DYNAVAX TECHNOLOGIES CORP
Form 10-K
March 10, 2014

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2013
¨ 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: 001-34207

Dynavax Technologies Corporation

(Exact name of registrant as specified in its charter)

Delaware	33-0728374
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

2929 Seventh Street, Suite 100

Berkeley, CA 94710-2753

(510) 848-5100

(Address, including Zip Code, and telephone number, including area code, of the registrant’s principal executive offices)

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

Title of Each Class:	Name of Each Exchange on Which Registered:
Common Stock, $0.001 Par Value	The NASDAQ Stock Market LLC
Preferred Shares Purchase Rights	

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 Section 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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registration was required to submit and post such files). Yes x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K 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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨	Accelerated filer x	Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

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

The aggregate market value of the voting and non-voting stock held by non-affiliates of the registrant, based upon the closing sale price of the common stock on June 28, 2013 as reported on the NASDAQ Capital Market, was approximately $105,519,624. Shares of common stock held by each officer and director and by each person known to the Company who owns 5% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of February 28, 2014, the registrant had outstanding 262,855,958 shares of common stock.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Definitive Proxy Statement for the registrant's 2014 Annual Meeting of Stockholders are incorporated by reference into Part III, Items 10-14 of this Form 10-K.

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DYNAVAX TECHNOLOGIES CORPORATION

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 which are subject to a number of risks and uncertainties. All statements that are not historical facts are forward-looking statements, including statements about our ability to successfully develop and achieve regulatory approval for HEPLISAV-B™, our business strategy, our intellectual property position, our product development efforts, our ability to commercialize our product candidates, our ability to manufacture commercial supply and meet regulatory requirements, the timing of the introduction of our products, uncertainty regarding our capital needs and future operating results and profitability, anticipated sources of funds as well as our plans, objectives, expectations and intentions. These statements appear throughout our document and can be identified by the use of forward-looking language such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “believe,” “estimate,” “predict,” “future,” or “intend,” or the negative of these terms or other variations or comparable terminology.

Actual results may vary materially from those in our forward-looking statements as a result of various factors that are identified in “Item 1A—Risk Factors” and “Item 7—Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this document. No assurance can be given that the risk factors described in this Annual Report on Form 10-K are all of the factors that could cause actual results to vary materially from the forward-looking statements. All forward-looking statements speak only as of the date of this Annual Report on Form 10-K. Readers should not place undue reliance on these forward-looking statements and are cautioned that any such forward-looking statements are not guarantees of future performance. We assume no obligation to update any forward-looking statements.

This Annual Report on Form 10-K includes trademarks and registered trademarks of Dynavax Technologies Corporation. Products or service names of other companies mentioned in this Annual Report on Form 10-K may be trademarks or registered trademarks of their respective owners.

PART I

ITEM 1. BUSINESS

OVERVIEW

Dynavax Technologies Corporation (“we,” “our,” “us,” “Dynavax” or the “Company”), a clinical-stage biopharmaceutical company, develops products to prevent and treat infectious and inflammatory diseases and cancer based on Toll-like Receptor (“TLR”) biology and its ability to modulate the innate immune system. Our lead product candidate is HEPLISAV-B™ (also known as “HEPLISAV”), an investigational adult hepatitis B vaccine in Phase 3 clinical development. HEPLISAV-B combines our proprietary TLR 9 agonist adjuvant and hepatitis B surface antigen (“HBsAg”) to elicit an immune response after two doses. In the spring of 2014 we expect to initiate a Phase 3 study of HEPLISAV-B compared with Engerix-B® in adults 18-70 years of age in order to provide a sufficiently-sized safety database for the U.S. Food and Drug Administration (“FDA”) to complete its review of Dynavax’s biologics license application (“BLA”).

