Immune Design Corp.
Form 10-Q
November 09, 2016

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.
For the quarterly period ended September 30, 2016
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	26-2007174
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

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)

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 x 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 x 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 x
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 x
As of November 7, 2016, the number of outstanding shares of the registrant's common stock was 25,409,177.

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

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NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements and information within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act, which are subject to the "safe harbor" created by those sections. In some cases you can identify these statements by forward-looking words such as "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "could," "would," "project," "plan," "expect," or similar expressions, or 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 are able to establish and maintain for intellectual property rights covering our technology and product candidates;
- 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, including, without limitation, the risks set forth in Part II, Item 1A, "Risk Factors" in this Quarterly Report on Form 10-Q and in our other filings with the Securities and Exchange Commission (SEC). You should not rely upon forward-looking statements as predictions of future events.

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

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PART I. FINANCIAL INFORMATION
Item 1. Financial Statements

IMMUNE DESIGN CORP.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share amounts)

	September 30, 2016 (unaudited)	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 70,434	$ 112,921
Short-term investments	42,037	—
Accounts receivable	7,494	972
Inventory	709	13
Prepaid expenses and other current assets	4,552	1,654
Total current assets	125,226	115,560
Property and equipment, net	433	585
Total assets	$ 125,659	$ 116,145
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,863	$ 3,074
Accrued liabilities	4,696	3,959
Accrued litigation-related settlement, current	4,600	—
Deferred revenue and other current liabilities	2,931	78
Total current liabilities	17,090	7,111
Accrued litigation-related settlement, noncurrent	1,250	—
Other noncurrent liabilities	60	41
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Common stock, $0.001 par value; 100,000,000 shares authorized at September 30, 2016 (unaudited) and December 31, 2015; 25,409,177 and 20,153,202 shares issued and outstanding at September 30, 2016 (unaudited) and December 31, 2015, respectively	25	20
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued or outstanding	—	—
Additional paid-in capital	276,519	239,181
Accumulated other comprehensive income	7	—
Accumulated deficit	(169,292)	(130,208)
Total stockholders' equity	107,259	108,993
Total liabilities and stockholders' equity	$ 125,659	$ 116,145

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

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IMMUNE DESIGN CORP.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)
(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
	(unaudited)			
Revenues:				
Licensing revenue	$7,000	$ 3,500	$7,000	$ 3,500
Product sales	426	824	$1,166	932
Collaborative revenue	780	329	3,036	3,939
Total revenues	8,206	4,653	11,202	8,371
Operating expenses:				
Cost of product sales	72	298	347	421
Research and development	11,173	8,263	33,129	24,209
General and administrative	9,554	3,506	17,416	11,086
Total operating expenses	20,799	12,067	50,892	35,716
Loss from operations	(12,593)	(7,414)	(39,690)	(27,345)
Interest and other income	150	7	606	15
Net loss	$(12,443)	$ (7,407)	$(39,084)	$ (27,330)
Other comprehensive income (loss):				
Unrealized (loss) gain on investments	(23)	—	7	—
Comprehensive loss	$(12,466)	$ (7,407)	$(39,077)	$ (27,330)
Basic and diluted net loss per share	$(0.60)	$ (0.37)	$(1.92)	$ (1.45)
Weighted-average shares used to compute basic and diluted net loss per share	20,803,776	20,131,260	20,372,376	18,822,517

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

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

	Nine Months Ended September 30,	
	2016	2015
	(unaudited)	
Operating activities		
Net loss	$(39,084)	$(27,330)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	228	177
Amortization of premium/discount on investments	(30)	—
Stock-based compensation expense	6,907	4,451
Changes in operating assets and liabilities:		
Accounts receivable	(6,522)	(1,173)
Inventory	(696)	(282)
Prepaid expenses and other current assets	(2,898)	(792)
Accounts payable	1,277	(4,224)
Accrued liabilities	737	(557)
Accrued litigation-related settlement	5,850	—
Deferred revenue and other current liabilities	2,872	(528)
Net cash used in operating activities	(31,359)	(30,258)
Investing activities		
Purchases of property and equipment	(76)	(308)
Maturities of short-term investments	23,000	—
Purchases of short-term investments	(65,000)	—
Net cash used in investing activities	(42,076)	(308)
Financing activities		
Issuance of common stock to the public, net of offering costs	30,822	75,359
Proceeds from exercise of stock options and employee stock purchases	126	343
Net cash provided by financing activities	30,948	75,702
Net (decrease) increase in cash and cash equivalents	(42,487)	45,136
Cash and cash equivalents, beginning of period	112,921	75,354
Cash and cash equivalents, end of period	$70,434	$120,490
Supplemental cash flow information		
Stock offering costs incurred, not yet paid	$512	$—

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

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IMMUNE DESIGN CORP.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Information as of September 30, 2016 and for the three and nine months ended September 30, 2016 and 2015 is unaudited)

1. Description of the Business

Immune Design Corp. (we, us or our) is a clinical-stage immunotherapy company focused on cancer with next-generation in vivo approaches designed to enable the body's immune system to fight disease. We have engineered our technologies to activate the immune system's natural ability to create tumor-specific cytotoxic T cells (CTLs) to fight cancer. We are developing multiple product candidates from our two discovery platforms, ZVex® and GLAAS™. Our primary product candidates, CMB305 and G100, utilize multiple immuno-oncology approaches and are in Phase 1 and Phase 2 clinical trials. In addition, we have licensed to third parties the right to use the GLAAS platform in select infectious disease and allergy indications. We were incorporated in February 2008 in the State of Delaware. Our operations are headquartered in Seattle, Washington, and we have an additional facility in South San Francisco, California.

2. Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

The accompanying condensed consolidated 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 condensed consolidated 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. 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.

Principles of Consolidation

Our condensed consolidated financial statements include the financial position and results of operations of Immune Design Corp. and Immune Design Ltd., our wholly owned subsidiary. Immune Design Ltd. was incorporated in the United Kingdom in February 2016 and to date there have been no financial transactions or balances related to this entity.

Unaudited Interim Financial Information

The accompanying unaudited condensed consolidated financial statements as of September 30, 2016 and for the three and nine months ended September 30, 2016 and 2015 and the related interim information contained within the notes to the condensed consolidated financial statements are unaudited. The unaudited interim financial statements have been prepared on the same basis as the audited financial statements and in the opinion of management, reflect all normal recurring adjustments necessary for a fair statement of our financial position for the interim periods presented. The results of operations for the three and nine months ended September 30, 2016 are not necessarily indicative of the results to be expected for the year ended December 31, 2016 or for other future interim periods or years.

The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 2015 included in our Annual Report on Form 10-K for the year ended December 31, 2015, filed with the Securities and Exchange Commission (SEC) on March 15, 2016 (Annual Report).

Short-Term Investments

Our short-term investments include funds invested in U.S. Treasury securities with a final maturity of each security of less than one year. All investments are classified as available-for-sale securities and are recorded at fair value based on quoted prices in active markets, with unrealized gains and losses excluded from earnings and reported in other comprehensive income (loss). Purchase premiums and discounts are recognized in interest income using the

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IMMUNE DESIGN CORP.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)
(Information as of September 30, 2016 and for the three and nine months ended September 30, 2016 and 2015 is unaudited)

interest method over the terms of the securities. Realized gains and losses and declines in fair value that are deemed to be other than temporary are reflected in the condensed consolidated statements of operations and comprehensive income (loss) using the specific-identification method.

Comprehensive Loss

Comprehensive loss is composed of net loss and other comprehensive income or loss that are excluded from net loss. For the periods presented, other comprehensive income consists of unrealized gains on our available-for-sale securities.

Revenue Recognition

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

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

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

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

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

Revenue from product sales of glucopyranosyl lipid A (GLA), a product from our GLAAS platform, is recognized when the risk of loss has passed to the customer or deferred until such time that risk of loss has passed. All revenues associated from the sale of GLA products supplied by us are reported under product sales with the applicable costs reported under cost of product sales. Cost of 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.

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IMMUNE DESIGN CORP.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)
(Information as of September 30, 2016 and for the three and nine months ended September 30, 2016 and 2015 is unaudited)

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB), issued Accounting Standards Update (ASU) No. 2014-09, related to the recognition of revenue. ASU 2014-09 requires entities to recognize revenue through the application of a five step model, which includes identification of the contract, identification of the performance obligations, determination of the transaction price, allocation of the transaction price to the performance obligations, and recognition of revenue as the entity satisfies the performance obligations. The FASB has continued to issue ASUs to clarify and provide implementation guidance related to this standard, including ASU No. 2016-08, which clarifies the implementation guidance on principal versus agent considerations, ASU No. 2016-10, which clarifies the identification of performance obligations and the implementation of licensing guidance and ASU No. 2016-12 which provides narrow scope improvements and practical expedients. These standards are effective retrospectively for annual or interim reporting periods beginning after December 15, 2017, with early application permitted for annual reporting periods beginning after December 15, 2016. Early adoption prior to that date is not permitted. We are evaluating the guidance to determine the potential impact on our results of operations, financial condition, cash flows, and financial statement disclosures.

