

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 10-Q

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

For the quarterly period ended September 30, 2018

or

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

For the transition period from to

Commission File Number: 001-36561

Immune Design Corp.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

26-2007174

(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 No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files). Yes No

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input checked="" type="checkbox"/>		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

As of November 5, 2018, the number of outstanding shares of the registrant's common stock was 48,164,828.

TABLE OF CONTENTS

	<u>Page</u>
<u>NOTE REGARDING FORWARD-LOOKING STATEMENTS</u>	<u>ii</u>
<u>PART I. FINANCIAL INFORMATION</u>	<u>1</u>
Item 1. <u>Financial Statements</u>	<u>1</u>
<u>Condensed Consolidated Balance Sheets</u>	<u>1</u>
<u>Condensed Consolidated Statements of Operations and Comprehensive Loss for the Three and Nine Months Ended September 30, 2018 and 2017</u>	<u>2</u>
<u>Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2018 and 2017</u>	<u>3</u>
<u>Notes to Condensed Consolidated Financial Statements</u>	<u>4</u>
Item 2. <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>20</u>
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>30</u>
Item 4. <u>Controls and Procedures</u>	<u>31</u>
<u>PART II. OTHER INFORMATION</u>	<u>32</u>
Item 1. <u>Legal Proceedings</u>	<u>32</u>
Item 1A. <u>Risk Factors</u>	<u>32</u>
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>59</u>
Item 3. <u>Defaults Upon Senior Securities</u>	<u>59</u>
Item 4. <u>Mine Safety Disclosures</u>	<u>59</u>
Item 5. <u>Other Information</u>	<u>59</u>
Item 6. <u>Exhibits</u>	<u>59</u>

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” and “GLAAS” are our registered trademarks, and the Immune Design logo is our unregistered trademark. 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.

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 the negative or plural of these words or expressions. These forward-looking statements include statements concerning the following:

- our estimates regarding our expenses, revenues, anticipated capital requirements and our needs for additional financing;
- the implementation of our business model and strategic plans for our business and technology;
- the timing of the commencement and progress of, and the 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.

[Table of Contents](#)**PART I. FINANCIAL INFORMATION**
Item 1. Financial Statements**IMMUNE DESIGN CORP.**
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share amounts)

	<u>September 30, 2018</u>	<u>December 31, 2017</u>
	<u>(unaudited)</u>	
Assets		
Current assets:		
Cash and cash equivalents	\$ 68,535	\$ 72,454
Short-term investments	38,853	68,653
Accounts receivable	780	647
Inventory	1,354	684
Prepaid expenses	2,728	1,571
Restricted cash	—	6,000
Other receivables	243	3,134
Total current assets	<u>112,493</u>	<u>153,143</u>
Property and equipment, net	492	491
Security deposit	200	200
Total assets	<u>\$ 113,185</u>	<u>\$ 153,834</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 2,819	\$ 2,334
Accrued liabilities	5,764	6,186
Accrued litigation-related settlement	—	6,000
Total current liabilities	<u>8,583</u>	<u>14,520</u>
Other non-current liabilities	108	102
Commitments and contingencies	—	—
Stockholders' equity:		
Common stock, \$0.001 par value; 100,000,000 shares authorized at September 30, 2018 (unaudited) and December 31, 2017; 48,164,828 and 48,068,650 shares issued and outstanding at September 30, 2018 (unaudited) and December 31, 2017, respectively	48	48
Preferred stock, \$0.001 par value; 10,000,000 shares authorized; no shares issued or outstanding	—	—
Additional paid-in capital	381,379	374,970
Accumulated deficit	(276,914)	(235,757)
Accumulated other comprehensive loss	(19)	(49)
Total stockholders' equity	<u>104,494</u>	<u>139,212</u>
Total liabilities and stockholders' equity	<u>\$ 113,185</u>	<u>\$ 153,834</u>

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
	(unaudited)		(unaudited)	
Revenues:				
Collaborative revenue	\$ 233	\$ 510	\$ 1,063	\$ 6,395
Product sales	229	6	657	315
Total revenues	462	516	1,720	6,710
Operating expenses:				
Cost of product sales	32	16	179	71
Research and development	11,268	10,246	32,579	35,147
General and administrative	3,802	3,909	11,803	11,932
Total operating expenses	15,102	14,171	44,561	47,150
Loss from operations	(14,640)	(13,655)	(42,841)	(40,440)
Interest and other income	591	239	1,684	558
Net loss	\$ (14,049)	\$ (13,416)	\$ (41,157)	\$ (39,882)
Other comprehensive income (loss):				
Unrealized gain on investments	16	29	30	10
Comprehensive loss	\$ (14,033)	\$ (13,387)	\$ (41,127)	\$ (39,872)
Basic and diluted net loss per share	\$ (0.29)	\$ (0.52)	\$ (0.85)	\$ (1.56)
Weighted-average shares used to compute basic and diluted net loss per share	48,164,828	25,620,781	48,137,781	25,551,065

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

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

	Nine Months Ended	
	September 30,	
	2018	2017
	(unaudited)	
Operating activities		
Net loss	\$ (41,157)	\$ (39,882)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	268	256
Amortization of premium/discount on investments	(431)	45
Stock-based compensation expense	6,052	6,601
Changes in operating assets and liabilities:		
Accounts receivable	(133)	(3)
Inventory	(670)	(1)
Prepaid expenses	(1,157)	109
Other receivables	2,891	43
Other assets	—	(350)
Accounts payable	485	(2,007)
Accrued liabilities	(422)	646
Accrued litigation-related settlement	(6,000)	—
Deferred rent and other liabilities	6	(2,477)
Net cash used in operating activities	<u>(40,268)</u>	<u>(37,020)</u>
Investing activities		
Purchases of property and equipment	(269)	(344)
Maturities of short-term investments	59,000	50,000
Purchases of short-term investments	(28,739)	(23,964)
Net cash provided by investing activities	<u>29,992</u>	<u>25,692</u>
Financing activities		
Proceeds from issuances of common stock under equity incentive plans	357	683
Net cash provided by financing activities	<u>357</u>	<u>683</u>
Net decrease in cash, cash equivalents and restricted cash	(9,919)	(10,645)
Cash, cash equivalents and restricted cash, beginning of period	78,654	45,214
Cash, cash equivalents and restricted cash, end of period	<u>\$ 68,735</u>	<u>\$ 34,569</u>
Supplemental cash flow information		
	September 30,	
	2018	2017
	(unaudited)	
Cash and cash equivalents	\$ 68,535	\$ 28,369
Restricted cash	—	6,000
Security deposit	200	200
Total cash, cash equivalents and restricted cash	<u>\$ 68,735</u>	<u>\$ 34,569</u>

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

IMMUNE DESIGN CORP.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Information as of September 30, 2018 and for the three and nine months ended September 30, 2018 and 2017 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. Our lead product candidate, G100, is being evaluated in multiple arms of a Phase 2 clinical trial. In addition, we have licensed to third parties the right to use our 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, 2018 and for the three and nine months ended September 30, 2018 and 2017 and the related interim information contained within the notes to the condensed consolidated financial statements are unaudited. The unaudited interim consolidated financial statements have been prepared on the same basis as the audited consolidated 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, 2018 are not necessarily indicative of the results to be expected for the year ended December 31, 2018 or for other future interim periods or years.

The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements for the year ended December 31, 2017 included in our Annual Report on Form 10-K for the year ended December 31, 2017, filed with the Securities and Exchange Commission (SEC) on March 14, 2018 (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 interest method over the terms of the securities. Realized gains and losses and declines in fair value that are deemed

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

(Information as of September 30, 2018 and for the three and nine months ended September 30, 2018 and 2017 is unaudited)

to be other than temporary are reflected in the condensed consolidated statements of operations and comprehensive income (loss) using the specific-identification method.

Restricted Cash

Restricted cash included funds used to secure our obligations associated with the settlement of all claims and disputes under our Settlement Agreement with TheraVectys SA (TVS). A deposit of zero and \$6.0 million was held in escrow restricted from withdrawal as of September 30, 2018 and December 31, 2017, respectively. See Note 12 for additional information. In addition, we held a security deposit under a standby letter of credit associated with our laboratory and office space lease in Seattle, Washington, to be drawn down by our landlord if the lease is breached. The security deposit is classified as a non-current asset on our Condensed Consolidated Balance Sheets.

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

Effective January 1, 2018, we adopted Accounting Standards Codification (ASC) Topic 606, *Revenue from Contracts with Customers*, using the modified retrospective method and there was no impact to our financial position and results of operations as a result of the adoption. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. We only apply the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, we assess the goods or services promised within each contract and determine those that are performance obligations, and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

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

License, Collaboration and Other Revenues

We enter into collaboration and out-licensing agreements which are within the scope of Topic 606, under which we perform research and development activities and license certain rights to our intellectual property to third parties. The terms of these arrangements typically include payment to us of one or more of the following: non-refundable, up-front license fees; development, regulatory and commercial milestone payments; payments for manufacturing supply services we provide through our contract manufacturers; and royalties on net sales of licensed products. Each of these payments results in license, collaboration and other revenues, except for revenues from royalties on net sales of licensed products, which are classified as royalty revenues.

In determining the appropriate amount of revenue to be recognized as we fulfill our obligations under each of these agreements, we perform the following steps: (1) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable

IMMUNE DESIGN CORP.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

(Information as of September 30, 2018 and for the three and nine months ended September 30, 2018 and 2017 is unaudited)

consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) we satisfy each performance obligation. As part of the accounting for these arrangements, we must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. We use key assumptions to determine the stand-alone selling price, which may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success.

Licensing of intellectual property. If the license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

Milestone payments. At the inception of each arrangement that includes development milestone payments, we evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our control or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which we recognize revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, we re-evaluate the probability of achievement of such development milestones and any related constraint, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect license, collaboration and other revenues and earnings in the period of adjustment.