In addition to HEPLISAV-B, we are conducting clinical and preclinical programs that utilize our expertise in TLR biology. Our product candidates include both TLR agonists and TLR inhibitors. Our clinical stage programs include our autoimmune program partnered with GlaxoSmithKline (“GSK”), our asthma therapeutic program partnered with AstraZeneca AB (“AstraZeneca”), and our cancer immunotherapy program. We also are advancing preclinical development programs in adjuvant technology and TLR 7, 8, and 9 inhibition. We compete with pharmaceutical companies, biotechnology companies, academic institutions and research organizations in developing therapies to prevent or treat infectious and inflammatory diseases and cancer.

THE COMPANY AND BACKGROUND

We were incorporated in California in August 1996 under the name Double Helix Corporation, and we changed our name to Dynavax Technologies Corporation in September 1996. We reincorporated in Delaware in 2000. Dynavax Technologies Corporation is listed on the NASDAQ Capital Market under the ticker symbol “DVAX.”

Our principal executive offices are located at 2929 Seventh Street, Suite 100, Berkeley, California, 94710-2753. Our telephone number is (510) 848-5100. We make available, free of charge on our website located at www.dynavax.com, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to those reports, as soon as reasonably practicable after filing such reports with the Securities and Exchange Commission. Our code of conduct, audit committee charter, nominating and corporate governance committee charter, compensation committee charter and audit committee complaint procedures are also posted on our website and are each available in print to any stockholder upon request by writing to: 2929 Seventh Street, Suite 100, Berkeley, California 94710-2753. The contents of our website are not incorporated by reference into this report.

PROPRIETARY TECHNOLOGY

Toll-like Receptors

TLRs, structures located on different immune cell types, are activated by the binding of certain pathogens and other ligands and their activity is essential to generation of innate immunity. By either activating or inhibiting specific TLRs, it is possible to selectively modulate elements of the innate immune response on the cellular level to address dysfunction associated with both excessive immune activity (autoimmunity) and suboptimal immune function. Dynavax research has resulted in the identification of proprietary synthetic oligonucleotides (short segments of the deoxyribonucleic acid ("DNA"), that selectively activate or inhibit specific TLRs, allowing their use in a range of immune-mediated therapeutic and preventative applications.

TLR Agonists

TLR agonists bind to receptors on specific cell types activating a cascade that enhances the ability of the immune system to identify and fight disease. TLR agonists work by enhancing or reprogramming the innate immune response.

Currently, our development programs focus on TLR 9 agonists. Since TLR 9 is found exclusively in a specialized subset of dendritic and B cells, TLR 9 agonists do not cause a generalized activation of the immune system but rather redirect the response of only those T-cells involved in a given disease. We have developed a number of proprietary TLR 9 agonist compositions and formulations that make use of the different ways in which the innate immune system responds to stimulation.

TLR 9 agonists can be administered therapeutically to stimulate immune responses for the treatment of cancer and infectious diseases. They can also be combined with vaccine antigens to enhance the specific immune response to the vaccine. TLR 9 agonists help generate memory T Helper ("Th") 1 cells that can stimulate the immune system to induce long-lasting effects. We use this approach in HEPLISAV-B by combining the TLR 9 agonist adjuvant with HBsAg. This combination induces a highly specific Th1 immune response and durable levels of protective antibodies. HEPLISAV-B has been shown to provide significantly greater seroprotection in persons with reduced immune function due to disease processes (diabetes, chronic kidney disease), overall health (smoking, obesity), and advanced age.

TLR 9 agonists can also be used alone to modify the course of the viral and respiratory disease by modulating the immune system. TLR 9 agonists have the potential to suppress the Th2 inflammatory response to modify the underlying cause of allergic inflammation.

For several programs, we have used our advanced proprietary knowledge to design modifications of the molecular structure of CPG oligonucleotide TLR 9 agonists to significantly increase their versatility and potency. These second-generation TLR 9 agonists stimulate specific immune responses, including potent interferon-alpha induction.

TLR Inhibitors

TLR inhibitors are short DNA sequences that selectively block the abnormal activation of TLRs associated with autoimmune and inflammatory diseases. In animal studies, our TLR inhibitors have demonstrated broad potential to reduce such inflammatory responses characteristic of multiple autoimmune diseases, including lupus, inflammatory skin disorders and rheumatoid arthritis.

