowing it to terminate thereafter. We believe the time to appeal that order has expired.

## TheraVectys SA v. Immune Design Corp.

In October 2013, TVS filed a complaint against us in the U.S. District Court for the District of Delaware. TVS alleged that it had entered into a contractual relationship with Henogen in 2010 with respect to the production of lentiviral vector vaccines for TVS. TVS alleged that the 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 Flap vectors for third parties and 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 injunctive relief enjoining us from importing, receiving, possessing or using lentiviral vector vaccines developed or produced by Henogen, but did not file a motion seeking that 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.

Table of Contents

IMMUNE DESIGN CORP.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (CONTINUED)

(Information as of June 30, 2014 and for the three and six months ended June 30, 2014 and 2013 is unaudited)

**Henogen SA v. TheraVectys SA**

In October 2013, Henogen filed an action in the Paris Commercial Court against TVS. We were not a party to this action. The action sought declarations that the provisions of the contract between Henogen and TVS upon which TVS in part based its claims in the Commercial Court of Charleroi is either null or does not apply to Henogen's contract with us, that Henogen has not engaged in an act of unfair competition and that TVS wrongfully obtained an order of the Commercial Court of Charleroi in Belgium temporarily enjoining Henogen from manufacturing, dispatching, delivering or communicating about batches of lentiviral vectors to any company or individual other than TVS based on unfounded allegations. The action also sought damages, publication of the Paris Commercial Court's judgment in Belgian and French national newspapers at TVS's expense, and an order forbidding TVS from initiating any action that could prevent the performance of the contract between Henogen and us for the manufacture of our lentiviral vector. Henogen also requested the Court to appoint an expert to describe the know-how of Henogen prior to its collaboration with TVS and the know-how transferred by us to Henogen and the know-how transferred by TVS to Henogen. TVS requested that the Commercial Court of Paris order Henogen to cease working with us and pay damages to TVS. TVS opposed the appointment of an expert. The Commercial Court of Paris heard arguments from Henogen and TVS at a hearing on March 7, 2014. The Commercial Court of Paris rendered a decision on April 11, 2014. In that decision, the court dismissed all claims raised by Henogen and declined its request for the appointment of an expert. The court determined that Henogen had breached the agreement with TVS and, among other things, ordered Henogen to pay TVS €15,000,000 in compensatory damages, €100,000 for initiating abusive proceedings, €150,000 for legal fees as well as an award for court costs incurred in the matter. The court ordered provisional enforcement of the judgment. On April 14, 2014, Henogen filed an appeal against the judgment and filed summary proceedings to suspend the provisional execution of the judgment. In June 2014, Henogen's request to suspend the provisional judgment was denied.

**European Patent Opposition**

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 owned by IDRI and under license to us. We are vigorously defending the grant of this patent, with a reply to the opposition brief having been filed on September 27, 2013. No date for an oral hearing has yet been set. 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 two to five years.

**12. Subsequent Events**

**Initial Public Offering**

On July 23, 2014, our registration statements on Form S-1 (File No. 333-196979) relating to our IPO of common stock became effective. The IPO closed on July 29, 2014 at which time we sold 5,000,000 shares of our common stock. On August 1, 2014, we sold an additional 250,000 shares of our common stock directly to the underwriters when they partially exercised their over-allotment option. On August 26, 2014, we sold an additional 160,564 shares of our common stock directly to the underwriters when they again partially exercised their over-allotment option. We sold an aggregate of 5,410,564 shares of our common stock in the IPO and received cash proceeds of \$60.4 million from the IPO, net of underwriting discounts and commissions and expenses paid by us.

Upon completion of the IPO the total authorized common stock was increased to 100,000,000 and the total authorized preferred stock was increased to 10,000,000.

**Stock Option Plan**

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,

we will cease granting stock awards under the 2008 Plan, and any 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 any common stock being issued will become available for issuance under the 2014 Plan.

In July 2014, 1,400,000 shares of our common stock were reserved for issuance under the 2014 Plan and 155,520 shares of our common stock were reserved for issuance under our 2014 Employee Stock Purchase Plan, which became effective immediately prior to the closing of the IPO.

#### Reverse Stock Split

On July 14, 2014, the Company filed an amendment to its 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.

#### License Agreements

In August 2014, we entered into a license agreement with Sanofi for use of our GLAAS discovery platform to develop therapeutic agents to treat a selected food allergy. Under terms of the agreement, we granted Sanofi an exclusive license to discover, develop and commercialize products to treat the selected food allergy, and in addition to an undisclosed upfront payment, we will be eligible to receive development and commercialization milestones totaling \$168.0 million and tiered royalties on sales of approved products.

