IMMUNE DESIGN CORP.
Form 10-K
March 13, 2019
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2018
or
¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to
Commission File Number: 001-36561

IMMUNE DESIGN CORP.
(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)	26-2007174 (I.R.S. Employer Identification Number)
1616 Eastlake Ave. E., Suite 310 Seattle, Washington (address of principal executive officers)	98102 (Zip code)

(206) 682-0645
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, par value $0.001 per share	Nasdaq Global Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No x
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ¨ No x
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨
Indicate by check mark whether the registrant has submitted electronically 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 x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

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

Large accelerated filer	¨	Accelerated filer x
Non-accelerated filer	¨	Smaller reporting company x
		Emerging Growth Company x

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. x

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

As of June 30, 2018, the aggregate market value of the 41,157,170 shares of Common Stock held by non-affiliates of the registrant was approximately $187.3 million, computed by reference to the closing price as reported on The Nasdaq Global Market. The calculation excludes shares of the registrant's common stock held by current executive officers, directors and stockholders that the registrant has concluded are affiliates of the registrant. This determination of affiliate status is not a determination for other purposes.

As of March 8, 2019, the registrant had 48,365,248 shares of common stock, par value $0.001 par value, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive Proxy Statement for the 2019 Annual Meeting of Stockholders of the registrant are incorporated by reference into Part III of this Annual Report on Form 10-K. The Proxy Statement will be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2018.

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In this report, unless otherwise stated or as the context otherwise requires, references to “Immune Design,” “the Company,” “we,” “us,” “our” and similar references refer to Immune Design Corp. “ZVex” 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.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS
AND INDUSTRY DATA

This Annual Report on Form 10-K contains forward looking statements. In some cases, you can identify forward-looking statements by terminology such as “may,” “will,” “should,” “expects,” “plans,” “anticipates,” “believes,” “esti “predicts,” “potential,” “targets,” “intends” or “continue,” or the negative of these terms or other comparable terminology. Forward-looking statements include, but are not limited to, statements about:

- the anticipated timing and completion of the tender offer, or the Offer, by Cascade Merger Sub Inc., or the Purchaser, a subsidiary of Merck Sharp & Dohme Corp., or Parent, and subsequent merger of Purchaser with and into the Company with the Company surviving as a wholly owned subsidiary of Parent (Merger, and, together with the Offer, the Proposed Transaction), pursuant to that certain Agreement and Plan of Merger by and among the Company, Purchaser and Parent, dated as of February 20, 2019 (the Merger Agreement);
- our estimates regarding our expenses, use of proceeds, future revenues, anticipated capital requirements and our needs for additional financing;
- the implementation of our business model and strategic plans for our business and technology;
- the timing of the commencement, progress and receipt of data from any of our preclinical and clinical trials;
- the expected results of any clinical trial and the impact on the likelihood or timing of any regulatory approval;
- the scope of protection we establish and maintain for intellectual property rights covering our technology;
- the timing or likelihood of regulatory filings and approvals;
- the timing and outcome of any current or future litigation;
- developments relating to our competitors and our industry; and
- our expectations regarding licensing, acquisitions and strategic operations.

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

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Except as required by law, after the date of this report, 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.

This report also contains estimates, projections and other information concerning our industry, the market and our business. Information that is based on estimates, forecasts, projections or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. We obtained the industry, market and competitive position data in this report from our own internal estimates and research as well as from industry and general publications and research surveys and studies conducted by third parties.

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PART I

Item 1. Business

Overview

We are a clinical-stage immunotherapy company employing 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 tumor-specific cytotoxic T cells, or CTLs, while also enhancing other immune effectors, to fight cancer via distinct mechanisms. G100, our lead product candidate, uses the body's immune system in different ways that, we believe, addresses the shortcomings of other therapies and has the potential to treat a broad patient population. In the Fall of 2018, we elected to focus our resources on G100 and pause development of our other programs generated from our discovery platforms, ZVex® and GLAAS®, including a late-stage cancer vaccine program, CMB305. Building upon positive G100 data in multiple tumor types, including from a randomized Phase 2 clinical trial, and after receiving feedback from the Food and Drug Administration, or FDA, we are planning to further develop G100 with a potential first approval path in follicular lymphoma patients, a type of non-Hodgkin lymphoma that affects thousands of patients annually.

Recent Events

On February 20, 2019, we entered into the Merger Agreement with Merck Sharp & Dohme Corp., a New Jersey corporation, or Parent, and Cascade Merger Sub Inc., a Delaware corporation and a wholly owned subsidiary of Parent, or Purchaser (or together with Parent, Merck), pursuant to which we agreed to be acquired by Merck in an all-cash transaction for an approximate value of $300 million, representing an over three hundred percent premium over our stock's closing price on the day prior to the announcement of the Merger Agreement. In accordance with the terms of the Merger Agreement, Purchaser has commenced a tender offer, or Offer, to acquire all of our outstanding shares of common stock for $5.85 per share, to be paid to the seller in cash, without interest and subject to any applicable withholding taxes. The consummation of Purchaser's pending Offer and subsequent Merger will be subject to certain conditions, including the tender of shares representing at least one more than 50% of the total number of our shares of common stock outstanding at the time of the expiration of the Offer, the expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and other customary conditions. The Merger Agreement provides, among other things, that following the consummation of the Offer and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement and in accordance with the relevant provisions of the Delaware General Corporation Law and other applicable law, Purchaser will merge with and into the Company, the separate existence of Purchaser will cease and the Company will continue as the surviving corporation and as a wholly owned subsidiary of Parent. We expect the Proposed Transaction to close early in the second quarter of 2019.

Additional information about the Proposed Transaction is set forth in our filings with the SEC.

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G100 Product Development

G100 was developed from the GLAAS platform and activates both innate and adaptive immunity in the tumor microenvironment, including dendritic cells, to create an immune response against the tumor's pre-existing, diverse set of antigens, including neoantigens. G100 contains a potent, synthetic, small molecule toll-like receptor-4, or TLR4, agonist called GLA, which stands for Glucopyranosyl Lipid A.

We have been developing G100 as a monotherapy and combination therapy in patients with follicular non-Hodgkin Lymphoma, or FL, in a randomized Phase 1b/2 clinical trial. The monotherapy Phase 1b portion of the trial evaluated G100 with local radiation at multiple doses, and the randomized Phase 2 portion of the trial evaluated G100 with local radiation alone or in combination with the anti-PD-1 agent, Keytruda® (pembrolizumab), pursuant to a collaboration with Merck. In December 2017, we presented the first data from this trial at the American Society of Hematology, or ASH, Annual Meeting, and in March 2018 and at the ASH Annual Meeting in December 2018, we reported longer-term follow-up data observing additional responses. The G100 monotherapy and pembrolizumab combination resulted in a 54% objective response rate, or ORR, with a 75% ORR in those patients who expressed a potential predictive biomarker related to high TLR4 expression (6/8 patients). These data compare favorably to the pembrolizumab monotherapy data presented at ASH 2017, which showed an 11% ORR in a separate follicular lymphoma study. In addition, 77% of patients in the combination arm experienced abscopal tumor shrinkage in un-injected tumors, compared to 54% of patients in the monotherapy arm. Given these clinical benefit data and G100's continued favorable safety profile, and after receiving feedback from the FDA we are planning to develop G100 first in relapsed/refractory FL patients who have received at least three prior lines of therapy – a patient population whom the FDA stated may represent an unmet medical need. In addition, we are evaluating development of G100 in other lymphomas and solid tumors.

We have received orphan drug designation in the United States and European Union for G100 in FL. Orphan drug designation provides certain benefits, such as research tax credits and waivers of certain regulatory fees, but does not provide any assurance of regulatory approval or expedite regulatory review.

Our Strategy

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 in comparison to the G100 program, we discontinued our SYNOVATE Phase 3 clinical trial in patients with synovial sarcoma. We plan to seek external collaborators to explore the continued development of CMB305 in sarcoma.

Our ongoing strategy is multi-faceted:

- Develop product candidates to treat a broad patient population. We believe our product candidates may benefit a wide range of patients in both orphan diseases and larger indications because they are designed to create tumor-killing CTLs, could potentially target any tumor and have potential utility as both individual therapies and in combination with multiple types of other anti-cancer mechanisms of action.

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- Rapidly advance first-in-class immuno-oncology product candidates through clinical development. We intend to continue to execute a focused clinical development plan that takes selected product candidates through approval. We are initially focused on indications with an unmet need in targeted patient populations, such as G100 in relapsed and refractory FL patients.
- Position Immune Design to potentially play a broad role in the immuno-oncology treatment paradigm. Our agents are designed to work either individually or together, as well as with multiple other mechanisms of action. In addition to our ongoing clinical collaboration combining G100 with a checkpoint inhibitor, we intend to explore additional combinations with other immuno-oncology approaches to demonstrate this broad potential benefit.
- Selectively monetize non-oncology indications, while retaining optionality for future internal development. ZVex and GLAAS also have potential applications in infectious disease and allergy. We have licensed the right to use the GLAAS platform in specific infectious disease indications to large pharmaceutical companies. These collaborations provide us with both near- and long-term potential revenue and external validation of our technology, while preserving optionality for future growth beyond oncology.
- Establish infrastructure and capabilities to support the future commercialization of our products. Our management team has extensive experience developing and commercializing pharmaceutical products and as our product candidates advance, we intend to add the appropriate additional expertise to maximize the potential for successful product launches and franchise management. In certain instances, we will seek partners to maximize the commercial potential of our product candidates.

Our Approaches to Treating Cancer

Immuno-oncology broadly refers to the modulation of the immune system to eradicate tumor cells, and is often colloquially divided into two categories: “create and expand” the anti-tumor immune response and “remove the brakes” placed on the immune response by the tumor’s defenses.

We believe alteration of the tumor microenvironment and trafficking of CTLs into the tumor are increasingly being recognized as important for the efficacy of any immunotherapy. Our platforms focus on the “create and expand” category and are designed to generate strong, tumor-specific CTLs and effector cells in vivo that infiltrate the tumor (known as making the tumor “hot”), while addressing many of the shortcomings of previous approaches. Our platforms can generate individual product candidates, such as G100, or complimentary product candidates administered in sequence, such as CMB305. Additionally, we designed our therapies to be combined with other immuno-oncology therapeutic mechanisms such as checkpoint inhibitors from the “remove the brakes” category, which we believe will generate a greater anti-tumor response.

In addition to G100, we are also investigating the potential use of our ZVex platform for intratumoral injection. For example, we presented preclinical data at the American Association for Cancer Research Annual Meeting in 2016 and Society for Immunotherapy of Cancer Annual Meeting in 2017 describing the intratumoral administration of a ZVex vector designed to generate localized expression of IL-12, a potent modulator of innate and adaptive immune responses. The results demonstrated strong local and systemic anti-tumor efficacy in multiple murine models, and this use of the ZVex platform offers a potential expansion opportunity of our intratumoral approach beyond G100.

Therapeutic Applications Outside Oncology

Although immuno-oncology development is robust with therapies for an estimated 10 liquid and 18 solid tumors in development and with a market for immuno-oncology therapies projected to approach $35 billion by 2023, the broader market for immunotherapy applications also includes infectious and allergic diseases. The worldwide infectious diseases vaccine market garnered approximately $30 billion in sales in 2014 and the market for allergy therapies and diagnostics is projected to reach $41 billion by 2022. Beyond oncology, we believe our technologies offer several promising applications in the fields of infectious and allergic diseases. We have been executing on our strategy to partner the use of our GLAAS platform in individual indications outside of oncology in infectious and allergic diseases, which provide potential downstream revenue while preserving growth opportunity in the future.

Infectious Diseases

Historically, antigens have been used with sub-optimal immune adjuvants and have mainly focused on generating antibodies, which have been limited by low affinity and a narrow spectrum of activity. We believe using GLA, a novel molecular adjuvant, combined with infectious disease antigens will boost pre-existing T cells and trigger a broad

antibody response, allowing for diverse antigen recognition. The results of these trials that we have reviewed to date support the finding of increased magnitude and breadth of the antibody response.

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We have a preclinical vaccine product candidate called G103 to treat herpes simplex virus type 2, or HSV2. G103 consists of several recombinantly expressed proteins adjuvanted with a specific formulation of GLA. In October 2014, we announced a collaboration with Sanofi Pasteur, the vaccines division of Sanofi, to develop G103 along with additional assets contributed by us and Sanofi Pasteur.

Allergic Diseases

We believe allergic diseases represent an exciting area for the application of GLAAS. Allergies to pollen or food often occur because of aberrant immune reactions, which are characterized by helper T cells producing signals that induce other immune cells to cause the allergy symptoms. We have a large set of preclinical data demonstrating that certain formulations of GLAAS, when given prophylactically or therapeutically with or without the allergen, can shift the responses in a way that results in significant protection from allergy symptoms. In essence, the immune system can be taught to redirect the T cells to respond in better ways.

Manufacturing

Overview

We are continuing to establish manufacturing processes and supply agreements for all of the components used in our product candidates to support ongoing and planned clinical trials, primarily bulk and formulated GLA for our G100 product candidate. We rely on third-party contract manufacturing organizations, or CMOs, to produce our product candidates for clinical use and currently do not own or operate manufacturing facilities. We require that our CMOs produce bulk drug substances and finished drug products used in our clinical trials in accordance with current Good Manufacturing Practices, or cGMPs, and all other applicable laws and regulations. We may continue to rely on CMOs to develop and manufacture our products for commercial sale. We maintain agreements with our CMOs that include confidentiality and intellectual property provisions to protect our proprietary rights related to our product candidates and manufacturing processes.

GLAAS Product Candidates

Manufacturing for the GLAAS platform generally encompasses the synthesis of bulk GLA, its formulations and the fill-finish of formulated GLA. We have established a supply chain for bulk GLA and our stable-emulsion formulation, referred to as GLA-SE. Our synthetic process for the manufacture of bulk GLA is a trade secret, and we retain control and ownership of this process. Our CMOs also perform release and stability testing on the bulk GLA. The scale of the GLA synthetic manufacturing process is adequate to support commercial production for our G100 product candidate. We have also contracted with a CMO to formulate and fill-finish our GLA-SE drug product. We have manufactured multiple lots in support of our clinical trials and those of our partners. The formulation process utilizes technology that is readily scalable to support commercial manufacturing of our product candidates and to supply our licensees. Release and stability testing on the GLA-SE drug product is contracted to several CMOs.

Intellectual Property

Overview

Our intellectual property strategy is to protect our technologies by filing patent applications and obtaining patent rights both in the United States and in foreign countries that we consider important to our current and future business. In addition, we have acquired and will seek to acquire, as needed or desired, intellectual property rights of others through assignment or license to complement and enhance our portfolio of patent rights. We also rely upon trade secrets, know-how and continuing technological innovations to develop and maintain our competitive position.

Patents

GLAAS

We license exclusive rights to seven granted U.S. patents and numerous granted foreign patents from the Infectious Disease Research Institute, or IDRI, directed to antigen-containing vaccine formulations containing GLA, medical uses of the formulations to generate antigen-specific immune response for cancer, infectious disease and autoimmune disease antigens and medical uses for generating an immune response by administering pharmaceutical compositions containing GLA. The license rights from IDRI include patents in the United States, Europe, Australia, China, Japan, India and Hong Kong. We own two granted U.S. patents and own or license numerous additional pending domestic and foreign patent applications directed to our GLAAS platform. Key patents and pending applications in our portfolio are directed to vaccine compositions and uses of compositions containing GLA in a variety of disease

indications including cancer, infectious diseases and allergy. We also own two granted U.S. patents, seven foreign patents and pending domestic and foreign patent applications directed to G103.

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Our granted patents directed to the GLAAS platform will expire in 2027, with one U.S. patent that will expire in early 2028 due to patent term adjustment, not giving effect to any potential extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. The 20-year projected expiration dates for our pending patent applications range from 2027 to 2035, not giving effect to any potential extensions and assuming payment of all associated fees.

We require employees, consultants, advisors and collaborators to enter into agreements with appropriate confidentiality and intellectual property provisions standard for the industry.

ZVex

We are the owner or exclusive licensee to proprietary patent positions related to our ZVex platform. Our patent portfolio includes a patent family licensed from the California Institute of Technology, or Caltech, and is directed to our dendritic cell targeting lentiviral vector platform technology. This patent family includes patents granted domestically and in Europe, Australia, China, Japan, India and South Africa and has granted claims that include composition of matter claims to our lentiviral vector and packaging cells as well as methods of using our lentiviral vector to elicit an immune response against a target antigen of interest and methods of preparing our lentiviral vector. Our patent portfolio also includes three patent families solely owned by us, directed to improvements to the lentiviral vector, methods of making the lentiviral vector and our next generation lentiviral vector, with patents granted domestically and in various countries including in Europe, China, Japan, South Korea, Australia and New Zealand. The granted patents include composition of matter claims to our lentiviral vector, a lentiviral vector packaging system, methods of using our lentiviral vectors to induce an immune response to an antigen and methods of making lentiviral vector particles.