DEVELOPMENT PROGRAMS

Our pipeline of product candidates includes the following:

Product Candidate	Description	Clinical Indication(s)	Phase	Partnership/Funding
HEPLISAV-B	TLR 9 agonist & HBsAg	Hepatitis B prevention	Phase 3	Dynavax
DV1179	TLR 7/9 inhibitor	Autoimmune and inflammatory diseases	Phase 1	GSK
AZD1419	TLR 9 agonist	Asthma	Phase 1	AstraZeneca
SD-101	TLR 9 agonist	Cancer immunotherapy	Phase 1	Dynavax
DV230	TLR 9 agonist	Adjuvant technology	Preclinical	NIAID

HEPLISAV-B Hepatitis B Vaccine

HEPLISAV-B is an investigational adult hepatitis B vaccine that combines our proprietary TLR agonist, 1018, with HBsAg manufactured in our Dynavax facility in Düsseldorf, Germany (“Rhein” or “Dynavax Europe”). In Phase 3 trials, HEPLISAV-B demonstrated higher and earlier protection with fewer doses than currently-licensed vaccines. Dynavax has worldwide commercial rights to HEPLISAV-B.

On February 25, 2013, we received a complete response letter ("CRL") from the FDA indicating that it would not approve HEPLISAV-B for the indication proposed in our BLA. Following extensive discussions with the FDA, we finalized the design of an additional clinical study of HEPLISAV-B that is intended to provide a sufficiently-sized safety database for the FDA to complete its review of our BLA and make a final determination regarding the safety and immunogenicity of the product. The planned study will be a Phase 3, observer-blinded, randomized, active-controlled, multicenter trial of the safety and immunogenicity of HEPLISAV-B compared with Engerix-B in adults 18 to 70 years of age. The study will include 5,500 HEPLISAV-B subjects and 2,500 Engerix-B subjects, stratified by age and diabetes diagnosis. HEPLISAV-B subjects will receive two doses at 0 and 1 month, while Engerix-B subjects will receive three doses at 0, 1 and 6 months.

The primary objectives of the study will be: (1) to evaluate the overall safety of HEPLISAV-B with respect to clinically significant adverse events and (2) to demonstrate the noninferiority of the peak seroprotection rate ("SPR") induced by HEPLISAV-B versus Engerix-B in subjects with type 2 diabetes mellitus. HEPLISAV-B subjects will be evaluated for safety for one year following the second dose, all potential autoimmune events will be adjudicated by a Safety Evaluation and Adjudication Committee and safety will be monitored by a Data and Safety Monitoring Board. We intend to initiate this study in the first quarter of 2014 and conclude subject visits by the end of 2015. We estimate the external costs of the study to be in the range of $50-55 million.

We submitted our Marketing Authorization Application ("MAA") for HEPLISAV-B to the European Medicines Agency's ("EMA") in July of 2012. In late 2012 we received the Day 120 List of Questions issued by the Committee for Medicinal Products for Human Use of the EMA regarding our MAA, which related primarily to the suitability of different patient populations, the safety database size, and Good Manufacturing Practices ("GMP") and Good Clinical Practices ("GCP") matters. In the early summer of 2013, EMA added to the list of questions, resetting the clock for our response. EMA also inspected several study sites, Dynavax and our clinical contract research organization. The focus of the GCP inspection was HBV-17, a 500 patient study in Chronic Kidney Disease ("CKD") patients that is part of the EMA application but not the U.S. application. In the fourth quarter of 2013, we submitted our responses to the 120-Day Questions. The Day 180 List of Outstanding Issues ("LOI") provided by the EMA in February 2014 indicated that, based primarily on the GCP inspection findings, HBV-17 was not acceptable and because some of the findings were related to the Dynavax's overall systems, the other pivotal HEPLISAV-B studies (HBV-10 and HBV-16) were questioned. The LOI also noted that the HEPLISAV-B safety database was considered to be too small to rule out a risk of less common serious adverse events, particularly in light of the GCP concerns. On February 18, 2014 we announced the withdrawal of the MAA for HEPLISAV-B under review by the EMA. We withdrew the application, in part, because the required time frame for response under the MAA procedure was not long enough to permit the collection of the necessary clinical data. The Phase 3 study to be initiated in the U.S. in 2014 is expected to provide additional data to support the safety of HEPLISAV-B.