#### TheraVectys SA v. Immune Design Corp.

On or about July 24, 2014, shortly after our Registration Statement on Form S-1 was declared effective by the SEC, TVS filed a new complaint against us in the Chancery Court of the State of Delaware, alleging facts substantially similar to the prior complaint. TVS has alleged in the new complaint 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 are 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 U.S. Food and Drug Administration (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 held that the proceedings should be expedited and set a hearing date in mid-November 2014 for Thervectys's anticipated motion for preliminary injunction. The court has not yet made any determination on the merits of the suit

We are not currently using Henogen to manufacture our lentiviral vectors for our clinical trials. We developed our own vector manufacturing process that was then transferred to Henogen, and did not have any knowledge of the exclusivity provision in TVS' contract with Henogen or its manufacturing processes when we entered into our agreement with Henogen. We intend to vigorously defend this lawsuit. In the event we are unable to use any of our lentiviral vectors or the clinical data from the ongoing Phase 1 trial of LV305 as a result of an injunction ordered by the Delaware Chancery Court, the development of LV305 could be substantially delayed and our business could be harmed. In addition, an adverse outcome could result in the payment of damages by us to TVS, which could have a material adverse effect on our cash flows, financial position and results of operations.

Table of Contents

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 our financial condition and results of operations in conjunction with our unaudited condensed 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, 2013, included in our prospectus dated July 23, 2014, filed with the Securities and Exchange Commission, or the SEC, pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, or the Prospectus.

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, or CTLs, to fight cancer. We are developing multiple product candidates from our two discovery platforms, IMDZVex™ or "ZVex™" for short and GLAAS™, which we believe have the potential to treat a broad patient population. Our product candidates, LV305, CMB305 and G100, utilize multiple immuno-oncology approaches and, we believe, address the shortcomings of existing therapies. LV305 and G100 are in Phase 1 clinical trials and we expect to initiate a Phase 1 clinical trial for CMB305 by the end of the year. CMB305 combines our two platforms in a prime-boost approach that we believe should be more effective than either LV305 or G305 alone. Although we plan to focus our development efforts on CMB305 and G100, we plan to conduct a small exploratory trial to compare LV305 and CMB305 in the same tumor types. After reviewing those data, we may elect to separately develop LV305.

We have devoted substantially all of our resources since inception to our product 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. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years as we continue our research and development efforts. For the three and six months ended June 30, 2014, we reported a net loss of \$6.1 million and \$14.3 million, respectively, compared with a three and six months ended June 30, 2013 net loss of \$3.6 million and \$6.6 million, respectively. As of June 30, 2014, we had an accumulated deficit of \$71.0 million.

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

Second Quarter 2014 and Other Recent Highlights

In May 2014, MedImmune LLC, or MedImmune, one of our licensees for the application of our GLAAS discovery platform, initiated their Phase 1 clinical trial of MEDI7510, an investigational agent for respiratory syncytial virus, or RSV. MEDI7510 is composed of MedImmune's RSV sF antigen plus glucopyranosyl lipid A, or GLA, a synthetic molecule licensed from our GLAAS discovery platform. The Phase 1a, double-blind, randomized, placebo-controlled cohort escalation study is designed to evaluate the safety, tolerability and immunogenicity of a single ascending intramuscular dose of MEDI7510 or placebo in adults 60 years or older who are healthy or who have stable, underlying medical conditions. The trial is expected to enroll 144 patients at several clinical centers in the United States.

In June 2014, we announced the first patient in a Phase 1 clinical trial of LV305, an immuno-oncology investigational agent from our ZVex discovery platform. The Phase 1 open label, multi-center trial is designed to evaluate the safety, tolerability and immunogenicity of LV305 in patients with locally advanced, relapsed, or metastatic breast cancer, melanoma, non-small cell lung cancer, ovarian cancer or sarcoma. The trial will enroll up to 36 patients at several clinical centers in the United States.

On July 23, 2014, our registration statements on Form S-1 (File No. 333-196979) relating to our initial public offering, or the IPO, of common stock was declared effective by the SEC. Our IPO closed on July 29, 2014 at which time we sold 5,000,000 shares of our common stock. On August 1, 2014, we sold an additional 250,000 shares of our common stock directly to the underwriters when they partially exercised their over-allotment option. On August 26,

2014, we sold an additional 160,564 shares of our common stock directly to the underwriters when they again partially exercised their over-allotment option. We sold an aggregate of 5,410,564 shares of our common stock in the IPO and received cash proceeds of \$60.4 million from the IPO, net of underwriting discounts and commissions excluding expenses.