We exclusively license one patent family from the University of North Carolina at Chapel Hill, or UNC Chapel Hill, directed to a specific component of our lentiviral vectors, with patents granted domestically, in Europe and in Japan. Together, we own or license 13 issued U.S. patents, over 30 granted foreign patents and numerous pending U.S. and foreign patent applications related to our ZVex platform. We also own a granted patent in the U.S., eight granted foreign patents and pending domestic and foreign patent applications directed to methods of using our lentiviral vectors in combination with our GLAAS platform.

Granted patents directed to our lentiviral vectors have expiration dates ranging from 2027 to 2037, not giving effect to any potential extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. The 20-year projected expiration dates for our pending patent applications range from 2027 to 2037, not giving effect to any potential extensions and assuming payment of all associated fees.

Licensing Agreements

We have in-licensed both exclusive and non-exclusive intellectual property rights related to our discovery platform technologies, including the following:

Second Amended and Restated License Agreement with the Infectious Disease Research Institute

In December 2015, we entered into a second amended and restated license agreement with IDRI, and paid an upfront fee of $2.3 million, pursuant to which we license certain patent rights, know-how and technologies relating to our GLAAS discovery platform, including products and formulations containing GLA and another synthetic TLR4 agonist referred to as SLA. The original license agreement with IDRI was entered into in July 2008, and the first restated agreement was entered into with IDRI in November 2010. We also entered into a separate agreement with IDRI in November 2015 to license a related patent in the field of cancer. The patent rights licensed from IDRI are directed to GLA and SLA, compositions and formulations that include these molecules, and methods of using these compositions to elicit or enhance an immune response. The licensed patent rights cover all of our GLAAS platform products in clinical development. Under the license agreement, we generally obtained an exclusive license in the fields of oncology, allergy, addiction and select infectious disease indications, which vary depending on the licensed GLA or SLA product. In addition, we have an option to obtain additional exclusive licenses in select infectious disease indications for GLA and SLA products. IDRI has retained exclusive rights with respect to infectious diseases and other indications not licensed to us. Under the license agreement, we are obligated to use commercially reasonable efforts to develop and commercialize licensed products to which we have exclusive rights. We and IDRI are not permitted to sell or transfer GLA or SLA outside our respective exclusive fields.

We recognized $500,000, zero and $925,000 in license-related milestone fees, which were expensed in research and development expenses, for the years ended December 31, 2018, 2017 and 2016, respectively. We are obligated to pay IDRI in aggregate up to $1.8 million and $1.3 million, respectively, in additional payments for the first and each subsequent exclusive licensed product we develop, and $1.3 million and $625,000, respectively, for the first and each subsequent non-exclusive licensed product we develop based on the achievement of certain developmental and regulatory milestones. We are obligated to pay IDRI a low single-digit royalty on net sales of licensed products that varies according to the product and indication, as well

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as a percentage share of any payments that we receive from sub-licensees, ranging from the low double-digits to the middle single-digits. Our royalty obligations continue for the life of the relevant licensed patents or 12 years after the first commercial sale of a licensed product, whichever is longer. Currently, we expect that the last-to-expire licensed patent in the United States will expire in 2028 with respect to GLA products and 2032 with respect to SLA products. Our license agreement with IDRI will remain in effect until the expiration of our payment obligations under the license agreement. We may terminate the license agreement at any time with advance written notice. IDRI may terminate the license agreement if we challenge any of the licensed patents. Either party may terminate the license agreement for the other party's uncured material breach or upon certain insolvency events.

Exclusive License Agreement with Caltech

In January 2009, we entered into an exclusive license agreement with Caltech, pursuant to which we obtained a worldwide, exclusive license under certain patent rights directed to the production of dendritic cell-targeted therapeutic and prophylactic immunization strategies, with the right to sublicense. In September 2009, we exercised an option to expand the field of use to include human cancer applications. Additionally, we have a non-exclusive, sub-licensable worldwide license to unpatented know-how related to the licensed patents. Under the license agreement, we are obligated to use diligent commercial efforts to develop and commercialize licensed products and to make them available to the developing world.

In partial consideration for the patent rights licensed to us under the license agreement, we issued shares of our common stock to Caltech. We are obligated to pay Caltech a low single-digit percentage royalty on net sales of licensed products, subject to a non-material annual minimum, as well as a mid single-digit to low double-digit percentage share of any payments that we receive from sub-licensees, which percentage depends on the stage of development when the sublicense was granted. We are also obligated to pay Caltech up to an aggregate of $1.5 million in additional payments based on the achievement of certain development and regulatory milestones. Our royalty obligations continue for the life of the relevant licensed patent rights. Currently, we expect that the last-to-expire licensed patent in the United States will expire in 2027.

Our license agreement with Caltech will remain in effect until the later of the expiration of the last-to-expire licensed patent rights or the end of our payment obligations under the license agreement. Either party may terminate the license agreement in the event of the other party's uncured material breach or certain insolvency events.

Exclusive License Agreement with UNC Chapel Hill

In January 2013, we entered into a license agreement with UNC Chapel Hill, pursuant to which we obtained a worldwide, sub-licensable, non-exclusive license to certain modified retroviral vectors, including a license under all patent rights owned or controlled by UNC Chapel Hill covering such vectors. In January 2015, we exercised an option to obtain an exclusive license under these patent rights. Under the license agreement, we are obligated to use commercially reasonable efforts to diligently pursue the development and commercialization of licensed products, and we are required to meet certain performance milestones relating to the development of licensed products.

We will owe UNC Chapel Hill one or more non-material milestone payments upon the occurrence of certain events relating to the development or regulatory approval of licensed products. We are also obligated to pay UNC Chapel Hill non-material annual renewal fees, a low double-digit percentage share of any payments that we receive from sub-licensees, and a low single-digit royalty on net sales of licensed products by us or our sub-licensees. Our royalty obligations continue for the life of the licensed patent rights, on a product-by-product and country-by-country basis, and in any event will cease upon termination or expiration of the license agreement. Currently, we expect that the last-to-expire licensed patent in the United States will expire in 2028.

Our license agreement with UNC Chapel Hill will expire upon the expiration of the last-to-expire licensed patent rights, or, if no patents issue from the licensed patent rights, in January 2028. We may terminate the license agreement at any time upon advance written notice to UNC Chapel Hill. UNC Chapel Hill may terminate the license agreement in the event of our uncured material breach or if we become insolvent, and either party may terminate the license agreement for uncured fraud, willful misconduct, or illegal conduct of the other party.

License Agreement with TheraVectys SA

In October 2016, we entered into a license agreement with TheraVectys SA, or 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. The license agreement was entered into simultaneously with a settlement agreement resolving litigation brought by TVS against us related to our use of a third party contract manufacturing organization, Henogen, for the manufacture of our LV305 product candidate. We resolved the TVS allegations pursuant to the settlement agreement, and we additionally received certain present and future intellectual property rights under the license agreement, including, among other things, a sublicense to certain patent rights licensed by TVS from the Institut Pasteur.

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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.

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

License and Collaboration Agreements

Collaboration Agreement with Sanofi Pasteur

In October 2014, we entered into a collaboration for the development of a herpes simplex virus, or HSV, immune therapy with Sanofi Pasteur, the vaccines division of Sanofi. We and Sanofi Pasteur 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. We 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, and we will provide a specific formulation of GLA from the GLAAS platform at our cost through Phase 2 studies. We are eligible to receive future milestone and royalty payments on any licensed product developed from the collaboration.

Exclusive License Agreement with MedImmune

We are party to a license agreement with MedImmune LLC, or MedImmune, dated October 2010, pursuant to which we granted MedImmune a worldwide, sub-licensable, exclusive license to use GLA to develop and sell vaccines in an infectious disease indication. Under the license agreement, 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.

Under the license agreement, if certain development regulatory and commercial milestones are achieved, MedImmune is obligated to make additional aggregate payments of up to $72.5 million. We have recognized no revenue for the achievement of milestones under this license agreement. MedImmune is also obligated to pay us a low double-digit percentage share of non-royalty payments that it receives from sub-licensees and a mid single-digit royalty on net sales of licensed products, which royalty is subject to reduction under certain circumstances. Under our license agreement with IDRI, we are obligated to share with IDRI a percentage of payments received from third-party licensees, including MedImmune. MedImmune's royalty obligations will continue, on a country-by-country basis, for at least 10 years after the first commercial sale of the first licensed product in the applicable country and will continue on a country-by-country and product-by-product basis, for the life of the licensed patents that cover the sale of the applicable product in the applicable country.

Our license agreement with MedImmune will remain in effect until the later of October 2060 or the expiration of MedImmune's payment obligations. MedImmune may terminate the license agreement at any time with advance written notice. We or MedImmune may terminate the license agreement in case of the other party's uncured material breach or upon certain insolvency events.

Previously, we were parties to two additional license agreements with MedImmune, each dated October 2010, pursuant to which we granted MedImmune an exclusive license to use GLA to develop and sell vaccines in two additional infectious disease indications, which license agreements have each been terminated. Under the terminated license agreements, we recognized no revenue for the achievement of development milestones for the years ended

December 31, 2018, 2017 and 2016.

Exclusive License Agreement with Sanofi

In August 2014, we granted Sanofi an exclusive license to use the GLAAS platform to discover, develop and commercialize products to treat peanut allergy. On December 6, 2018, Sanofi provided notice terminating this license agreement as of June 6, 2019. We recognized no milestone revenue under this agreement for the years ended December 31, 2018, and 2017, and $7.0 million in milestone revenue under this agreement for the year ended December 31, 2016.

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Competition

The biotechnology and pharmaceutical industries are characterized by continuing technological advancement and significant competition. While we believe that our product candidates, technology, knowledge and experience provide us with competitive advantages, we face competition from established and emerging pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions, among others. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. Key product features that would affect our ability to effectively compete with other therapeutics include the efficacy, safety and convenience of our product candidates. The availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of our product candidates. Our competitors may also obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Many of the companies against which we may compete have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Government Regulation and Product Approval

In the United States, the FDA regulates our current product candidates as biological drug products, or biologics, under the Federal Food, Drug, and Cosmetic Act, or FDCA, the Public Health Service Act and related regulations. Biologics are also subject to other federal, state and local statutes and regulations. Failure to comply with the applicable United States regulatory requirements at any time during the product development process, approval process or after approval may subject an applicant to administrative or judicial actions. These actions could include the suspension or termination of clinical trials by the FDA or an Institutional Review Board, or IRB, the FDA's refusal to approve pending applications or supplements, revocation of a biologics license, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, import detention, injunctions, civil penalties or criminal prosecution. Any administrative or judicial action could have a material adverse effect on us.

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture and marketing of biologics. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, purity, potency, labeling, storage, distribution, record keeping and reporting, approval, import and export, advertising and promotion and post-market surveillance of our products.

The FDA's policies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of any future product candidates or approval of product or manufacturing changes, new disease indications, or label changes. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the United States or abroad.

Biologics Marketing Approval

The process required by the FDA before biologics may be marketed in the United States generally involves nonclinical laboratory and animal tests; submission of an IND application, which must become effective before clinical trials may begin; adequate and well-controlled human clinical trials to establish the safety, purity and potency of the proposed biologic for its intended use or uses; pre-approval inspection of manufacturing facilities and clinical trial sites; and FDA approval of a Biologics License Application, or BLA, which must occur before a biologic can be marketed or sold.

Before testing any compound in human subjects, a company must develop extensive preclinical data. Preclinical testing generally includes laboratory evaluation of product chemistry and formulation, as well as toxicological and pharmacological studies in several animal species to assess the quality and safety of the product. Animal studies must

be performed in compliance with the FDA's Good Laboratory Practice, or GLP, regulations and the United States Department of Agriculture's Animal Welfare Act and related regulations.

Prior to commencing the first clinical trial in humans, an initial IND application must be submitted to the FDA. A company must submit preclinical testing results to the FDA as part of the IND, and the FDA must evaluate whether there is an adequate basis for testing the drug in humans. The IND automatically becomes effective 30 days after receipt by the FDA unless the FDA within the 30-day time period raises concerns or questions about the conduct of the clinical trial and places the trial on clinical

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hold. In such case, the IND application sponsor must resolve any outstanding concerns with the FDA before the clinical trial may begin. A separate submission to the existing IND must be made for each successive clinical trial to be conducted during product development. Further, an independent IRB for each site proposing to conduct the clinical trial must review and approve the protocol and informed consent for any clinical trial before it commences at that site. Informed consent must also be obtained from each study subject. Regulatory authorities, an IRB, a data safety monitoring board or the trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the participants are being exposed to an unacceptable health risk.

A study sponsor is also required to submit to NIH for public posting on NIH's clinical trial website, details about certain active clinical trials and clinical trial results. For purposes of developing product candidates for BLA approval, human clinical trials are typically conducted in phases that may overlap:

- Phase 1—the investigational biologic is initially given to healthy human subjects or patients and tested for safety, dosage tolerance, reactivity, absorption, metabolism, distribution and excretion. These studies may also gain early evidence on effectiveness. During Phase 1 clinical trials, sufficient information about the investigational products may be obtained to permit the design of well-controlled and scientifically valid Phase 2 clinical trials.
- Phase 2—studies are conducted in a limited number of patients in the target population to identify possible adverse effects and safety risks, to assess the efficacy of the investigational product for specific targeted diseases and to determine dosage tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3—when Phase 2 evaluations demonstrate that a dosage range of the investigational product may be effective and may have an acceptable safety profile, and provide sufficient information for the design of Phase 3 clinical trials, Phase 3 clinical trials are undertaken to provide statistically significant evidence of clinical efficacy and to further test for safety in an expanded patient population at multiple clinical trial sites. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to further evaluate dosage, effectiveness and safety, to establish the overall benefit-risk relationship of the investigational drug, and to provide an adequate basis for product approval by the FDA.

All of these trials must be conducted in accordance with Good Clinical Practice, or GCP, requirements in order for the data to be considered reliable for regulatory purposes.

Products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. In addition, the FDA currently requires the pre-approval of promotional materials for products receiving accelerated approval.

The Biologic License Application Approval Process

In order to obtain approval to market a biologic in the United States, a BLA must be submitted to the FDA that provides data establishing to the FDA's satisfaction the safety and effectiveness of the investigational product for the proposed indication. Each BLA submission requires a substantial user fee payment unless a waiver or exemption applies. The application includes all relevant data available from pertinent nonclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from a number of alternative sources, including studies initiated by investigators.

The FDA will initially review the BLA for completeness before it accepts it for filing. Under the FDA's procedures, the agency has 60 days from its receipt of a BLA to determine whether the application will be accepted for filing based on the agency's threshold determination that the application is sufficiently complete to permit substantive review. After the BLA submission is accepted for filing, the FDA reviews the BLA to determine, among other things,

whether the proposed product is safe, pure and potent, which includes determining whether it is effective for its intended use, and whether the product is being manufactured in accordance with cGMP, to assure and preserve the product's identity, strength, quality, potency and purity. The FDA may refer applications for novel products or products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and, if so, under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

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During the approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to assure that the benefits of the biologic outweighs the risks. A REMS may include various elements depending on what the FDA considers necessary for the safe use of the drug. These elements may range from a medication guide or patient package insert to training and certification requirements for prescribers and/or pharmacies to safe use conditions that must be in place before the drug is dispersed. If the FDA concludes that a REMS is needed, the BLA sponsor must submit a proposed REMS and the FDA will not approve the BLA without a REMS that the agency has determined is acceptable.

Certain applications for approval must include an assessment, generally based on clinical study data, of the safety and effectiveness of the subject drug or biological product in relevant pediatric populations. The FDA may waive or defer the requirement for a pediatric assessment, either at the Company's request or by the agency's initiative.

The Orphan Drug Act provides incentives for the development of drugs and biological products intended to treat rare diseases or conditions, which generally are diseases or conditions affecting less than 200,000 individuals in the United States. If a sponsor demonstrates that a drug or biologic is intended to treat a rare disease or condition, the FDA grants orphan drug designation to the product for that use. The benefits of orphan drug designation include research and development tax credits and exemption from user fees. A drug or biologic that is approved for the orphan designated indication is granted seven years of orphan drug exclusivity. During that period, the FDA generally may not approve any other application for the same product for the same indication, although there are exceptions, most notably when the later product is shown to be clinically superior to the product with exclusivity.

For investigational products that are intended to treat serious diseases, certain mechanisms may expedite the FDA approval process. For example, FDA may grant Priority Review designation for a product that could provide significant improvement in the treatment, diagnosis, or prevention of a serious condition. Priority Review sets the target date for FDA action on the application at six months from the FDA's filing of the BLA, rather than the standard 10 months. Priority review designation does not, however, change the scientific or medical standard for approval or the quality of evidence necessary to support approval. Another potential approach is Fast Track designation, which a sponsor can request at any time during the development process to facilitate development and expedite review of a product intended to treat a serious condition and fill an unmet medical need. Fast Track designation involves early and frequent communication between the FDA and the sponsor, which often leads to earlier approval. Breakthrough Therapy designation is another approach that is intended to expedite development and review of a product that is intended to treat a serious condition and where preliminary clinical evidence indicates that the product may demonstrate substantial improvement over available therapy on a clinically significant endpoint. Like Fast Track designation, Breakthrough Therapy designation provides a sponsor with the opportunity to obtain early and intensive guidance from FDA for an efficient drug development program.