Commercial Opportunity

Hepatitis B infection can become a chronic disease that, in some patients, leads to cirrhosis of the liver, hepatocellular carcinoma and death. There is no cure for chronic hepatitis B infection, and disease prevention through effective vaccines is critical to reducing the spread of the disease. Available hepatitis B vaccines for adults have several limitations, including:

- Slow onset of protection—the current regimen for adults is usually 3 doses given over 6 months to provide seroprotection of approximately 30%, 75% and 90% after the first, second and third doses respectively;
- Poor protection in populations that are hypo-responders—current vaccines provide a lower seroprotection rate for persons over 40 years of age including males, the obese, smokers, diabetics and immunocompromised persons, such as end-stage renal disease patients; and
- Poor compliance—in certain settings only 30% of people receive all 3 doses.

HEPLISAV-B is designed to address the limitations of currently-licensed vaccines by providing higher and earlier protection with fewer doses.

We estimate the total worldwide market for adult hepatitis B vaccines approximates $680 million annually. This market is primarily comprised of GSK's Engerix-B and Twinrix® as well as Merck & Co.'s ("Merck") Recombivax-HB®. Key market segments consisting of persons considered to be at high risk for hepatitis B virus ("HBV") infection include chronic kidney disease patients, people with multiple sexual partners or injection drug use, healthcare workers and first responders, travelers, chronic liver disease patients and, in the U.S., people with diabetes mellitus (type 1 and type 2).

We intend to focus our initial commercialization efforts on the U.S. market. Currently, the U.S. market for adult hepatitis B vaccines is approximately $270 million annually. In late 2012 the Advisory Committee on Immunization Practices ("ACIP") expanded its recommendation for adults who should be vaccinated against hepatitis B to include people with diabetes mellitus (type 1 and type 2). According to the Centers for Disease Control and Prevention ("CDC") there are 20 million adults diagnosed with diabetes and another 1.5 million new cases diagnosed each year. This population represents a significant increase in the number of adults recommended for vaccination against hepatitis B in the U.S.

DV1179 TLR Inhibitor for Autoimmune and Inflammatory Diseases

DV1179 is a novel inhibitor of TLR 7 and TLR 9 that is being evaluated as a therapeutic for autoimmune and inflammatory diseases, under a worldwide strategic alliance with GSK. In late 2011, we initiated a proof-of-mechanism clinical trial of DV1179 in systemic lupus erythematosus ("SLE") patients. This indication was selected because SLE is characterized by spontaneous lymphoproliferation, expansion of autoreactive B and T cells, and production of polyclonal autoantibodies against numerous nuclear antigens. TLR 7 and TLR 9 have been implicated in the chronic inflammatory response in this disease. GSK has an exclusive option to obtain a license to this program following completion of this trial expected in the second half of 2014.

AZD1419 TLR Agonist for Asthma Therapy

We are developing AZD1419, a novel candidate drug for asthma, under our collaboration agreement with AstraZeneca. AZD1419 is a proprietary second-generation TLR agonist and represents a new disease-modifying approach to the treatment of allergic respiratory diseases. AZD1419 is designed to change the basic immune response to environmental allergens, such as house dust and pollens, leading to prolonged reduction in asthma symptoms by converting the response from one primarily mediated by type-2 helper T cells (Th2) to type-1 helper T cells (Th1).

In October 2013 we initiated dosing in a Phase 1 study to assess the safety of AZD1419. In the first part of the study, up to approximately 45 healthy subjects will receive inhaled doses of AZD1419 or a placebo in single and multiple ascending doses, followed by up to approximately 24 patients with mild asthma in the second (Phase 1b) part of the study. Safety data from the first part of the study is expected in mid-2014.