Table of Contents

In August 2014, we entered into a license agreement with Sanofi for use of our GLAAS discovery platform to develop therapeutic agents to treat a selected food allergy. Under terms of the agreement, we granted Sanofi an exclusive license to discover, develop and commercialize products to treat the selected food allergy, and in addition to an undisclosed upfront payment, we will be eligible to receive development and commercialization milestones totaling \$168.0 million and tiered royalties on sales of approved products.

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 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. For the three and six months ended June 30, 2014, we received an aggregate of \$1.0 million in licensing revenue based on the achievement of milestones. This compares to approximately \$0.5 million and \$0.7 million for the three and six months ended June 30, 2013, respectively.

GLA Product Sales

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, 2014, we recognized approximately \$60,000 and \$90,000 in revenues, respectively, and \$20,000 and \$30,000 in cost of GLA product sales, respectively. This compares to approximately \$370,000 and \$740,000 in revenues, respectively, and \$250,000 and \$460,000 in cost of GLA product sales, respectively, through these arrangements for the three and six months ended June 30, 2013.

Research and Development Expenses

We focus our resources on our 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 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 following table summarizes our direct research and development expenses by platform for the periods indicated. Our direct research and development expenses consist principally of external costs, such as fees paid to contract manufacturing organizations, or CMOs, clinical research organizations, or 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 following table:



Table of Contents

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
	(in thousands) (unaudited)			
Direct research and development expense by platform:				
ZVex	\$1,849	\$1,653	\$3,892	\$2,716
GLAAS	490	718	1,049	1,078
Other	28	31	30	120
Total direct research and development program expense	2,367	2,402	4,971	3,914
Indirect research and development expense by type:				
Personnel related costs	1,107	639	2,254	1,320
Research and development supplies and services	202	190	360	416
Allocated facility, equipment, travel and other expense	207	125	376	249
Total indirect research and development expense	1,516	954	2,990	1,985
Total research and development expense	\$3,883	\$3,356	\$7,961	\$5,899

The successful development of our product candidates is highly uncertain. 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 and research that we may conduct.

**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 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**

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

**Change in Fair Value of Convertible Preferred Stock Warrant Liabilities**

Upon the IPO, the preferred stock warrant liability was reclassified to additional paid-in capital and we no longer record any related periodic fair value adjustment.

**Critical Accounting Policies and Estimates**

Our management's discussion and analysis of financial condition and results of operations are based upon our unaudited condensed financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets,

liabilities, revenues and expenses. On an on-going basis, we evaluate our critical accounting policies and estimates. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable in 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. Actual results may differ from these estimates under different assumptions and conditions. Our significant accounting policies are more fully described in Note 2 of the accompanying unaudited condensed financial statements and in Note 2 to our audited financial statements contained in the Prospectus. There have been no significant or material changes in our critical

Table of Contents

accounting policies during the three months or six months ended June 30, 2014, 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 the Prospectus.

## Results of Operations

## Comparison of Three Months Ended June 30, 2014 and 2013

The following table summarizes our results of operations for the three months ended June 30, 2014 and 2013:

	Three Months Ended		Increase/ (Decrease)
	June 30, 2014	2013	
	(in thousands)		
	(unaudited)		
Total revenues	\$1,064	\$882	\$182
Operating expenses:			
Cost of product sales	18	250	(232 )
Research and development	3,883	3,356	527
General and administrative	1,850	914	936
Total operating expenses	5,751	4,520	1,231
Loss from operations	(4,687 )	(3,638 )	(1,049 )
Interest and other income	—	4	(4 )
Change in fair value of convertible preferred stock warrant liability	(1,439 )	—	(1,439 )
Net loss attributable to common stockholders	\$(6,126 )	\$(3,634 )	\$(2,492 )

## Total Revenues and Cost of Product Sales

The \$0.2 million increase in total revenues was attributable to \$1.0 million milestone completed in 2014 offset by a decrease in GLA sales in 2014, as compared to the sale of multiple GLA clinical lots in 2013. The cost of product sales also decreased \$0.2 million in the second quarter of 2014 associated with the decrease in GLA sales.