In February 2016, FASB issued ASU 2016-02 related to lease accounting. This standard will require organizations that lease assets to recognize on the balance sheet the assets and liabilities for the rights and obligations created by those leases that are greater than 12 months in duration. The recognition, measurement, and presentation of expenses and cash flows arising from a lease by a lessee have not significantly changed from previous GAAP. There continues to be a differentiation between finance leases and operating leases; however, the principal difference from previous guidance is that the lease assets and lease liabilities arising from operating leases will be recognized on the balance sheets. For capital or finance leases, lessees will recognize amortization of the right-of-use asset separately from interest on the lease liability. For operating leases, lessees will recognize a single total lease expense. This standard is effective for public companies for the fiscal years and interim reporting periods beginning after December 15, 2018. We are evaluating the guidance to determine the potential impact on our results of operations, financial condition, cash flows, and financial statement disclosures.

In March 2016, FASB issued ASU No. 2016-09 related to stock-based compensation, which primarily changes the accounting for forfeitures and taxes in connection with share-based payment transactions. The amended guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016, with early adoption permitted. We are evaluating the guidance to determine the potential impact on our results of operations, financial condition, cash flows, and financial statement disclosures.

3. Net Loss Per Share

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

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

	September 30,	
	2016	2015
	(unaudited)	
Outstanding options to purchase common stock	3,481,952	2,307,967
Unvested restricted stock units	115,250	—

Total outstanding shares of common stock equivalents	3,597,202	2,307,967

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4. Cash Equivalents and Short-Term Investments

The amortized cost and fair value of our cash equivalents and short-term investments are as follows (in thousands):

	September 30, 2016 (unaudited)			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	$70,398	$ —	$ —	$70,398
U.S. Treasury securities	42,030	35	(28)	42,037
Total	$112,428	$ 35	$ (28)	$112,435
Classified as:				
Cash equivalents				$70,398
Short-term investments				42,037
Total				$112,435

All U.S. Treasury securities held as of September 30, 2016 were classified as available-for-sale securities and had contractual maturities of less than one year. There were no realized gains or losses on these securities for the period presented.

5. Fair Value of Financial Instruments

We measure and record cash and cash equivalents and short-term investments at fair value in the accompanying condensed consolidated 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.

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 and U.S. Treasury securities. The fair value of Level 1 assets has been determined using quoted prices in active markets for identical assets.

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

	September 30, 2016 (unaudited)			
Assets:	LEVEL 1	LEVEL 2	LEVEL 3	TOTAL
Money market funds	$70,398	$ —	$ —	$70,398
U.S. Treasury securities	42,037	—	—	42,037
	$112,435	$ —	$ —	$112,435

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)
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	December 31, 2015			
Assets:	LEVEL 1	LEVEL 2	LEVEL 3	TOTAL
Money market funds	$110,657	$ —	$ —	$110,657

6. Inventory

Inventory consists of the following (in thousands):

	September 30, 2016 (unaudited)	December 31, 2015
Work in process	$ 669	$ —
Finished goods	40	13
Total inventory	$ 709	$ 13

7. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	September 30, 2016 (unaudited)	December 31, 2015
Research and development services	$ 3,603	$ 2,043
Legal and professional services	—	378
Employee compensation	1,093	1,538
Total accrued liabilities	$ 4,696	$ 3,959

8. Commitments and Contingencies

Operating Leases

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

We also lease office space under an operating lease in South San Francisco, California. The lease commenced in January 2015 and continues through January 2020, with an option to extend for an additional five years. In connection with this lease, we were required to provide a $121,000 letter of credit as a security deposit. As of September 30, 2016, no funds had been drawn on the letter of credit.

In January 2016, we entered into a lease agreement to lease approximately 20,133 square feet of office and laboratory space in the building located at 1616 Eastlake Ave. E., Seattle, Washington. This lease includes and expands on the space we currently sublease for our headquarters. The term of the lease is five years with one option to extend the lease term by three years. The lease term is expected to commence on January 1, 2017. The annual base rent due under the lease is $1.1 million for the first year and will increase by 2.5% each year thereafter. In connection with this lease agreement, we will be required to provide a $200,000 letter of credit as a security deposit.

Contingencies

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(Information as of September 30, 2016 and for the three and nine months ended September 30, 2016 and 2015 is unaudited)

In June 2015, we entered into a clinical supply agreement with NanoPass Technologies LTD (NanoPass) for the use of its intradermal delivery device in certain of our clinical trials. In July 2015, in connection with the execution of the clinical supply agreement, we paid NanoPass an upfront fee of $600,000 for access and rights to use its device. In December 2015, we initiated our Phase 2 clinical trial of CMB305 in patients with soft tissue sarcoma which triggered a milestone payment to NanoPass of $500,000. Both the upfront fee and milestone payment were capitalized to prepaid expenses on the accompanying condensed consolidated balance sheets and are being amortized to research and development expense over the related milestone periods. As of September 30, 2016, $111,000 of the payments remain in prepaid expenses. We amortized to research and development expense $111,000 and $150,000 during the three months ended September 30, 2016 and 2015, respectively, and $633,000 and $150,000 during the nine months ended September 30, 2016 and 2015, respectively. In addition, we agreed to pay certain future milestone fees up to an aggregate of $4.0 million upon the achievement of certain clinical milestones using the device.

Under our license agreements with the Infectious Disease Research Institute (IDRI), we are contingently obligated to pay potential future milestone payments for products developed from our GLAAS platform, which could total up to $2.3 million and $1.3 million, respectively, for the first and each subsequent exclusive licensed product we develop, and $1.3 million and $625,000, respectively, for the first and each subsequent non-exclusive licensed product we develop.

We are contingently obligated to pay potential future milestone payments to third parties as part of certain licensing agreements for the ZVex products we develop, which could total up to $2.0 million in aggregate payments.

We also have potential future royalty payments under our licensing agreements as described in Note 9. Payments under these agreements are uncertain due to the occurrence of the events requiring payment under these agreements, including our share of potential future milestone and royalty payments. These payments generally become due and payable only upon achievement of certain clinical development, regulatory or commercial milestones.

9. License and Collaboration Agreements

Licenses Granted

In August 2014, we entered into an agreement with Sanofi under which we granted Sanofi an exclusive license for use of our GLAAS platform to discover, develop and commercialize products to treat peanut allergy. Sanofi may terminate the agreement at any time upon six months' written notice. We recognized milestone revenue under this agreement of $7.0 million for the three and nine months ended September 30, 2016, and $1.0 million for the three and nine months ended September 30, 2015, respectively. The agreement provides for additional payments of up to $160.0 million based upon the attainment of certain development and commercialization milestones, and tiered royalties on sales of approved products.

In October 2010, we entered into three separate license agreements with MedImmune, LLC (MedImmune) pursuant to which we granted MedImmune a worldwide, sublicensable, exclusive license to use GLA to develop and sell vaccines in three different infectious disease indications. Two of the three agreements remain in full force and effect, and the rights granted under the third have returned to us. Under the license agreements, MedImmune is obligated to use commercially reasonable efforts to develop and obtain regulatory approval for a licensed product in certain markets and to market and sell licensed products in any country where it obtains regulatory approval. In 2010, MedImmune paid us upfront payments under the license agreements. Under each license agreement, MedImmune is obligated to make additional payments based on achievement of certain development, regulatory, and commercial milestones for the licensed indication. MedImmune is also obligated to pay us a low double-digit percentage share of non-royalty payments that it receives from sublicensees and a mid single-digit percentage royalty payment on net sales of licensed products, which royalty is subject to reduction under certain circumstances. Under each license agreement, MedImmune is obligated to make additional aggregate payments of up to $62.9 million to $72.5 million, depending on the infectious disease indication, upon the achievement of certain development, regulatory and commercial

milestones for the licensed indication. We did not recognize any revenue

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IMMUNE DESIGN CORP.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)
(Information as of September 30, 2016 and for the three and nine months ended September 30, 2016 and 2015 is unaudited)

under these agreements for the three and nine months ended September 30, 2016. For the three and nine months ended September 30, 2015, we recognized $2.5 million.

Licenses Acquired

In July 2008, we licensed certain patent rights, know-how and technology related to our GLAAS platform from IDRI, specifically products and formulations containing GLA and another synthetic TLR4 agonist referred to as SLA. This license was first amended and restated in 2010.

In November 2015, we entered into a separate agreement with IDRI to license a patent related to our GLAAS technology in the field of cancer. Under this agreement, we paid IDRI an upfront license fee in the amount of $250,000, which was recognized as research and development expense. Upon the achievement of certain developmental and regulatory milestones, we will be obligated to pay IDRI up to $250,000 and $125,000, respectively, for the first and each subsequent licensed product we develop.