SD-101 for Immunotherapy of Cancer

SD-101 is a proprietary second-generation TLR 9 agonist that was designed to stimulate a specific immune response, including potent interferon-alpha induction. This product candidate has been evaluated in two phase 1 studies to assess its safety and tolerability and is currently being tested in an investigator-sponsored study in patients with relapsed lymphoma after allogeneic bone marrow transplant.

DV230 Adjuvant Technology

We have developed a new adjuvant platform, DV230, with funding received from the National Institute of Allergy and Infectious Diseases ("NIAID"). Oligonucleotide TLR 9 agonists are strong activators of innate immunity and highly effective adjuvants. However, in situations where an extraordinarily rapid development of protective antibody titers is desired, it is beneficial to enhance the adjuvant function further by means of a nanoparticle formulation. The nanoparticle form of molecule DV230, covalently linked to the highly cross-linked sucrose polymer Ficoll, has demonstrated significant potency advantages in enhancing the magnitude and durability of the primary immune response in preclinical models of anthrax infection. We are currently evaluating this technology for a range of potential applications.

PARTNERSHIPS AND OTHER FUNDING AGREEMENTS

Our objective is to discover novel therapies based on our proprietary technologies and develop a diversified pipeline of product candidates to build a product-based commercial business. To reach this objective, an important part of our strategy is to establish partnerships with leading pharmaceutical and biotechnology companies and enter into funding agreements. Our pharmaceutical partners provide valuable resources, expertise and abilities that allow us to further advance the development of our product candidate programs. We also have funding agreements with U.S. government institutions.

GlaxoSmithKline

In December 2008, we entered into a worldwide strategic alliance with GSK to discover, develop and commercialize TLR inhibitors. Under the terms of the arrangement, we agreed to conduct research and early clinical development in up to four programs: the Lead TLR 7/9 program, a Follow-On TLR 7/9 program, and up to two other TLR programs. In 2011 we began development of a TLR 8 program as one of the two additional programs under the collaboration. GSK subsequently returned all rights to this program to us. In December 2013, we amended our agreement with GSK to extend the research term until conclusion of the ongoing phase 1 study of DV1179. In addition, the exclusivity provisions of the agreement were modified, giving us rights to immediately begin preclinical and clinical research on inhibitors of TLR 7 and 9 (other than DV1179) for oncology indications.

We are currently conducting a Phase 1 clinical trial in the Lead TLR 7/9 program with DV1179 in systemic lupus erythematosus patients. The Company is not currently performing any activities on the Follow-On TLR 7/9 program. GSK has not yet chosen to initiate development of the remaining program under the agreement.

GSK can exercise its exclusive option to license each program. If GSK exercises an option, GSK would carry out further development and commercialization of the corresponding products. If GSK exercises their option on the Lead TLR 7/9 program, then we are eligible to receive payments of up to approximately $125 million, comprised of contingent option exercise payments and additional payments based on GSK's achievement of certain development, regulatory and commercial objectives.

We are also eligible to receive up to $60 million if aggregate worldwide annual net sales milestones are achieved and tiered royalties ranging from the mid–single digit to mid-teens on sales of any products originating from the collaboration. We have retained an option to co-develop and co-promote one product under this agreement.

We received an initial payment of $10 million in 2008. In 2011, we earned and recognized $12 million in substantive development milestone payments related to the initiation of Phase I and proof-of-mechanism clinical trials of DV1179 in systemic lupus erythematosus patients. In 2011, we earned and recognized $3 million in substantive development milestone payments related to the initiation of development of the TLR 8 program.

Absent early termination, the agreement will expire when all of GSK's payment obligations expire. Either party may terminate the agreement early upon written notice if the other party commits an uncured material breach of the agreement. Either party may terminate the agreement in the event of insolvency of the other party. GSK also has the option to terminate the agreement without cause upon prior written notice within a specified window of time dependent upon the stage of clinical development of the programs.

AstraZeneca AB

In September 2006, we entered into a three-year research collaboration and license agreement with AstraZeneca for the discovery and development of TLR 9 agonist-based therapies for the treatment of asthma and chronic obstructive pulmonary disease. The research term of this agreement was extended through July 2010.