After the FDA completes its initial review of a BLA, it will either communicate to the sponsor that it will approve the product, or issue a complete response letter to communicate that it will not approve the BLA in its current form and to inform the sponsor of changes that the sponsor must make or additional clinical, nonclinical or manufacturing data that must be received before the FDA can approve the application, with no implication regarding the ultimate approvability of the application. If a complete response letter is issued, the sponsor may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and are adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA may inspect one or more clinical sites to assure compliance with GCP. If the FDA determines the application, manufacturing process or manufacturing facilities are not acceptable, it typically will outline the deficiencies and often will request additional testing or information. This may significantly delay further review of the application. If the FDA finds that a clinical site did not conduct the clinical trial in accordance with GCP, the FDA may determine that the data generated by the clinical site should be excluded from analyses provided in the BLA. Additionally, notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The FDA may require, or companies may pursue, additional clinical trials after a product is approved. These so-called Phase 4 clinical trials may be made a condition to be satisfied for continuing product approval. The results of Phase 4 clinical trials can confirm the effectiveness of a product candidate and can provide important safety information. Conversely, the results of Phase 4 clinical trials can raise new safety or efficacy issues that were not apparent during the original review of the product, which may result in product restrictions or even withdrawal of the product approval. In addition, the FDA has express statutory authority to require sponsors to conduct post-market studies or clinical trials to specifically address safety issues identified by the agency.

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Even if a product candidate receives regulatory approval, the approval will be limited to specific disease states, patient populations and/or dosages, or might contain significant limitations on use in the form of warnings, precautions or contraindications, or in the form of a REMs, restrictions on distribution, or post-marketing study or trial requirements. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product requirements to conduct additional studies or trials, or even complete withdrawal of the product from the market. In addition, we cannot predict what adverse governmental regulations may arise from future United States or foreign governmental action.

FDA Post-Approval Requirements

Any products manufactured or distributed by us or on our behalf pursuant to FDA approvals are subject to continuing regulation by the FDA, including requirements for record-keeping, reporting of adverse experiences with the biologic, submitting annual reports, and reporting biological product deviations. Manufacturers are required to register their facilities with the FDA and certain state agencies, and are subject to periodic inspections by the FDA and certain state agencies for compliance with cGMP standards, which impose certain quality processes, manufacturing controls and documentation requirements upon us and our third-party manufacturers in order to ensure that the product is safe, has the identity and strength, and meets the quality, purity and potency characteristics that it purports to have. We cannot be certain that we or our present or future suppliers will be able to comply with the cGMP and other FDA regulatory requirements. If our present or future suppliers are not able to comply with these requirements, the FDA may halt our clinical trials, refuse to approve any BLA or other application, force us to recall a drug from distribution, shut down manufacturing operations or withdraw approval of the BLA for that biologic. Noncompliance with cGMP or other requirements can result in issuance of warning letters, civil and criminal penalties, seizures, and injunctive action.

The FDA and other federal and state agencies closely regulate the labeling, marketing and promotion of biologics. While doctors may prescribe any product approved by the FDA for any use as long as consistent with any REMS restrictions, if applicable, a company can only make claims about a product that are consistent with its FDA approval, and the Company is allowed to market a drug only for the particular use approved by the FDA. In addition, any claims we make for our products in advertising or promotion must be appropriately balanced with important safety information and otherwise be adequately substantiated. Failure to comply with these requirements can result in adverse publicity, untitled or warning letters, corrective advertising requirements, injunctions, potential civil and criminal penalties, criminal prosecution, and agreements with governmental agencies that materially restrict the manner in which a company promotes or distributes drug products. Government regulators, including the Department of Justice and the Office of the Inspector General of the Department of Health and Human Services, or OIG, as well as state authorities, recently have increased their scrutiny of the promotion and marketing of drugs.

Finally, post-approval modifications to a licensed biological product, such as changes in indications, labeling, or manufacturing processes or facilities, may require a sponsor to develop additional data or conduct additional preclinical or clinical trials, to be submitted in a new or supplemental BLA, which would require FDA review and approval.

Biologics Price Competition and Innovation Act of 2009

The Biologics Price Competition and Innovation Act, or BPCIA, created a licensure framework for biosimilar products, or biosimiliars, which could ultimately subject our biological product candidates to competition from biosimiliars. Under the BPCIA, a manufacturer may submit an abbreviated application for licensure of a biologic that is “biosimilar to” an already licensed biologic, or reference product. This abbreviated approval pathway is intended to permit a biosimilar to come to market more quickly and less expensively, by relying to some extent on the FDA’s previous review and approval of the reference biologic to which the proposed product is biosimilar.

Under the BPCIA, a biosimilar sponsor’s ability to seek or obtain approval through the abbreviated pathway is limited by periods of exclusivity granted to the sponsor of the reference product. No biosimilar application may be accepted by the FDA for review until four years after the date of approval of the reference product, and no such application, once accepted, may receive final approval until 12 years after that same date. Once approved, biosimilar products likely would compete with, and in some circumstances may be deemed under the law to be “interchangeable with”, the previously approved reference product.

FDA Regulation of Companion Diagnostics

Companion diagnostics are classified as medical devices under the FDCA in the United States. In the United States, the FDA regulates the medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, reporting, recordkeeping, advertising and promotion, export and import, sales and distribution, and post-market surveillance of medical devices. Unless an exemption applies, companion diagnostics require marketing clearance or approval from the FDA prior to commercial distribution. The two primary types of FDA marketing authorization applicable to a medical device are premarket notification, also called 510(k) clearance, and premarket approval, or PMA.

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The FDA previously has required in vitro companion diagnostics intended to select the patients who will respond to the cancer treatment to obtain a PMA simultaneously with approval of the drug. The review of these companion diagnostics in conjunction with the review of our product candidates involves coordination of review by the FDA's Center for Drug Evaluation and Research and by the FDA's Center for Devices and Radiological Health.

Coverage and Reimbursement

In both domestic and foreign markets, sales of any product candidates for which we may receive regulatory approval will depend in part upon the availability of coverage and reimbursement from third-party payors. Such third-party payors include governmental healthcare programs, such as Medicare and Medicaid, private health insurers and managed care organizations and other entities. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Assuming coverage is granted, the reimbursement rates paid for covered products might not be adequate. Even if favorable coverage status and adequate reimbursement rates are attained, less favorable coverage policies and reimbursement rates may be implemented in the future. The marketability of any products for which we may receive regulatory approval for commercial sale may suffer if governmental healthcare programs and other third-party payors fail to provide coverage and adequate reimbursement to allow us to sell such products on a competitive and profitable basis. For example, under these circumstances, physicians may limit how much or under what circumstances they will prescribe or administer our product, and patients may decline to purchase such products. This, in turn, could affect our ability to successfully commercialize our products and impact our profitability, results of operations, financial condition, and future success.

The market for any product candidates for which we may receive regulatory approval will depend significantly on the degree to which these products are listed on third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included on such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug on their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available. In addition, because each third-party payor individually establishes coverage and reimbursement policies, obtaining coverage and adequate reimbursement can be a time-consuming and costly process. We may be required to provide scientific and clinical support for the use of any product to each third-party payor separately with no assurance that approval will be obtained, and we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. We cannot be certain that our product candidates will be considered cost-effective by third-party payors. This process could delay the market acceptance of any product candidates for which we may receive approval and could have a negative effect on our future revenues and operating results.

Additionally, we may develop companion diagnostic tests for use with our product candidates. We will be required to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement we seek for our product candidates, once approved. While we have not yet developed any companion diagnostic test for our product candidates, if we do, there is significant uncertainty regarding our ability to obtain coverage and adequate reimbursement for the same reasons applicable to our product candidates.

Other Healthcare Laws

In the United States, the research, manufacturing, distribution, marketing, sale and promotion of drug products and medical devices are subject to numerous regulations by various federal, state and local authorities in addition to the FDA, including but not limited to, the U.S. Department of Health and Human Services, or HHS, and its various divisions, including but not limited to, the Centers for Medicare and Medicaid Services, or CMS. These regulations are enforced by various federal, state and local authorities, including but not limited to, the U.S. Department of Justice, state Attorneys General, state Medicaid Fraud Control Units, HHS' various enforcement divisions, including but not limited to, the Office of Inspector General, the Office for Human Research Protections, or OHRP, and the Office of Research Integrity and other state and local government agencies. Pricing and rebate programs must comply with the Medicaid Drug Rebate Program requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Health Care Act of 1992. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also

potentially subject to federal and state consumer protection and unfair competition laws.

We are subject to complex laws pertaining to healthcare "fraud and abuse," including, but not limited to, the federal Anti-Kickback Statute, the federal False Claims Act, the federal Physician Payments Sunshine Act and other state and federal laws.

The federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good or service for which payment may be made under federal health care programs such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, formulary managers, and others on the other hand.

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The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the Affordable Care Act, among other things, amended the intent requirement of the federal Anti-Kickback Statute. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal false claims statutes. There are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions; however, the exceptions and safe harbors are drawn narrowly, and practices that do not fit squarely within an exception or safe harbor may be subject to scrutiny.

The federal civil and criminal false claims laws, including the federal False Claims Act, prohibit, among other things, any person from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment, or knowingly making, or causing to be made, a false record or statement material to a false or fraudulent claim. Private "qui tam" actions may be brought by individual whistleblowers in the name of the government to enforce the federal False Claims Act. Many pharmaceutical and other healthcare companies have faced investigations and private lawsuits and, in many cases, have agreed to significant and burdensome settlements under these laws for a variety of allegedly improper promotional and marketing activities, including inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. The majority of U.S. states also have statutes or regulations similar to the federal Anti-Kickback Statute and False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, and in some states, apply regardless of the payor. The federal False Statements Statute prohibits knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry, in connection with the delivery of or payment for healthcare benefits, items, or services. The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, prohibits, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense, or knowingly and willfully making false statements relating to healthcare matters. The civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and their implementing regulations, impose obligations on certain covered entity health care providers, health plans, and health care clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information.

The federal Physician Payments Sunshine Act, being implemented as the Open Payments Program, requires certain manufacturers of products for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program to track and annually report to CMS payments and other transfers of value to physicians and teaching hospitals, as well as physician ownership and investment interests, and to publicly report such data.

Several states now require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products in those states and to report gifts and payments to individual health care providers in those states. Some of these states also prohibit certain marketing related activities including the provision of gifts, meals, or other items to certain health care providers. In addition, some states require pharmaceutical companies to implement compliance programs or marketing codes and have privacy laws that may be more stringent that HIPAA. Further, some state laws require the reporting of information related to drug pricing, and certain state and local laws require the registration of pharmaceutical sales and medical representatives.

Because of the breadth of these laws and the narrowness of available statutory exceptions and regulatory safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our

operations are found to be in violation of any of the federal or state laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including significant administrative, criminal and civil monetary penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government programs, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, 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.

To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

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The Affordable Care Act

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our product candidates profitably, even if they are approved for sale. 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 and medical device industries have been a particular focus of these efforts and have been significantly affected by major legislative initiatives.

In March 2010, the Affordable Care Act was enacted, which includes measures that have or will significantly change health care delivery and financing by both governmental and private insurers. Among the provisions of the Affordable Care Act of importance to the pharmaceutical and medical device industries are the following:

- The Affordable Care Act increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program from 15.1% to 23.1% and from 11% to 13% of the average manufacturer price, or AMP, for most branded and generic drugs and biologic agents, respectively. The Affordable Care Act also added a rebate calculation for “line extensions” (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products and potentially impacted manufacturers’ Medicaid Drug Rebate liability by modifying the statutory definition of AMP. The Affordable Care Act also expanded manufacturers’ rebate liability under the Medicaid program from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well and by expanding the population potentially eligible for Medicaid drug benefits.
- On February 1, 2016, CMS, the federal agency that administers the Medicaid Drug Rebate Program, issued final regulations to implement the changes to the Medicaid Drug Rebate program under the Affordable Care Act. These regulations became effective on April 1, 2016.
- Federal law requires that any company that participates in the Medicaid rebate program also participate in the Public Health Service’s 340B drug pricing program in order for federal funds to be available for the manufacturer’s drugs under Medicaid and Medicare Part B. The 340B drug pricing program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B “ceiling price” for the manufacturer’s covered outpatient drugs.
- The Affordable Care Act imposes a requirement on manufacturers of branded drugs and biologic agents to provide a 70% discount off the negotiated price of branded drugs dispensed to Medicare Part D patients in the coverage gap (i.e., “donut hole”) as a condition for the manufacturers’ outpatient drugs to be covered under Medicare Part D.
- The Affordable Care Act imposes an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, although this fee would not apply to sales of certain products approved exclusively for orphan indications. The Affordable Care Act expanded healthcare fraud and abuse laws, including the federal False Claims Act and the federal Anti-Kickback Statute, and added new government investigative powers, and enhanced penalties for noncompliance.
- The Affordable Care Act established the Physician Payments Sunshine Act (as referenced above), which requires pharmaceutical and medical device manufacturers to track and report annually certain financial arrangements with physicians and teaching hospitals, as defined in the Affordable Care Act and its implementing regulations, including reporting any “payments or other transfers of value” made or distributed to such entities, and it requires applicable manufacturers and applicable group purchasing organizations to report annually any ownership and investment interests held by physicians and certain other healthcare providers and their immediate family members.
- The Affordable Care Act added a new requirement to annually report drug samples that manufacturers and distributors provide to physicians.
- The Affordable Care Act created a licensure framework for follow on biologic products.
- A new Patient-Centered Outcomes Research Institute was established pursuant to the Affordable Care Act to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.
- The research conducted by the Patient-Centered Outcomes Research Institute may affect the market for certain pharmaceutical products.

- The Affordable Care Act established the Center for Medicare & Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

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Since its enactment, there have been judicial and Congressional challenges to numerous aspects of the Affordable Care Act. For example, since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the Affordable Care Act and otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the Affordable Care Act have been signed into law. The Tax Cuts and Jobs Act of 2017, or Tax Act, included a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act 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". On January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain Affordable Care Act-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. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act.

Other Legislative Changes and Regulations

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

More recently, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. For example, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. On January 31, 2019, the HHS OIG proposed modifications to the federal Anti-Kickback Statute discount safe harbor for the purpose of reducing the cost of drug products to consumers which, among other things, if finalized, will affect discounts paid by manufacturers to Medicare Part D plans, Medicaid managed care organizations and pharmacy benefit managers working with these organizations. While some of these and other proposed measures may require additional authorization 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.

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially

hazardous substances.

Corporate Information and Employees

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. Our principal executive offices are located at 1616 Eastlake Ave. E., Suite 310, Seattle, WA 98102, and our telephone number is (206) 682-0645. As of December 31, 2018, we had 48 full-time employees and 2 part-time employees. None of our employees are represented by labor unions or covered by collective bargaining agreements.

Available Information

Our website address is www.immunedesign.com. We make available on our website, free of charge, our Annual Report on Form 10-K, our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K and any amendments to those reports

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filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission, or the SEC. The SEC maintains a website that contains reports, proxy and information statements and other information regarding our filings at www.sec.gov. The information found on our website is not incorporated by reference into this Annual Report on Form 10-K or any other report we file with or furnish to the SEC.

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Item 1A. Risk Factors

This Annual Report on Form 10-K 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 Annual Report on Form 10-K as well as our other publicly available filings with the SEC.

Risks Related to the Merger Agreement

The conditions under the Merger Agreement to Purchaser's consummation of the Offer and our subsequent Merger with Purchaser may not be satisfied at all or in the anticipated timeframe.

Under the terms of the Merger Agreement, the consummation of Purchaser's pending Offer and subsequent Merger is subject to customary conditions. Satisfaction of certain of the conditions is not within our control, and difficulties in otherwise satisfying the conditions may prevent, delay, or otherwise materially adversely affect the consummation of the pending Offer and subsequent Merger. These conditions include, among other things, there being validly tendered (and not validly withdrawn), a number of shares of our common stock that, considered together with all other shares of our common stock beneficially owned by Parent or any of its wholly owned subsidiaries (including Purchaser), subject to certain conditions, represent one more than 50% of the total number of our shares of common stock outstanding at the time of the expiration of the Offer. We cannot predict with certainty whether and when any of the required conditions will be satisfied. If the Proposed Transaction does not receive, or timely receive, the required regulatory approvals and clearances, or if another event occurs delaying or preventing the Proposed Transaction, such delay or failure to complete the Proposed Transaction may create uncertainty or otherwise have negative consequences that may materially and adversely affect our financial condition and results of operations, as well as the price per share for our common stock.

While Purchaser's Offer and the proposed Merger are pending, we are subject to business uncertainties and contractual restrictions that could disrupt our business.

Whether or not the pending Offer and subsequent Merger is consummated, the Proposed Transaction may disrupt our current plans and operations, which could have an adverse effect on our business and financial results. The pendency of the pending Offer and subsequent Merger may also divert management's attention and our resources from ongoing business and operations, and our employees and other key personnel may have uncertainties about the effect of the pending Offer and subsequent Merger, and the uncertainties may impact our ability to retain, recruit, and hire key personnel while the Proposed Transaction is pending or if it fails to close.

The preparations for the consummation of the Proposed Transaction have placed and we expect will continue to place a significant burden on many of our management, employees and on our internal resources. The diversion of management's attention away from operating the Company in the ordinary course could adversely affect our financial results. Also, if, despite our efforts, key personnel depart because of these uncertainties and burdens, or because they do not wish to remain with the combined company, our business and results of operations may be adversely affected.