In December 2015, we entered into a second amended and restated license agreement with IDRI, in which we obtained additional rights under the licensed technology, which rights vary by disease indication, and we returned to IDRI certain previously licensed GLA rights in select, primarily developing-world infectious disease indications. We received an exclusive license for SLA products in oncology, human allergy and addiction, as well as an option to obtain additional exclusive licenses in select infectious disease indications. In December 2015, in connection with the execution of the second amended and restated license agreement, we paid an upfront fee of $2.3 million, which was recorded as research and development expense. We are obligated to pay IDRI up to $2.3 million and $1.3 million, respectively, in additional payments for the first and each subsequent exclusive licensed product we develop, and $1.3 million and $625,000, respectively, for the first and each subsequent non-exclusive licensed product we develop, based on the achievement of certain developmental and regulatory milestones. In addition, we will be obligated to pay certain commercialization milestones and royalty payments of single-digit percentage of net sales, if and when a licensed product is commercialized. We are also obligated to share with IDRI a percentage of payments received from any third-party sublicensees. Additionally, if we exercise our option for additional infectious disease indications, we will be required to make upfront, milestone and royalty payments for such additional indications, which payments are subject to similar terms and conditions as are applicable to other milestone and royalty payments.

We recognized $225,000 of IDRI license-related milestone fees for the three and nine months ended September 30, 2016, and nothing in IDRI license-related milestone fees for the three and nine months ended September 30, 2015.

In 2009, we licensed certain patent rights utilized in our ZVex development platform from the California Institute of Technology (Caltech). As part of acquiring this license, we issued shares of our common stock to Caltech valued at $25,000. We make annual minimum royalty payments under the license. In addition, we are obligated to pay Caltech up to an aggregate of $1.6 million upon the achievement of certain development and regulatory milestones and will owe royalty payments on net sales of licensed products in the low single-digit percentage, if and when commercialized. We recognized no Caltech milestone fees for the three and nine months ended September 30, 2016 and 2015.

In June 2015, we entered into a clinical supply agreement with NanoPass for the use of their intradermal delivery device in certain of our clinical trials. See Note 8 for additional information.

Collaborations

In October 2014, we entered into a collaboration with Sanofi Pasteur, the vaccines division of Sanofi, for the development of a Herpes Simplex Virus (HSV) immune therapy. Sanofi Pasteur and Immune Design are each contributing product candidates to the collaboration: Sanofi Pasteur is contributing HSV-529, a clinical-stage replication-defective HSV vaccine product candidate, and we are contributing G103, our preclinical trivalent vaccine product candidate. The collaboration will explore the potential of various combinations of agents, including leveraging our GLAAS platform, with the goal to select the best potential immune therapy for patients. Each

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company will develop the products jointly through Phase 2 clinical trials, at which point Sanofi Pasteur intends to continue development of the most promising candidate and be responsible for commercialization. Sanofi Pasteur will bear the costs of all preclinical and clinical development, with Immune Design providing a specific formulation of GLA from the GLAAS platform at its cost through Phase 2 studies. Immune Design will be eligible to receive future milestone and royalty payments on any product developed from the collaboration.

We recognize funding from collaborative research and development efforts as revenue as we perform or deliver the related services in accordance with contract terms as long as we will receive payment for such services upon standard payment terms. The costs of the related services performed are recorded as research and development expenses on the condensed consolidated statements of operations and comprehensive income (loss). We recognized revenue under this collaboration of $780,000 and $329,000 for the three months ended September 30, 2016 and 2015, respectively, and $3.0 million and $3.9 million for the nine months ended September 30, 2016 and 2015, respectively. As of September 30, 2016, we have $2.9 million in unearned revenue on our accompanying condensed consolidated balance sheets related to this agreement.

10. Stockholders' Equity

Preferred Stock

Our board of directors has the authority to fix and determine and to amend the number of shares of any series of preferred stock that is wholly unissued or to be established and to fix and determine and to amend the designation, preferences, voting powers and limitations, and the relative, participating, optional or other rights, of any series of shares of preferred stock that is wholly unissued or to be established. There was no preferred stock issued and outstanding as of September 30, 2016 or December 31, 2015.

Common Stock

In September 2016, we completed an underwritten follow-on public offering of 4,800,000 shares of our common stock at a price of $6.25 per share. Also that same month, we sold an additional 426,369 shares when our underwriters when they exercised a portion of their option to purchase additional shares at $6.25 per share. We received net proceeds of $30.3 million (inclusive of the exercise of a portion of the underwriters' option to purchase additional shares), after underwriting discounts and commissions and offering expenses totaling $2.4 million.

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

We had 25,409,177 and 20,153,202 shares of common stock outstanding as of September 30, 2016 and December 31, 2015, respectively. Shares of common stock reserved for future issuance were as follows:

	September 30, 2016 (unaudited)	December 31, 2015
Shares available for issuance under the employee stock purchase plan	507,498	316,322
Options granted and outstanding	3,481,952	2,832,467
Unvested restricted stock units	115,250	—
Shares available for future stock option grants	825,164	804,553
Shares of common stock reserved for future issuance	4,929,864	3,953,342

Equity Incentive Plans

On January 1, 2016, in accordance with provisions of our 2014 Employee Stock Purchase Plan (2014 ESPP) the authorized shares available under the 2014 ESPP were increased by 200,000 shares.

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On January 1, 2016, in accordance with provisions of our 2014 Omnibus Incentive Plan (2014 Plan), the authorized shares available under the 2014 Plan were increased by 806,128 shares. There were a total of 2,918,334 shares of common stock authorized under the 2014 Plan as of September 30, 2016.

Employee Stock Purchase Plan

During the nine months ended September 30, 2016, 8,824 shares were issued under the 2014 ESPP at a purchase price of $6.94.

Restricted Stock Units

In 2016, we began issuing restricted stock units (RSUs) to employees under the 2014 Plan. The fair value of the RSUs is determined on the date of grant based on the market price of our common stock. RSUs are recognized as expense ratably over the vesting period and our RSUs generally vest over four years with 25% of the total award vesting on each anniversary of the vesting commencement date.

The activity for our RSUs is summarized as follow:

	Shares	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2015	—	—
Granted	118,000	$ 19.39
Vested	—	$ —
Forfeited	(2,750)	$ 19.39
Outstanding at September 30, 2016	115,250	$ 19.39

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, 2015	2,832,467	$ 11.48	8.24	
Granted (unaudited)	827,088	$ 17.38		
Exercised (unaudited)	(20,782)	$ 3.12		
Expired (unaudited)	(29,797)	$ 25.65		
Forfeited (unaudited)	(127,024)	$ 19.06		
Outstanding at September 30, 2016 (unaudited)	3,481,952	$ 12.53	7.86	$ 7,591
Vested and expected to vest after September 30, 2016 (unaudited)	3,331,546	$ 12.32	7.81	$ 7,542
Exercisable as of September 30, 2016 (unaudited)	1,517,001	$ 7.95	6.65	$ 6,304

As of September 30, 2016, there was $18.4 million of total unrecognized stock-based compensation expense related to nonvested stock options that is expected to be recognized over a weighted-average period of 2.5 years. The total intrinsic value of options exercised during the nine months ended September 30, 2016 and 2015 was $124,000 and $4.9 million, respectively.

Stock-Based Compensation Expense

Employee stock-based compensation expense recognized was calculated based on awards ultimately expected to vest and has been reduced for estimated forfeitures. Forfeitures are estimated at the time of grant and revised, as

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necessary, in subsequent periods if actual forfeitures differ from those estimates. Total stock-based compensation expense recognized in our condensed consolidated statements of operations and comprehensive income (loss) is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
	(unaudited)			
Employee:				
Research and development	$957	$480	$2,893	$1,369
General and administrative	1,198	866	3,753	2,811
Non-Employee:				
Research and development	165	(8)	202	88
General and administrative	6	69	59	183
Total stock-based compensation expense	$2,326	$1,407	$6,907	$4,451

We use the Black-Scholes option pricing model to estimate the fair value of stock options at the grant date. The fair values of stock options granted to employees were calculated using the following assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
	(unaudited)			
Weighted-average estimated fair value	$3.25	$12.60	$11.72	$21.20
Risk-free interest rate	1.10% - 1.26%	1.64% - 1.86%	1.10% - 1.84%	1.50% - 1.86%
Expected term of options (in years)	6.08	6.08	5.50 - 6.08	5.50 - 6.08
Expected stock price volatility	77%	78% - 83%	77% - 80%	78% - 91%
Expected dividend yield	—	—	—	—

11. Subsequent Event

Settlement and License Agreements with TheraVectys SA

On October 17, 2016, we entered into a Settlement Agreement and a License Agreement with TheraVectys SA (TVS) obtaining certain present and future intellectual property rights and resolving the litigation initiated against us by TVS in July 2014, as well as related claims and counterclaims. The history of the litigation with TVS is described in our quarterly report on Form 10-Q for the quarter ended June 30, 2016.

Under the Settlement Agreement, TVS has agreed to dismiss all pending litigation brought by TVS against us and to withdraw patent opposition proceedings (EPO Proceeding) brought by TVS against our European Patent No EP 2 456 786 (EU Patent). Also under the Settlement Agreement, both parties have agreed to a broad release of claims against one another based on acts or omissions arising out of the litigation, or the facts and circumstances giving rise to the litigation.