In October 2011, we amended our agreement with AstraZeneca to provide that we would conduct initial clinical development of AZD1419. Under the terms of the amended agreement, AstraZeneca will fund all program expenses to cover the cost of development activities through Phase 2a. A Phase 1 study was initiated in 2013 and is expected to conclude in 2015.

In March, 2014 we announced a $5.4 million milestone payment and amendment of our AstraZeneca agreement to transfer responsibility for all clinical development to AstraZeneca following conclusion of the ongoing Phase 1 clinical trial of AZD1419. If AstraZeneca continues development of AZD1419, we will receive milestones upon initiation of the first Phase 2 trial and the first Phase 3 trial. Additionally, we are eligible to receive potential future development payments and, upon commercialization, we are eligible to receive royalties based on product sales of any products originating from the collaboration. We have the option to co-promote in the U.S. products arising from the collaboration, if any. AstraZeneca has the right to sublicense its rights upon our prior consent.

Absent early termination, the agreement will expire when all of AstraZeneca's payment obligations expire. AstraZeneca has the right to terminate the agreement at any time upon prior written notice and either party may terminate the agreement early upon written notice if the other party commits an uncured material breach of the agreement.

National Institutes of Health and Other Funding

In September 2008, we were awarded a $17 million contract to develop our advanced TLR 9 agonist technology as vaccine adjuvants. This five-year contract was awarded by the National Institute of Health's ("NIH") NIAID and supports adjuvant development for biodefense vaccines, including anthrax as well as other diseases. NIAID is funding 100% of the total $17 million cost of our program under Contract No. HHSN272200800038C. The NIH may

terminate performance of work under the contract if the contracting officer determines that a termination is in the government's interest or if we default in performing and fail to cure after notice. In 2013, the NIAID agreed to extend the contract term by one year to continue the research efforts as defined in the original contract. The activities under this agreement are expected to conclude in the second half of 2014.

During 2010, we were awarded a grant from the NIAID to take a systems biology approach to study the differences between individuals who do or do not respond to vaccination against hepatitis B. This study will be one of several projects conducted under a grant to the Baylor Institute of Immunology Research in Dallas as part of the Human Immune Phenotyping Centers program, from which we were awarded $0.2 million in 2013, $0.3 million in 2012, $0.3 million in 2011 and $0.5 million in 2010. We were also awarded a $0.6 million grant in 2010 from the NIH to explore the feasibility of developing a universal vaccine to prevent infection by human papilloma virus.

During 2011, 2012 and 2013, we were awarded grants from the NIH to fund research in the amounts of $0.6 million, $1.0 million, and $0.2 million, respectively. The 2012 grant included $0.4 to fund research in screening for inhibitors of TLR 8 for treatment of rheumatoid arthritis and $0.6 million to fund development of TLR 8 inhibitors.

INTELLECTUAL PROPERTY

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our drug candidates, technology and know-how, to operate without infringing the proprietary rights of others and to prevent others from infringing our proprietary rights. In addition to seeking patent protection in the U.S., we generally file patent applications in Australia, Canada, Japan, Western European countries and additional foreign countries on a selective basis to further protect the inventions that we or our partners consider important to the development of our business. We also rely on trade secrets and contracts to protect our proprietary information.

As of December 31, 2013, our intellectual property portfolio included 28 issued U.S. patents, over 200 issued or granted foreign patents and over 50 additional pending U.S. and foreign patent applications claiming compositions and formulations of TLR agonist and inhibitors, their methods of use or processes for their manufacture. We also have exclusive licenses under two agreements to several patents and applications owned by the Regents of the University of California.

We have an issued U.S. patent covering the TLR agonist contained in our HEPLISAV-B investigational vaccine that will expire in 2018, and have correspondingly issued patents in several major European and other countries. We own or have an exclusive license to U.S. and foreign patent applications pending for each of our other product candidates and/or their uses. At present, it is not known or determinable whether patents will issue from any of these applications or what the specific expiration dates would be for any patents that do issue.