Manufacturing supply services. Arrangements that include a promise for future supply of drug substance or drug product for either clinical development or commercial supply at the customer's discretion are generally considered as options. We assess if these options provide material rights to the licensee and if so, they are accounted for as separate performance obligations. If we are entitled to additional payments when the customer exercises these options, any additional payments are recorded when the customer obtains control of the goods, which is upon shipment.

Royalties. Arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, we have not recognized any royalty revenue resulting from any of our collaboration or out-licensing agreements.

Product Sales

Revenue from product sales of glucopyranosyl lipid A (GLA), a product from our GLAAS platforms, is recognized when the Customer obtains control of the Company's product, which occurs at a point in time, typically upon shipment to the Customer. All revenues associated from the sale of GLA products supplied by us are reported under product sales with the applicable costs reported under cost of product sales. Product sales consist of the direct costs associated with the manufacture and formulation of GLA, including costs to purchase raw materials, third-party contract manufacturing costs, assay testing and ongoing product stability testing.

IMMUNE DESIGN CORP.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

(Information as of September 30, 2018 and for the three and nine months ended September 30, 2018 and 2017 is unaudited)

Accrued Liabilities and Research and Development Related Accruals

Accrued liabilities and research and development related accruals represent accrued compensation including vacation accruals and accrued expenses. As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued professional services and research and development expenses. This process involves reviewing contracts and vendor agreements, communicating with appropriate internal personnel to identify services that have been performed on our behalf and estimating the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known to us and periodically confirming the accuracy of our estimates with service providers and making adjustments, if necessary.

We base our expenses related to contract manufacturing and clinical studies on our estimates of the services received and efforts expended pursuant to contracts with multiple contract manufacturing organizations and clinical research organizations that conduct and manage supply and clinical studies on our behalf. The financial terms of these agreements vary from contract to contract and may result in uneven payment flows. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, we may report amounts that are too high or too low in any particular period.

Accounting estimates and judgments related to contract manufacturing activities and clinical trials are inherently uncertain. We base our estimates on the best information available at the time. As appropriate, estimates are assessed periodically and updated to reflect current information and any changes will generally be reflected in the period first identified. To date, we have not experienced any significant adjustments to our estimates.

Recently Adopted Accounting Pronouncements

In August 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standard Update (ASU) No. 2016-15 which provides new guidance on the classification of certain cash receipts and payments in the statement of cash flows. The new guidance is intended to reduce diversity in practice in how certain transactions are classified in the statement of cash flows. We adopted the new standard in the first quarter of 2018. Adoption of this standard did not have a material impact on our consolidated financial statements.

In November 2016, the FASB issued ASU No. 2016-18 that relates to restricted cash. The new guidance requires amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. We adopted the new standard in the first quarter of 2018. Adoption of this standard did not have a material impact on our consolidated financial statements.

In May 2017, the FASB issued ASU No. 2017-09 to provide clarity and reduce both diversity in practice and cost and complexity when applying the guidance in Topic 718 about a change to the terms and conditions of a share-based payment award. The amendments in this update provide guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. We adopted the new standard in the first quarter of 2018. Adoption of this standard did not have a material impact on our consolidated financial statements.

Recent Accounting Pronouncements

In February 2016, the 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

IMMUNE DESIGN CORP.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

(Information as of September 30, 2018 and for the three and nine months ended September 30, 2018 and 2017 is unaudited)

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. The standard is effective for public companies for the fiscal years and interim reporting periods beginning after December 15, 2018. We plan to adopt this new standard prospectively on January 1, 2019. The Company believes the largest impact to its balance sheet will be from recognizing a right of use asset and corresponding lease liability related to its property leases in South San Francisco and Seattle. The Company is continuing to evaluate the full impact the adoption of ASU 2016-02 will have on its consolidated financial statements and related disclosures and will continue to monitor industry activities and any additional guidance provided by regulators, standards setters or the accounting profession and may adjust the Company's assessment and implementation plans accordingly. In July 2018, the FASB issued ASU 2018-11, related to another transition method in lease accounting. If elected, the transition method allows entities to initially apply the new leases standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. The Company plans to adopt ASU 2016-02 on January 1, 2019 and intends to initially apply the new lease standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of accumulated deficit in the period of adoption as permitted under ASU 2018-11.

In February 2018, the FASB issued ASU 2018-02, which allows companies to reclass stranded tax effects resulting from the Tax Cuts and Jobs Act of 2017 (2017 Act), from accumulated other comprehensive income to retained earnings. These stranded tax effects refer to the tax amounts included in accumulated other comprehensive income at the previous 35% U.S. statutory tax rate, for which the related deferred tax asset or liability was remeasured to the new 21% U.S. corporate statutory federal tax rate in the period of the 2017 Act enactment. The new standard is effective for fiscal years beginning after December 15, 2018, with early adoption permitted, and can be applied either in the period of adoption or retrospectively to each period impacted by the 2017 Act. We plan to adopt this standard prospectively on January 1, 2019. We are evaluating the impact of the adoption of this standard on the consolidated financial statements.

In June 2018, the FASB issued ASU 2018-07 to reduce complexity and to improve financial reporting for share-based payments issued to non-employees. ASU 2018-07 expands the scope of Topic 718, Compensation-Stock Compensation (which currently only includes share-based payments to employees) to include share-based payments issued to non-employees for goods or services. Consequently, the accounting for share-based payments to non-employees and employees will be substantially aligned. ASU 2018-07 supersedes Subtopic 505-50, Equity-Based Payments to Non-Employees. ASU 2018-07 is effective for the Company for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year and early adoption is permitted. We plan to adopt this standard prospectively on January 1, 2019. We are evaluating the impact of the adoption of this standard on the consolidated financial statements.

In August 2018, the SEC adopted amendments to certain disclosure requirements in Securities Act Release No. 33-10532, Disclosure Update and Simplification. These amendments eliminate, modify, or integrate into other SEC requirements certain disclosure rules. Among the amendments is the requirement to present an analysis of changes in stockholders' equity in the interim financial statements included in quarterly reports on Form 10-Q. The analysis, which can be presented as a footnote or separate statement, is required for the current and comparative quarter and year-to-date interim periods. The amendments are effective for all filings made on or after November 5, 2018. In light of the anticipated timing of effectiveness of the amendments and expected proximity of effectiveness to the filing date for most filers' quarterly reports, the SEC's Division of Corporate Finance issued a Compliance and Disclosure Interpretation related to Exchange Act Forms, or CDI - Question 105.09, that provides transition guidance related to this disclosure requirement. CDI - Question 105.09 states that the SEC would not object if the filer's first presentation of the changes in shareholders' equity is included in its Form 10-Q for the quarter that begins after the effective date of the amendments. As such, the Company adopted these SEC amendments on November 5, 2018 and will present the analysis of changes in stockholders' equity in its interim financial statements

IMMUNE DESIGN CORP.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

(Information as of September 30, 2018 and for the three and nine months ended September 30, 2018 and 2017 is unaudited)

in its March 31, 2019 Form 10-Q. The Company does not anticipate that the adoption of these SEC amendments will have a material effect on the Company's financial position, results of operations, cash flows or shareholders' equity.

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 diluted net loss per share attributable to common stockholders calculation because their effect would have been anti-dilutive for the periods presented:

	September 30,	
	2018	2017
	(unaudited)	(unaudited)
Outstanding options to purchase common stock	4,310,454	4,135,938
Unvested restricted stock units	782,552	296,155
Total outstanding shares of common stock equivalents	<u>5,093,006</u>	<u>4,432,093</u>

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, 2018			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Money market funds	\$ 64,785	\$ —	\$ —	\$ 64,785
U.S. Treasury securities	38,872	—	(19)	38,853
Total	<u>\$ 103,657</u>	<u>\$ —</u>	<u>\$ (19)</u>	<u>\$ 103,638</u>
Classified as:				
Cash equivalents				\$ 64,785
Short-term investments				38,853
Total				<u>\$ 103,638</u>

	December 31, 2017			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Money market funds	\$ 70,502	\$ —	\$ —	\$ 70,502
U.S. Treasury securities	68,702	—	(49)	68,653
Total	<u>\$ 139,204</u>	<u>\$ —</u>	<u>\$ (49)</u>	<u>\$ 139,155</u>
Classified as:				
Cash equivalents				\$ 70,502
Short-term investments				68,653
Total				<u>\$ 139,155</u>

IMMUNE DESIGN CORP.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

(Information as of September 30, 2018 and for the three and nine months ended September 30, 2018 and 2017 is unaudited)

All U.S. Treasury securities held as of September 30, 2018 and December 31, 2017 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 periods 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, 2018			
	LEVEL 1 (unaudited)	LEVEL 2 (unaudited)	LEVEL 3 (unaudited)	TOTAL (unaudited)
Assets:				
Money market funds	\$ 64,785	\$ —	\$ —	\$ 64,785
U.S. Treasury securities	38,853	—	—	38,853
Total	\$ 103,638	\$ —	\$ —	\$ 103,638

	December 31, 2017			
	LEVEL 1	LEVEL 2	LEVEL 3	TOTAL
Assets:				
Money market funds	\$ 70,502	\$ —	\$ —	\$ 70,502
U.S. Treasury securities	68,653	—	—	68,653
Total	\$ 139,155	\$ —	\$ —	\$ 139,155

6. Inventory

Inventory consists of the following (in thousands):

	September 30, 2018	December 31, 2017
	(unaudited)	
Raw materials	\$ 515	\$ —
Work in process	729	541
Finished goods	110	143
Total inventory	\$ 1,354	\$ 684

IMMUNE DESIGN CORP.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

(Information as of September 30, 2018 and for the three and nine months ended September 30, 2018 and 2017 is unaudited)

7. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	September 30, 2018	December 31, 2017
	(unaudited)	
Research and development services	\$ 4,027	\$ 3,352
Employee compensation	1,671	2,777
Other	66	57
Total accrued liabilities	\$ 5,764	\$ 6,186

8. Commitments and Contingencies***Operating Leases***

We lease laboratory and office space under an operating lease in Seattle, Washington. In January 2016, we entered into a new lease agreement for approximately 20,133 square feet of office and laboratory space, which includes and expands on the space we previously subleased. The lease commenced on January 1, 2017 with a term of five years and an option to extend the term for an additional three years. The annual base rent is \$1.1 million for the first year and increases by 2.5% each year thereafter. Under the terms of this lease agreement, we provided a \$200,000 security deposit in January 2017 under a standby letter of credit. In May 2017, we entered into a sublease agreement with a third party subtenant. As sublandlord under this agreement, we are subleasing 5,048 square feet of the Seattle laboratory and office space for a period of three years. The annual base rent payable under this sublease is \$273,000 for the first year and will increase by 2.5% each year thereafter. Rent under this sublease agreement is reflected in other income.