## Research and Development Expenses

The \$0.5 million increase was primarily attributable to an increase of \$0.5 million in personnel-related expenses as a result of growth in research and development headcount to support clinical development and an increase of \$0.5 million of clinical costs to support the G100, G305, and LV305 Phase 1 clinical trials off set by a decrease of \$0.5 million in contract manufacturing and research and development expenses.

## General and Administrative Expenses

The \$0.9 million increase was primarily attributable to the \$0.5 million increase in professional service fees to support our preparations for becoming a public company and a \$0.4 million increase in personnel-related expenses, 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

The increase in other expense is related to the revaluation of the convertible preferred stock warrant liability, which was driven by an increase in the valuation of our stock. There were no warrants outstanding during the three months ended June 30, 2013.

Table of Contents

## Comparison of Six Months Ended June 30, 2014 and 2013

The following table summarizes the results of our operations for the six months ended June 30, 2014 and 2013.

	Six Months Ended		Increase/ (Decrease)
	June 30, 2014	2013	
	(in thousands) (unaudited)		
Total revenues	\$1,089	\$1,446	\$(357)
Operating expenses:			
Cost of product sales	32	462	(430)
Research and development	7,961	5,899	2,062
General and administrative	3,296	1,695	1,601
Total operating expenses	11,289	8,056	3,233
Loss from operations	(10,200)	(6,610)	(3,590)
Interest and other income	1	35	(34)
Change in fair value of convertible preferred stock warrant liability	(4,150)	—	(4,150)
Net loss attributable to common stockholders	\$(14,349)	\$(6,575)	\$(7,774)

**Total Revenue and Cost of Product Sales**

The \$0.4 million decrease in total revenues was primarily attributable to a \$0.7 million decrease as a result of fewer GLA sales offset by a \$0.3 million increase in licensing revenue in 2014. The cost of product sales also decreased \$0.4 million associated with the decrease in GLA sales.

**Research and Development Expenses**

The \$2.0 million increase was primarily attributable to an increase of \$1.0 million of clinical costs to support the G100, G305 and LV305 Phase 1 clinical trials, a \$0.9 million increase in personnel-related expenses as a result of growth in research and development headcount to support clinical development and an increase of \$0.1 million in research and development activities to support LV305 development.

**General and Administrative Expenses**

The \$1.6 million increase was primarily attributable to the \$1.0 million increase in costs associated to support operating as a public company and a \$0.6 million increase in personnel-related expenses and facilities, 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**

The increase in other expense is related to the revaluation of the convertible preferred stock warrant liability, which was driven by an increase in the valuation of our stock. There were no warrants outstanding during the six months ended June 30, 2013.

**Liquidity and Capital Resources**

Since our inception through June 30, 2014, we have raised a total of \$93.7 million in cash, including \$84.3 million from the sale of our common stock, convertible preferred stock and warrants, \$6.3 million from the licensing of our technology and \$3.1 million primarily from GLA sales and contract research services.

In July 2014, we completed our initial public offering of shares of our common stock, or IPO, pursuant to which we issued 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 \$60.4 million (inclusive of the exercise of the over-allotment) after deducting underwriting discounts and commissions and offering expenses from our IPO. In connection with the closing of the IPO, all of our 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 were cash exercised for \$8.1 million 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

Table of Contents

automatically net exercised, resulting in an issuance of an additional 311,923 shares of common stock. The significant increase in shares outstanding in July 2014 is expected to impact the year-over-year comparability of our net loss per share calculations over the next year. 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 at any point in time. 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 collaboration arrangements and, if necessary, equity or debt financings. 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 will 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 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.

**Cash Flows**

The following is a summary of cash flows for the six months ended June 30, 2014 and 2013:

	Six Months Ended	
	June 30,	
	2014	2013
	(unaudited)	
Net cash used in operating activities	\$(10,899	) \$(7,864
Net cash used in investing activities	(117	) (76
Net cash (used in) provided by financing activities	(1,368	) 6

**Net Cash Used in Operating Activities**

Net cash used in operating activities was \$10.8 million during the six months ended June 30, 2014 compared to \$7.9 million for the six months ended June 30, 2013. The increase in cash used in operating activities in the first six months of 2014 compared with the first six months of 2013 was due to the increase in clinical costs to support the G100, G305 and LV305 Phase 1 clinical trials and increases in personnel-related expenses as a result of growth to support clinical development and administration.