Individual patents extend for varying periods depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, patents issued in the U.S. are effective for:

- the longer of 17 years from the issue date or 20 years from the earliest effective filing date, if the patent application was filed prior to June 8, 1995; and
- 20 years from the earliest effective filing date, if the patent application was filed on or after June 8, 1995.

In addition, in certain instances, a patent term can be extended to recapture a portion of the term effectively lost as a result of the FDA regulatory review period. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is 20 years from the earliest effective filing date. Our patent estate, based on patents existing now and expected by us to issue based on pending applications, will expire on dates ranging from 2017 to 2033.

The actual protection afforded by a patent varies on a product-by-product basis, from country-to-country and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patents.

Because patent applications in the U.S. and many foreign jurisdictions typically are not published until 18 months after filing and publications of discoveries in the scientific literature often lag behind actual discoveries, we cannot be certain that we were the first to make the inventions claimed in each of our issued patents or pending patent applications or that we were the first to invent and/or the first to file for protection of the inventions set forth in these patent applications. The U.S. Patent and Trademark Office (“PTO”) may declare interference proceedings to determine the priority of inventions with respect to our patent applications and those of other parties or reexamination or reissue proceedings to determine if the scope of a patent should be narrowed.

Our commercial success depends significantly on our ability to operate without infringing patents and proprietary rights of third parties. A number of pharmaceutical companies and biotechnology companies, including Pfizer, Inc. (“Pfizer”), as well as universities and research institutions, may have filed patent applications or may have been granted patents that cover inventions similar to the inventions owned or licensed to us. We cannot determine with certainty whether patents or patent applications of other parties may materially affect our ability to make, use or sell any

products. If another party controls patents or patent applications covering our products, we may not be able to obtain the rights we need to those patents or patent applications in order to commercialize our products. Two of our potential competitors, Merck and GSK, are exclusive licensees of broad patents covering recombinant HBsAg, a component of HEPLISAV-B. In addition, the Institut Pasteur owns or has exclusive licenses to patents covering HBsAg. While some of these patents have expired or will soon expire outside the U.S., they remain in force in the U.S.. To the extent we are able to commercialize HEPLISAV-B in the U.S. while these patents remain in force, Merck, GSK, their licensors or the Institut Pasteur may bring claims against us.

Litigation may be necessary to enforce patents issued or licensed to us or to determine the scope or validity of another party's proprietary rights. The existence of third-party patent applications and patents could significantly reduce the coverage of the patents owned by or licensed to us and limit our ability to obtain meaningful patent protection. For example, Pfizer has issued U.S. and foreign patent claims as well as patent claims pending with the PTO and foreign patent offices that, if held to be valid, could require us to obtain a license in order to commercialize one or more of our formulations of TLR agonist other than with respect to HEPLISAV-B, for which we have a license. Litigation or any other proceedings, such as patent interferences, could result in substantial costs to and diversion of effort by us, and an adverse outcome in a court or patent office could subject us to significant liabilities, require disputed rights to be licensed from other parties, or require us to cease using some of our technology. We may not prevail of these actions or proceedings, if any.

In addition, other parties may duplicate, design around or independently develop similar or alternative technologies to ours or our licensors.

We may rely, in some circumstances, on trade secrets and confidentiality agreements to protect our technology. Although trade secrets are difficult to protect, wherever possible, we use confidential disclosure agreements to protect the proprietary nature of our technology. Our policy is to require each of our commercial partners, employees, consultants and advisors to enter into an agreement before beginning their employment, consulting or advisory relationship with us that in general provides that the individuals must keep confidential and not disclose to other parties any of our confidential information developed or learned by the individuals during the course of their relationship with us except in limited circumstances. These agreements also generally provide that we own all inventions conceived by the individuals in the course of rendering their employment or services to us. However, there can be no assurance that these agreements will not be breached, that we will have adequate remedies for any breach, or that our trade secrets and/or proprietary information will not otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants or contractors use intellectual property owned by others in their work for us, disputes may also arise as to the rights in related or resulting know-how and inventions.