As a non-contingent fee for a license to certain present and future intellectual property of TVS and in consideration for the settlement of all claims and disputes between the parties, we are required to pay $6.0 million into an escrow account within 30 days of the effective date of the Settlement Agreement(Escrowed Payment). As an additional fee for a license to certain present and future intellectual property of TVS and for the settlement of all claims and disputes between the parties, we will be required to pay $1.25 million to TVS when, following the effective date of the

Settlement Agreement, we raise $25.0 million, in the aggregate, through equity sales, debt or licensing revenue.

The Escrowed Payment will be disbursed to TVS as follows: (a) fifty percent (50%) when Institut Pasteur consents to the granting by TVS to us of a sublicense to certain patents licensed by TVS (or to be licensed by TVS) from

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Institut Pasteur and the litigation in the United States and Belgium has been dismissed; and (b) fifty percent (50%) upon the final resolution of the EPO Proceeding if the scope of the EU Patent remains unchanged; provided, that the events described in item (a) are a condition to the release of any portion of the Escrowed Payment to TVS and must occur by certain agreed time periods. Currently, we believe that the condition under item (b) has been satisfied, because following an oral hearing in front of the EPO in September 2016, the EU Patent was maintained without a reduction in scope, and TVS has withdrawn from the EPO proceeding, thereby waiving the right to appeal the EPO's decision.

The License Agreement provides us with a field limited, non-exclusive, sublicensable license for oncology uses to certain current and future intellectual property rights owned, controlled and licensed by TVS. For licensed products developed under the License Agreement, we would be obligated to pay certain development and commercial milestones and royalties.

For each licensed product under the License Agreement, we will be obligated to pay TVS: (a) up to an aggregate of $5.75 million upon achievement of certain development and regulatory milestones, except that the first two milestone payments are waived for CMB305/LV305; (b) royalties on net sales made directly by us or our affiliates; (c) a mid-single digit percentage of sublicensing revenues received by us attributable to the sublicensing of TVS' intellectual property; and (d) a single commercial milestone payment based on the product achieving a specified net sales amount. The royalties on the first four licensed products (including CMB305/LV305 as a single product) will be on a low-single digit percentage of net sales, and royalties on subsequent licensed products will be tiered on low-to-mid-single digit percentages of net sales, in each case subject to royalty-offset provisions.

The term of the License Agreement expires upon the last to expire valid patent claim that is licensed to us under the License Agreement. The License Agreement may also be terminated by either party for customary reasons, such as an uncured material breach by the other party, or the other party’s insolvency. We may terminate the License Agreement upon 30 days’ prior written notice to TVS.

Per the terms of the Settlement Agreement, we determined that the aggregate payment amount expected to be paid to TVS is $7.25 million and as such, the aggregate payment amount should be allocated between (1) dismissal of the litigation; and (2) license to current and future TVS intellectual property (IP). As we are not able to reliably estimate the fair value of the litigation dismissal, we assigned a fair value to the aggregate amount of the license to current and future TVS IP through the use of a benchmarking approach and determined the fair value of the license to current and future IP obtained from TVS by benchmarking this deal against similar recent (within the last 5 years) deals within our industry. The metrics we used in our benchmarking approach included similarities in industry, product type, therapeutic area, stage of product development and exclusivity. Based upon the results of our benchmark approach, we determined that the fair value assigned to the license to current and future TVS IP to be $1.4 million with the remaining residual amount of $5.85 million allocated to the dismissal of the litigation.

Because the litigation existed as of September 30, 2016, the dismissal of the litigation per the terms of the Settlement Agreement entered into on October 17, 2016 is deemed to be a recognized subsequent event, and the $5.85 million allocated to the dismissal of litigation is recorded as general and administrative expense for the three and nine months ended September 30, 2016. Since the $1.4 million allocated to the license acquired is for current and future TVS IP granted to us subsequent to September 30, 2016, this is considered a nonrecognized subsequent event, and will be recognized in the quarter ended December 31, 2016.

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

You should read the following management's discussion and analysis of financial condition and results of operations in conjunction with our unaudited condensed consolidated 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, 2015, included in our Annual Report on Form 10-K (Annual Report), filed with the SEC.

Overview

We are a clinical-stage immunotherapy company employing next-generation in vivo approaches to enable the body's immune system to fight disease. Although we believe our approaches have broad potential across multiple therapeutic areas, we are focused in oncology and have engineered our technologies to activate the immune system's natural ability to generate and expand tumor-specific cytotoxic T cells to fight cancer. Our two primary product candidates, CMB305 and G100, utilize distinct immuno-oncology approaches that, we believe, address the shortcomings of existing therapies and have the potential to treat a broad patient population either as individual therapies or in combination with other mechanisms of action, such as checkpoint inhibitors. We have also been executing a strategy to partner individual indications outside of oncology in infectious and allergic diseases, which provide potential downstream economics while preserving growth opportunity in the future.

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

Our net loss was $12.4 million and $39.1 million for the three and nine months ended September 30, 2016, respectively, compared to $7.4 million and $27.3 million for the three and nine months ended September 30, 2015, respectively. As of September 30, 2016, we had an accumulated deficit of $169.3 million. We have incurred net losses to date and we expect to continue to incur significant expenses and increasing operating losses for at least the next several years.

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

- complete our current and planned Phase 1 and Phase 2 clinical trials, as well as potentially initiate new clinical trials for existing product candidates, including pivotal trials;
- continue research and development efforts to build our pipeline beyond the current product candidates;
- perform additional process development for our product candidates, including initial commercial scale up efforts;
- seek regulatory approvals for our product candidates, if any, that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize and market products for which we obtain regulatory approval;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, quality control, scientific and management personnel; and
- add operational and financial personnel to support our product development efforts and operational support applicable to operating as a public company.

We do not expect to generate significant revenue unless and until we successfully complete development of, obtain marketing approval for and commercialize our product candidates, either alone or in collaboration with third parties. We expect these activities will take a number of years and our success in these efforts is subject to significant uncertainty. Accordingly, we will need to raise additional capital prior to the regulatory approval and commercialization of any of our product candidates. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our operating activities through public or private equity or debt financings,

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collaborations or licenses, capital lease transactions or other available financing transactions. However, additional capital may not be available on reasonable terms, if at all, and if we raise additional funds through the issuance of additional equity or debt securities, it could result in dilution to our existing stockholders and increased fixed payment obligations.

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

Third Quarter 2016 and Other Recent Highlights

In September 2016, we completed an underwritten follow-on public offering, which resulted in the sale of 4,800,000 shares of our common stock to the public at a price of $6.25 per share. We sold an additional 426,369 shares when our underwriters exercised a portion of their option to purchase additional shares at $6.25 per share. We received net proceeds from the offering of $30.3 million (inclusive of the exercise of a portion of the underwriters' option to purchase additional shares) after deducting underwriting discounts and commissions and estimated expenses.

In September 2016, Sanofi initiated a Phase 1 clinical trial applying our GLAAS platform with Sanofi's novel therapeutic candidate for the treatment of peanut allergy. For beginning this trial, we received milestone revenue of $7.0 million under our License Agreement with Sanofi.

In October 2016, we entered into a Settlement Agreement and a License Agreement with TheraVectys SA (TVS) resolving litigation initiated by TVS in July 2014 against the Company, as well as related claims and counterclaims. As a non-contingent fee for a license to certain present and future intellectual property of TVS and in consideration for the settlement of all claims and disputes between the parties, within 30 days of the effective date of the Settlement Agreement we are required to pay $6.0 million into an escrow account, which amount will be released from escrow to TVS upon achieving certain conditions of the Settlement Agreement. Additional information relating to the Settlement Agreement and License Agreement is described in this Quarterly Report under Note 11 to the Financial Statements (Subsequent Event).

Clinical Development Programs

In June 2016, we announced and presented results from the following three Phase 1 clinical trials of our immuno-oncology product candidates at medical meetings and investor events, including data on LV305 and G100 at the 2016 annual meeting of the American Society of Clinical Oncology (ASCO):

- CMB305. Enrollment is ongoing in the expansion arm of our Phase 1 single agent trial of CMB305 in patients with cancers expressing the NY-ESO-1 tumor antigen. Shortly after ASCO, we presented early patient data from a completed first-in-human dose-escalation trial and an early subset of patients from an expansion trial of CMB305 in patients with soft tissue sarcoma showed that CMB305 had a favorable safety profile with only grade 1 and 2 adverse events and without dose-limiting toxicities. In addition, patients who responded immunologically had a greater degree of antigen-specific T cell response than previously reported in the Phase 1 trial of LV305 alone, which is consistent with the rationale of the prime boost approach. We also observed preliminary clinical benefit in the form of a median progression-free survival (PFS) of 5.5 months, with a 93% patient survival as of the data review date.
- LV305. We completed enrollment in our Phase 1 single agent trial of LV305 in 24 patients with advanced or metastatic sarcoma expressing NY-ESO-1. At ASCO, we presented data showing that 58% had clinical benefit in the form of stable disease (SD) and one patient showed a partial response (PR), and median PFS was 4.6 months. In addition, median OS had not yet been reached, with 81% survival at one year. A different arm of this trial will explore the use of LV305 with Merck's anti-PD-1 agent, KEYTRUDA®, in melanoma patients who have an inadequate response to anti-PD1 therapy, pursuant to a collaboration with Merck.
- G100. We completed enrollment of our Phase 1 trial of G100, in combination with radiation, in patients with Merkel cell carcinoma (MCC). At ASCO, we presented data on all 10 patients, which showed an overall

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response rate (ORR) of 50% per protocol, a favorable safety profile with no treatment-related serious adverse events observed, and that G100 significantly altered the tumor microenvironment in responding patients..