We have incurred and will continue to incur significant expenses due to legal, advisory, printing and financial services fees related to the Proposed Transaction. These expenses must be paid regardless of whether the Proposed Transaction is consummated, which may materially and adversely affect our financial condition and results of operations.

Furthermore, we cannot predict how our business partners will view or react to the pending Offer and subsequent Merger upon consummation. If we are unable to reassure our business partners to continue transacting business with us, our financial condition and results of operations may be adversely affected.

In addition, the Merger Agreement generally requires the Company to operate its business and operations in the ordinary course pending consummation of the Merger and also restricts us from taking certain actions without Parent's prior written consent during the interim period between the execution of the Merger Agreement and the effective time of the Merger (or the date on which the Merger Agreement is earlier terminated). For these and other reasons, the pendency of the proposed Merger could adversely affect our business and results of operations.

Our executive officers and directors may have interests that are different from, or in addition to, those of our stockholders generally.

Our executive officers and directors may have interests in the Merger that are different from, or are in addition to, those of our stockholders generally. These interests include direct or indirect ownership of our common stock, stock options and restricted stock units, and for executive officers, employment agreements, retention bonuses and employee benefits following the completion of the pending Offer and subsequent Merger.

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Litigation filed or that may be filed against us and/or the members of our board of directors could prevent or delay the consummation of the Proposed Transaction.

Lawsuits could be filed that could delay or prevent our acquisition by Parent, divert the attention of our management and employees from our day-to-day business and otherwise adversely affect us financially. The outcome of any lawsuit that may be filed challenging the Proposed Transaction is uncertain. One of the conditions to the closing of the Proposed Transaction is that there has not been issued by any court of competent jurisdiction and remains in effect any judgment, temporary restraining order, preliminary or permanent injunction or other order preventing the consummation of the Proposed Transaction. Accordingly, if any future lawsuit is successful in obtaining an order enjoining the Proposed Transaction, then the Proposed Transaction may not be consummated within the expected time frame, or at all, and could result in substantial costs, including but not limited to, costs associated with the indemnification of our directors and officers.

In the event that the Proposed Transaction is not consummated, the trading price of our common stock and our future business and results of operations may be negatively affected.

The conditions to the consummation of the pending Offer and subsequent Merger may not be satisfied, as noted above. If the Proposed Transaction is not consummated, we would remain liable for significant transaction costs, and the focus of our management would have been diverted from seeking other potential strategic opportunities, in each case without realizing any benefits of the Proposed Transaction. For these and other reasons, not consummating the Proposed Transaction could adversely affect our business and results of operations.

Furthermore, if we do not consummate the pending Offer and subsequent Merger, the price of our common stock may decline significantly from the current market price, which we believe reflects a market assumption that the Proposed Transaction will be consummated. Further, a failure of the Proposed Transaction may result in negative publicity and a negative impression of us in the investment community, and have a negative impact on our ability to raise additional financing in the future. Finally, any disruptions to our business resulting from the announcement and pendency of the Proposed Transaction, including any adverse changes in our relationships with our business partners and employees or recruiting and retention efforts, could continue or accelerate in the event of a failed transaction.

If the Merger Agreement is terminated, we may, under certain circumstances, be obligated to pay a termination fee to Parent. These costs could require us to use available cash that would have otherwise been available for other uses.

If the Proposed Transaction is not completed, in certain circumstances, we could be required to pay a termination fee of $10.5 million to Parent. If the Merger Agreement is terminated, the termination fee we may be required to pay, if any, under the Merger Agreement may require us to use available cash that would have otherwise been available for general corporate purposes or other uses. For these and other reasons, termination of the Merger Agreement could materially and adversely affect our business, results of operations or financial condition, which in turn would materially and adversely affect the price per share of our common stock.

The following risk factors assume that we remain a stand-alone company except as otherwise noted.

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 years ended December 31, 2018, 2017 and 2016, we reported net losses of $54.8 million, $51.9 million and $53.5 million, respectively. As of December 31, 2018, we had an accumulated deficit of $290.5 million.

We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates. We may also encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely

affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues, if any. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

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

To date, we have only generated limited revenues from 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;
- 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;

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- revenues received from any existing or future products; and
- payments received under any current or future strategic partnerships.

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

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

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

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

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

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

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

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

On December 22, 2017, the Tax Cuts and Jobs Act of 2017, or the 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 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.

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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. For example, 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, or IRBs, or ethics committees, or ECs, or institutional biosafety committees, to begin clinical trials at study sites;
- imposition of a clinical hold by the FDA or other regulatory authorities, or a decision by the FDA, other regulatory authorities, IRBs, ECs, or recommendation by a data safety monitoring board, to suspend or terminate clinical trials at any time for safety issues or for any other reason;
- 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.

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

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

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

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate or 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.

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We may be required to suspend, repeat, redesign or terminate our clinical trials if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive or the trials are not well designed. Clinical trials must be conducted in accordance with the FDA's current Good Clinical Practices, or cGCP, or other applicable foreign government guidelines. Clinical trials are subject to oversight by the FDA, other foreign governmental agencies, 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, or cGMP. Clinical trials may be suspended by the FDA, other foreign governmental agencies, or us for various reasons, including:

- deficiencies in the conduct of the clinical trials, including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols;
- deficiencies in the clinical trial operations or trial sites;
- the product candidate may have unforeseen adverse side effects;
- deficiencies in the trial design necessary to 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.

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. Clinical data are subject to varying interpretations and the FDA and comparable foreign regulatory authorities may not agree with our interpretation of results. Subsequent clinical trials may not validate earlier clinical or non-clinical findings. 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.

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

In order to market and sell our products in jurisdictions outside the United States, we must obtain separate marketing approvals for those jurisdictions and comply with their numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, we must secure product reimbursement approvals before regulatory authorities will approve the product for sale in that country. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not ensure approval in any other country, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. Also, if regulatory approval for any of our product candidates is granted, it may be later withdrawn. If we fail to comply with the regulatory requirements in international markets and receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected. We may not obtain foreign regulatory approvals on a timely basis, if at all. Our failure to obtain approval of any of our product candidates by regulatory authorities in countries outside of the United States may significantly diminish the commercial prospects of that product candidate and our business prospects could decline.

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

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

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

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

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

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Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the Department of Justice, the Department of Health and Human Services' Office of Inspector General, or 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 significant administrative, civil and criminal penalties, damages, monetary fines, disgorgement, 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

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- unfavorable publicity relating to the product candidate.

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

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

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

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

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

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

- the efficacy and safety profile of our product candidates, including relative to marketed products and product candidates in development by third parties;
- the time it takes for our product candidates to complete clinical development and receive marketing approval;
- the ability to commercialize any of our product candidates that receive regulatory approval;
- the price of our products, including in comparison to branded or generic competitors;
- whether coverage and adequate levels of reimbursement are available under private and governmental health insurance plans, including Medicare;
- the ability to establish, maintain and protect intellectual property rights related to our product candidates;
- the ability to manufacture commercial quantities of any of our product candidates that receive regulatory approval; and
- acceptance of any of our product candidates that receive regulatory approval by physicians and other healthcare providers.

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

We 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:

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- 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.

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 third-party payors, such as 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.

The market for any product candidates for which we may receive regulatory approval will also depend significantly on the degree to which these products are listed on third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included on such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug on their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available. We cannot be certain that our product candidates will be considered cost-effective by third-party payors.

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This process could delay the market acceptance of any product candidates for which we may receive approval and could have a negative effect on our future revenues and operating results.

Additionally, we may develop companion diagnostic tests for use with our product candidates. We will be required to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement we seek for our product candidates, once approved. While we have not yet developed any companion diagnostic test for our product candidates, if we do, there is significant uncertainty regarding our ability to obtain coverage and adequate reimbursement for the same reasons applicable to our product candidates.

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, as amended by the Health Care and Education Reconciliation Act of 2010, (collectively, 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 now agree to offer 70% 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. For example, since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the PPACA and otherwise circumvent some of the requirements for health insurance mandated by the PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the PAPCA. 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, or Tax Act, included a provision which repealed, 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.” 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. The Bipartisan Budget Act of 2018 (BBA) among other things, amended the PPACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole.” On December 14, 2018, a Texas U.S. District Court Judge ruled that the PPACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress as part of the Tax Act. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the PPACA will impact the PPACA and our

business. We continue to evaluate the effect that the PPACA and its possible repeal and replacement has on our business.

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.

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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. Further, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services (HHS) has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2019, and in October 2018, CMS proposed a new rule that would require direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product. On January 31, 2019, the HHS Office of Inspector General, proposed modifications to the federal Anti-Kickback Statute discount safe harbor for the purpose of reducing the cost of drug products to consumers which, among other things, if finalized, will affect discounts paid by manufacturers to Medicare Part D plans, Medicaid managed care organizations and pharmacy benefit managers working with these organizations. While some of these and other proposed measures may require additional authorization 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 have increasingly passed legislation and implemented 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.

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

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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 may 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, healthcare 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 CMS 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 CMS 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 federal False Claims Act, which can be enforced by individuals, on behalf of the government, through civil whistleblower or qui tam actions, prohibits individuals or entities from, among other things, 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 Civil Monetary Penalties Law, which prohibits, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, prohibits 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 their implementing regulations, also imposes obligations on certain covered entity health care providers, health plans, and health care clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers;

- state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers;
- state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers,marketing expenditures, or drug pricing; and

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- state and foreign laws, including the General Data Protection Regulation (EU) 2016/679, 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 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, disgorgement, 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 significant criminal, civil and 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 a collaboration agreement with Sanofi Pasteur for the development of a herpes simplex virus immune therapy. We have granted an exclusive license to MedImmune to use our GLAAS discovery platform to develop and commercialize product candidates relating to an infectious disease indication. We cannot control whether or not these partners will devote sufficient time and resources to the ongoing clinical and preclinical programs or whether these partners will fulfill their obligations under the agreements. The product candidates developed pursuant to these agreements may not be scientifically, medically or commercially successful.

In addition, we could be adversely affected by:

- our partners' 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 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.

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

A part of our strategy is to enter into product development collaborations, 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;
- 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

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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 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.

The loss of our current CMO could result in manufacturing delays for the component substitution, and we may need to accept changes in terms or price from our existing supplier in order to avoid such delays. If we utilize an alternative source, we may be required to demonstrate comparability of the drug product before releasing the product for clinical use.

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.

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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 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 found by a court to infringe our patents. The possibility exists that others will develop products

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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. 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.

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

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

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance 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

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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.

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, TheraVectys 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

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

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

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

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

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 December 31, 2018, the sale price of our common stock as reported on The Nasdaq Global Market, or Nasdaq, has ranged from $40.13 to $1.10. 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;

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- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- 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, 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, 2018, the holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 55% of our voting stock. These stockholders may have the ability to control us through this ownership position and be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

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

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

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

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- the "say on pay" provisions (requiring a non-binding shareholder vote to approve compensation of certain executive officers) and the "say on golden parachute" provisions (requiring a non-binding shareholder vote to approve golden parachute arrangements for certain executive officers in connection with mergers and certain other business combinations) of the Dodd-Frank Wall Street Reform and Protection Act, or Dodd-Frank Act, and some of the disclosure requirements of the Dodd-Frank Act relating to compensation of our chief executive officer;
- the requirement to provide detailed compensation discussion and analysis in proxy statements and reports filed under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and instead provide a reduced level of disclosure concerning executive compensation; and
- any rules that the Public Company Accounting Oversight Board may adopt requiring mandatory audit firm rotation or a supplement to the auditor's report on the financial statements.

We may take advantage of these exemptions until we are no longer an "emerging growth company." We would cease to be an "emerging growth company" upon the earliest of: (i) the first fiscal year following the fifth anniversary of our initial public offering in July 2014; (ii) the first fiscal year after our annual gross revenues are $1.07 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 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.

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Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.
Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.
Our common stock is thinly traded and in the future, may continue to be thinly traded, and our stockholders may be unable to sell at or near asking prices or at all if they need to sell their shares to raise money or otherwise desire to liquidate such shares.
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 year ended December 31, 2018 was approximately 416,000 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 shares 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;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

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

control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

Item 1B. Unresolved Staff Comments.

None.

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Item 2. Properties.

We currently lease approximately 20,133 square feet of office and laboratory space in Seattle, Washington. This lease commenced on January 1, 2017, and the lease term is for five years, with an option to extend for an additional three years. In May 2017, we entered into a sublease agreement, under which we are subleasing 5,048 square feet to a third party for a period of three years.

We also lease 9,640 square feet of office space in South San Francisco, California. This lease expires in January 2020, with an option to extend the lease term for an additional five years.

We believe that our existing facilities are sufficient for our current needs.

Item 3. Legal Proceedings

European Patent Opposition

In February 2013, a third party filed an opposition at the European Patent Office (EPO) requesting revocation of European Patent No. 2068918 directed to GLA formulations and uses. This patent is owned by Infectious Disease Research Institute (IDRI), and we hold an exclusive license to this patent in certain fields. 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 decision. However, the outcome of an appeal to this proceeding will not be known for several years.

Stockholder Action

The Company filed a Schedule 14D-9 (Schedule 14D-9) with the SEC on March 5, 2019, relating to the Merger Agreement. On March 11, 2019, a complaint captioned Tullman v. Immune Design Corp., et al., Case No. 2:19-cv-00350, was filed in the United States District Court for the Western District of Washington against the Company and each member of the Company's board of directors. The action was brought by James Tullman, who claims to be a stockholder of the Company, on his own behalf, and seeks certification as a class action on behalf of all of the Company's stockholders. The complaint alleges, among other things, that the process leading up to the proposed acquisition was inadequate and that this Schedule 14D-9 omits certain material information, which the complaint alleges renders the information disclosed materially misleading. The complaint seeks to enjoin the proposed transaction, or in the event the proposed transaction is consummated, to recover money damages.

Item 4. Mine Safety Disclosures.

Not applicable.

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PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock has been listed on The Nasdaq Global Market under the symbol "IMDZ" since July 24, 2014. Prior to July 24, 2014, there was no public trading market for our common stock.

As of March 8, 2019, we had 48,365,248 shares of common stock outstanding held by approximately 17 stockholders of record. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock and do not anticipate paying any cash dividends in the foreseeable future. Payment of cash dividends, if any, in the future will be at the discretion of our board of directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

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Item 6. Selected Financial Data.

The following selected financial data should be read in conjunction with the "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the accompanying notes included elsewhere in this report. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period.

	YEARS ENDED DECEMBER 31,				
	2018	2017	2016	2015	2014
	(in thousands, except share and per share amounts)				
Statements of Operations Data:					
Total revenues	$2,196	$7,195	$13,260	$9,510	$6,433
Operating expenses:					
Cost of product sales	1,435	84	481	774	638
Research and development	42,415	43,670	45,134	33,087	22,746
General and administrative	15,396	16,253	21,859	15,134	12,927
Total operating expenses	59,246	60,007	67,474	48,995	36,311
Loss from operations	(57,050)	(52,812)	(54,214)	(39,485)	(29,878)
Interest and other income	2,292	950	684	40	4
Change in fair value of convertible preferred stock warrant liability	—	—	—	—	(4,277)
Net loss attributable to common stockholders	$(54,758)	$(51,862)	$(53,530)	$(39,445)	$(34,151)
Basic and diluted net loss per share attributable to common stockholders (1)	$(1.14)	$(1.75)	$(2.47)	$(2.06)	$(4.56)
Weighted-average shares used to compute basic and diluted net loss per share attributable to common stockholders (1)	48,145,225	29,626,941	21,638,468	19,155,918	7,494,790

(1) See Note 3 of our consolidated financial statements included elsewhere herein for an explanation of the method used to compute basic and diluted net loss per share of common stock and the weighted-average number of shares used in computation of the per share amounts.

	AS OF DECEMBER 31,				
	2018	2017	2016	2015	2014
	(in thousands)				
Balance Sheet Data:					
Cash and cash equivalents	$77,941	$72,454	$39,214	$112,921	$75,354
Working capital	91,380	138,623	94,818	108,449	66,035
Total assets	100,960	153,834	114,495	116,145	78,383
Total stockholders' equity	92,005	139,212	95,176	108,993	66,346

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Item 7. 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 consolidated financial statements and the related notes appearing elsewhere in this Annual Report on Form 10-K. 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, 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 devoted substantially all of our resources since inception to our drug development efforts, including undertaking clinical trials of our product candidates, development of our 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 $54.8 million, $51.9 million and $53.5 million for the years ended December 31, 2018, 2017 and 2016, respectively. As of December 31, 2018, we had an accumulated deficit of $290.5 million. We have incurred net losses to date and we expect to continue to incur significant expenses and increasing operating losses for at least the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will significantly increase as we:

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

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

Recent Events

On February 20, 2019, we entered into the Merger Agreement with Merck Sharp & Dohme Corp., a New Jersey corporation, or Parent, and Cascade Merger Sub Inc., a Delaware corporation and a wholly owned subsidiary of Parent, or Purchaser (or together with Parent, Merck), pursuant to which we agreed to be acquired by Merck in an all-cash transaction for an

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approximate value of $300 million, representing an over three hundred percent premium over our stock's closing price on the day prior to the announcement of the Merger Agreement. In accordance with the terms of the Merger Agreement, Purchaser has commenced a tender offer, or Offer, to acquire all of our outstanding shares of common stock for $5.85 per share, to be paid to the seller in cash, without interest and subject to any applicable withholding taxes. The consummation of Purchaser's pending Offer and subsequent Merger will be subject to certain conditions, including the tender of shares representing at least one more than 50% of the total number of our shares of common stock outstanding at the time of the expiration of the Offer, the expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and other customary conditions. The Merger Agreement provides, among other things, that following the consummation of the Offer and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement and in accordance with the relevant provisions of the Delaware General Corporation Law and other applicable law, Purchaser will merge with and into the Company, the separate existence of Purchaser will cease and the Company will continue as the surviving corporation and as a wholly owned subsidiary of Parent. We expect the Proposed Transaction to close early in the second quarter of 2019. For additional information on this transaction see Note 16 to our consolidated financial statements appearing elsewhere in this report.