Net Cash Used in Investing Activities

Net cash used in investing activities was \$0.1 million during the six months ended June 30, 2014, compared to \$0.1 million during the six months ended June 30, 2013. Net cash used in investing activities for the periods presented primarily relates to the purchase of property and equipment. Property and equipment purchases primarily related to lab equipment purchased to support our research and development efforts.

## Table of Contents

### Net Cash (Used In) Provided By Financing Activities

Net cash used in financing activities was \$1.3 million during the six months ended June 30, 2014 and primarily consisted of direct legal and accounting fees related to preparing to become a public company. Net cash provided by financing activities during the six months ended June 30, 2014 related to the exercise of stock options.

### Contractual Obligations and Contingent Liabilities

During the three months ended June 30, 2014, there were no material changes to our contractual obligations and commitments described under the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" in the Prospectus.

### Off-Balance Sheet Arrangements

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

### JOBS Act

On April 5, 2012, the Jumpstart Our Business Startups Act of 2012, or the 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, or the Securities Act, 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 date of the completion of this offering, (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 Securities and Exchange Commission.

### 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, 2014, we had cash and cash equivalents of \$18.0 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

Table of Contents

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 (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.

Table of Contents

PART II: OTHER INFORMATION

Item 1. Legal Proceedings

TheraVectys

TheraVectys SA v. Henogen SA

In September 2013, TheraVectys SA, or TVS, a French biotechnology company, filed an action in the Commercial Court of Charleroi in Belgium against Henogen SA, or Henogen. Henogen is a contract manufacturing organization with which we contracted for the manufacture of our LV305 product candidate. We were not named as a defendant in the action. In this action, TVS alleged that Henogen was preparing to transfer TVS's proprietary and patent-protected technology to us by dispatching batches of our lentiviral vector and was acting in breach of an alleged exclusivity obligation towards TVS. On September 11, 2013, Henogen was served with an ex parte order of the Commercial Court of Charleroi temporarily enjoining Henogen from manufacturing, dispatching, delivering, or communicating about batches of lentiviral vectors to any company or individual other than TVS. On September 18, 2013, Henogen filed an opposition to the ex parte order, and, in a hearing on September 19, 2013, requested the annulment of the ex parte order. We filed an application to intervene and our counsel appeared at the hearing in support of Henogen's request to annul the ex parte order. On October 7, 2013, the Commercial Court of Charleroi issued an order extending the temporary injunction by an additional 15-day period starting on the date of the serving of the judgment by the most diligent party but declining to extend the injunction permanently. We believe the time to appeal that order has expired.

Henogen SA v. TheraVectys SA

In October 2013, Henogen filed an action in the Paris Commercial Court against TVS. We were not a party to this action. The action sought declarations that the provisions of the contract between Henogen and TVS upon which TVS in part based its claims in the Commercial Court of Charleroi is either null or does not apply to Henogen's contract with us, that Henogen has not engaged in an act of unfair competition and that TVS wrongfully obtained an order of the Commercial Court of Charleroi in Belgium temporarily enjoining Henogen from manufacturing, dispatching, delivering or communicating about batches of lentiviral vectors to any company or individual other than TVS based on unfounded allegations. The action also sought damages, publication of the Paris Commercial Court's judgment in Belgian and French national newspapers at TVS's expense, and an order forbidding TVS from initiating any action that could prevent the performance of the contract between Henogen and us for the manufacture of our lentiviral vector. Henogen also requested the Court to appoint an expert to describe the know-how of Henogen prior to its collaboration with TVS and the know-how transferred by us to Henogen and the know-how transferred by TVS to Henogen. TVS requested that the Commercial Court of Paris order Henogen to cease working with us and pay damages to TVS. TVS opposed the appointment of an expert. The Commercial Court of Paris heard arguments from Henogen and TVS at a hearing on March 7, 2014. The Commercial Court of Paris rendered a decision on April 11, 2014. In that decision, the court dismissed all claims raised by Henogen and declined its request for the appointment of an expert. The court determined that Henogen had breached the agreement with TVS and, among other things, ordered Henogen to pay TVS €15,000,000 in compensatory damages, €100,000 for initiating abusive proceedings, €150,000 for legal fees as well as an award for court costs incurred in the matter. The court also ordered Henogen to comply with the exclusivity provision of the agreement with TVS under penalty of €5,000,000 per infraction. The court ordered provisional enforcement of the judgment. On April 14, 2014, Henogen filed an appeal against the judgment and filed summary proceedings to suspend the provisional execution of the judgment. In June 2014, Henogen's request to suspend the provisional judgment was denied.