In later stage clinical development, enrollment is ongoing in both of our randomized Phase 2 trials: (1) CMB305 in patients with NY-ESO-1 positive soft tissue sarcoma who receive either CMB305 combined with Genentech's investigational cancer immunotherapy, atezolizumab (anti-PD-L1), or atezolizumab alone, pursuant to a collaboration with Genentech; and (2) G100 in patients with follicular non-Hodgkin Lymphoma in combination with local radiation and Merck's anti-PD-1 agent, KEYTRUDA®, or G100 in combination with local radiation alone, pursuant to a collaboration with Merck.

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.

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.

Research and Development Expenses

We focus our resources on our internal and collaborative research and development activities, including the conduct of preclinical studies, product development, and 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 stock-based compensation, lab supplies and facility costs, as well as fees paid to other entities that conduct certain research and development activities, including clinical studies and manufacturing, on our behalf.

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

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

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	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
	(unaudited)			
Direct research and development expense by platform:				
ZVex	$2,641	$4,911	$12,309	$11,712
GLAAS	2,628	656	4,479	1,747
G103	832	314	2,943	3,735
Total direct research and development program expense	6,101	5,881	19,731	17,194
Indirect research and development expense by type:				
Personnel related costs	2,720	2,003	8,048	5,920
Research and development supplies and services	1,779	141	3,985	408
Allocated facility, equipment, travel and other expense	573	238	1,365	687
Total indirect research and development expense	5,072	2,382	13,398	7,015
Total research and development expense	$11,173	$8,263	$33,129	$24,209

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

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

General and Administrative Expenses

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

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

Interest and Other Income (Expense)

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

Critical Accounting Policies and Estimates

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

conditions.

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Our significant accounting policies are more fully described in Note 2 of the accompanying unaudited condensed consolidated financial statements and in Note 2 to the audited financial statements contained in our Annual Report. There have been no significant or material changes in our critical accounting policies during the nine months ended September 30, 2016, as compared to those disclosed in "Management's Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies and Use of Estimates" in our Annual Report, except the following:

Principles of Consolidation

Our condensed consolidated financial statements include the financial position and results of operations of Immune Design Corp. and Immune Design Ltd., our wholly owned subsidiary. Immune Design Ltd. was incorporated in the United Kingdom in February 2016 and to date there have been no financial transactions or balances related to this entity.

Short-term Investments

Our short-term investments include funds invested in U.S. Treasury securities with a final maturity of each security of less than one year. All investments are classified as available-for-sale securities and are recorded at fair value based on quoted prices in active markets, with unrealized gains and losses excluded from earnings and reported in other comprehensive income (loss). Purchase premiums and discounts are recognized in interest income using the interest method over the terms of the securities. Realized gains and losses and declines in fair value that are deemed to be other than temporary are reflected in the condensed consolidated statements of operations and comprehensive income (loss) using the specific-identification method.

Comprehensive Income (Loss)

Comprehensive loss is composed of net loss and other comprehensive income or loss that are excluded from net loss. For the periods presented, other comprehensive income consists of unrealized gains on our available-for-sale securities.

Results of Operations

Comparison of Three Months Ended September 30, 2016 and 2015

The following table summarizes our results of operations for the three months ended September 30, 2016 and 2015:

	Three Months Ended September 30,		Increase/ (Decrease)
	2016	2015	
	(in thousands) (unaudited)		
Total revenues	$8,206	$4,653	$ 3,553
Operating expenses:			
Cost of product sales	72	298	(226)
Research and development	11,173	8,263	2,910
General and administrative	9,554	3,506	6,048
Total operating expenses	20,799	12,067	8,732
Loss from operations	(12,593)	(7,414)	(5,179)
Interest and other income	150	7	143
Net loss	$(12,443)	$(7,407)	$ (5,036)

Total Revenues and Cost of Product Sales

The $3.6 million increase in total revenues was primarily attributable to a $3.5 million increase in licensing revenue as a result of the $7.0 million milestone revenue recognized under our License Agreement with Sanofi during the three months ended September 30, 2016 compared to $3.5 million in licensing revenue recognized in the same period in prior year. In addition, we had a $0.5 million increase in collaboration revenue related to timing of research services associated with the Sanofi Pasteur G103 collaboration that was entered into in the fourth quarter of 2014. These increases were partially offset by a $0.4 million decrease in product sales related to the timing of product shipments to our collaboration partners.

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Research and Development Expenses

The $2.9 million increase in research and development expenses was primarily attributable to an increase of $2.5 million in our clinical trials costs related to the continuing advancement of our Phase 1 and Phase 2 clinical trials. In addition, we had an increase of $0.9 million in personnel-related expenses, which was primarily due to an increase in compensation and benefits and higher stock-based compensation as a result of an increase in research and development headcount to support our advancing research and clinical pipeline, and an increase of $0.5 million in license and royalty fees due to other third parties. These increases were partially offset by a decrease of $0.9 million in our ongoing contract manufacturing and process development programs due primarily to the timing of services.

General and Administrative Expenses

The $6.0 million increase in general and administrative expenses was primarily attributable to the $5.85 million litigation-related settlement recorded during the three months ended September 30, 2016, as part of our Settlement Agreement with TVS. In addition, we had an increase of $0.3 million in personnel-related expenses due to higher stock-based compensation expense.

Comparison of Nine Months Ended September 30, 2016 and 2015

The following table summarizes our results of operations for the nine months ended September 30, 2016 and 2015:

	Nine Months Ended September 30,		Increase/ (Decrease)
	2016	2015	
	(in thousands) (unaudited)		
Total revenues	$11,202	$8,371	$2,831
Operating expenses:			
Cost of product sales	347	421	(74)
Research and development	33,129	24,209	8,920
General and administrative	17,416	11,086	6,330
Total operating expenses	50,892	35,716	15,176
Loss from operations	(39,690)	(27,345)	(12,345)
Interest and other income	606	15	591
Net loss attributable to common stockholders	$(39,084)	$(27,330)	$(11,754)

Total Revenues and Cost of Product Sales

The $2.8 million increase in total revenues was primarily attributable to a $3.5 million increase in licensing revenue as a result of the $7.0 million milestone revenue recognized under our License Agreement with Sanofi during the nine months ended September 30, 2016 compared to $3.5 million in licensing revenue recognized in the same period in prior year. In addition, we had a $0.2 million increase in product sales related to product shipments to our collaboration partners. These increases were partially offset by a $0.9 million decrease in collaboration revenue related to timing of research services associated with the Sanofi Pasteur G103 collaboration that was entered into in the fourth quarter of 2014.

Research and Development Expenses

The $8.9 million increase in research and development expenses was primarily attributable to an increase of $6.8 million in our clinical trials costs related to the continuing advancement of our Phase 1 and Phase 2 clinical trials. In addition, we had an increase of $2.3 million in personnel-related expenses, which was primarily due to an increase in compensation and benefits and higher stock-based compensation as a result of an increase in research and development headcount to support our advancing research and clinical pipeline, an increase of $0.5 million in license and royalty fees due to other third parties and an increase of $0.3 million in facility-related expenses as a result of our growth in research and development. These increases were partially offset by a decrease of $1.0 million in our ongoing contract manufacturing and process development programs due primarily to the timing of services.

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General and Administrative Expenses

The $6.3 million increase in general and administrative expenses was primarily attributable to the $5.85 million litigation-related settlement recorded during the nine months ended September 30, 2016, as part of our Settlement Agreement with TVS. In addition, we had an increase of $0.7 million in personnel-related expenses due to higher stock-based compensation expense. These increases were partially offset by a decrease of $0.3 million in professional services due primarily to a decrease in legal costs related to defending our litigation with TVS.

Liquidity and Capital Resources

Liquidity

As of September 30, 2016, we had cash and cash equivalents and short-term investments totaling $112.5 million. In addition to our existing cash, cash equivalents and short-term investments, 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.

In September 2016, we completed an underwritten follow-on public offering, which resulted in the sale of 4,800,000 shares of our common stock to the public at a price of $6.25 per share. We sold an additional 426,369 shares when our underwriters exercised a portion of their option to purchase additional shares at $6.25 per share. We received net proceeds from the offering of $30.3 million (inclusive of the exercise of a portion of the underwriters' option to purchase additional shares), after deducting underwriting discounts and commissions and estimated expenses totaling $2.4 million.