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 was 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 completed a reduction in force that affected approximately 18% of our employees, primarily those focused on advancing the CMB305 program.

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. 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. 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.

In October 2014, we entered into a collaboration with Sanofi Pasteur for the development of an HSV immune therapy. Sanofi Pasteur and Immune Design each contribute product candidates to the collaboration: Sanofi Pasteur contributes 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 bears the costs of all preclinical and clinical development, and we provide a specific formulation of GLA from the GLAAS platform at cost through Phase 2 studies. We will be eligible to receive future milestone and royalty

payments on any licensed product developed from the collaboration. We recognized $1.5 million, $6.9 million and $4.6 million in collaboration service revenue under this agreement for the years ended December 31, 2018, 2017 and 2016, respectively.

In August 2014, we entered into an agreement with Sanofi under which we granted Sanofi an exclusive license for use of our GLAAS platform to discover, develop and commercialize products to treat peanut allergy. On December 6, 2018, Sanofi provided notice terminating this license agreement effective as of June 6, 2019, as the result of a portfolio prioritization by Sanofi. We recognized no milestone revenue under this agreement for the years ended December 31, 2018, and 2017, and $7.0 million in milestone revenue under this agreement for the year ended December 31, 2016.

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In October 2010, we entered into three separate license agreements with MedImmune pursuant to which we granted MedImmune a worldwide, sublicensable, exclusive license to use GLA to develop and sell vaccines in three different infectious disease indications. MedImmune paid us upfront payments under the license agreements in 2010. One of the agreements remains in full force and effect, and the rights granted under the other two have returned to us. Under the license agreement, MedImmune is obligated to make additional payments based on the achievement of certain developmental, regulatory and commercial milestones for the licensed indication. We recognized no revenue for the achievement of development milestones under these license agreements for the years ended December 31, 2018, 2017, and 2016. MedImmune is also obligated to pay us a low double-digit percentage share of any non-royalty payments that it receives from sublicensees and mid single-digit royalty payments on net sales of licensed products, which royalty is subject to reduction under certain circumstances.

From time to time, we also enter into non-exclusive license arrangements, material transfer agreements or option agreements with respect to GLA in specified non-oncology indications. The parties with whom we contract are in certain cases obligated to make additional payments based on achievement of milestones.

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:

	YEARS ENDED DECEMBER 31,		
	2018	2017	2016
	(in thousands)		
Direct research and development expense by platform:			
ZVex	$13,063	$11,692	$15,465
GLAAS	4,486	3,971	5,298
G103	1,079	6,646	4,432
Other	3,402	2,100	—
Total direct research and development program expense	22,030	24,409	25,195
Indirect research and development expense by type:			
Personnel related costs	14,513	12,775	11,591
Research and development supplies and services	2,655	3,915	6,531
Allocated facility, equipment, travel and other expense	3,217	2,571	1,817
Total indirect research and development expense	20,385	19,261	19,939

Total research and development expense	$42,415	$43,670	$45,134

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

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

General and Administrative Expenses

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

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

Interest and Other Income

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.

Results of Operations

Comparison of Years Ended December 31, 2018 and 2017

The following table summarizes our results of operations for the years ended December 31, 2018 and 2017:

	YEARS ENDED DECEMBER 31,		INCREASE/ DECREASE
	2018	2017	
	(in thousands)		
Total revenues	$2,196	$7,195	$ (4,999)
Operating expenses:			
Cost of product sales	1,435	84	1,351
Research and development	42,415	43,670	(1,255)
General and administrative	15,396	16,253	(857)
Total operating expenses	59,246	60,007	(761)
Loss from operations	(57,050)	(52,812)	(4,238)
Interest and other income	2,292	950	1,342
Net loss attributable to common stockholders	$(54,758)	$(51,862)	$ (2,896)

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.

The $1.3 million increase in Cost of Product Sales was primarily attributable to a $1.2 million inventory write-off as a result of the termination of our License Agreement with Sanofi Aventis. On December 6, 2018, Sanofi Aventis provided notice terminating this license agreement, effective as of June 6, 2019. We determined the $1.2 million of inventory has been impaired and recorded in Cost of Product Sales in the twelve month period ended December 31, 2018.

Research and Development Expenses

The $1.3 million decrease in research and development expense was primarily attributable to a decrease of $5.5 million related to contract manufacturing costs related to various process development and manufacturing services performed at our contract manufacturers due primarily to the timing of when the services are completed and

performed. Contract manufacturing costs

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will fluctuate from period to period based upon the timing of when contract manufacturing services are performed during the periods. This overall decrease was offset by a $2.3 million increase in personnel related expenses, and general operating expenses, primarily due to increased headcount during three quarters of the year, as well as severance costs related to our restructuring in the fourth quarter. Additionally, there was a $1.5 million increase in licensing fees due to third parties as result of commencing of our SYNOVATE clinical trial in September 2018 and a $0.4 million increase in clinical trial costs primarily related to opening and closing the SYNOVATE clinical trial.

General and Administrative Expenses

The $0.9 million decrease in general and administrative expense was primarily attributable to a $0.8 million recoupment of an Escrow Payment by the Company as a part of a legal settlement, which was recognized during the period ended December 31, 2018 as a reduction to general and administrative expenses. Additional facility, office, and equipment expenses decreased by $0.5 million and compensation costs decreased by $0.3 million. This was partially offset by an increase in professional fees and services of $0.7 million, primarily attributable to increased legal expenses and related patent expenses during the period to support our ongoing operations.

Interest and Other Income

The $1.3 million increase in interest and other income is primarily attributable to our higher cash balances and short-term investments during the twelve month period ended December 31, 2018 compared to the twelve month period ended December 31, 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.

Comparison of Years Ended December 31, 2017 and 2016

The following table summarizes the results of our operations for the years ended December 31, 2017 and 2016:

	YEARS ENDED DECEMBER 31,		INCREASE/ DECREASE
	2017	2016	
	(in thousands)		
Total revenues	$7,195	$13,260	$ (6,065)
Operating expenses:			
Cost of product sales	84	481	(397)
Research and development	43,670	45,134	(1,464)
General and administrative	16,253	21,859	(5,606)
Total operating expenses	60,007	67,474	(7,467)
Loss from operations	(52,812)	(54,214)	1,402
Interest and other income	950	684	266
Net loss attributable to common stockholders	$(51,862)	$(53,530)	$ 1,668

Total Revenue and Cost of Product Sales

The $6.1 million decrease in total revenues was primarily attributable to a $7.0 million decrease in licensing revenue as a result of the $7.0 million milestone revenue recognized under our License Agreement with Sanofi during the year ended December 31, 2016. There was no such licensing revenue from Sanofi or any other collaboration partner recognized during the year ended December 31, 2017. In addition, product sales to collaboration partners and other third parties under material transfer agreements decreased by $1.3 million during the year ended December 31, 2017 compared to the year ended December 31, 2016, as there were no product sales to any of our collaboration partners and one shipment of $0.3 million made to other third parties under material transfer agreements during 2017 compared to $1.5 million made to collaboration partners during 2016. These increases were partially offset by a $2.2 million increase in collaboration revenue related to the performance 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 $1.5 million decrease in research and development expense was primarily attributable to a decrease of $3.2 million in-licensing royalties and fees due to other third parties from which we license various technologies and a $0.3 million decrease in clinical trial costs based upon the level of patient activities performed during the comparable periods. Offsetting these decreases was a $1.2 million increase in personnel-related expenses, which was primarily due to an increase in compensation and benefits as a result of an increase in research and development headcount, which included a new VP of Regulatory Affairs and a new VP

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of Oncology Platform to the executive team to support our advancing research and clinical pipeline activities. In addition, there was a $0.7 million increase in facility related costs and expenses associated with our new facility lease for our headquarters in Seattle, which commenced on January 1, 2017 and an increase of $0.3 million in contract manufacturing costs related to the various process development and manufacturing services performed at our contract manufacturers due primarily to the timing of when the services are completed and performed. Contract manufacturing costs will fluctuate from period to period based upon the timing of when contract manufacturing services are performed during the periods.

General and Administrative Expenses

The $5.6 million decrease in general and administrative expense was primarily attributable to the $5.9 million litigation-related settlement recorded during the year ended December 31, 2016, as part of our Settlement Agreement with TVS. In addition, we had an increase of $0.7 million in personnel related expenses due to a slight increase in headcount to support operations which was offset by a $0.6 million decrease in professional services.

Liquidity and Capital Resources

Since our inception through December 31, 2018, we have raised or earned a total of $388.4 million in cash, including:

- $343.9 million from the sale of our common stock, convertible preferred stock and warrants, which also included proceeds related to our IPO and follow-on offerings;
- $21.3 million from the licensing of our technology;
- $15.2 million from our collaboration agreements; and
- $8.0 million primarily from GLA sales.

As of December 31, 2018, we had cash and cash equivalents, short-term investments and interest receivable totaling $95.9 million. In addition to our existing cash and cash equivalents and short-term investments, we are eligible to receive research and development funding and to earn milestone and other contingent payments for the achievement of defined collaboration objectives and certain development, regulatory and commercial milestones and royalty payments under our collaboration agreements. Our ability to earn these milestone and contingent payments and the timing of achieving these milestones is primarily dependent upon the outcome of our collaborators' research and development activities and is uncertain at this time.

Funding Requirements

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

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

Based on our underwritten follow-on public offerings, and our research and development plans and our timing expectations related to the progress of our programs, we expect that our existing cash and cash equivalents, short-term investments and interest receivable as of December 31, 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:

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

Cash Flows

The following is a summary of our cash flows:

	YEARS ENDED DECEMBER 31,		
	2018	2017	2016
	(in thousands)		
Net cash used in operating activities	$(51,666)	$(46,859)	$(35,740)
Net cash provided by (used in) investing activities	50,925	(7,039)	(62,421)
Net cash provided by financing activities	228	87,338	30,454

Net Cash Used in Operating Activities

Net cash used in operating activities was $51.7 million for the year ended December 31, 2018 and consisted primarily of our net loss of $54.8 million, which was offset by non-cash charges of $7.3 million for stock-based compensation expense and $1.2 million of inventory impairment charges. Changes in operating assets and liabilities used net cash of $5.2 million for the year ended December 31, 2018.

Net cash used in operating activities was $46.9 million for the year ended December 31, 2017 and consisted primarily of our net loss of $51.9 million, which was offset by non-cash charges of $8.6 million for stock-based compensation expense and $0.3 million in depreciation and amortization, and a net increase in operating assets and liabilities of $4.0 million.

Net cash used in operating activities was $35.7 million for the year ended December 31, 2016 and consisted primarily of our net loss of $53.5 million, which was offset by non-cash charges of $9.3 million for stock-based compensation expense and $0.4 million for depreciation and amortization, and a net decrease in operating assets and liabilities of $8.1 million.

Net Cash Provided by and Used in Investing Activities

Net cash provided by investing activities was $50.9 million for the year ended December 31, 2018 and consisted primarily of purchases of $34.7 million in short-term investments in U.S. Treasury securities and $0.4 million in property and equipment, primarily lab equipment to support research and development efforts, which was offset by $86.0 million in maturities of these investments.

Net cash used in investing activities was $7.0 million for the year ended December 31, 2017 and consisted primarily of purchases of $71.6 million in short-term investments in U.S. Treasury securities, which was offset by $65.0 million in maturities of these investments.

Net cash used in investing activities was $62.4 million for the year ended December 31, 2016 and consisted primarily of purchases of $102.3 million in short-term investments in U.S. Treasury securities, which was offset by $40.0 million in maturities of these investments.

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Net Cash Provided by Financing Activities

Net cash provided by financing activities was $0.2 million for the year ended December 31, 2018 from the issuances of common stock under our stock-based compensation plans.

Net cash provided by financing activities was $87.3 million for the year ended December 31, 2017 and consisted of $86.6 million in net proceeds from our October 2017 public common stock offering and $0.7 million in cash received from the issuances of common stock under our stock-based compensation plans.

Net cash provided by financing activities was $30.5 million for the year ended December 31, 2016 and consisted primarily of $30.3 million in net proceeds received from our secondary offering in September 2016, and $0.1 million in cash received from the issuances of common stock under our stock-based compensation plans.

Contractual Obligations and Contingent Liabilities

The following summarizes our significant contractual obligations as of December 31, 2018:

CONTRACTUAL OBLIGATIONS	TOTAL	1 YEAR	2 TO 4 YEARS	MORE THAN 4 YEARS
	(in thousands)			
Operating leases (1)	$3,928	$ 1,525	$ 2,403	$ —

(1) Represents future minimum lease payments under non-cancelable operating leases in effect as of December 31, 2018, for our facilities in Seattle, Washington and South San Francisco, California. The minimum lease payments above do not include common area maintenance charges or real estate taxes. We were required to provide a $121,000 letter of credit as a security deposit on our lease for facilities in South San Francisco, of which no funds had been drawn down as of December 31, 2018. In addition, we provided a $200,000 letter of credit as a security deposit on our lease for facilities in Seattle, which commenced on January 1, 2017. See Note 9 to our consolidated financial statements appearing elsewhere in this report for further discussion of our leases.

The contractual obligations table above does not include any potential future milestone payments to third parties as part of certain collaboration and licensing agreements, due to the fact that the timing and uncertainty surrounding these potential future milestone payments. We could owe additional payments to IDRI of up to $1.8 million and $1.3 million, respectively, for the first and each subsequent exclusive licensed GLA/SLA product we develop and $1.3 million and $625,000, respectively, for the first and each subsequent non-exclusive licensed GLA/SLA product we develop. We could owe up to $6.5 million aggregate payments for ZVex products we develop. These milestone payments do not include any potential future royalty payments we may be required to make under our licensing agreements as described in Note 10 to our consolidated financial statements appearing elsewhere in this report.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which we have prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of these 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 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 value 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.

While our significant accounting policies are more fully described in Note 2 to our consolidated financial statements appearing at the end of this report, we believe that the following accounting policies are the most critical to fully understanding and evaluating our financial condition and results of operations.

Principles of Consolidation

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

Short-Term Investments

Our short-term investments include funds invested in U.S. Treasury securities with a final maturity of each security of less than one year. All investments are classified as available-for-sale securities and are recorded at fair value based on quoted prices in

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active markets, with unrealized gains and losses excluded from earnings and reported in other comprehensive income (loss). Purchase premiums and discounts are recognized in interest income using the interest method over the terms of the securities. Realized gains and losses and declines in fair value that are deemed to be other than temporary are reflected in the condensed consolidated statements of operations and comprehensive income (loss) using the specific-identification method.

Comprehensive Loss

Comprehensive loss is comprised of net loss and other comprehensive income or loss that are excluded from net loss. For the years ended December 31, 2018, 2017, and 2016, other comprehensive loss consisted of unrealized gains and losses on our available-for-sale securities.

Revenue Recognition

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

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.

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Royalties. Under sales-based royalty arrangements with milestone payments, revenue is recognized at the later of (i) when the related sales occur, or (ii) when the performance obligation 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

Accrued liabilities represent accrued compensation including vacation accruals, unearned revenue 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 our applicable personnel to identify services that have been performed on our behalf. We estimate the level of service performed and 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.

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. 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. To date, we have not experienced any significant adjustments to our estimates.

Stock-Based Compensation

In accordance with ASC 718, Stock Compensation, we determine the fair value of stock options and other stock-based compensation issued to employees as of the grant date. We recognize the fair value of stock-based compensation as compensation expense over the requisite service period, which is the vesting period. We also record stock options and other stock-based compensation issued to non-employees at their fair value as of the grant date. We then periodically remeasure the awards to reflect the current fair value at each reporting period and recognize expense over the related service period.

Stock-based compensation expense includes stock options granted to employees and non-employees and has been reported in our statements of operations as follows:

	YEARS ENDED DECEMBER 31,		
	2018	2017	2016
Employee:			
Research and development	$3,030	$3,613	$3,923
General and administrative	4,212	4,879	5,029
Non-Employee:			
Research and development	28	85	268
General and administrative	6	56	63
Total stock-based compensation expense	$7,276	$8,633	$9,283

We calculate the fair value of stock-based compensation awards using the Black-Scholes option pricing model. The Black-Scholes option pricing model requires the use of subjective assumptions, including the expected term of the stock options, stock price volatility, risk free interest rate and the fair value of the underlying common stock on the

date of grant. We used the following assumptions in the model:

We determine the risk-free interest rate by reference to implied yields available from U.S. Treasury securities with a remaining term equal to the expected life assumed at the date of grant.