TheraVectys SA v. Immune Design Corp.

In October 2, 2013, TVS 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 in 2010 with respect to the production of lentiviral vector vaccines for TVS. TVS alleged that the 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 Flap vectors for third parties and 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

Table of Contents

they exceed \$75,000. TVS also requested injunctive relief enjoining us from importing, receiving possessing or using lentiviral vector vaccines developed or produced by Henogen, but did not file a motion seeking that 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, 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 are 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 held that the proceedings should be expedited and set a hearing date in mid-November 2014 for Thervectys's anticipated motion for preliminary injunction. The court has not yet made any determination on the merits of the suit

We are not currently using Henogen to manufacture our lentiviral vectors for our clinical trials. We developed our own vector manufacturing process that was then transferred to Henogen, and did not have any knowledge of the exclusivity provision in TVS' contract with Henogen or its manufacturing processes when we entered into our agreement with Henogen. We intend to vigorously defend this lawsuit. In the event we are unable to use any of our lentiviral vectors or the clinical data from the ongoing Phase 1 trial of LV305 as a result of an injunction ordered by the Delaware Chancery Court, the development of LV305 could be substantially delayed and our business could be harmed.

Item 1A. Risk Factors

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, 2014, we reported a net loss of \$6.1 million and \$14.3 million, respectively, compared with a three and six months ended June 30, 2013 net loss of \$3.6 million and \$6.6 million, respectively. As of June 30, 2014, we had an accumulated deficit of \$71.0 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

Table of Contents

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;
- 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 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;
- 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.





## Table of Contents

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. Raising additional funds through the issuance of additional debt or equity securities 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

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 two product candidates that have recently commenced 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



Table of Contents

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 one of our product candidates, 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:

- 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;
  - 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.



Table of Contents

We are subject to litigation which 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 SAS, 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, 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 for this suit. As a result of the action in Belgium, Henogen was temporarily enjoined from producing or delivering the lentiviral vectors we need for our ZVex platform-based product candidates.

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 raised by Henogen, determined that Henogen had breached the agreement with TVS and, among other things, ordered Henogen to comply with the exclusivity provision of the agreement. Henogen is currently appealing the judgment, however the court ordered provisional enforcement of the judgment in the meantime.

On or about July 24, 2014, shortly after our Registration Statement on Form S-1 was declared effective by the SEC, 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 are 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 held that the proceedings should be expedited and set a hearing date in mid-November 2014 for Thervectys's anticipated motion for preliminary injunction. The court has not yet made any determination on the merits of the suit

We have transitioned the manufacture of our lentiviral vectors to a new manufacturer as a result of the Paris Court's order to Henogen to comply with the exclusivity provision of its contract with TVS and to mitigate the risk of future supply interruptions. However, in the event we are unable to use our Henogen manufactured lentiviral vectors, any subsequently manufactured lentiviral vectors from our new manufacturer or any future manufacturer or the clinical data from the ongoing Phase 1 trial of LV305 as a result of an injunction ordered by the Delaware Chancery Court, the development of LV305 could be substantially delayed and our business could be harmed. We also cannot be certain that TVS will not bring separate actions against 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 LV305 needed for our clinical trials. In addition, an adverse outcome could result in the payment of damages by us to TVS, which could have a material adverse effect on our cash flows, financial position and results of operations.

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

31

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## Table of Contents

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.

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





## Table of Contents

Our IMDZVex, or 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 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

Table of Contents

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, recordkeeping 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 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.

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

Table of Contents

finances 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;
- 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 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

35

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Table of Contents

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 is only one approved in vivo immuno-oncology therapy, 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. This may make it 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;
- 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.



Table of Contents

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, 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.

Recently enacted 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.

Table of Contents

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. 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 imposed a significant annual fee on companies that manufacture or import branded prescription drug products. Furthermore, as of 2011, the new 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

Table of Contents

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.

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

Table of Contents

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 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 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

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.

40

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## Table of Contents

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 third parties to conduct all of 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 third-party CROs to conduct all of 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 third parties to conduct all of 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 MedImmune LLC, or MedImmune, for the development and commercialization of three of our non-cancer treatment product candidates.

We have entered into three exclusive license and development agreements with MedImmune, or the MedImmune Licenses, pursuant to which we have granted MedImmune exclusive licenses to develop and commercialize product candidates relating to certain infectious diseases. We cannot control whether or not MedImmune will devote sufficient time and resources to the ongoing clinical and preclinical programs or whether MedImmune will fulfill its obligations under the licenses. The product candidates developed pursuant to the MedImmune Licenses may not be scientifically, medically or commercially successful.