We also lease 9,640 square feet of 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. Under this lease, we were required to provide a \$121,000 letter of credit as a security deposit. As of September 30, 2018, no funds had been drawn on the letter of credit.

Contingencies

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 agreement, we paid an upfront fee of \$600,000 for access and rights to use this device. In December 2015, we initiated a Phase 2 clinical trial using the device which triggered a milestone payment of \$500,000. Both the upfront fee and milestone payments were capitalized to prepaid expenses, and fully amortized to research and development expense as of December 31, 2017. In October 2016, we entered into a letter agreement with NanoPass, which amended our clinical supply agreement to expand the field of use to include all oncology immunotherapy applications, which provided for additional milestone payments to NanoPass upon achievement of future clinical milestones. Per the terms of the letter agreement, we paid NanoPass an additional upfront, one-time, non-refundable payment of \$150,000. In addition, we agreed to pay certain future milestone fees up to an aggregate of \$8.8 million upon the achievement of certain clinical milestones. However, we did not use the NanoPass intradermal delivery device in our SYNOVATE study, a Phase 3 clinical trial studying CMB305 in patients with synovial sarcoma. We announced the discontinuation of our SYNOVATE study in October 2018 and do not expect to incur any additional milestone fees in connection with the CMB305 program.

Under our license agreements with the Infectious Disease Research Institute (IDRI), we are contingently obligated to pay potential future milestone payments, which could total up to \$1.8 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 collaboration and licensing agreements, which

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

(Information as of September 30, 2018 and for the three and nine months ended September 30, 2018 and 2017 is unaudited)

could total up to \$6.5 million in aggregate payments for the ZVex products we develop. We also have potential future royalty payments we may be required to make under our licensing agreements as described in Note 9.

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 the use of our GLAAS platform to discover, develop and commercialize products to treat peanut allergy. In 2014, Sanofi paid us an upfront payment under the license agreement of \$3.5 million. We recognized no milestone revenue under this agreement for the three and nine months ended September 30, 2018 and 2017. 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. Sanofi may terminate the agreement at any time upon six months' written notice.

We currently have two separate license agreements with MedImmune, LLC (MedImmune), entered into in October 2010, pursuant to which we granted MedImmune a worldwide, sublicensable, exclusive license to use GLA to develop and sell vaccines in two different infectious disease indications. 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 of \$4.5 million. 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 \$62.9 million to \$72.5 million, depending on the infectious disease indication and the achievement of certain development, regulatory and commercial milestones for the licensed indication. We recognized no revenue for the achievement of development milestones under these license agreements for the three and nine months ended September 30, 2018 and 2017.

We assessed these arrangements in accordance with Topic 606 and concluded that the contract counterparties, Sanofi and MedImmune, are customers. Based on our assessment, we determined that the licenses were the only performance obligations at the inception of the agreements and the upfront fees were recognized in the period the arrangements were executed.

Licenses Acquired

In July 2008, we licensed certain patent rights, know-how and technology related to our GLAAS platform from the Infectious Disease Research Institute (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 restated 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 \$1.8 million and \$1.3 million, respectively,

IMMUNE DESIGN CORP.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

(Information as of September 30, 2018 and for the three and nine months ended September 30, 2018 and 2017 is unaudited)

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. As a result of the commencement of our SYNOVATE study, we recognized \$500,000 in IDRI license-related milestone fees for the three and nine months ended September 30, 2018, and zero milestone fees for the three and nine months ended September 30, 2017, respectively.

In 2009, we licensed certain patent rights directed to the production of dendritic cell-targeted therapeutic and prophylactic immunization strategies from the California Institute of Technology (Caltech) in exchange for shares of our common stock valued at \$25,000. We made annual minimum royalty payments of \$25,000 under the license until we recognized \$100,000 in license-related milestone fees, expensed in research and development expenses for the year ended December 31, 2017. In addition, we agreed to pay certain fees in the future, including milestone payments upon achievement of certain development and commercialization milestones and royalty payments on net sales in the low single-digit percentage. We are required to pay Caltech up to an aggregate of \$1.5 million in additional payments upon the achievement of certain regulatory and sales milestones. We recognized no Caltech milestone fees for the three and nine months ended September 30, 2018, and zero and \$100,000 for the three and nine months ended September 30, 2017, respectively.

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.

In October 2016, we entered into a license agreement with TheraVectys SA (TVS), pursuant to which we received a field limited, non-exclusive, sublicensable license for oncology uses to certain current and future intellectual property rights owned, controlled and licensed by TVS relating to lentiviral vector technologies. We will owe TVS milestone payments based on the achievement of certain development and regulatory milestones for each licensed product, in the aggregate amount of up to \$4.8 million, except that the first two milestones payments are waived for CMB305/LV305. In addition, we will be obligated to pay a single commercial milestone payment for each product that achieves a specified net sales amount. We will owe royalties to TVS on product sales that are made directly by us or our affiliates, subject to certain royalty-offset provisions. For the first four products, including LV305/CMB305, royalties will be based on a low-single digit percentage of net sales, and for subsequent products, tiered royalties will be based on low-to-mid-single digit percentages of net sales. TVS will also receive a mid-single digit percentage of revenues that we receive for sublicensing the licensed intellectual property. As a result of the commencement of our SYNOVATE study, we recognized \$1.0 million for the three and nine months ended September 30, 2018, and no TVS milestone fees for the three and nine months ended September 30, 2017, respectively.

Collaborations

In October 2014, we entered into a collaboration with Sanofi Pasteur 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 contribute 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 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

IMMUNE DESIGN CORP.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

(Information as of September 30, 2018 and for the three and nine months ended September 30, 2018 and 2017 is unaudited)

studies. Immune Design will be eligible to receive future milestone and royalty payments on any licensed 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 loss. Under this collaboration arrangement, we recognized revenue of \$233,000 and \$510,000 for the three months ended September 30, 2018 and 2017, respectively, and \$1.0 million and \$6.4 million for the nine months ended September 30, 2018 and 2017, respectively. As of September 30, 2018 and December 31, 2017, we had an outstanding net unbilled receivable of \$310,000 and \$605,000, respectively, due from Sanofi Pasteur on our accompanying condensed consolidated balance sheets related to this agreement. The net unbilled receivable represents collaboration research services earned, but not yet billed to Sanofi Pasteur as of September 30, 2018 and December 31, 2017. We assessed the arrangement in accordance with Topic 606 and concluded that the counterparty Sanofi Pasteur is a customer. Based on our assessment, we determined that the research and development services are the only performance obligation at the inception of the agreement. There was no day one license fee paid by Sanofi Pasteur and Sanofi Pasteur pays fair value for the research and development services provided.

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, 2018 or December 31, 2017.

Common Stock

We had 48,164,828 and 48,068,650 shares of common stock outstanding as of September 30, 2018 and December 31, 2017, respectively. Shares of common stock reserved for future issuance were as follows:

	September 30, 2018	December 31, 2017
	(unaudited)	
Shares available for issuance under the employee stock purchase plan	435,565	475,010
Options granted and outstanding	4,310,454	4,094,532
Unvested restricted stock awards	782,552	195,172
Shares available for future stock option grants and restricted stock awards	2,009,910	947,199
Shares reserved for future issuance under equity incentive plans	7,538,481	5,711,913

In July 2017, we entered into a Sales Agreement (ATM Agreement) with Cowen and Company, LLC (Cowen) under which we may offer and sell, from time to time at our sole discretion through Cowen, as our sales agent, shares of our common stock having an aggregate offering price of up to \$50.0 million. Cowen may sell the common stock by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) of the Securities Act of 1933, as amended, including sales made directly on or through the Nasdaq Global Market (Nasdaq) or on any other existing trading market for our common stock. Any common stock sold will be issued pursuant to our shelf registration statement on Form S-3 (File No. 333-206324). We will pay Cowen a commission equal to 3.0% of the gross sales proceeds of any common stock sold under the ATM Agreement and also have provided Cowen with indemnification and contribution rights. To date, we have not sold any common stock under the ATM Agreement.

IMMUNE DESIGN CORP.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

(Information as of September 30, 2018 and for the three and nine months ended September 30, 2018 and 2017 is unaudited)

Equity Incentive Plans

Under our 2014 Omnibus Incentive Plan (2014 Plan), the total number of shares of common stock available for issuance increases annually on January 1 of each year in an amount equal to 4% of the total number of shares of our common stock issued and outstanding as of December 31 of the immediately preceding year, or such lesser amount as deemed appropriate by our Board of Directors. On January 1, 2018, the authorized shares available under the 2014 Plan were increased by 1,922,746 shares. There were a total of 6,050,633 shares of common stock authorized under the 2014 Plan as of September 30, 2018.