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

Capital Resources

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

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

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Based on our research and development plans and our timing expectations related to the progress of our programs, we expect that our existing cash and cash equivalents as of September 30, 2016 will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we expect. Additionally, the process of developing products and testing them in clinical trials is costly, and the timing of progress and expenses in these trials is uncertain. Our future capital requirements will depend on many factors, including, among others:

- the scope, rate of progress, results and costs of our clinical trials, preclinical studies and other research and development activities;
- the scope, rate of progress and costs of our manufacturing development and commercial manufacturing activities;
- the cost, timing and outcomes of regulatory proceedings, including the U.S. Food and Drug Administration (FDA) review of any Biologics License Application (BLA) we file;
- payments required with respect to development milestones we achieve under our in-licensing agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims;
- the costs associated with commercializing our product candidates, if they receive regulatory approval;
- the cost and timing of developing our ability to establish sales and marketing capabilities;
- the costs of current or future litigation or judgments;
- competing technological efforts and market developments;
- changes in our existing research relationships;
- our ability to establish collaborative arrangements to the extent necessary;
- revenues received from any existing or future products; and
- payments received under any current or future strategic partnerships.

Cash Flows

The following is a summary of our cash flows (in thousands) for the nine months ended September 30, 2016 and 2015:

	Nine Months Ended September 30,	
	2016	2015
	(unaudited)	
Net cash used in operating activities	$(31,359)	$(30,258)
Net cash used in investing activities	(42,076)	(308)
Net cash provided by financing activities	30,948	75,702

Net Cash Used in Operating Activities

Net cash used in operating activities was $31.4 million during the nine months ended September 30, 2016 and consisted primarily of our net loss of $39.1 million, partially offset by non-cash charges of $6.9 million for stock-based compensation expense and a net increase in operating assets and liabilities of $0.6 million.

Net cash used in operating activities was $30.3 million during the nine months ended September 30, 2015 and consisted of our net loss of $27.3 million, partially offset by non-cash charges of $4.5 million for stock-based compensation expense and a net decrease in operating assets and liabilities of $7.6 million.

Net Cash Used in Investing Activities

Net cash used in investing activities was $42.1 million during the nine months ended September 30, 2016 and consisted primarily of our purchase of $65.0 million in short-term investments in U.S. Treasury securities, partially offset by $23.0 million in maturities of these investments. Net cash used in investing activities was $0.3 million for the nine months ended September 30, 2015 and primarily relates to the purchase of property and equipment, primarily lab equipment, to support research and development efforts.

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Net Cash Provided by Financing Activities

Net cash provided by financing activities was $30.9 million for the nine months ended September 30, 2016, primarily attributable to net proceeds of $30.8 million from an underwritten public equity offering completed in September 2016, as well as cash received from the exercise of stock options and purchase of ESPP shares. Net cash provided by financing activities was $75.7 million for the nine months ended September 30, 2015, which consisted of $75.4 million in net proceeds received from our Secondary Offering plus cash received for the exercise of stock options and purchase of ESPP shares.

Contractual Obligations and Contingent Liabilities

During the nine months ended September 30, 2016, there were no material changes to our contractual obligations and commitments described under the section titled "Management’s Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report.

Off-Balance Sheet Arrangements

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

JOBS Act

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

We will remain an “emerging growth company” until the earliest of (a) the last day of the fiscal year in which we have total annual gross revenues of $1.0 billion or more, (b) the last day of our fiscal year following the fifth anniversary of the completion of the our IPO in July 2014, (c) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years or (d) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates and concentration of credit risk. As of September 30, 2016, we had cash and cash equivalents of $70.4 million consisting of bank deposits and interest-bearing money market accounts and short-term investments of $42.0 million consisting of U.S. Treasury securities. Our cash balances deposited in a bank in the United States may be in excess of insured levels. We do not believe our cash, cash equivalents and short-term investments have significant risk of default or illiquidity.

Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because the majority of our investments are in short-term marketable debt securities. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our investments without significantly increasing risk. In an attempt to limit interest rate risk, we follow guidelines to limit the average and longest single maturity dates, place our investments with high quality issuers and follow internally developed guidelines to limit the amount of credit exposure to any one issuer. Some of the securities that we invest in may be subject to market risk. This means that a change in prevailing interest rates may cause the value of the investment to fluctuate. For example, if we purchase a security that was issued with a fixed interest rate and the prevailing interest rate later rises, the value of our investment may decline. If a ten percent change in interest rates were to have occurred on September 30, 2016, this change would not have had a material effect on the fair value of our investment portfolio as of that date. In general, money market funds are not subject to market risk because the interest paid on such funds fluctuates with the prevailing interest rate.

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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 Executive Vice President, Strategy & Finance, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities and Exchange Act of 1934, as amended (the Exchange Act)), as of the end of the period covered by this report. Based upon the evaluation, the President and Chief Executive Officer and Executive Vice President, Strategy & Finance 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 Exchange Act 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 Executive Vice President, Strategy & Finance, as appropriate to allow timely discussion regarding required disclosure.

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

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PART II: OTHER INFORMATION

Item 1. Legal Proceedings

TheraVectys SA v. Immune Design Corp.

On October 17, 2016, we entered into a Settlement Agreement and a License Agreement with TheraVectys SA (TVS) obtaining certain present and future intellectual property rights and resolving the litigation initiated against us by TVS in July 2014, as well as related claims and counterclaims. The history of the litigation with TVS is described in our quarterly report on Form 10-Q for the quarter ended June 30, 2016.

Under the Settlement Agreement, TVS has agreed to dismiss all pending litigation brought by TVS against us and to withdraw patent opposition proceedings (EPO Proceeding) brought by TVS against our European Patent No EP 2 456 786 (EU Patent). Also under the Settlement Agreement, both parties have agreed to a broad release of claims against one another based on acts or omissions arising out of the litigation, or the facts and circumstances giving rise to the litigation. Neither party made any admission of liability or wrongdoing under the Settlement Agreement. The Settlement Agreement includes customary representations and warranties that each party has made to the other party, as well as an agreement that TVS will not use certain manufacturers with lentiviral vector manufacturing expertise for a defined period of time or for so long as we are making use of those manufacturers.

As a non-contingent fee for a license to certain present and future intellectual property of TVS and in consideration for the settlement of all claims and disputes between the parties, we are required to pay $6.0 million into an escrow account within 30 days of the effective date of the Settlement Agreement (Escrowed Payment). As an additional fee for a license to certain present and future intellectual property of TVS and for the settlement of all claims and disputes between the parties, we will be required to pay $1.25 million to TVS when, following the effective date of the Settlement Agreement, we raise $25.0 million, in the aggregate, through equity sales, debt or licensing revenue.

The Escrowed Payment will be disbursed to TVS as follows: (a) fifty percent (50%) when Institut Pasteur consents to the granting by TVS to us of a sublicense to certain patents licensed by TVS (or to be licensed by TVS) from Institut Pasteur and the litigation in the United States and Belgium has been dismissed; and (b) fifty percent (50%) upon the final resolution of the EPO Proceeding if the scope of the EU Patent remains unchanged; provided, that the events described in item (a) are a condition to the release of any portion of the Escrowed Payment to TVS and must occur by certain agreed time periods. Currently, we believe that the condition under item (b) has been satisfied, because following an oral hearing in front of the EPO in September 2016, the EU Patent was maintained without a reduction in scope, and TVS has withdrawn from the EPO proceeding, thereby waiving the right to appeal the EPO's decision.

The License Agreement provides us with a field limited, non-exclusive, sublicensable license for oncology uses to certain current and future intellectual property rights owned, controlled and licensed by TVS. For licensed products developed under the License Agreement, we would be obligated to pay certain development and commercial milestones and royalties.

For each licensed product under the License Agreement, we will be obligated to pay TVS: (a) up to an aggregate of $5.75 million upon achievement of certain development and regulatory milestones, except that the first two milestone payments are waived for CMB305/LV305; (b) royalties on net sales made directly by us or our affiliates; (c) a mid-single digit percentage of sublicensing revenues received by us attributable to the sublicensing of TVS' intellectual property; and (d) a single commercial milestone payment based on the product achieving a specified net sales amount. The royalties on the first four licensed products (including CMB305/LV305 as a single product) will be on a low-single digit percentage of net sales, and royalties on subsequent licensed products will be tiered on low-to-mid-single digit percentages of net sales, in each case subject to royalty-offset provisions.

The term of the License Agreement expires upon the last to expire valid patent claim that is licensed to us under the License Agreement. The License Agreement may also be terminated by either party for customary reasons, such as an uncured material breach by the other party, or the other party’s insolvency. We may terminate the License Agreement upon 30 days’ prior written notice to TVS.

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European Patent Opposition

In February 2013, a third party filed an opposition at the European Patent Office (EPO) requesting revocation of European Patent No. 2068918 directed to GLA formulations and uses. This patent is owned by Infectious Disease Research Institute (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. The oral proceedings for this opposition were held in September 2016. At the oral proceedings, the EPO maintained the patent in an amended form, which continues to cover the GLAAS products being developed by us and our licensees. We and the opponent may appeal this outcome, and we cannot be certain that this patent will be maintained by the EPO at an appeal hearing, or if any reduction to the 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 outcome of an appeal to this proceeding would not be known for several years.