In addition, we could be adversely affected by:

- MedImmune's failure to timely perform its obligations under the license agreements;
- MedImmune's failure to timely or fully develop or effectively commercialize the product candidates; and
- a material contractual dispute between us and MedImmune.

Any of the foregoing could adversely impact the likelihood and timing of any milestone or royalty payments we are eligible to receive from MedImmune 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.

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 licenses with MedImmune, 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

41

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Table of Contents

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 terminated 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.

We have no 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 no 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 manufacturers 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 contract manufacturers 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

## Table of Contents

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. No manufacturer currently has the experience or ability to produce our vectors and product candidates at commercial levels. In addition, the manufacturer of LV305 has only recently begun to manufacture LV305. Our contract manufacturing organizations, or CMO, may encounter technical or scientific issues related to manufacturing or development that we may be unable to resolve in a timely manner or with available funds, which could delay our clinical trials.

The manufacturing process for the full length NY-ESO-1 protein in CMB305 is difficult and we currently obtain the protein from a single source. While we are developing methods to produce this protein internally, we may not be successful. If we utilize an alternative source, we may be required to demonstrate comparability of the drug product before releasing the product for clinical use. The loss of our current supplier 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.

### 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 licensors' 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 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.



Table of Contents

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. We cannot be certain that we are the first to invent the inventions covered by pending patent applications and, if we are not, we may be subject to priority disputes. 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 licensee'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 biosimilars 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.

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 two to five 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



Table of Contents

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. 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.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our and our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents. 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.

Table of Contents

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 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.

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.

Table of Contents

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 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 or certain insolvency events, 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.

Third parties may initiate legal proceedings against us alleging that we infringe their intellectual property rights or we may initiate legal proceedings against third parties to challenge the validity or scope of intellectual property rights controlled by third parties, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Third parties may initiate legal proceedings against us or our licensors, collaborators or suppliers alleging that we or our licensors, collaborators or suppliers infringe their intellectual property rights or we or our licensors or collaborators may initiate legal proceedings against third parties to challenge the validity or scope of intellectual property rights controlled by third parties, including in oppositions, interferences, reexaminations, inter partes reviews or derivation proceedings or other preissuance or post-grant proceedings in the United States or other jurisdictions. These proceedings can be expensive and time-consuming and many of our or our licensors' 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.

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, with a reply to the opposition brief having been filed on September 27, 2013. No date for an oral hearing has yet been set. 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 two to five 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.

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

Table of Contents

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.

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.

**Risks Related to Ownership of Our Common Stock**

The market price of our stock may be volatile.

The trading price of our common stock is likely to be highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock:

- 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 directors, officers or their affiliated funds or our other stockholders;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors; and

general economic, industry and market conditions.

48

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Table of Contents

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.

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

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

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 July 31, 2014, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially own approximately 77% of our common stock. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The 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 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 recently completed initial public offering, or IPO; (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

Table of Contents

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 intend to 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 Securities and Exchange Commission, or 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 will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to meet compliance obligations.

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. We will be subject to the reporting requirements of the 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 corporate governance practices. The Exchange Act will require, 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. In addition, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers.

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 by our existing stockholders could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. As of July 31, 2014, 11,450,073 shares of our common stock are currently restricted as a result of securities laws or lock-up agreements but will be able to be sold upon expiration of the lockup period.

50

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Table of Contents

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.

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.

Table of Contents

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

Recent Sales of Unregistered Equity Securities

During the three months ended June 30, 2014 and pursuant to our 2008 Equity Incentive Plan, as amended, we granted stock options to purchase up to an aggregate of 370,606 shares of our common stock to our employees and directors at a weighted-average exercise price of \$8.49 per share. The sales of these securities were deemed to be exempt from registration under Rule 701 promulgated under the Securities Act of 1933, as amended, or the Securities Act, as transactions pursuant to compensatory benefit plans or contracts relating to compensation as provided under Rule 701.