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The expected term represents the period that the stock-based awards are expected to be outstanding. Our historical option exercise experience does not provide a reasonable basis upon which to estimate an expected term because of a lack of sufficient data. Therefore, we estimate the expected term by using the "simplified method," which calculates the expected term as the average of the time-to-vesting and the contractual life of the options.

Volatility is a measure of the amount by which a financial variable, such as share price, has fluctuated or is expected to fluctuate during a period. We analyzed the stock price volatility of companies at a similar stage of development to estimate expected volatility of our stock price, and utilized our historical volatility starting in October 2018.

The assumed dividend yield is based on our expectation of not paying dividends in the foreseeable future.

The assumptions that we used in the Black-Scholes option pricing model are set forth below:

	YEARS ENDED DECEMBER 31,		
	2018	2017	2016
Weighted-average estimated fair value	$3.90	$4.41	$10.07
Risk-free interest rate	2.3% - 3.0%	1.9% - 2.4%	1.1% - 2.4%
Expected term of options (in years)	5.5 - 9.3	5.5 - 9.2	5.5 - 9.5
Expected stock price volatility	77% - 85%	80% - 91%	77% - 93%
Expected dividend yield	—%	—%	—%

Prior to the adoption of ASU No. 2016-09 on January 1, 2017, compensation expense recognized was calculated based on awards ultimately expected to vest and was reduced for estimated forfeitures. Upon adoption of ASU No. 2016-09, effective January 1, 2017, we have elected to account for forfeitures as they occur. As of January 1, 2017, we had unrecorded forfeitures of $157,000. Upon adoption, we recognized this expense as a cumulative effect adjustment to retained earnings with a corresponding increase to APIC.

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 JOBS Act was enacted. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, or the Securities Act, for complying with new or revised accounting standards. 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.

Item 7A. 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 December 31, 2018, we had cash and cash equivalents of $77.9 million consisting of bank deposits and interest-bearing money market accounts and short-term investments of $17.9 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 risk, we follow guidelines to limit the average and longest single maturity dates, place our investments with high quality

issuers and follow internally developed guidelines to limit the amount of credit exposure to any one issuer. Some of the securities that we invest in may be subject to market risk. This means that a change in prevailing interest rates may cause the value of the investment to fluctuate. For example, if we purchase a security that was issued with a fixed interest rate and the prevailing interest rate later rises, the value of our investment may decline. If a ten percent change in interest rates were to have occurred on December 31, 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.

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

Item 8. Financial Statements and Supplementary Data.

The financial statements required by this Item 8 are set forth beginning at page F-1 of this Annual Report on Form 10-K and are incorporated herein by reference.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As of December 31, 2018, Management, including our Principal Executive Officer and Principal Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)), as of the end of the period covered by this report. Based upon the evaluation, our President and Chief Executive Officer and Executive Vice President, Strategy and 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 Securities Exchange Act of 1934, as amended, is (i) recorded, processed, summarized and reported as and when required and (ii) accumulated and communicated to our management, including our President and Chief Executive Officer and Executive Vice President, Strategy and 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.

Management’s Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles, or GAAP. Our internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets, (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors, and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective.

Under the supervision and with the participation of our management, including our Principal Executive Officer and Principal Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2018 based on the criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework), or COSO. Based on our evaluation under the criteria set forth in Internal Control - Integrated Framework issued by the COSO, our management concluded our internal control over financial reporting was effective as of December 31, 2018.

Attestation Report of the Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm due to an exemption established by the JOBS Act for emerging growth companies.

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.

Item 9B. Other Information.

None.

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PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item is incorporated by reference to the information set forth in the sections titled "Election of Directors" and "Section 16(a) Beneficial Ownership Reporting Compliance" in our Proxy Statement. If such Proxy Statement is not filed on or before April 30, 2019, the information called for by this item will be filed as part of an amendment to this Annual Report on Form 10-K on or before such date.

Item 11. Executive Compensation.

The information required by this item is incorporated by reference to the information set forth in the sections titled "Executive Compensation," "Director Compensation" and "Committees of the Board of Directors - Compensation Committee Interlocks and Insider Participation" in our Proxy Statement. If such Proxy Statement is not filed on or before April 30, 2019, the information called for by this item will be filed as part of an amendment to this Annual Report on Form 10-K on or before such date.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item is incorporated by reference to the information set forth in the sections titled "Security Ownership of Certain Beneficial Owners and Management" and "Securities Authorized for Issuance under Equity Compensation Plans" in our Proxy Statement. If such Proxy Statement is not filed on or before April 30, 2019, the information called for by this item will be filed as part of an amendment to this Annual Report on Form 10-K on or before such date.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this item is incorporated by reference to the information set forth in the sections titled "Transactions with Related Persons" and "Election of Directors" in our Proxy Statement. If such Proxy Statement is not filed on or before April 30, 2019, the information called for by this item will be filed as part of an amendment to this Annual Report on Form 10-K on or before such date.

Item 14. Principal Accounting Fees and Services.

The information required by this item is incorporated by reference to the information set forth in the section titled "Ratification of Appointment of Independent Registered Public Accounting Firm" in our Proxy Statement. If such Proxy Statement is not filed on or before April 30, 2019, the information called for by this item will be filed as part of an amendment to this Annual Report on Form 10-K on or before such date.

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PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The financial statements schedules and exhibits filed as part of this Annual Report on Form 10-K are as follows:

(1) Financial Statements

Reference is made to the financial statements included in Item 8 of Part II hereof.

(2) Financial Statement Schedules

All other schedules are omitted because they are not required or the required information is included in the financial statements or notes thereto.

(3) Exhibits

The exhibits listed below are filed as part of this Form 10-K other than Exhibits 32.1 and 32.1, which shall be deemed furnished.

EXHIBIT NUMBER	EXHIBIT DESCRIPTION
2.1	Agreement and Plan of Merger, dated February 20, 2019, by and among Immune Design Corp., Merck Sharp & Dohme Corp. and Cascade Merger Sub Inc. (incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K (File No. 001-36561), as filed with the SEC on February 20, 2019).
3.1	Amended and Restated Certificate of Incorporation of Immune Design Corp. (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-36561) filed with the SEC on July 29, 2014).
3.2	Amended and Restated Bylaws of Immune Design Corp. (incorporated herein by reference to Exhibit 3.4 to the Company's Registration Statement on Form S-1 (File No. 333-196979), as filed with the SEC on June 23, 2014).
4.1	Specimen Common Stock Certificate of Immune Design Corp. (incorporated herein by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1 (File No. 333-196979), as filed with the SEC on June 23, 2014).
10.1	Amended and Restated Investor Rights Agreement, dated October 16, 2013, by and among Immune Design Corp. and the investors named therein (incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1 (File No. 333-196979), as filed with the SEC on June 23, 2014).
10.2+	Immune Design Corp. 2008 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.2 to the Company's Registration Statement on Form S-1 (File No. 333-196979), as filed with the SEC on June 23, 2014).
10.3+	Form of Option Agreement under the Immune Design Corp. 2008 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-1 (File No. 333-196979), as filed with the SEC on June 23, 2014).
10.4+	Immune Design Corp. 2014 Omnibus Incentive Plan (incorporated herein by reference to Exhibit 4.6 to the Company's Registration Statement on Form S-8 (File No. 333-197748), as filed with the SEC on July 31, 2014).
10.5+	

	Form of Incentive Stock Option Agreement under the Immune Design Corp. 2014 Omnibus Incentive Plan (incorporated herein by reference to Exhibit 10.5 to Amendment No. 2 to the Company's Registration Statement on Form S-1/A (File No. 333-196979), as filed with the SEC on July 14, 2014).
10.6+	Form of Non-Qualified Option Agreement under the Immune Design Corp. 2014 Omnibus Incentive Plan (incorporated herein by reference to Exhibit 10.6 to Amendment No. 2 to the Company's Registration Statement on Form S-1/A (File No. 333-196979), as filed with the SEC on July 14, 2014).
10.7+	Form of Restricted Stock Unit Agreement under the Immune Design Corp. 2014 Omnibus Incentive Plan (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-36561), as filed with the SEC on January 10, 2017).
10.8+	Immune Design Corp. 2014 Employee Stock Purchase Plan (incorporated herein by reference to Exhibit 4.9 to the Company's Registration Statement on Form S-8 (File No. 333-197748), as filed with the SEC on July 31, 2014).
10.9+	Employment Agreement, dated June 20, 2014, by and between Immune Design Corp. and Carlos Paya, M.D., Ph.D. (incorporated herein by reference to Exhibit 10.8 to the Company's Registration Statement on Form S-1 (File No. 333-196979), as filed with the SEC on June 23, 2014).

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10.10+	Employment Agreement, dated June 23, 2014, by and between Immune Design Corp. and Stephen Brady (incorporated herein by reference to Exhibit 10.10 to the Company's Registration Statement on Form S-1 (File No. 333-196979), as filed with the SEC on June 23, 2014).
10.11+	Employment Agreement, dated June 19, 2014, by and between Immune Design Corp. and Jan Henrik ter Meulen, M.D. (incorporated herein by reference to Exhibit 10.11 to the Company's Registration Statement on Form S-1 (File No. 333-196979), as filed with the SEC on June 23, 2014).
10.12+	Employment Agreement, dated September 30, 2016, by and between Immune Design Corp. and Sergey Yurasov, M.D., Ph.D. (incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q (File No. 001-36561), as filed with the SEC on November 9, 2016).
10.13+	Form of Indemnification Agreement, by and between Immune Design Corp. and each of its directors and officers (incorporated herein by reference to Exhibit 10.14 to the Company's Registration Statement on Form S-1 (File No. 333-196979), as filed with the SEC on June 23, 2014).
10.14+	Retention Bonus Payback Agreement, dated August 13, 2018, by and between Immune Design Corp. and Sergey Yurasov, M.D., Ph.D. (incorporated herein by reference to Exhibit 99(E)(15) to the Company's Recommendation Statement on Schedule 14D-9 (File No. 005-88256), as filed with the SEC on March 5, 2019).
10.15+	Retention Bonus Payback Agreement, dated November 7, 2018, by and between Immune Design Corp. and Jan ter Meulen, M.D. (incorporated herein by reference to Exhibit 99(E)(16) to the Company's Recommendation Statement on Schedule 14D-9 (File No. 005-88256), as filed with the SEC on March 5, 2019).
10.16+	Retention Bonus Payback Agreement, dated November 7, 2018, by and between Immune Design Corp. and Stephen Brady (incorporated herein by reference to Exhibit 99(E)(17) to the Company's Recommendation Statement on Schedule 14D-9 (File No. 005-88256), as filed with the SEC on March 5, 2019).
10.17	Second Amended and Restated License Agreement, dated December 23, 2015, by and between Immune Design Corp. and the Infectious Disease Research Institute (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K/A (File No. 001-36561), as filed with the SEC on February 16, 2016).
10.18	License Agreement, dated January 1, 2009, by and between Immune Design Corp. and the California Institute of Technology (incorporated herein by reference to Exhibit 10.21 to the Company's Registration Statement on Form S-1 (File No. 333-196979), as filed with the SEC on June 23, 2014).
10.19	Confidential Settlement Agreement, dated October 17, 2016, by and between Immune Design Corp. and TheraVectys SA (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K/A (File No. 001-36561), as filed with the SEC on March 3, 2017).
10.20	License Agreement, dated October 17, 2016, by and between Immune Design Corp. and TheraVectys SA (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K/A (File No. 001-36561), as filed with the SEC on March 3, 2017).
10.21	Office Lease, dated November 21, 2013, by and between Immune Design Corp. and BXP 601& 651 Gateway Center LP, formerly known as Gateway Center LLC (incorporated herein by reference to Exhibit 10.22 to the

	Company's Registration Statement on Form S-1 (File No. 333-196979), as filed with the SEC on June 23, 2014).
10.22	First Amendment to Office Lease, dated October 27, 2014, by and between Immune Design Corp. and BXP 601 & 651 Gateway Center LP, formerly known as Gateway Center LLC (incorporated herein by reference to Exhibit 10.19 to the Company's Annual Report on Form 10-K (File No. 001-36561), as filed with the SEC on March 31, 2015).
10.23	Second Amendment to Office Lease, dated November 20, 2014, by and between Immune Design Corp. and BXP 601 & 651 Gateway Center LP, formerly known as Gateway Center LLC (incorporated herein by reference to Exhibit 10.20 to the Company's Annual Report on Form 10-K (File No. 001-36561), as filed with the SEC on March 31, 2015).
10.24	Lease Agreement, dated January 1, 2016, by and between Immune Design Corp. and ARE-Eastlake Avenue No. 3, LLC (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q (File No. 001-36561), as filed with the SEC on August 9, 2016).
23.1	Consent of Independent Registered Public Accounting Firm
24.1	Power of Attorney (included on the signature page to this registration statement).
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.

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32.1*	Certifications of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certifications of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	Consolidated financial statements from the Annual Report on Form 10-K of Immune Design Corp. for the year ended December 31, 2018, formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated Balance Sheets; (ii) the Consolidated Statements of Operations and Comprehensive Income (Loss); (iii) the Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity; (iv) the Consolidated Statements of Cash Flows; and (v) Notes to Consolidated Financial Statements.

+ Indicates a management contract or compensatory plan.

* 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.

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

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities and Exchange Act of 1934, as amended, the registrant has duly caused this report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

IMMUNE DESIGN CORP.
(Registrant)

Date: March 13, 2019 /s/ Carlos Paya, M.D., Ph.D.
Carlos Paya, M.D., Ph.D.
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: March 13, 2019 /s/ Stephen Brady
Stephen Brady
Executive Vice President, Strategy and Finance
(Principal Accounting Officer and Principal Financial Officer)

POWER OF ATTORNEY

Each person whose signature appears below constitutes and appoints Carlos Paya, M.D., Ph.D. and Stephen Brady, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place, and stead, in any and all capacities, to sign any and all amendments to this report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming that all said attorneys-in-fact and agents, or any of them or their or his substitute or substitutes, may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

SIGNATURE	TITLE	DATE
/s/ Carlos Paya, M.D., Ph.D. Carlos Paya, M.D., Ph.D.	President, Chief Executive Officer and Director (Principal Executive Officer)	March 13, 2019
/s/ Stephen Brady Stephen Brady	Executive Vice President, Strategy and Finance (Principal Accounting Officer and Principal Financial Officer)	March 13, 2019
/s/ Ed Penhoet, Ph.D. Ed Penhoet, Ph.D.	Chairman of the Board	March 13, 2019
/s/ David Baltimore, Ph.D. David Baltimore, Ph.D.	Director	March 13, 2019
/s/ Franklin Berger	Director	March 13, 2019

Franklin Berger		
/s/ Lewis Coleman Lewis Coleman	Director	March 13, 2019
/s/ Susan Kelley, M.D. Susan Kelley, M.D.	Director	March 13, 2019
/s/ William Ringo William Ringo	Director	March 13, 2019

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IMMUNE DESIGN CORP
REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of Immune Design Corp.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Immune Design Corp. (the Company), as of December 31, 2018 and 2017, the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2018, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2010.