Item 1A. Risk Factors

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

Risks Related to Our Financial Position and Capital Needs

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

We are a clinical-stage biotechnology company with a limited operating history. Investment in biotechnology product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, obtain regulatory approval or become commercially viable. We have no products approved for commercial sale and have generated only limited revenue to date. We continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not and have never been profitable and have incurred losses in each period since our inception in 2008. For the three and nine months ended September 30, 2016, we reported net losses of $12.4 million and $39.1 million, respectively, compared with net losses of $7.4 million and $27.3 million for the three and nine months ended September 30, 2015, respectively. As of September 30, 2016, we had an accumulated deficit of $169.3 million.

We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates. 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.

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We currently have limited revenues and may never achieve or maintain profitability.

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

- successfully complete the research and clinical development of and receive regulatory approval for current and future product candidates, including those of our licensees for the use of GLA in specific indications;
- launch, commercialize and achieve market acceptance of our 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 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 or 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 BLA we file;
- payments required under our existing or future in-licensing agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims;
- the costs associated with commercializing our product candidates, if they receive regulatory approval;
- the cost and timing of developing our ability to establish sales and marketing capabilities;
- the costs of current or future litigation, judgments or settlements;

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- 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.

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

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

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

Until we can generate a sufficient amount of revenue from our product candidates, if ever, we expect to finance future cash needs through public or private equity or debt offerings or from other sources. Additional capital may not be available on reasonable terms, if at all. If we raise additional funds through the issuance of additional equity or debt securities, it could result in dilution to our existing stockholders and increased fixed payment obligations. Furthermore, these securities may have rights senior to those of our common stock and could contain covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these restrictions 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 (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.

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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 product candidates that are in Phase 1 and Phase 2 clinical development. 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 or approved by the FDA.

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. If our clinical results are not successful, we may terminate the clinical trials for a product candidate and abandon any further research or testing of the product candidate. Any delay in, or termination of, our clinical trials will delay and possibly preclude the filing of any BLAs with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues.

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

Our product candidates may not prove to be safe and effective in clinical trials and may not meet all of the applicable regulatory requirements needed to receive regulatory approval. 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 medical indication being evaluated, the role of other products being evaluated in combination, results of previous trials and the 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 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 initiating clinical trial sites to conduct our clinical trials and reaching agreement on acceptable terms and budgets with prospective clinical trial sites;
- delays in, or failure to obtain, approval from institutional review boards (IRBs), ethics committees (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;
- 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;

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- 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 enroll in a trial, complete participation in a trial or return for post-treatment follow-up;
- delays caused by patients dropping out of a trial due to side effects, disease progression or other reasons;
- slow patient enrollment because of the perceived risk of contracting HIV because the viral vector we use in LV305 and CMB305 was constructed from genetic sequences, some of which were derived from HIV;
- withdrawal of clinical trial sites from our clinical trials as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials; or
- changes in government regulations or administrative actions or lack of adequate funding to continue the clinical trials.

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

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

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

- the nature and size of the patient population;
- the number and location of clinical sites we enroll;
- competition with other companies for clinical sites and patients;
- design of the trial protocol;
- eligibility criteria for the study in question;
- slow enrollment because of the perceived risk by patients of contracting HIV because the viral vector we use in LV305 and CMB305 was constructed from genetic sequences, some of which were derived from HIV;
- ability to obtain and maintain patient consents; and
- clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay or terminate ongoing or planned clinical trials, either of which would have an adverse effect on our business.

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

Undesirable side effects caused by our product candidates, alone or in combination with other therapies being studied in our clinical trials, 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

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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 (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 class of product candidates or otherwise materially harm the commercial prospects for the product candidate, if approved, and could significantly harm our business, results of operations and prospects.

We may be required to suspend, repeat, redesign or terminate our clinical trials if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive or the trials are not well designed.

Clinical trials must be conducted in accordance with the FDA’s current Good Clinical Practices (cGCP) or other applicable foreign government guidelines. Clinical trials are subject to oversight by the FDA, other foreign governmental agencies and 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 (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 adequately 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.

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

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

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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 jurisdictions outside the United States, 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 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

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affected. We may not obtain foreign regulatory approvals on a timely basis, if at all. Our failure to obtain approval of any of our product candidates by regulatory authorities in countries outside of the United States may significantly diminish the commercial prospects of that product candidate and our business prospects could decline.

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

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

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

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

The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenue.

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

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false claims statutes include, but are not limited to, the federal civil False Claims Act, which allows any individual to bring a lawsuit against an individual or entity, including a pharmaceutical or biopharmaceutical company on behalf of the federal government alleging the knowing submission of false or fraudulent claims, or causing to present such false or fraudulent claims, for payment or approval by a federal program such as Medicare or Medicaid. If the government decides to intervene and prevails in the lawsuit, the individual initiating the lawsuit will share in any fines or settlement funds. These False Claims Act lawsuits against pharmaceutical and biopharmaceutical companies have increased significantly in number and breadth, leading to several substantial civil and criminal settlements regarding certain sales practices, including promoting off-label drug uses involving fines in excess of $1.0 billion. This growth in litigation has increased the risk that a pharmaceutical or biopharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations, and be excluded from Medicare, Medicaid and other federal and state healthcare programs. If we do not lawfully promote our approved products, if any, we may become subject to such litigation, which would 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, frequency and ease of administration;
- the frequency and severity of adverse events;
- the effectiveness of sales and marketing efforts; and
- unfavorable publicity relating to the product candidate.

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

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

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

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

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

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

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

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

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

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

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

- train, manage and motivate a growing employee base;
- accurately forecast demand for our products; and
- expand existing operational, financial and management information systems.

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

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

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

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and retain qualified personnel necessary for the development of our business or to recruit suitable replacement personnel.

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

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

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

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

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

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or, collectively, the Affordable Care Act. Among other things, the Affordable Care Act expanded manufacturers’ rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs, effective the first quarter of 2010 and revising the definition of “average manufacturer price,” or AMP, for calculating and reporting purposes. 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 expanded manufacturers' rebate liability under the Medicaid program from fee-for-service Medicaid utilization, to include utilization of Medicaid managed care organization as well 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. Federal law requires that any company that participates in the Medicaid rebate program also participate in the Public Health Service’s 340B drug pricing program in order for federal funds to be available for the manufacturer’s drugs under Medicaid and Medicare Part B. The 340B drug pricing program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B “ceiling price” for the manufacturer’s covered outpatient drugs. The Affordable Care Act expanded the types of entities eligible to receive discounted 340B pricing. In addition, because 340B pricing is determined based on AMP and Medicaid drug rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discounts to increase. The Affordable Care Act also imposes a significant annual fee on companies that manufacture or import branded prescription drug products. Furthermore, as of 2011, this law changed the Medicare Part D coverage gap discount program by requiring manufacturers to provide a 50% point-of-sale-discount off the negotiated price of applicable brand drugs to certain eligible beneficiaries during their coverage gap period as a condition for the manufacturers’ outpatient drugs to be covered under Medicare Part D. On February 1, 2016, the Centers for Medicare and Medicaid

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Services, the federal agency that administers the Medicaid Drug Rebate Program, issued final regulations to implement the changes to the Medicaid Drug Rebate program under the Affordable Care Act. These regulations become effective on April 1, 2016.

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.

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. The legislation's automatic reduction to several government programs was triggered. This includes aggregate reductions to Medicare payments to providers, on average, of up to 2% through 2025. 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 remain in effect unless Congress repeals or amends the reductions in future legislation. Continuation of sequestration or enactment of other reductions in Medicare reimbursement for drugs could affect our ability to achieve a profit on any candidate products that are approved for marketing.

Moreover, the recently enacted Drug Supply Chain Security Act imposes new obligations on manufacturers of pharmaceutical products, related to product tracking and tracing. Among the requirements of this new legislation, manufacturers will be required to provide certain information regarding drug products to individuals and entities to which product ownership is transferred, label drug product with a product identifier, and keep certain records regarding the drug product. The transfer of information to subsequent product owners by manufacturers will eventually be required to be done electronically. Manufacturers will also be required to verify that purchasers of the manufacturers' products are appropriately licensed. Further, manufacturers will have drug product investigation, quarantine, disposition, and notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products, as well as products that are the subject of fraudulent transactions or that are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death. In the European Union, the Falsified Medicines Directive imposes similar requirements which are expected to add materially to product costs.

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

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

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our business, results of operations, financial condition and prospects. Alternatively, in response to legislation such as this, we might elect not to seek approval for or market our products in foreign jurisdictions in order to minimize the risk of re-importation, which could also reduce the revenue we generate from our product sales.

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

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

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

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

While we currently hold $5.0 million in trial liability insurance coverage, this may not adequately cover all liabilities that we may incur. We also may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise in the future. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain marketing approval for our product candidates, but we may be unable to obtain commercially reasonable product liability insurance. A successful product liability 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 healthcare providers, physicians, customers and third-party payors will be subject to applicable transparency, anti-kickback, fraud and abuse 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 Physician Payment Sunshine Act (federal Open Payments program), created under Section 6002 of the Affordable Care Act and its implementing regulations, requires manufacturers of drugs, devices,

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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;

- 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 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;
- 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.