Use of Proceeds

On July 23, 2014, our registration statement on Form S-1 (File No. 333-196979) relating to the IPO of our common stock 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 \$74.865 million. On June 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. On August 1, 2014, we sold an additional 250,000 shares of our common stock directly to the underwriters when they partially exercised their over-allotment option at the initial public offering price of \$12.00 per share. On August 26, 2014, we sold an additional 160,564 shares of our common stock directly to the underwriters when they again partially exercised their over-allotment option at the initial public offering price of \$12.00 per share. We sold an aggregate of 5,410,564 shares of our common stock in the IPO and received aggregate net proceeds of approximately \$60.4 million, after deducting underwriting discounts and commissions of approximately \$4.5 million, excluding expenses. 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 and an exploratory trial comparing LV305 and CMB305 in the same tumor types; (ii) to fund an additional Phase 1 clinical trial of G100 in a second indication; and (iii) 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 prospectus dated July 24, 2014, filed with the SEC pursuant to Rule 424(b)(4) of the Securities Act.

The IPO, and the sale of the 5,410,564 shares of our common stock, occurred after the period covered by this Quarterly Report on Form 10-Q. As such, none of the proceeds from the IPO were used during the period covered by this Quarterly Report on Form 10-Q.

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 are incorporated herein by reference.

Table of Contents

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: September 8, 2014

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

Date: September 8, 2014

/s/ Paul Rickey  
Paul Rickey  
Vice President, Finance and Administration  
(Principal Accounting Officer and Principal Financial Officer)

Table of Contents

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	2014 Omnibus Incentive Plan (incorporated herein by reference to Exhibit 4.6 to the Company's Registration Statement on Form S-8 (File No. 333-197748), as filed with the SEC on July 31, 2014).
10.2	Form of Incentive Stock Option Agreement under 2013 Omnibus Incentive Plan (incorporated herein by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1/A (File No. 333-196979), as filed with the SEC on July 14, 2014).
10.3	Form of Non-Qualified Option Agreement under 2013 Omnibus Incentive Plan (incorporated herein by reference to Exhibit 10.6 to the Company's Registration Statement on Form S-1/A (File No. 333-196979), as filed with the SEC on July 14, 2014).
10.4	2014 Employee Stock Purchase Plan (incorporated herein by reference to Exhibit 4.9 to the Company's Registration Statement on Form S-8 (File No. 333-197748), as filed with the SEC on July 31, 2014).
10.5	Employment Agreement, dated June 20, 2014, by and between Immune Design Corp. and Carlos Paya, M.D., Ph.D. (incorporated herein by reference to Exhibit 10.8 to the Company's Registration Statement (File No. 333-196979), as filed with the SEC on June 23, 2014).
10.6	Employment Agreement, dated June 19, 2014, by and between Immune Design Corp. and Wayne Gombotz, Ph.D. (incorporated herein by reference to Exhibit 10.9 to the Company's Registration Statement (File No. 333-196979), as filed with the SEC on June 23, 2014).
10.7	Employment Agreement, dated June 23, 2014, by and between Immune Design Corp. and Stephen Brady (incorporated herein by reference to Exhibit 10.10 to the Company's Registration Statement (File No. 333-196979), as filed with the SEC on June 23, 2014).
10.8	Employment Agreement, dated June 19, 2014, by and between Immune Design Corp. and Jan Henrik ter Meulen, M.D. (incorporated herein by reference to Exhibit 10.11 to the Company's Registration Statement (File No. 333-196979), as filed with the SEC on June 23, 2014).
10.9	Employment Agreement, dated June 19, 2014, by and between Immune Design Corp. and Richard Kenney (incorporated herein by reference to Exhibit 10.12 to the Company's Registration Statement (File No. 333-196979), as filed with the SEC on June 23, 2014).
10.10	Employment Agreement, dated June 18, 2014, by and between Immune Design Corp. and Paul Rickey (incorporated herein by reference to Exhibit 10.13 to the Company's Registration Statement (File No. 333-196979), as filed with the SEC on June 23, 2014).
10.11	Form of Indemnification Agreement, by and between Immune Design Corp. and each of its directors and officers (incorporated herein by reference to Exhibit 10.14 to the Company's Registration Statement (File No. 333-196979), as filed with the SEC on June 23, 2014).
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.

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- 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, 2014, formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated Balance Sheets, ii) the Consolidated Statements of Comprehensive Income, (iii) the Consolidated Statements of Stockholders' Deficit, (iv) the Consolidated Statements of Cash Flow and (v) Notes to Consolidated Financial Statements.
- \* Filed herewith.
- Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files on Exhibit 101 hereto are deemed not filed or \*\*part of a registration statement or prospectus for purposes of Section 11 or 12 of the Securities Act of 1933, as amended,
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Table of Contents

are deemed not filed for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.