Redwood City, California
March 13, 2019

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

	DECEMBER 31,	
	2018	2017
Assets		
Current assets:		
Cash and cash equivalents	$77,941	$72,454
Short-term investments	17,946	68,653
Accounts receivable	705	647
Inventory	92	684
Prepaid expenses	1,755	1,571
Restricted cash	—	6,000
Other assets	1,786	3,134
Total current assets	100,225	153,143
Property and equipment, net	535	491
Security deposit	200	200
Total assets	$100,960	$153,834
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$1,478	$2,334
Accrued liabilities	7,367	6,186
Accrued litigation-related settlement	—	6,000
Total current liabilities	8,845	14,520
Other noncurrent liabilities	110	102
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Common stock, $0.001 par value per share; 100,000,000 authorized at December 31, 2018 and 2017; 48,210,520 and 48,068,650 shares issued and outstanding at December 31, 2018 and 2017, respectively	48	48
Additional paid-in capital	382,474	374,970
Accumulated deficit	(290,515)	(235,757)
Accumulated other comprehensive loss	(2)	(49)
Total stockholders' equity	92,005	139,212
Total liabilities and stockholders' equity	$100,960	$153,834

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

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

	YEARS ENDED DECEMBER 31,		
	2018	2017	2016
Revenues:			
Collaborative revenue	$1,533	$6,880	$4,633
Licensing revenue	—	—	7,000
Product sales	663	315	1,627
Total revenues	2,196	7,195	13,260
Operating expenses:			
Cost of product sales	1,435	84	481
Research and development	42,415	43,670	45,134
General and administrative	15,396	16,253	21,859
Total operating expenses	59,246	60,007	67,474
Loss from operations	(57,050)	(52,812)	(54,214)
Interest and other income	2,292	950	684
Net loss	$(54,758)	$(51,862)	$(53,530)
Other comprehensive loss:			
Unrealized gain (loss) on investments	47	(25)	(24)
Comprehensive loss	$(54,711)	$(51,887)	$(53,554)
Basic and diluted net loss per share	$(1.14)	$(1.75)	$(2.47)
Weighted-average shares used to compute basic and diluted net loss per share	48,145,225	29,626,941	21,638,468

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

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IMMUNE DESIGN CORP
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except share and per share amounts)

	COMMON STOCK		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED DEFICIT	ACCUMULATED OTHER COMPREHENSIVE GAIN (LOSS)	TOTAL STOCKHOLDERS' EQUITY
	SHARES	AMOUNT				
Balance, December 31, 2015	20,153,202	$ 20	$ 239,181	$ (130,208)	$ —	$ 108,993
Issuance of common stock at $6.25 per share upon completion of public offering, net of offering costs of $2,355	5,226,369	5	30,305	—	—	30,310
Issuance of common stock under stock-based compensation plans	33,484	—	144	—	—	144
Stock-based compensation	—	—	9,283	—	—	9,283
Net loss	—	—	—	(53,530)	—	(53,530)
Unrealized loss on investments	—	—	—	—	(24)	(24)
Balance, December 31, 2016	25,413,055	$ 25	$ 278,913	$ (183,738)	$ (24)	$ 95,176
Issuance of common stock at $4.10 per share upon completion of public offering, net of offering costs of $5,367	22,425,000	23	86,553	—	—	86,576
Issuance of common stock under stock-based compensation plans	230,595	—	714	—	—	714
Stock-based compensation	—	—	8,633	—	—	8,633
Cumulative effect adjustment from adoption of accounting standard on stock-based compensation	—	—	157	(157)	—	—
Net loss	—	—	—	(51,862)	—	(51,862)
Unrealized loss on investments	—	—	—	—	(25)	(25)
Balance, December 31, 2017	48,068,650	$ 48	$ 374,970	$ (235,757)	$ (49)	$ 139,212
Issuance of common stock under stock-based compensation plans	141,870	—	228	—	—	228
Stock-based compensation	—	—	7,276	—	—	7,276
Net loss	—	—	—	(54,758)	—	(54,758)
Unrealized gain on investments	—	—	—	—	47	47
Balance, December 31, 2018	48,210,520	$ 48	$ 382,474	$ (290,515)	$ (2)	$ 92,005

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

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

	YEARS ENDED DECEMBER 31,		
	2018	2017	2016
Operating activities			
Net loss	$(54,758)	$(51,862)	$(53,530)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	346	351	304
Amortization of premium/discount on investments	(561)	(26)	126
Impairment of inventory	1,244	—	—
Stock-based compensation	7,276	8,633	9,283
Changes in operating assets and liabilities:			
Accounts receivable	(58)	(130)	455
Inventory	(652)	(77)	(594)
Prepaid expenses	(184)	975	(892)
Other assets	1,348	22	(3,059)
Accounts payable	(856)	(2,225)	1,485
Accrued liabilities	1,181	1,203	976
Accrued litigation-related settlement	(6,000)	(1,250)	7,250
Deferred revenue	—	(2,545)	2,496
Deferred rent and other noncurrent liabilities	8	72	(40)
Net cash used in operating activities	(51,666)	(46,859)	(35,740)
Investing activities			
Purchases of property and equipment	(390)	(428)	(133)
Purchases of short-term investments	(34,685)	(71,611)	(102,288)
Maturities of short-term investments	86,000	65,000	40,000
Net cash provided by (used in) investing activities	50,925	(7,039)	(62,421)
Financing activities			
Issuance of common stock in public offering, net of offering costs	—	86,624	30,310
Proceeds from issuances of common stock under stock-based compensation plans	228	714	144
Net cash provided by financing activities	228	87,338	30,454
Net (decrease) increase in cash and cash equivalents	(513)	33,440	(67,707)
Cash, cash equivalents and restricted cash, beginning of year	78,654	45,214	112,921
Cash, cash equivalents and restricted cash, end of year	$78,141	$78,654	$45,214
Supplemental cash flow information			
Unpaid stock offering costs	$—	$48	$—

	DECEMBER 31,		
	2018	2017	2016
Cash and cash equivalents	$77,941	$72,454	39,214
Restricted cash	—	6,000	6,000
Security deposit	200	200	—
Total cash, cash equivalents and restricted cash	78,141	78,654	45,214

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

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IMMUNE DESIGN CORP
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Description of the Business

Immune Design Corp. (the Company, 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 indications.

On February 20, 2019, we entered into an Agreement and Plan of Merger (Merger Agreement) with Merck Sharp & Dohme Corp., a New Jersey corporation (the Parent), and Cascade Merger Sub Inc., a Delaware corporation and a wholly owned subsidiary of Parent (the Purchaser). Pursuant to the Merger Agreement, upon the terms and subject to the conditions thereof, Purchaser commenced a tender offer (the Offer) on March 5, 2019, to acquire all of our outstanding shares of common stock, at a purchase price of $5.85 per share in cash, without interest and subject to any required withholding of taxes.

We were incorporated in February 2008 in the State of Delaware. Our operations are headquartered in Seattle, Washington, and we have an additional facility in South San Francisco, California.

2. Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

The accompanying financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP). To conform with GAAP, the preparation of our financial statements requires management to make judgments, assumptions, and estimates that affect the amounts reported in our financial statements and accompanying notes. Estimates are used for, but not limited to, accruals for clinical trial activity, other accrued liabilities, and assumptions used in determining stock-based compensation expense. 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 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.

Segments

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

Offering Costs

Offering costs represent legal, accounting and other direct costs related to our efforts to raise capital through our follow-on public offerings in October 2017 and September 2016. These costs were deferred until completion of the follow-on public offerings, at which time they were reclassified to additional paid-in capital as a reduction of the proceeds.

Cash and Cash Equivalents

Cash equivalents are highly liquid investments with a maturity of 90 days or less at the date of purchase and primarily consist of investments in money market funds. In addition, we maintain cash balances with financial institutions in excess of insured limits and do not anticipate any losses on such cash balances.

Concentration of Risk

We limit our credit risk associated with cash and cash equivalents by placing our deposits with banks we believe are highly creditworthy and our investments with highly rated money market funds.

Short-Term Investments

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

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IMMUNE DESIGN CORP
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

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 December 31, 2018 and 2017, respectively. See Note 13 for additional information. In addition, we hold 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 Consolidated Balance Sheets.

Accounts Receivable

Accounts receivable are amounts due from other companies related primarily to licensing fees, product sales and research and development services. As of December 31, 2018 and 2017 we had an allowance for doubtful accounts of $29,000 and zero, respectively.

Inventory

Inventory is recorded at the lower of cost or market. Cost includes amounts related to materials and labor, and is determined on a specific identification basis in a manner which approximates the first-in, first-out method. For the year ended December 31, 2018, we recorded an inventory impairment of $1.2 million, and zero for the years ended December 31, 2017 and 2016 (see Note 6).

Property and Equipment

Property and equipment are stated at cost, net of accumulated depreciation. Depreciation is computed using the straight-line method over an estimated useful life that is generally three years, while leasehold improvements are amortized over the shorter of their estimated useful lives or the related lease term. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is credited or charged to operations. Maintenance and repairs are expensed as incurred. Asset improvements are capitalized.

Impairment of Long-Lived Assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets might not be recoverable. Conditions that would necessitate an impairment assessment include a significant decline in the observable market value of an asset, a significant change in the extent or manner in which an asset is used, or any other significant adverse change that would indicate that the carrying amount of an asset is not recoverable.

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.

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IMMUNE DESIGN CORP
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

Leases and Deferred Rent

We have entered into lease agreements for laboratory and office facilities. These leases are classified as operating leases. Rent expense is recognized on a straight-line basis over the term of the lease. Incentives granted under our facilities leases, including allowances to fund leasehold improvements and rent escalations are accrued as deferred rent. Leasehold improvements funded by the lessor are capitalized and are recognized as reductions to rental expense on a straight-line basis over the term of the lease.

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 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.

We consider significant revenue concentrations to be customers who account for 10% or more of total revenues generated by us during the periods presented. We had three customers who accounted for 69%, 19% and 10% of revenue for the year ended December 31, 2018, one collaboration partner that accounted for 96% of revenue for the year ended December 31, 2017, and two collaboration partners that accounted for 64% and 35% of revenue for the year ended December 31, 2016. The collaboration partners accounted for 51%, 100% and 100% of accounts receivable as of December 31, 2018, 2017 and 2016, respectively.

Stock-Based Compensation

We account for stock-based compensation under the fair value method. Stock-based compensation costs related to employees and directors is measured at the grant date, based on the fair-value-based measurement of the award estimated using the Black-Scholes option-pricing model, and is recognized as expense over the requisite service period on a straight-line basis.

Options granted to non-employee service providers are accounted for at estimated fair value using the Black-Scholes option-pricing model and are remeasured over the vesting term as earned.

Prior to the Financial Accounting Standards Board (FASB) adoption of Accounting Standards Update (ASU) No. 2016-09 on January 1, 2017, stock-based compensation expense recognized was calculated based on awards ultimately expected to vest and was reduced for estimated forfeitures. Upon the adoption of ASU No. 2016-09, effective January 1, 2017, we have elected to account for forfeitures as they occur. As of January 1, 2017, we had unrecorded forfeitures of $157,000. Upon adoption, we recognized this expense as an adjustment to retained earnings with a corresponding increase to additional paid-in-capital. In addition, under this guidance, on a prospective basis, companies will no longer record excess tax benefits and certain tax deficiencies in additional paid-in-capital. Instead, they will record all excess tax benefits and tax deficiencies as income tax expense or benefit in the income statement. The Standard also eliminates the requirement that excess tax benefits be realized before companies can recognize them. As of January 1, 2017, we had an unrecognized excess tax benefit of $1.2 million and upon adoption, we

recognized this excess tax benefit as a deferred tax asset with a corresponding increase to our deferred tax asset valuation allowance.

Research and Development

Research and development costs are expensed as incurred. Research and development costs primarily include personnel costs, materials and manufacturing to support clinical trials, fees paid to consultants and outside service providers, costs to conduct clinical trials and allocated overhead. Amounts incurred in connection with collaboration agreements are also included in research and development expense. Payments made prior to the receipt of goods or services to be used in research and development are deferred until the goods or services are received.

Income Taxes

Income taxes are accounted for under the liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to the differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and the operating loss and tax credit carry forwards. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. Deferred tax assets and liabilities are measured at the balance sheet date using the enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period such tax rate changes are enacted. Our net deferred tax asset has been fully offset by a valuation allowance because of our history of losses. Any potential accrued interest and penalties related to unrecognized tax benefits within operations would be recorded as income tax expense. To date, there have been no interest or penalties charged to us related to the underpayment of income taxes.

Comprehensive Loss

Comprehensive loss is composed of net loss and other comprehensive income or loss that are excluded from net loss. Other comprehensive loss consists of unrealized gains and losses on our available-for-sale securities.

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 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. 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 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

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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.

3. Net Loss Per Share

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

The common stock equivalents issuable upon the conversion or exercise of the following dilutive securities 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:

	DECEMBER 31,		
	2018	2017	2016
Outstanding stock option grants	3,872,273	4,094,532	3,590,393
Unvested restricted stock awards	465,396	195,172	107,250
Total	4,337,669	4,289,704	3,697,643

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):

	December 31, 2018			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	$76,225	$ —	$ —	$76,225
U.S. Treasury securities	17,948	—	(2)	17,946
Total	$94,173	$ —	$ (2)	$94,171
Classified as:				
Cash equivalents				$76,225
Short-term investments				17,946
Total				$94,171

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

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All U.S. Treasury securities held as of December 31, 2018 and 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 period presented.

5. Fair Value of Financial Instruments

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

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

Level 2: Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

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

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

In certain cases where there is limited activity or less transparency around inputs to valuation, securities are classified as Level 3 within the valuation hierarchy.

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

	December 31, 2018			
	LEVEL 1	LEVEL 2	LEVEL 3	TOTAL
Assets:				
Money market funds	$76,225	$ —	$ —	$76,225
U.S. Treasury securities	17,946	—	—	17,946
Total	$94,171	$ —	$ —	$94,171

	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):

	DECEMBER 31,	
	2018	2017
Work in process	$ —	$ 541
Finished goods	92	143
Total inventory	$ 92	$ 684

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In August 2014, we granted Sanofi Aventis an exclusive license to use the GLAAS platform to discover, develop and commercialize products to treat peanut allergy. On December 6, 2018, Sanofi Aventis provided notice terminating this license agreement, effective as of June 6, 2019. As a result of this termination, we determined that inventory of $1.2 million as of December 2018 has been impaired and written-off. The write-off of $1.2 million was charged to Cost of Product Sales in our Consolidated Statements of Operations and Comprehensive Loss as of December 31, 2018.

7. Property and Equipment

Property and equipment consists of the following (in thousands):

	DECEMBER 31,	
	2018	2017
Laboratory equipment	$2,812	$2,624
Leasehold improvements	256	183
Computer equipment and software	695	584
Office equipment, furniture, and fixtures	196	178
Total	3,959	3,569
Less: accumulated depreciation and amortization	(3,424)	(3,078)
Total property and equipment, net	$535	$491

Depreciation and amortization expense was $346,000, $351,000 and $304,000 for the years ended December 31, 2018, 2017 and 2016, respectively.

8. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	DECEMBER 31,	
	2018	2017
Research and development services	$ 4,208	$ 3,352
Legal and professional services	294	57
Employee compensation	2,865	2,777
Total accrued liabilities	$ 7,367	$ 6,186

9. Commitments and Contingencies

Operating Leases

We lease laboratory and office space under an operating lease in Seattle, Washington. Our previous lease commenced February 2013 and ended December 31, 2016. 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 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. We recognize rent expense on a straight-line basis over the lease period and accrue for rent expense incurred but not paid. The lease also requires us to pay for operating and maintenance expenses. Through December 31, 2018 and 2017, we incurred $256,000 and $183,000, respectively, in leasehold improvements and accumulated amortization of $170,000 and $147,000, respectively. Also under the terms of the lease, in January 2017 we provided a $200,000 letter of credit as a security deposit. As of December 31, 2018, no funds had been drawn down on the letter of credit.

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. The terms of the office lease provide for rental payments on a monthly basis and on a graduated scale. We recognize rent expense on a straight-line basis over the lease period and accrue for rent expense incurred but not paid.

The lease also requires us to pay additional amounts for operating and maintenance expenses beginning January 2016. In connection with the lease, we were

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required to provide a $121,000 letter of credit as a security deposit. As of December 31, 2018, no funds had been drawn down on the letter of credit.

As of December 31, 2018, future minimum lease payments are as follows (in thousands):

2019	$1,525
2020	1,203
2021	1,200
2022	—
2023	—
Total future minimum lease payments	$3,928

Rent expense under operating leases was approximately $1.5 million, $1.5 million and $713,000, for the years ended December 31, 2018, 2017 and 2016, respectively.

In May 2017, we entered into a sublease agreement with a third party subtenant, pursuant to which we are subleasing 5,048 square feet of our 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.

Contingencies

Under our license agreements with the Infectious Disease Research Institute (IDRI), we are contingently obligated to pay any 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 also contingently obligated to pay potential future milestone payments to third parties as part of certain collaboration and licensing agreements, which 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 10.

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

10. License and Collaboration Agreements

Licenses Granted

In August 2014, we entered into an agreement with Sanofi under which we granted Sanofi an exclusive license for use of our GLAAS platform to discover, develop and commercialize products to treat peanut allergy. On December 6, 2018, Sanofi provided notice terminating this license agreement as of June 6, 2019. We recognized no milestone revenue under this agreement for the years ended December 31, 2018, and 2017, and $7.0 million in milestone revenue under this agreement for the year ended December 31, 2016.

In October 2010, we entered into three separate license agreements with MedImmune, LLC (MedImmune) pursuant to which we granted MedImmune a worldwide, sublicensable, exclusive license to use GLA to develop and sell vaccines in three different infectious disease indications. MedImmune paid us upfront payments under the license agreements in 2010. One of the three license agreements remains in full force and effect, and the rights granted under the other two have returned to us. Under the ongoing license agreement, 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. 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 the license agreement, MedImmune

is obligated to make additional aggregate payments of up to $72.5 million, depending on 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 years ended December 31, 2018, 2017, and 2016.

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 TLR 4 agonist referred to as SLA. This license was 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, in additional payments for the first and each subsequent exclusive licensed product we develop, and $1.3 million and $625,000, respectively, for the first and each subsequent non-exclusive licensed product we develop, based on the achievement of certain developmental and regulatory milestones. In addition, we will be obligated to pay certain commercialization milestones and royalty payments of single-digit percentage of net sales, if and when a licensed product is commercialized. We are also obligated to share with IDRI a percentage of payments received from any third-party sublicensees. Additionally, if we exercise our option for additional infectious disease indications, we will be required to make upfront, milestone and royalty payments for such additional indications, which payments are subject to similar terms and conditions as are applicable to other milestone and royalty payments.

We recognized $500,000, zero and $925,000 in IDRI license-related milestone fees, which were expensed in research and development expenses, for the years ended December 31, 2018, 2017 and 2016, 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, which we expensed in research and development expenses for the year ended December 31, 2017. No license-related milestone fees were recognized or paid for the years ended December 31, 2018 and 2016. 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.