Under our 2014 Employee Stock Purchase Plan (2014 ESPP), the total number of shares of common stock available for issuance increases annually on January 1 of each year in an amount equal to the lesser of (i) 1% of the total number of shares issued and outstanding as of December 31 of the immediately preceding year, (ii) 200,000 shares, or such lesser amount as deemed appropriate by our Board of Directors. For 2018, the Board of Directors determined the current shares available for issuance under the 2014 ESPP were sufficient and did not increase the amount of authorized shares. There were a total of 435,565 shares of common stock authorized under the 2014 ESPP as of September 30, 2018.

Restricted Stock Units

In January 2018, the Compensation Committee of our Board of Directors granted 198,835 time-based restricted stock units (RSUs) and 367,500 performance-based restricted stock units (January PSUs) to our employees. Restricted stock units are awards that entitle the holder to receive shares of our common stock upon vesting. The RSUs and January PSUs cannot be transferred and are subject to forfeiture if the holder's employment terminates prior to vesting. One-third of the RSUs will vest on each anniversary of the grant date over three (3) years. The fair value of each RSU is equal to the closing price of our common stock on the applicable grant date. Fifty percent of the January PSUs would have vested on each of June 30, 2018 and December 31, 2018 upon the achievement of certain performance criteria by such date. If the performance criteria are not met by the specified dates, the corresponding number of January PSUs will expire. Stock-based compensation for the January PSUs is recognized over the service period beginning in the period management determines it is probable that the performance criteria will be achieved. During the period ending March 31, 2018, we began recognizing stock compensation expense on the January PSUs as the outcome of the performance criteria being achieved was deemed probable. As of June 30, 2018, 183,750 shares of the January PSUs that were granted in January 2018 expired unvested as the performance criteria was not met by the specified date. In addition, management has determined that the performance criteria associated with the remaining January PSUs will not be achieved by the specified date due to a change in program strategy, and accordingly, we reversed the related stock-based compensation expense of \$508,000 recorded in the period ending March 31, 2018. Due to the continued improbable likelihood of achieving the performance criteria by the specified date on the remaining January PSUs, no expense has been recorded on the January PSUs for the period ending September 30, 2018.

In July 2018, the Compensation Committee of the Board of Directors granted 322,020 additional PSUs to our employees (July PSUs). The July PSUs would vest on or before December 31, 2018, as to either fifty percent (50%) or one hundred percent (100%) of the total shares, upon achievement of certain performance criteria on or before such date, subject to the employee's continued service with us upon the vesting date. If the performance criteria are not met by December 31, 2018, the corresponding July PSUs will expire. Stock-based compensation for the July PSUs is recognized over the service period beginning in the period management determines it is probable that the performance criteria will be achieved. During the period ending September 30, 2018, management has determined that the performance criteria associated with the July PSUs will most likely not be achieved by December 31, 2018. Due to the improbable likelihood of achieving the performance criteria by December 31, 2018, no expense has been recorded on the July PSUs for the period ending September 30, 2018.

IMMUNE DESIGN CORP.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

(Information as of September 30, 2018 and for the three and nine months ended September 30, 2018 and 2017 is unaudited)

Summary of RSUs and PSUs information is as follows:

	SHARES	WEIGHTED AVERAGE GRANT DATE FAIR VALUE (per share)
Outstanding at December 31, 2017	195,172	\$ 10.99
Granted (unaudited)	888,355	4.04
Vested (unaudited)	(55,135)	11.96
Forfeited (unaudited)	(245,840)	4.37
Outstanding at September 30, 2018 (unaudited)	782,552	5.11

Stock Option Activity

Summary of 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, 2017	4,094,532	\$ 10.96	7.21	\$ 2,771
Granted (unaudited)	2,287,619	\$ 4.15		
Exercised (unaudited)	(1,598)	\$ 1.15		
Expired (unaudited)	(201,046)	\$ 14.05		
Forfeited (unaudited)	(1,869,053)	\$ 15.77		
Outstanding at September 30, 2018 (unaudited)	4,310,454	\$ 5.12	6.99	\$ 2,203
Exercisable as of September 30, 2018 (unaudited)	1,842,786	\$ 5.93	5.28	\$ 2,183

As of September 30, 2018, there was \$7.5 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 2.0 years. The total intrinsic value of options exercised during the nine months ended September 30, 2018 and 2017 was \$4,000 and \$868,000, respectively.

Stock-Based Compensation Expense

Prior to the adoption of ASU No. 2016-09 on January 1, 2017, employee stock-based compensation expense recognized was calculated based on awards ultimately expected to vest and was reduced for estimated forfeitures. Effective January 1, 2017, upon our adoption of ASU No. 2016-09, we have elected to account for forfeitures as they occur. 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,	
	2018 (unaudited)	2017 (unaudited)	2018 (unaudited)	2017 (unaudited)
Employee:				
Research and development	\$ 795	\$ 905	\$ 2,683	\$ 2,742
General and administrative	1,001	1,181	3,334	3,703
Non-Employee:				
Research and development	6	39	29	96
General and administrative	1	24	6	60
Total stock-based compensation expense	\$ 1,803	\$ 2,149	\$ 6,052	\$ 6,601

IMMUNE DESIGN CORP.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

(Information as of September 30, 2018 and for the three and nine months ended September 30, 2018 and 2017 is unaudited)

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,	
	2018	2017	2018	2017
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Weighted-average estimated fair value	\$2.33	\$7.44	\$2.67	\$4.32
Risk-free interest rate	2.7% - 2.9%	1.9% - 2.0%	2.3% - 2.9%	1.9% - 2.1%
Expected term of options (in years)	4.02 - 6.08	6.08	4.02 - 6.08	5.50 - 6.08
Expected stock price volatility	77% - 81%	90% - 91%	77% - 81%	79% - 91%
Expected dividend yield	—	—	—	—

Stock Option Exchange Program

On June 18, 2018, we filed a Tender Offer Statement on Schedule TO relating to an option exchange program for our officers and employees (Option Exchange) to exchange certain stock options to purchase up to an aggregate of 2,462,566 shares of our common stock that had been granted to eligible holders, for a lesser number of new stock options with a lower exercise price. Stock options with an exercise price equal to or greater than \$5.00 and held by eligible holders in continuous service through the termination of the Option Exchange were eligible for exchange in the program. The eligible shares were exercisable for a reduced number of shares based on the following exchange ratios:

Eligible Option Exercise Price Ranges	Exchange Ratio (Surrendered Eligible Options: New Options)*
\$5.00-\$14.99	1.50 to 1
\$15.00-\$29.99	1.75 to 1
\$30.00-And Up	2.00 to 1

* Rounded up to the nearest share

Upon the closing of the Option Exchange on July 17, 2018, 31 eligible employees had tendered an aggregate of 1,590,083 options, representing 65% of the total eligible options, for 962,099 new options to purchase shares of our common stock. Each new stock option was granted on July 17, 2018, pursuant to our 2014 Omnibus Incentive Plan with an exercise price per share of \$4.40 per share, which was the closing market price on the grant date of the new options. The exchange of stock options was treated as a modification for accounting purposes and resulted in an incremental expense of \$12,000 for the vested options, which was calculated using the Black-Scholes option pricing model. We elected the “bifurcated approach” to amortize the incremental expense over the new vesting period of the new options and will continue to amortize the unamortized expense on the original grants through the end of the original vesting term.

11. Income Taxes

On December 22, 2017, the Tax Cuts and Jobs Act of 2017 (Tax Act) was signed into law. Although the Tax Act is generally effective January 1, 2018, GAAP requires recognition of the tax effects of new legislation during the reporting period that includes the enactment date, which was December 22, 2017. The Company has adjusted its deferred tax assets and liabilities based on the reduction of the U.S. federal corporate tax rate from 35% to 21% and assessed the realizability of our deferred tax assets based on our current understanding of the provisions of the Tax Act. The primary impact of the Tax Act resulted from the re-measurement of deferred tax assets and liabilities due to the change in the corporate tax rate, reducing our deferred tax assets by \$30.5 million with a corresponding reduction in our valuation allowance. Overall, this had a net zero effect on our effective tax rate for the year as the Company has a full valuation allowance against its deferred tax assets and is currently in a taxable loss. Additional work will be necessary for a more detailed analysis of our deferred tax assets and liabilities as well as potential

IMMUNE DESIGN CORP.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

(Information as of September 30, 2018 and for the three and nine months ended September 30, 2018 and 2017 is unaudited)

correlative adjustments. We do not expect any material subsequent adjustments to these amounts. Adjustments, if any, are not expected to have any impact to our results of operations due to our loss position and valuation allowance. As of September 30, 2018, we have not yet completed our accounting for all the tax effects of the Tax Act, however, as noted above we have made a reasonable estimate of the effects on our existing deferred tax balances. In all cases, we will continue to make and refine our calculations through the measurement period ending December 22, 2018.

12. Legal Proceedings

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 that TVS initiated against us in the Chancery Court of the State of Delaware in July 2014, as well as related claims and counterclaims. In the proceeding, TVS had alleged that it had entered into a contractual relationship with Henogen SA (Henogen) in 2010 with respect to the production of lentiviral vector vaccines for TVS. Henogen is a contract manufacturing organization with which we contracted for the manufacture of our LV305 product candidate. TVS alleged that its contractual relationship with Henogen contained an exclusivity provision limiting Henogen's ability to participate in the manufacturing process of a vaccine based on lentiviral DNA vectors for third parties. TVS alleged that we entered into a contractual relationship with Henogen to manufacture lentiviral vectors, which TVS contends interfered with its contract with Henogen and resulted in the use of certain TVS confidential information and trade secrets. The complaint asserted four counts for relief: tortious interference with contractual relationship, unfair competition, misappropriation of trade secrets, and unjust enrichment. Claimed damages were not specified.

Under the Settlement Agreement, TVS agreed to dismiss all pending litigation against us and to withdraw its patent opposition proceedings (EPO Proceeding) against our European Patent No EP 2 456 786 (EU Patent). Also under the Settlement Agreement, both parties 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. In addition, 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.