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

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

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

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

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

In addition, we could be adversely affected by:

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

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

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

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

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Moreover, if we fail to establish and maintain additional development collaborations related to our product candidates:

- the development of certain of our current or future product candidates may be impaired or delayed;
- our cash expenditures related to development of certain of our current or future product candidates would increase significantly and we may need to seek additional financing;
- we may be required to hire additional employees or otherwise devote resources and 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 internal manufacturing capacity and anticipate continued reliance on third-party manufacturers for the development and commercialization of our products.

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

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

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

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

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

Risks Related to Intellectual Property

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

Our success depends in significant part on our and our 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

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

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

In February 2013, a third party filed an opposition at the EPO requesting revocation of European Patent No. 2068918 directed to GLA vaccine formulations and uses. This patent is licensed to us by IDRI and is an important part of our proprietary GLAAS platform in Europe. We are vigorously defending the grant of this patent. The oral proceedings for this opposition were held in September 2016. At the oral proceedings, the EPO maintained the patent in an amended form, which continues to cover the GLAAS products being developed by us and our licensees. We and the opponent may appeal this outcome, and we cannot be certain that this patent will be maintained by the

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EPO at an appeal hearing, or if any reduction to the 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 outcome of an appeal to this proceeding would not be known for several years.

The laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. For example, some of our patents relate to treatment methods or dosing regimens that are not considered patentable subject matter in some foreign countries. Consequently, we and our licensors may not be able to prevent third parties from practicing our and our licensors' inventions in countries outside the United States, or from selling or importing products made using our and our licensors' inventions in and into the United States or other jurisdictions. Competitors may use our and our licensors' technologies in jurisdictions where we have not obtained patent protection to develop their own products and may export otherwise infringing products to territories where we and our licensors have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates and our and our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

The requirements for patentability may differ in certain countries, particularly developing countries. Furthermore, generic drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' patents, requiring us or our licensors to engage in complex, lengthy and costly litigation or other proceedings. Generic drug manufacturers may develop, seek approval for, and launch generic versions of our products. Certain countries in Europe and developing countries, including China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our and our licensors' efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

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.

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Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our and our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents, all of which could have a material adverse effect on our business and financial condition.

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

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors or collaborators fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which would have a material adverse effect on our business.

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

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

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proceeding that awards our patent claims to a third party could require us or our licensors or collaborators to cease using related technology. Our business could be harmed if the prevailing party does not offer us or our licensors or collaborators a license on commercially reasonable terms or at all. Even if we or our licensors or collaborators obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors or collaborators. In addition, if the breadth or strength of protection provided by our or our licensors' or collaborators' patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Even if we successfully defend such litigation or proceeding, we may incur substantial costs and it may distract our management and other employees. We could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent.

For example, in February 2013, a third party filed an opposition at the EPO requesting revocation of European Patent No. 2068918 directed to GLA vaccine formulations and uses. This patent is licensed to us by IDRI and is an important part of our proprietary GLAAS platform in Europe. We are vigorously defending the grant of this patent. The oral proceedings for this opposition were held in September 2016. At the oral proceedings, the EPO maintained the patent in an amended form, which continues to cover the GLAAS products being developed by us and our licensees. We and the opponent may appeal this outcome, and we cannot be certain that this patent will be maintained by the EPO at an appeal hearing, or if any reduction to the 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 outcome of an appeal to this proceeding would not be known for several years.

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

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock.

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

Our commercial success depends upon our ability to identify, test, develop, manufacture, market and sell product candidates and use our and our licensors' or collaborators' proprietary technologies without infringing the proprietary rights of third parties. Pursuant to the license agreement with IDRI, we obtained licensing rights to certain GLA technologies, which we utilize in the development of our GLA product candidates. Similarly, under our licenses with Caltech and UNC Chapel Hill, we obtained rights to certain patents which we utilize in the development of our ZVex based product candidates. If we fail to comply with the obligations under the license agreements, including a material breach by us, certain insolvency events or failure to diligently pursue the development of products, the other party may have the right to terminate the license agreements. In addition, IDRI may terminate our licenses in the event we challenge the validity, enforceability or scope of any patent licensed to us by IDRI. In the event one of these licenses is terminated, we will not be able to develop, manufacture, market or sell any product candidate that is covered by the license agreement. Such an occurrence would adversely affect our ability to continue to develop our current product candidates as well as potential future product candidates. Termination of any of these licenses or reduction or

elimination of our rights under any license agreement may

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result in our having to negotiate a new or reinstated agreement, which may not be available to us on equally favorable terms, or at all, or cause us to lose our rights under the license agreement, including our rights to intellectual property or technology important to our development programs.

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

Many of our employees, including our senior management, were previously employed at universities or at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defending against claims of misappropriation of trade secrets could be costly and time consuming, regardless of the outcome. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we successfully prosecute or defend against such claims, litigation could result in substantial costs and distract management.

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, and you could lose all or part of your investment.

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

- the success of competitive products or technologies;
- regulatory actions with respect to our products or our competitors' products;
- actual or anticipated changes in our growth rate relative to our competitors;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- results of clinical trials of our product candidates or those of our competitors;

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

In addition, the stock market in general, and The NASDAQ Global Market (NASDAQ) and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this “Risk Factors” section, could have a dramatic and material adverse impact on the market price of our common stock.

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

As of December 31, 2015, our executive officers, directors and holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 71% of our voting stock. These stockholders may have the ability to control us through this ownership position and be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests 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

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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 Exchange Act and instead provide a reduced level of disclosure concerning executive compensation; and
- any rules that the Public Company Accounting Oversight Board may adopt requiring mandatory audit firm rotation or a supplement to the auditor's report on the financial statements.

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

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

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

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act as well as rules subsequently implemented by the SEC and NASDAQ that impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and financial condition. In addition, on July 21, 2010, the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. The requirements of these rules and regulations will increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and may also place undue strain on our personnel, systems and resources. Our management and other personnel will need to devote a substantial amount of time to these new compliance initiatives.

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

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures

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or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

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

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

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

To date, we have a low volume of daily trades in our common stock on NASDAQ. For example, the average daily trading volume in our common stock on NASDAQ during the nine months ended September 30, 2016 was approximately 104,000 shares per day. Our stockholders may be unable to sell their common stock at or near their asking prices or at all, which may result in substantial losses to our stockholders.

As a consequence of this lack of liquidity, the trading of relatively small quantities of shares by our stockholders may disproportionately influence the price of those shares in either direction. The price for our shares could, for example, decline significantly in the event that a large number of our common stock are sold on the market without commensurate demand, as compared to a seasoned issuer that could better absorb those sales without adverse impact on its share price.

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

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

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beneficial to our stockholders. Under the DGCL, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other things, the board of directors has approved the transaction. Any provision of our amended and restated certificate of incorporation or amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change of control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

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

Use of Proceeds

We completed the IPO of our common stock pursuant to a Registration Statement on Form S-1 (File No. 333-196979), which was declared effective by the SEC on July 23, 2014. The net offering proceeds to us, after deducting underwriting discounts and commissions and offering expenses, were approximately $57.8 million. As of September 30, 2016, we have used approximately $52.3 million of the net offering proceeds primarily to fund clinical development of our product candidates, litigation, legal and administration expenses to fund the growth of our operations.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

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

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SIGNATURES

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

Immune Design Corp.
(Registrant)

Date: November 9, 2016 /s/ Carlos Paya, M.D., Ph.D.
Carlos Paya, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 9, 2016 /s/ Stephen Brady
Stephen Brady
Executive Vice President, Strategy & Finance
(Principal Accounting Officer and Principal Financial Officer)

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EXHIBIT INDEX

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of the Company (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the SEC on July 29, 2014).
3.2	Amended and Restated Bylaws of the Company (incorporated herein by reference to Exhibit 3.4 to the Company's Registration Statement on Form S-1 (File No. 333-196979), as filed with the SEC on June 23, 2014).
4.1	Specimen Common Stock Certificate of the Company (incorporated herein by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1 (File No. 333-196979), as filed with the SEC on June 23, 2014).
10.1†	License Agreement, by and between the Company and Aventis Inc., dated August 6, 2014.
10.2	Executive Employment Agreement, by and between the Company and Sergey Yurasov, M.D., Ph.D., dated September 30, 2016.
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
32.1*	Certifications of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certifications of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	Financial statements from the Quarterly Report on Form 10-Q of Immune Design Corp. for the quarter ended September 30, 2016, formatted in XBRL (eXtensible Business Reporting Language): (i) the Condensed Consolidated Balance Sheets; (ii) the Condensed Consolidated Statements of Operations and Comprehensive Income (Loss); (iii) the Condensed Consolidated Statements of Cash Flow; and (iv) Notes to Condensed Consolidated Financial Statements.

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* Furnished herewith and not deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

† Registrant has requested confidential treatment for certain portions of this exhibit. This exhibit omits the information subject to this confidentiality request. Omitted portions have been filed separately with the SEC.