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. We recognized $1.0 million for the year ended December 31, 2018 and no milestone fees for the years ended December 31, 2017 and 2016.

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

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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 studies. Immune Design will be eligible to receive future milestone and royalty payments on any licensed product developed from the collaboration.

The costs of the related services performed are recorded as research and development expenses on the consolidated statement of operations. We recognized revenue under this collaboration arrangement of $1.5 million, $6.9 million and $4.6 million for the years ended December 31, 2018, 2017 and 2016, respectively. As of December 31, 2018 and 2017, we had an outstanding unbilled receivable of $363,000 and $605,000, respectively, and unearned revenue of zero under this collaboration arrangement. The unbilled receivable represents collaboration research services earned, but not yet billed Sanofi Pasteur as of December 31, 2018 and 2017.

11. 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 December 31, 2018 and December 31, 2017.

Common Stock

We had 48,210,520 and 48,068,650 shares of common stock outstanding as of December 31, 2018 and 2017, respectively. Shares of common stock reserved for future issuance were as follows:

	AS OF DECEMBER 31,	
	2018	2017
Shares available for issuance under the employee stock purchase plan	393,206	475,010
Options granted and outstanding	3,872,273	4,094,532
Unvested restricted stock units	465,396	195,172
Shares available for future option grants and restricted stock awards	2,761,914	947,199
Shares reserved for future issuance under equity incentive plans	7,492,789	5,711,913

In July 2017, we entered into a Sales Agreement (ATM Agreement) with Cowen and Company, LLC (Cowen) under which we could 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. Under the ATM Agreement, Cowen could 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. Cowen would receive 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. Any common stock sold under the ATM Agreement would have be issued pursuant to our shelf registration statement on Form S-3 (File No. 333-206324), which expired December 29, 2018. As of the expiration, we have not sold any common stock under the ATM Agreement.

Equity Incentive Plans

2014 Employee Stock Purchase Plan

In April 2014, our board of directors adopted, and in July 2014 our stockholders approved, the 2014 Employee Stock Purchase Plan (2014 ESPP). The total number of shares of common stock available for issuance under the 2014 ESPP may increase annually on January 1 by (i) the lesser of 1% of the total number of shares issued and outstanding as of

December 31 of the immediately preceding year or (ii) 200,000 shares, or less as deemed appropriate by the Board of Directors. For 2018 and 2017, the Board of Directors determined the current shares available to be issued under the 2014 ESPP was sufficient and did not increase the amount of authorized shares.

2008 Equity Incentive Plan and 2014 Omnibus Incentive Plan

In 2008, we adopted the 2008 Equity Incentive Plan (2008 Plan) for eligible employees, officers, directors, and consultants, which provided for the grant of incentive and non-statutory stock options, restricted stock awards, restructured stock unit awards grant, and stock appreciation rights. The terms of the stock awards, including vesting requirements, were determined by the board of directors, subject to the provisions of the 2008 Plan.

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

Stock options granted under the 2008 and 2014 Plans generally vest within two, three and four years, and vested options are generally exercisable until ten years after the date of grant. Vesting of certain employee options may be accelerated in the event of a change in control of our company. We grant stock options to employees with exercise prices equal to the fair value of our common stock on the date of grant. There were a total of 6,068,369 shares of common stock authorized under the 2014 Plan as of December 31, 2018.

The total number of shares of common stock available for issuance under the 2014 Plan will automatically increase each year on January 1 by 4% of the total number of shares issued and outstanding as of December 31 of the immediately preceding year. On January 1, 2018, in accordance with the annual increase provisions, the authorized shares under the 2014 Plan increased by 1,922,746 shares.

Restricted Stock Units

In 2016, we began issuing restricted stock units (RSUs) to employees under the 2014 Plan. The fair value of the RSUs is determined on the date of grant based on the market price of our common stock. RSUs are recognized as an expense ratably over the vesting period and our RSUs generally vest over one, three and four years. 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 was not met by the specified dates, the corresponding number of January PSUs would 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 determined that the performance criteria associated with the remaining January PSUs would not be achieved by December 31, 2018, 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. On December 31, 2018, the remaining January PSUs expired unvested, and no expense was recorded, as the performance criteria was not met by the specified date.

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 was not met

by December 31, 2018, the corresponding July PSUs would expire. During the period the July PSUs were outstanding, management determined that the performance criteria associated with the July PSUs would most likely not be achieved by December 31, 2018, and as a result, no expense was recorded in the second half of 2018. On December 31, 2018, the July PSUs expired unvested, and no expense was recorded, as the performance criteria was not met by the specified date.

In November 2018, the Compensation Committee of our Board of Directors granted an additional 225,500 time-based RSUs that vest 100% one year from date of grant.

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Summary RSU information is as follows:

	Shares	Weighted Average Grant Date Fair Value
Outstanding at January 1, 2017	107,250	$ 19.39
Granted	224,540	$ 5.60
Vested	(26,802)	$ 19.39
Canceled/Forfeited	(109,816)	$ 6.13
Outstanding at December 31, 2017	195,172	$ 10.99
Granted	1,113,855	$ 3.53
Vested	(58,468)	$ 11.85
Canceled/Forfeited	(785,163)	$ 4.34
Outstanding at December 31, 2018	465,396	$ 4.25

During the year ended December 31, 2018, the total estimated grant date fair value for RSUs granted was $3.9 million. The total fair value of RSUs vested was $228,000. In 2018, the Company recognized stock-based compensation expenses of $874,000 related to RSUs. As of December 31, 2018, total unrecognized stock-based compensation expenses related to unvested RSUs was $1.3 million, which is expected to be recognized on a straight-line basis over a weighted-average period of approximately 1.47 years.

Stock Option Activity

Summary stock option information is as follows:

	OPTIONS OUTSTANDING	WEIGHTED-AVERAGE EXERCISE PRICE	WEIGHTED-AVERAGE REMAINING CONTRACT TERM (IN YEARS)	AGGREGATE INTRINSIC VALUE (IN THOUSANDS)
Outstanding at January 1, 2017	3,590,393	$ 12.13		
Granted	954,301	$ 6.46		
Exercised	(175,183)	$ 2.56		
Forfeited	(117,124)	$ 14.35		
Expired	(157,855)	$ 17.19		
Outstanding at December 31, 2017	4,094,532	$ 10.96	7.2	$ 2,771
Granted	2,366,119	$ 4.10		
Exercised	(1,598)	$ 1.15		
Forfeited	(2,279,560)	$ 13.71		
Expired	(307,220)	$ 14.55		
Outstanding at December 31, 2018	3,872,273	$ 4.87	6.4	$ 50
Vested and expected to vest after December 31, 2018	3,872,273	$ 4.87	6.4	$ 50
Exercisable at December 31, 2018	1,920,745	$ 5.38	4.7	$ 50

As of December 31, 2018, there was $5.0 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 1.9 years. The total intrinsic value of options exercised during the years ended December 31, 2018, 2017 and 2016 was $4,000, $868,000 and $124,000, respectively.

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Stock-Based Compensation Expense

Total stock-based compensation expense recognized in our statements of operations is as follows (in thousands):

	YEARS ENDED DECEMBER 31,		
	2018	2017	2016
Employee:			
Research and development	$3,030	$3,613	$3,923
General and administrative	4,212	4,879	5,029
Non-Employee:			
Research and development	28	85	268
General and administrative	6	56	63
Total stock-based compensation expense	$7,276	$8,633	$9,283

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

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

	YEARS ENDED DECEMBER 31,		
	2018	2017	2016
Weighted-average estimated fair value	$3.90	$4.41	$10.07
Risk-free interest rate (1)	2.3% - 3.0%	1.9% - 2.2%	1.1% - 2.4%
Expected term of options (in years) (2)	5.5 - 6.1	5.5 - 6.1	5.5 - 9.5
Expected stock price volatility (3)	77% - 85%	80% - 91%	77% - 93%
Expected dividend yield (4)	—%	—%	—%

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

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

(3) Volatility is a measure of the amount by which a financial variable, such as share price, has fluctuated or is expected to fluctuate during a period. We analyzed the stock price volatility of companies at a similar stage of development to estimate expected volatility of our stock price, and utilized the Company’s historical volatility starting in October 2018.

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

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:

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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 out of 49 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 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.

12. Income Taxes

No provision for income taxes has been recorded for the years ended December 31, 2018 and 2017 due to the operating losses incurred since inception for which no benefit has been recorded.

The reconciliation of the U.S. income tax rate to the effective income tax rate for continuing operations is as follows:

	AS OF DECEMBER 31,	
	2018	2017
Statutory tax rate	21.0 %	35.0 %
Effect of:		
Permanent differences	(1.6)	(6.4)
Other	(2.3)	(0.5)
General business credits	8.0	15.1
Change in valuation allowance	(25.1)	15.6
Tax Reform - tax rate change	—	(58.8)
Effective tax rate	— %	— %

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes.

Significant components of our deferred taxes are as follows (in thousands):

	AS OF DECEMBER 31,	
	2018	2017
Deferred tax assets:		
Net operating loss carryforwards	$51,138	$39,971
Research and development credit	17,782	13,392
Depreciation and amortization	1,494	1,241
Other temporary differences	2,413	4,477
Gross deferred tax assets	72,827	59,081
Deferred tax asset valuation allowance	(72,827)	(59,081)
Net deferred tax assets	$—	$—

Accounting Standards Codification (ASC) 740, Income Taxes, requires companies to recognize the effect of the tax law changes in the period of enactment. However, the SEC staff issued Staff Accounting Bulletin 118 which will allow companies to record provisional amounts during a measurement period that is similar to the measurement period used when accounting for business combinations.

On December 22, 2017, the Tax Cuts and Jobs Act of 2017, or the Tax Act, was signed into law. Although the Tax Act was 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 remeasured 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 remeasurement 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 as the Company had a full valuation allowance against its deferred tax assets and currently in a taxable loss position. The deferred tax asset remeasurement was our reasonable estimate within the meaning of Staff Accounting Bulletin 118. As of December 31, 2018, we have completed our analysis of the Tax Act’s income tax effects. No material impact was recorded to our balance sheet and income statement when our analysis was completed in the 2018 fourth quarter.

Realization of deferred tax assets is dependent on future earnings, if any, the timing and amount of which are uncertain. Accordingly, the deferred tax assets have been offset by a valuation allowance. The valuation allowance relates primarily to net deferred tax assets from operating losses and research and development credits. The net deferred tax asset has been fully offset by a valuation allowance. The valuation allowance increased $13.7 million during the year ended December 31, 2018, and decreased $6.8 million during the year ended December 31, 2017.

As of December 31, 2018 and 2017, we had approximately $243.5 million and $190.3 million in federal net operating loss carryforwards and approximately $17.8 million and $13.4 million in federal research and development tax credit carryforwards, respectively. Federal net operating losses and federal research and development credits will begin to expire in varying amounts between 2028 and 2038, if not utilized. Federal net operating losses and federal research and development credits generated in 2018 and future years will be carried forward indefinitely, but are subject to an 80% taxable income limitation.

The Tax Reform Act of 1986, or the Tax Reform Act, provides for a limitation on the annual use of net operating loss and research and development tax credit carryforwards following certain ownership changes (as defined by the Act) that could limit our ability to utilize these carryforwards. We may have experienced an ownership change, as defined by the Act, as a result of past financings. Accordingly, our ability to utilize the aforementioned carryforwards may be limited. Additionally, U.S. tax laws limit the time during which these carryforwards may be applied against future taxes; therefore, we may not be able to take full advantage of these carryforwards for federal income tax purposes.

We file income tax returns in the U.S. federal jurisdiction as well as the state of California. We are not currently under audit in any tax jurisdiction. Tax years from 2008 through 2017 are currently open for audit by federal and state taxing authorities.

We recognize interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense. During the years ended December 31, 2018 and 2017, we did not recognize any accrued interest or penalties associated with unrecognized benefits. Additionally, we did not record any unrecognized tax benefits at December 31, 2018 and 2017.

13. 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.

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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 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.

14. Employee Benefit Plan

We sponsor a 401(k) defined contribution plan for our employees. Employee contributions are voluntary. We may match employee contributions in amounts to be determined at our sole discretion. Currently, we have elected to satisfy the safe-harbor rules by matching contributions equal to 100% of employee salary deferrals that do not exceed 3% of the employee’s compensation, plus 50% matching employee salary deferrals between 3% and 5% of the employee’s compensation. Employer contributions have totaled approximately $360,000, $300,000, and $243,000 for the years ended December 31, 2018, 2017 and 2016, respectively.

15. Restructuring Costs

In October 2018, the Company 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, the Company implemented a reduction in workforce in the R&D functional departments which impacted approximately 18% of the Company's headcount as of the end of October 2018, primarily those focused on advancing the CMB305 program. Restructuring charges included one-time termination severance and other employee-related costs of $0.8 million in research and development expenses during the year ended December 31, 2018 in the Consolidated Statements of Operations and Comprehensive Loss. The majority of the cash payments related to the personnel-related restructuring charges in the amount of

$0.7 million were paid during the three months ended December 31, 2018, with the remainder to be paid subsequently. As of December 31, 2018, $0.1 million of restructuring liabilities remain on the Company's Consolidated Balance Sheet.

16. Subsequent Event

On February 20, 2019, we entered into a Merger Agreement with Parent and Purchaser. Our board of directors unanimously approved the Merger Agreement. In accordance with the Merger Agreement, Purchaser commenced the Offer on March 5, 2019 to acquire all of our outstanding shares of common stock (Shares), at a purchase price of $5.85 per Share in cash (Offer Price), without interest and subject to any required withholding of taxes.

The obligation of Purchaser to purchase Shares tendered in the Offer is subject to the conditions set forth in the Merger Agreement, including that the number of Shares validly tendered in accordance with the terms of the Offer and not validly withdrawn, when considered together with all other Shares (if any) otherwise beneficially owned by Parent or any of its wholly owned subsidiaries (including Purchaser), would represent one more than 50% of the total number of Shares outstanding at the time of the expiration of the Offer (Minimum Condition). The Purchaser's obligation to consummate the Offer is not subject to a condition that any financing be received by Purchaser for the consummation of the transactions contemplated by the Merger Agreement.

Following the completion of the Offer and subject to the satisfaction or waiver of certain conditions set forth in the Merger Agreement, Purchaser will merge with and into the Company, with the Company surviving as a wholly owned subsidiary of Parent (Merger). Purchaser will effect the Merger after consummation of the Offer pursuant to Section 251(h) of the Delaware General Corporation Law. At the effective time of the Merger (Effective Time), the Shares not purchased pursuant to the Offer (other than Shares held by Parent, Purchaser, any other direct or indirect wholly owned subsidiary of Parent, the Company (or in the Company's treasury) or by stockholders of the Company who have perfected their statutory rights of appraisal under Delaware law) will each be converted into the right to receive an amount in cash equal to the Offer Price (Merger Consideration), without interest and subject to any required withholding of taxes.

The Merger Agreement includes a remedy of specific performance for the Company, Parent and Purchaser. The Merger Agreement also includes customary termination provisions for both the Company and Parent and provides that, in connection with the termination of the Merger Agreement under specified circumstances, including termination by the Company to accept and enter into a definitive agreement with respect to an unsolicited superior offer, the Company will be required to pay a termination fee of an amount in cash equal to $10.5 million (Termination Fee). Any such termination of the Merger Agreement by the Company is subject to certain conditions, including the Company's compliance with certain procedures set forth in the Merger Agreement and a determination by the board of directors of the Company that the failure to take such action would be inconsistent with the board's fiduciary duties to the Company's stockholders under applicable law, payment of the Termination Fee by the Company and the execution of a definitive agreement by the Company with such third party.

The Company filed a Schedule 14D-9 (Schedule 14D-9) with the SEC on March 5, 2019, relating to the Merger Agreement. On March 11, 2019, a complaint captioned Tullman v. Immune Design Corp., et al., Case No. 2:19-cv-00350, was filed in the United States District Court for the Western District of Washington against the Company and each member of the Company's board of directors. The action was brought by James Tullman, who claims to be a stockholder of the Company, on his own behalf, and seeks certification as a class action on behalf of all of the Company's stockholders. The complaint alleges, among other things, that the process leading up to the proposed acquisition was inadequate and that this Schedule 14D-9 omits certain material information, which the complaint alleges renders the information disclosed materially misleading. The complaint seeks to enjoin the proposed transaction, or in the event the proposed transaction is consummated, to recover money damages.

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17. Selected Quarterly Financial Information (Unaudited)
The following amounts are in thousands, except per share amounts:

	Quarter Ended			
	March 31 2018	June 30 2018	September 30 2018	December 31 2018
	(unaudited)			
Total revenues	$503	$755	$ 462	$ 476
Net loss	$(13,300)	$(13,808)	$ (14,049)	$ (13,601)
Basic and diluted net loss per share	$(0.28)	$(0.29)	$ (0.29)	$ (0.28)

	Quarter Ended			
	March 31 2017	June 30 2017	September 30 2017	December 31 2017
	(unaudited)			
Total revenues	$5,465	$729	$ 516	$ 485
Net loss	$(12,620)	$(13,846)	$ (13,416)	$ (11,980)
Basic and diluted net loss per share	$(0.50)	$(0.54)	$ (0.52)	$ (0.29)