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 paid \$6.0 million into an escrow account (Escrowed Payment), and we also agreed to pay \$1.25 million to TVS when we next raised \$25.0 million, in the aggregate, through equity sales, debt or licensing revenue. The Escrowed Payment was to be disbursed to TVS as follows: (a) fifty percent (50%) when (i) Institut Pasteur consented to the granting by TVS to us of a sublicense to certain patents licensed by TVS and (ii) the litigation in the United States and Belgium had been dismissed; and (b) fifty percent (50%) upon the final resolution of the EPO Proceeding if the scope of the EU Patent remained unchanged (Escrow Conditions); provided, that delays in satisfying the Escrow Conditions would potentially result in a reduction of the amount of the Escrowed Payment that would be disbursed to TVS.

After entering into the Settlement Agreement, we determined that the aggregate payment amount expected to be paid to TVS was \$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 were 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

IMMUNE DESIGN CORP.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

(Information as of September 30, 2018 and for the three and nine months ended September 30, 2018 and 2017 is unaudited)

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.

For the year ended December 31, 2016, the \$5.85 million allocated to the dismissal of litigation was recorded as a general and administrative expense, and the \$1.4 million allocated to the license was recorded as a research and development expense on the condensed consolidated statements of operations and comprehensive income (loss).

In November 2017, we paid \$1.25 million to TVS upon completion of an underwritten public offering in which we raised net proceeds of \$86.6 million, after deducting underwriting discounts, commissions and offering expenses.

In February 2018, the parties came to an agreement on the timing and satisfaction of the Escrow Conditions, and the escrow agent disbursed \$5.25 million of the Escrowed Payment to TVS and \$750,000 of the Escrowed Payment to Immune Design. The \$750,000 recoupment of the Escrow Payment by the Company was recognized during the period ended March 31, 2018 as a reduction to general and administrative expenses. No additional payments are expected to be made under the terms of the Settlement Agreement.

13. Subsequent Event

In October 2018, we completed a portfolio review and determined that the Company should focus on accelerating and expanding the development of G100. Accordingly, we discontinued our SYNOVATE study, a Phase 3 clinical trial of CMB305 in patients with synovial sarcoma. In connection with the discontinuation of our Phase 3 clinical trial, we implemented a reduction in workforce that affected approximately 18% of our employees, primarily those focused on advancing the CMB305 program. This reduction in workforce was completed by the end of October 2018.

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

You should read the following discussion and analysis of our financial condition and results of operations together 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 consolidated financial statements and related notes thereto for the year ended December 31, 2017, included in our Annual Report on Form 10-K (Annual Report), filed with the SEC. In addition to historical information, some of the information contained in this discussion and analysis or set forth elsewhere in this report, including information with respect to our plans and strategy for our business, future financial performance, development programs, expense levels and liquidity sources, includes forward-looking statements that involve risks and uncertainties. You should read the "Risk Factors" section of this report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage immunotherapy company with next-generation, diversified *in vivo* approaches designed 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 designed our technologies to activate the immune system's natural ability to generate and/or expand antigen-specific cytotoxic T cells, while also enhancing other immune effectors, to fight cancer via distinct mechanisms. Our lead product candidate, G100, has a unique mechanism of action that differs from current therapies in lymphomas. G100 triggers an immune-mediated anti-tumor effect with a favorable safety profile that we believe could position G100 as a pillar of chemo-free regimens for the treatment of lymphomas. We have also partnered individual indications outside of oncology in infectious and allergic diseases, which provide potential downstream economics while preserving growth opportunity in the future.

Since inception, we have devoted substantially all of our resources 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 \$14.0 million and \$41.2 million for the three and nine months ended September 30, 2018, respectively, compared to \$13.4 million and \$39.9 million for the three and nine months ended September 30, 2017, respectively. As of September 30, 2018, we had an accumulated deficit of \$276.9 million. We have incurred net losses to date and 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 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 our 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, regulatory, 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.

[Table of Contents](#)

We do not expect to generate significant revenue unless and until we successfully complete development of, obtain marketing approval for and commercialize our product candidates, either alone or in collaboration with third parties. We expect these activities will take a number of years and our success in these efforts is subject to significant uncertainty. Accordingly, we will need to raise additional capital prior to the regulatory approval and commercialization of any of our product candidates. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our operating activities through public or private equity or debt financings, collaborations or licenses, capital lease transactions or other available financing transactions. However, 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 GAAP for interim periods and with Regulation S-X promulgated under the Securities and Exchange Act of 1934, as amended.

Third Quarter 2018 and Other Recent Highlights

In October 2018, we completed a portfolio review and made a strategic decision to focus on accelerating and expanding the development of G100. Based on the review of our CMB305 program, including an early analysis of the ongoing Phase 2 clinical trial that showed the combination of CMB305 and atezolizumab is not likely to show a survival benefit in relapsed synovial sarcoma patients, we discontinued our SYNOVATE Phase 3 clinical trial. We plan to seek external collaborators to explore the continued development of CMB305 in sarcoma. In connection with the discontinuation of our Phase 3 clinical trial, we have completed a reduction in force that affects approximately 18% of our employees, primarily those focused on advancing the CMB305 program.

We are initially developing G100 in combination with pembrolizumab in follicular lymphoma patients who have received three prior lines of systemic therapy. These patients may represent an unmet medical need, which may allow for an accelerated approval path in this indication. We plan to evaluate the clinical activity of G100 based on objective response rate (ORR) in an open label setting. To accelerate enrollment, we plan to use both an open IND and submit a new IND for this specific unmet medical need population, as requested by the FDA. The data from both INDs could then be combined to support a potential biologics license application (BLA) filing. Based on existing ORR data, we expect that approximately 100 patients may be required, but that the final sample size will be adapted depending on the ORR observed in the initial patients.

Given its broad potential reach, we also expect to evaluate G100 beyond late-stage follicular lymphoma. We plan to evaluate G100 in earlier-stage follicular lymphoma patients in combination with rituximab, the backbone treatment for lymphomas in multiple lines of therapy. We also plan to explore G100 in combination with other agents in both indolent and aggressive lymphomas that are known to express TLR4. Additionally, we expect to evaluate the safety and efficacy of G100 in solid tumors, initially through supporting investigator-sponsored studies.

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. Revenues derived from funding of development costs are recognized when the related costs are incurred and when collectability is reasonable assured. Revenues from upfront fees and development services are classified as license and collaboration revenue, respectively, in our consolidated statements of operations. 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.

[Table of Contents](#)*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, clinical trials 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 associated stock-based compensation, lab supplies and facility costs, as well as fees paid to other entities that conduct certain research and development activities, including clinical studies and manufacturing, on our behalf.

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
	(unaudited and in thousands)		(unaudited and in thousands)	
Direct research and development expense by platform:				
ZVex	\$ 4,639	\$ 3,324	\$ 9,927	\$ 10,965
GLAAS	442	1,406	2,724	3,222
G103	361	333	1,136	6,284
Other	1,479	—	3,447	—
Total direct research and development program expense	6,921	5,063	17,234	20,471
Indirect research and development expense by type:				
Personnel related costs	2,979	3,229	10,382	9,476
Research and development supplies and services	650	1,306	2,860	3,307
Allocated facility, equipment, travel and other expense	718	648	2,103	1,893
Total indirect research and development expense	4,347	5,183	15,345	14,676
Total research and development expense	\$ 11,268	\$ 10,246	\$ 32,579	\$ 35,147

We plan to increase our research and development expenses for the foreseeable future as we continue to develop G100. 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

[Table of Contents](#)

- 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

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

Our significant accounting policies are more fully described in Note 2 of the accompanying unaudited condensed consolidated financial statements and in Note 2 to the audited consolidated 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, 2018, 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:

Revenue Recognition

Effective January 1, 2018, we adopted Accounting Standards Codification (ASC) Topic 606, *Revenue from Contracts with Customers*, using the modified retrospective method and there was no impact to our financial position and results of operations as a result of the adoption. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. We only apply the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, we assess the goods or services promised within each contract and determine those that are performance obligations, and assess whether each promised good or service is distinct. We then recognize as revenue the amount

[Table of Contents](#)

of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

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

License, Collaboration and Other Revenues

We enter into collaboration and out-licensing agreements which are within the scope of Topic 606, under which we perform research and development activities and license certain rights to our intellectual property to third parties. The terms of these arrangements typically include payment to us of one or more of the following: non-refundable, up-front license fees; development, regulatory and commercial milestone payments; payments for manufacturing supply services we provide through our contract manufacturers; and royalties on net sales of licensed products. Each of these payments results in license, collaboration and other revenues, except for revenues from royalties on net sales of licensed products, which are classified as royalty revenues.

In determining the appropriate amount of revenue to be recognized as we fulfill our obligations under each of these agreements, we perform the following steps: (1) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) we satisfy each performance obligation. As part of the accounting for these arrangements, we must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. We use key assumptions to determine the stand-alone selling price, which may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success.

Licensing of intellectual property. If the license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

Milestone payments. At the inception of each arrangement that includes development milestone payments, we evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our control or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which we recognize revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, we re-evaluate the probability of achievement of such development milestones and any related constraint, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect license, collaboration and other revenues and earnings in the period of adjustment.

Manufacturing supply services. Arrangements that include a promise for future supply of drug substance or drug product for either clinical development or commercial supply at the customer's discretion are generally considered as options. We assess if these options provide material rights to the licensee and if so, they are accounted for as separate performance obligations. If we are entitled to additional payments when the customer exercises these options, any additional payments are recorded when the customer obtains control of the goods, which is upon shipment.

[Table of Contents](#)

Royalties. Arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, we have not recognized any royalty revenue resulting from any of our collaboration or out-licensing agreements.

Product Sales

Revenue from product sales of glucopyranosyl lipid A (GLA), a product from our GLAAS platforms, is recognized when the Customer obtains control of the Company's product, which occurs at a point in time, typically upon shipment to the Customer. All revenues associated from the sale of GLA products supplied by us are reported under product sales with the applicable costs reported under cost of product sales. Product sales consist of the direct costs associated with the manufacture and formulation of GLA, including costs to purchase raw materials, third-party contract manufacturing costs, assay testing and ongoing product stability testing.

Accrued Liabilities and Research and Development Related Accruals

Accrued liabilities and research and development related accruals represent accrued compensation including vacation accruals and accrued expenses. As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued professional services and research and development expenses. This process involves reviewing contracts and vendor agreements, communicating with appropriate internal personnel to identify services that have been performed on our behalf and estimating the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known to us and periodically confirming the accuracy of our estimates with service providers and making adjustments, if necessary.

We base our expenses related to contract manufacturing and clinical studies on our estimates of the services received and efforts expended pursuant to contracts with multiple contract manufacturing organizations and clinical research organizations that conduct and manage supply and clinical studies on our behalf. The financial terms of these agreements vary from contract to contract and may result in uneven payment flows. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, we may report amounts that are too high or too low in any particular period.

Accounting estimates and judgments related to contract manufacturing activities and clinical trials are inherently uncertain. We base our estimates on the best information available at the time. As appropriate, estimates are assessed periodically and updated to reflect current information and any changes will generally be reflected in the period first identified. To date, we have not experienced any significant adjustments to our estimates.

Recently Adopted Accounting Pronouncements

See Note 2 of the Condensed Consolidated Financial Statements under the heading "Recent Accounting Pronouncements" for new accounting pronouncements or changes to the recent accounting pronouncements during the nine months ended September 30, 2018.

[Table of Contents](#)**Results of Operations****Comparison of Three Months Ended September 30, 2018 and 2017**

The following table summarizes our results of operations for the three months ended September 30, 2018 and 2017:

	Three Months Ended September 30,		
	2018	2017	Increase/(Decrease)
	(unaudited and in thousands)		
Total revenues	\$ 462	\$ 516	\$ (54)
Operating expenses:			
Cost of product sales	32	16	16
Research and development	11,268	10,246	1,022
General and administrative	3,802	3,909	(107)
Total operating expenses	15,102	14,171	931
Loss from operations	(14,640)	(13,655)	(985)
Interest and other income	591	239	352
Net loss	\$ (14,049)	\$ (13,416)	\$ (633)

Total Revenues and Cost of Product Sales

Revenues and costs of product sales did not materially differ over the comparable periods. While total revenues did not change significantly, there was a \$0.2 million increase in product sales to collaboration partners and other third parties under materials transfer agreements. This increase was offset by a \$0.3 million decrease in collaboration service revenue related to the timing of research services associated with the Sanofi Pasteur G103 collaboration that was entered into in the fourth quarter of 2014. Product sales to collaboration partners and other third parties and collaboration service revenue will fluctuate from period to period based upon the timing and amount of product shipments made to collaboration partners and other third parties and the amount of contract services performed during such period, respectively.

Research and Development Expenses

The \$1.0 million increase in research and development expenses was primarily attributable to in-licensing milestone payments of \$1.7 million due to third parties as a result of the commencement of our SYNOVATE Phase 3 clinical trial. This increase was offset by decreases of \$0.2 million in contract manufacturing services, \$0.2 million in personnel-related expenses, \$0.2 million in clinical trial costs and \$0.1 million in research and development supplies and services.

General and Administrative Expenses

General and administrative expenses did not materially differ over the comparative periods. The \$0.1 million decrease in general and administrative expenses was primarily attributable to an increase of \$0.2 million in professional fees and services to help support our ongoing operations. This increase was offset by a decrease of \$0.3 million in personnel-related expenses, which was primarily due to a decrease in stock-based compensation.

Interest and Other Income

The \$0.4 million increase in interest and other income is primarily attributable to our higher cash balances and short-term investments during the three month period ended September 30, 2018 compared to the three month period ended September 30, 2017 as a result of the completion of our follow-on public offering in October 2017 whereby we raised approximately \$86.6 million in net proceeds.

[Table of Contents](#)**Comparison of Nine Months Ended September 30, 2018 and 2017**

The following table summarizes our results of operations for the nine months ended September 30, 2018 and 2017:

	Nine Months Ended September 30,		
	2018	2017	Increase/(Decrease)
	(unaudited and in thousands)		
Total revenues	\$ 1,720	\$ 6,710	\$ (4,990)
Operating expenses:			
Cost of product sales	179	71	108
Research and development	32,579	35,147	(2,568)
General and administrative	11,803	11,932	(129)
Total operating expenses	44,561	47,150	(2,589)
Loss from operations	(42,841)	(40,440)	(2,401)
Interest and other income	1,684	558	1,126
Net loss	\$ (41,157)	\$ (39,882)	\$ (1,275)

Total Revenues and Cost of Product Sales

The \$5.0 million decrease in total revenues was primarily attributable to a decrease of \$5.3 million in collaboration service revenue related to the performance of research services for Sanofi Pasteur in connection with our G103 collaboration. This decrease was offset by an increase of \$0.3 million in product sales to collaboration partners and other third parties. Product sales to collaboration partners and other third parties and collaboration service revenue will fluctuate from period to period based upon the timing and amount of product shipments made to collaboration partners and other third parties and the amount of contract services performed during such period, respectively.

Research and Development Expenses

The \$2.6 million decrease in research and development expenses was primarily attributable to a decrease of \$4.9 million in contract manufacturing costs related to the timing and level of activities in support of our Sanofi Pasteur G103 collaboration and a slight decrease of \$0.3 million in clinical trial costs. This decrease was offset by an increase of \$0.9 million in personnel-related expenses, which were primarily due to increased compensation and benefits and increased research and development headcount to support the commencement of our SYNOVATE Phase 3 clinical trial and in-licensing milestone payments of \$1.7 million due to third parties as a result of the commencement of our SYNOVATE Phase 3 clinical trial. Contract manufacturing and clinical trial costs will fluctuate from period to period based upon the timing of when contract manufacturing services are performed and when patients are enrolled in the various clinical trials, respectively, during the periods.

General and Administrative Expenses

General and administrative expenses did not materially differ over the comparative periods. The \$0.1 million decrease in general and administrative expenses was primarily attributable to the \$0.8 million recoupment from the TVS settlement, when the final distribution of the Escrow Payment was released in February 2018, and a slight decrease of \$0.1 million in facility and office related expenditures, which were offset by an increase of \$0.8 million in professional fees and services to support our ongoing operations.

Interest and Other Income

The \$1.1 million increase in interest and other income is primarily attributable to our higher cash balances and short-term investments during the nine month period ended September 30, 2018 compared to the nine month period ended September 30, 2017 as a result of the completion of our follow-on public offering in October 2017 whereby we raised approximately \$86.6 million in net proceeds.

Liquidity and Capital Resources

Liquidity

As of September 30, 2018, we had cash and cash equivalents, short-term investments and other receivables totaling \$107.5 million. In addition to our existing cash, cash equivalents, short-term investments and other receivables, 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.

On October 27, 2017, we completed an underwritten follow-on public offering of 22,425,000 shares of our common stock, inclusive of the full exercise by the underwriters of the 30-day option to purchase 2,925,000 additional shares, at a public offering price of \$4.10 per share. We received estimated net proceeds of approximately \$86.6 million, after deducting underwriting discounts and commissions, and estimated offering expenses totaling approximately \$5.4 million.

The significant number of shares issued in connection with our public offerings has affected the year-over-year comparability of our net loss per share calculations.

At-The-Market Offering

On July 3, 2017, we filed a prospectus supplement for an at-the-market offering (ATM) program with the SEC related to the offer and sale from time to time of our common stock at an aggregate offering price of up to \$50.0 million through Cowen and Company, LLC, as sales agent. The shares of common stock will be issued pursuant to our shelf registration statement on Form S-3 (File No. 333-206324). No shares of common stock have been sold under this prospectus supplement.

Funding Requirements

Our primary uses of capital are, and we expect will continue to be, the conduct of our clinical trials, including accelerating and expanding the development of G100, 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.

[Table of Contents](#)

Based on our recent underwritten follow-on public offering, and our current research and development plans and our timing expectations related to the progress of our programs, we expect that our existing cash and cash equivalents, short-term investments and other receivables as of September 30, 2018 will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months following our financial statement issuance date. 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 FDA review of any 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 for the nine months ended September 30, 2018 and 2017:

	Nine Months Ended September 30,	
	2018	2017
	(unaudited and in thousands)	
Net cash used in operating activities	\$ (40,268)	\$ (37,020)
Net cash provided by investing activities	29,992	25,692
Net cash provided by financing activities	357	683

Net Cash Used in Operating Activities

Net cash used in operating activities was \$40.3 million during the nine months ended September 30, 2018 and consisted primarily of our net loss of \$41.2 million, a net decrease in operating assets and liabilities of \$5.0 million, which included the payment of the \$6.0 million accrued litigation-related settlement liability associated with the TVS Settlement Agreement as a result of the release of the Escrow Payment made to TVS in February 2018, and \$0.4 million in amortization on premium/discount on short-term investments, which was offset by non-cash charges of \$6.1 million for stock-based compensation expense and \$0.3 million in depreciation and amortization expense. Net cash used in operating activities was \$37.0 million during the nine months ended September 30, 2017 and consisted primarily of our net loss of \$39.9 million and a net decrease in operating assets and liabilities of \$4.0 million, which was offset by non-cash charges of \$6.6 million for stock-based compensation expense and \$0.3 million in depreciation and amortization expense and amortization on premium/discount on short-term investments.

[Table of Contents](#)

Net Cash Provided by Investing Activities

Net cash provided by investing activities was \$30.0 million during the nine months ended September 30, 2018 and consisted primarily of purchases of \$0.3 million in property and equipment, primarily lab equipment to support research and development efforts, and \$28.7 million in short-term investments in U.S. Treasury securities, offset by \$59.0 million in maturities of these investments. Net cash provided by investing activities was \$25.7 million for the nine months ended September 30, 2017 and consisted primarily of purchases of \$0.3 million in property and equipment, primarily lab equipment to support research and development efforts, and \$24.0 million in short-term investments in U.S. Treasury securities, offset by \$50.0 million in maturities of these investments.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was \$0.4 million for the nine months ended September 30, 2018 and is primarily attributable to cash received from the issuances of common stock under our equity incentive plans. Net cash provided by financing activities was \$0.7 million for the nine months ended September 30, 2017 and is primarily attributable to cash received from the issuances of common stock under our equity incentive plans.

Contractual Obligations and Contingent Liabilities

During the nine months ended September 30, 2018, 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 (Securities Act), for complying with new or revised accounting standards. Thus, 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 \$1.07 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, 2018, we had cash and cash equivalents of \$68.5 million consisting of bank deposits and interest-bearing money market accounts and short-term investments of \$38.9 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

[Table of Contents](#)

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 10 percent (or 1,000 basis point) change in interest rates were to have occurred on September 30, 2018, 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.

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 (Exchange Act) as of the end of the period covered by this report. Based upon the evaluation, our 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 our President and Chief Executive Officer and Executive Vice President, Strategy & Finance, as appropriate to allow timely discussion regarding required disclosure. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective.

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.

PART II: OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently subject to any material legal proceedings.

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, 2018, we reported a net loss of \$14.0 million and \$41.2 million, respectively, compared with a net loss of \$13.4 million and \$39.9 million for the three and nine months ended September 30, 2017, respectively. As of September 30, 2018, we had an accumulated deficit of \$276.9 million.

We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates. We may also encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues, if any. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

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

To date, we have only generated limited revenues from collaboration and licensing agreements and the sale of products associated with material transfer, collaboration and GLA supply agreements and such revenues have not been sufficient to cover our operating expenses. Product sales to collaboration partners and collaboration service revenue will fluctuate from period to period based upon the timing and amount of product shipments and contract services performed during such periods. 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;

Table of Contents

- 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;
- competing technological efforts and market developments;
- changes in our existing research relationships;
- our ability to establish collaborative arrangements to the extent necessary;
- revenues received from any existing or future products; and
- payments received under any current or future strategic partnerships.

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

[Table of Contents](#)

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

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

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

Until we can generate a sufficient amount of revenue from our product candidates, if ever, we expect to finance future cash needs through public or private equity or debt offerings or from other sources. We have a shelf registration statement on Form S-3 (Registration No. 333-206324), which was declared effective by the SEC in December 2015 and allows us to sell up to an aggregate of \$250 million of our common stock, including up to \$50.0 million designated in the prospectus supplement we filed with the SEC in July 2017 for an ATM offering program. To date, we have issued an aggregate of approximately \$125 million of our common stock pursuant to our shelf registration statement. 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.

Comprehensive tax reform legislation could adversely affect our business and financial condition.

On December 22, 2017, the Tax Cuts and Jobs Act of 2017 (Tax Act) was signed into law. The Tax Act, among other things, contains significant changes to corporate taxation, including (i) reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, (ii) limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), (iii) limitation of the deduction for net operating losses to 80% of current year taxable income in respect of net operating losses generated during or after 2018 and elimination of net operating loss carrybacks, (iv) one-time taxation of offshore earnings at reduced rates regardless of whether they are

[Table of Contents](#)

repatriated, (v) immediate deductions for certain new investments instead of deductions for depreciation expense over time, and (vi) modifying or repealing many business deductions and credits, including reducing the Orphan Drug Credit from 50% to 25% of clinical costs incurred in the United States. Any federal net operating loss incurred in 2018 and in future years may now be carried forward indefinitely pursuant to the Tax Act. It is uncertain if and to what extent various states will conform to the newly enacted federal tax law. We will continue to examine the impact the Tax Act may have on our business.

Risks Related to Our Business and Industry

We cannot predict if or when we will receive regulatory approval to commercialize our product candidates.

Our product candidates are in various stages of clinical development. We cannot predict with any certainty if or when we might submit a BLA for regulatory approval for G100 or any of our product candidates or whether any such BLA will be accepted for review or approved by the FDA.

In October 2018, we announced the discontinuation of our Phase 3 clinical trial of CMB305 following an early analysis of the ongoing Phase 2 study that showed the combination of CMB305 and atezolizumab is not likely to show a survival benefit in relapsed synovial sarcoma patients.

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;

Table of Contents

- 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;
- 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;
- 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;
- 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

[Table of Contents](#)

FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Drug-related side effects could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

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

- we may suspend marketing of, or withdraw or recall, such product;
- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- the FDA or other regulatory authorities may issue safety alerts, “Dear Healthcare Provider” letters, press releases or other communications containing warnings about such product;
- the FDA may require the establishment or modification of a Risk Evaluation and Mitigation Strategy (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

[Table of Contents](#)

LV305 and CMB305, which may lengthen the regulatory review process, increase our development costs and delay or prevent commercialization of our ZVex product candidates.

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

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

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

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

The FDA or a comparable foreign regulatory authority may require more information, including additional preclinical or clinical data to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. If we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Regulatory authorities' assessment of the data and results required to demonstrate safety and efficacy can change over time and can be affected by many factors, such as the emergence of new information, including on other products, changing policies and agency funding, staffing and leadership.

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

In order to market and sell our products in 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

[Table of Contents](#)

international markets and receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected. We may not obtain foreign regulatory approvals on a timely basis, if at all. Our failure to obtain approval of any of our product candidates by regulatory authorities in countries outside of the United States may significantly diminish the commercial prospects of that product candidate and our business prospects could decline.

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

Even if we obtain regulatory approval for a product candidate, it will be subject to ongoing regulation by the FDA and comparable foreign regulatory authorities, including requirements governing the manufacture, quality control, further development, labeling, packaging, tracking, storage, distribution, safety surveillance, import, export, advertising, promotion, 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 (OIG), 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

[Table of Contents](#)

penalties, damages, monetary fines, disgorgement, individual imprisonment, exclusion from participation in Medicare, Medicaid and other federal healthcare programs, curtailment or restructuring of our operations and agreements that materially restrict the manner in which a company promotes or distributes drug products. These false claims statutes include, but are not limited to, the federal 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 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.

[Table of Contents](#)

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.

[Table of Contents](#)

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 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.

[Table of Contents](#)

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. In the United States, third-party payors individually establish coverage and reimbursement policies, which makes obtaining such coverage and adequate reimbursement a time-consuming and costly process. 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 some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, the Patient Protection and Affordable Care Act of 2010 (PPACA) was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The PPACA, among other things: (i) addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; (ii) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations; (iii) established annual fees and taxes on manufacturers of certain branded prescription drugs; (iv) expanded the availability of lower pricing under the 340B drug pricing program by adding new entities to the program; and (v) established a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (and 70% commencing January 1, 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

Some of the provisions of the PPACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the PPACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the PPACA have been signed into law. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain PPACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018 (BBA) among other things, amends the PPACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." Congress may consider additional legislation to repeal or repeal and replace other elements of the PPACA. We continue to evaluate the effect that the PPACA and its possible repeal and replacement has on our business.

[Table of Contents](#)

Other legislative changes have been proposed and adopted since the PPACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013, and due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2027 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have an adverse effect on customers for our product candidates, if approved, and, accordingly, our financial operations.

Additional changes that may affect our business include the expansion of new programs such as Medicare payment for performance initiatives for physicians under the Medicare Access and CHIP Reauthorization Act of 2015 which will be fully implemented in 2019. At this time, it is unclear how the introduction of the Medicare quality payment program will impact overall physician reimbursement. Also, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which have resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. While any proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures are increasingly 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, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that these and other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. 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 revenue, attain profitability, or commercialize our products.

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.

[Table of Contents](#)

While we currently hold \$10.0 million in products liability insurance coverage related to our clinical trials, 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 current and future arrangements with third-party payors, providers 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 conduct clinical research and 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 Payments Sunshine Act (federal Open Payments program), created under Section 6002 of the PPACA and its implementing regulations, requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the U.S. Department of Health and Human Services (HHS) information related to "payments or other transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to the HHS 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, including the False Claims Act, 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 (HIPAA) imposes criminal liability for knowingly and willfully executing a scheme to defraud any healthcare benefit program, knowingly and willfully embezzling or stealing any money or other assets of a health care benefit program, willfully obstructing a criminal investigation of a health care fraud 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;

[Table of Contents](#)

- 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, individual imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, that person or entity may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Risks Related to our Dependence on Third Parties

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

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

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

We have entered into 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 have also entered into exclusive licenses and development agreements with MedImmune pursuant to which we have granted MedImmune exclusive licenses to use our GLAAS discovery platform to develop and commercialize product candidates relating to certain infectious diseases. 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

[Table of Contents](#)

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' technologies, products and selection of disease targets;
- 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 Sanofi, Sanofi Pasteur or MedImmune, and could result in a material adverse effect on our business, results of operations and prospects and would likely cause our stock price to decline. For example, in 2017, Medimmune published the results of its Phase 2b clinical trial assessing the efficacy of a vaccine for prevention of RSV-associated acute respiratory illness in older adults. The vaccine consisted of the RSV postfusion F protein with GLA in a stable emulsion. The trial did not meet its primary endpoint, and we do not expect MedImmune to continue development of this vaccine. According to the publication, even though the vaccine induced a significant immune response, which was enhanced by GLA as shown previously in a Phase 1 trial, the authors of the publication concluded that the postfusion F-based vaccine may not generate appropriate neutralizing antibodies to prevent RSV disease in older adults.

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

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

- the development of certain of our current or future product candidates may be impaired or delayed;
- our cash expenditures related to development of certain of our current or future product candidates would increase significantly and we may need to seek additional financing;
- we may be required to hire additional employees or otherwise 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;

Table of Contents

- 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 third-party 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 delays and additional cost. We have not secured commercial supply agreements with any contract manufacturers and can give no assurance that we will enter commercial supply agreements with any contract manufacturers on favorable terms or at all.

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

[Table of Contents](#)

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 from a single source. The loss of a 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.

Significant disruptions of our information technology systems or data security incidents could result in significant financial, legal, regulatory, business and reputational harm to us.

We are increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. In the ordinary course of our business, we collect, store, process and transmit large amounts of sensitive information, including intellectual property, proprietary business information, personal information and other confidential information. It is critical that we do so in a secure manner to maintain the confidentiality, integrity and availability of such sensitive information. We have also outsourced elements of our operations (including elements of our information technology infrastructure) to third parties, and as a result, we manage a number of third-party vendors who may or could have access to our computer networks or our confidential information. In addition, many of those third parties in turn subcontract or outsource some of their responsibilities to third parties. While all information technology operations are inherently vulnerable to inadvertent or intentional security breaches, incidents, attacks and exposures, the accessibility and distributed nature of our information technology systems, and the sensitive information stored on those systems, make such systems potentially vulnerable to unintentional or malicious, internal and external attacks on our technology environment. Potential vulnerabilities can be exploited from inadvertent or intentional actions of our employees, third-party vendors, business partners, or by malicious third parties. Attacks of this nature are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives (including, but not limited to, industrial espionage) and expertise, including organized criminal groups, “hacktivists,” nation states and others. In addition to the extraction of sensitive information, such attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. In addition, the prevalent use of mobile devices increases the risk of data security incidents.

Significant disruptions of our, our third-party vendors’ and/or business partners’ information technology systems or other similar data security incidents could adversely affect our business operations and/or result in the loss, misappropriation, and/or unauthorized access, use or disclosure of, or the prevention of access to, sensitive information, which could result in financial, legal, regulatory, business and reputational harm to us. In addition, information technology system disruptions, whether from attacks on our technology environment or from computer viruses, natural disasters, terrorism, war and telecommunication and electrical failures, could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

There is no way of knowing with certainty whether we have experienced any data security incidents that have not been discovered. While we have no reason to believe this to be the case, attackers have become very sophisticated in the way they conceal access to systems, and many companies that have been attacked are not aware that they have been attacked. Any event that leads to unauthorized access, use or disclosure of personal information, including but not limited to personal information regarding our patients or employees, could disrupt our business, harm our reputation, compel us to comply with applicable federal and/or state breach notification laws and foreign law equivalents, subject us to time consuming, distracting and expensive litigation, regulatory investigation and oversight, mandatory corrective action, require us to verify the correctness of database contents, or otherwise subject us to liability under laws, regulations and contractual obligations, including those that protect the privacy and security of personal information. This could result in increased costs to us, and result in significant legal and financial exposure and/or reputational harm. In addition, any failure or perceived failure by us or our vendors or business partners to comply with our privacy, confidentiality or data security-related legal or other obligations to

[Table of Contents](#)

third parties, or any further security incidents or other inappropriate access events that result in the unauthorized access, release or transfer of sensitive information, which could include personally identifiable information, may result in governmental investigations, enforcement actions, regulatory fines, litigation, or public statements against us by advocacy groups or others, and could cause third parties, including clinical sites, regulators or current and potential partners, to lose trust in us or we could be subject to claims by third parties that we have breached our privacy- or confidentiality-related obligations, which could materially and adversely affect our business and prospects. Moreover, data security incidents and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. While we have implemented security measures intended to protect our information technology systems and infrastructure, there can be no assurance that such measures will successfully prevent service interruptions or security incidents.

Risks Related to Intellectual Property

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

Our success depends in significant part on our and our licensors' and licensees' ability to establish, maintain and protect patents and other intellectual property rights and operate without infringing the intellectual property rights of others. We have filed patent applications both in the United States and in foreign jurisdictions to obtain patent rights to inventions we have discovered. We have also licensed from third parties rights to patent portfolios. Some of these licenses give us the right to prepare, file and prosecute patent applications and maintain and enforce patents we have licensed, and other licenses may not give us such rights.

The patent prosecution process is expensive and time-consuming, and we and our current or future licensors and licensees may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our licensors or licensees will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and are reliant on our licensors or licensees. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. If our current or future licensors or licensees fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our licensors or licensees are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors' or licensees' patent rights are highly uncertain. Our and our licensors' or licensees' pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. The patent examination process may require us or our licensors or licensees to narrow the scope of the claims of our or our licensors' or licensees' pending and future patent applications, which may limit the scope of patent protection that may be obtained. We may be required to disclaim part or all of the term of certain patents or part or all of the term of certain patent applications.

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

[Table of Contents](#)

found by a court to infringe our patents. The possibility exists that others will develop products which have the same effect as our products on an independent basis which do not infringe our or our licensor's patents or other intellectual property rights, or will design around the claims of patents that we have had issued that cover our products. We may analyze patents or patent applications of our competitors that we believe are relevant to our activities, and consider that we are free to operate in relation to our product candidates, but our competitors may achieve issued claims, including in patents we consider to be unrelated, which block our efforts or may potentially result in our product candidates or our activities infringing such claims. Our and our licensors' or licensees' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover the technology. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

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

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 have appealed 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 may 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.

[Table of Contents](#)

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.

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 (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 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.

[Table of Contents](#)

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 have appealed 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 may 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 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

[Table of Contents](#)

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. Since our initial public offering in July 2014 at a price of \$12.00 per share, and through September 30, 2018, the sale price of our common stock as reported on The Nasdaq Global Market (Nasdaq) has ranged from \$40.13 to \$2.80. Our announcement on October 11, 2018 of our plans to discontinue our Phase 3 clinical trial for our CMB305 product candidate in patients with synovial sarcoma resulted in a significant decline in the market price of our common stock. In addition, as with any public company, some investors hold a short position in our common stock. Activities by these investors may increase the volatility of the market price of our common stock, and may affect our ability to raise additional funds and to complete our clinical trials and operations. Our stock could also be 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 timing of the commencement and progress of, and the receipt of data from, any of our preclinical and clinical trials;
- unfavorable reports or downgrades by financial analysts;
- results of clinical trials of our competitor's product candidates;
- 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;

[Table of Contents](#)

- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the 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 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 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, 2017, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 60% of our voting stock. These stockholders may have the ability to control us through this ownership position and be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests 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 (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

[Table of Contents](#)

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 (Dodd-Frank Act) and some of the disclosure requirements of the Dodd-Frank Act relating to compensation of our chief executive officer;

- the requirement to provide detailed compensation discussion and analysis in proxy statements and reports filed under the Securities Exchange Act of 1934 (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 \$1.07 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

[Table of Contents](#)

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. In July 2017, we entered into a Sales Agreement with Cowen and Company, LLC under which we may offer and sell, from time to time at our sole discretion, shares of our common stock having an aggregate offering price of up to \$50.0 million. 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.

Although we have had periods of high volume daily trading in our common stock, generally our stock is thinly traded. For example, the average daily trading volume in our common stock on Nasdaq for the nine months ended September 30, 2018 was approximately 334,000 shares per day. 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.

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

The trading market for our common stock will rely in part on the research and reports that equity research analysts publish about us and our business. Although certain equity research analysts currently cover us, we do not have any control of the analysts or the content and opinions included in their reports or whether any such analysts will continue to, or whether new analysts will, cover us for any given period of time. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

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;

Table of Contents

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

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Other than as notated, the exhibits set forth below are filed as part of this Quarterly Report on Form 10-Q:

Table of Contents

Exhibit No.	Description
3.1	<u>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).</u>
3.2	<u>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).</u>
4.1	<u>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).</u>
31.1	<u>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.</u>
31.2	<u>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.</u>
32.1*	<u>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.</u>
32.2*	<u>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.</u>
101	Financial statements from the Quarterly Report on Form 10-Q of Immune Design Corp. for the quarter ended September 30, 2018, 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.

*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.

[Table of Contents](#)

SIGNATURES

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

Immune Design Corp.

(Registrant)

Date: November 6, 2018

/s/ Carlos Paya, M.D., Ph.D.

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

Date: November 6, 2018

/s/ Stephen Brady

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

CERTIFICATION OF PRESIDENT AND CHIEF EXECUTIVE OFFICER
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Carlos Paya, M.D., Ph.D., certify that:

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

Dated: November 6, 2018

/s/ Carlos Paya, M.D., Ph.D.

Carlos Paya, M.D., Ph.D.

President and Chief Executive Officer

(Principal Executive Officer)

CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Stephen Brady, certify that:

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

Dated: November 6, 2018

/s/ Stephen Brady

Stephen Brady
Executive Vice President, Strategy & Finance
(Principal Financial Officer)

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

In connection with the Quarterly Report on Form 10-Q of Immune Design Corp. (“Immune Design”) for the quarter ended September 30, 2018, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Carlos Paya, M.D., Ph.D., President and Chief Executive Officer of Immune Design, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Immune Design.

Dated: November 6, 2018

/s/ Carlos Paya, M.D., Ph.D.

Carlos Paya, M.D., Ph.D.

President and Chief Executive Officer

(Principal Executive Officer)

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

In connection with the Quarterly Report on Form 10-Q of Immune Design Corp. (“Immune Design”) for the quarter ended September 30, 2018, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Stephen Brady, Executive Vice President, Strategy and Finance of Immune Design, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Immune Design.

Dated: November 6, 2018

/s/ Stephen Brady

Stephen Brady
Executive Vice President, Strategy & Finance
(Principal Financial Officer)