Under the terms of our license agreements with the Regents of the University of California, we are required to pay license fees, make milestone payments, share a portion of fees from third party partnerships up to a specified amount and pay low single-digit royalties on net sales resulting from successful products originating from the licensed technologies. To date, we have paid the University of California a total of $1.9 million in license fees and shared third party partnership fees and milestone payments under these agreements. We estimate the total potential milestone payments payable for each such product will total approximately $3.1 million, not including royalties. We may terminate these agreements in whole or in part on 60 days advance notice. The Regents of the University of California may terminate these agreements if we are in breach for failure to make payments, meet diligence requirements, produce required reports or fund internal research and we do not cure such breach within 60 days after being notified of the breach. Otherwise, the agreements generally continue in effect until the last patent claiming a product licensed under the agreement or its manufacture or use expires, or in the absence of patents, until the date the last patent application claiming a licensed product is abandoned.

COMPETITION

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. Our products and development programs target a number of areas including viral, respiratory, autoimmune and inflammatory diseases. There are many commercially available products for the treatment of these diseases. Many companies and institutions are making substantial investments in developing additional products to treat these diseases that could compete directly or indirectly with our products under development.

HEPLISAV-B, a two-dose hepatitis B vaccine, if approved and commercialized, will compete directly with conventional three-dose marketed vaccines produced by GSK and Merck, among others. There are also modified schedules of conventional hepatitis B vaccines for limited age ranges that are approved in the European Union and U.S.. In addition, HEPLISAV-B will compete against a multivalent vaccine produced by GSK that simultaneously protect against hepatitis B and hepatitis A.

Our therapy for autoimmune and inflammatory diseases, DV1179, if developed, approved and commercialized will compete with key biologic therapies from companies such as F. Hoffman-La Roche Ltd. and its subsidiary Genentech, Inc. (“Roche/Genentech”), Amgen Inc., Biogen Idec, AbbVie and GSK. In addition, our product would compete with generic drugs commonly used to treat autoimmune diseases, including corticosteroids, non-steroidal anti-inflammatory drugs, antimalarials and immunosuppressive agents. Other companies, such as AstraZeneca and its subsidiary MedImmune, LLC, Roche/Genentech, Idera Pharmaceuticals, Pfizer and UCB S.A. and its partner Immunomedics, Inc., are developing anti-IFN-alpha-antibodies, B-cell targeted antibodies, immunosuppressants, and other TLR inhibitors that may compete directly with our product candidate.

Our asthma therapy, AZD1419, if developed, approved and commercialized, will compete indirectly with existing asthma therapies, such as inhaled beta-agonists, corticosteroids, leukotriene inhibitors and IgE monoclonal antibodies, including those marketed by Merck, Roche/Genentech, Novartis International AG, AstraZeneca and GSK. In addition, directly competing products may be in development by Sanofi-Aventis and Idera Pharmaceuticals.

Our cancer immunotherapy, SD101, if developed, approved and commercialized will compete with a range of biological therapies being used or studied to treat blood cancer including:

- Monoclonal antibody therapy, including radioimmunotherapy
- Interferons and interleukins
- Donor lymphocyte infusion
- Reduced-intensity allogeneic stem cell transplantation
- Therapeutic cancer vaccines

Approved and late-stage investigational cancer immunotherapeutics are marketed or being developed by numerous companies, including Bristol-Myers Squibb, Roche/Genentech, Merck, GSK, Gilead, and Pharmacyclics.

Many of the entities developing and marketing these competing products have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative agreements with large, established companies and access to capital. These entities may also compete with us in recruiting and retaining qualified scientific and management personnel, as well as in acquiring technologies complementary to or necessary for our programs.

REGULATORY CONSIDERATIONS

In the U.S., pharmaceutical and biological products are subject to rigorous review and approval by the FDA under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and other federal statutes and regulations. In Europe, under the centralized procedure, a company submits a single application to the European Medicines Agency. The steps ordinarily required by the regulatory authorities before a new drug or biological product may be marketed in the U.S. and in most other countries include but are not limited to the following:

- completion of preclinical laboratory tests, preclinical studies and formulation studies;
- submission to the regulatory authority of a clinical application for a new drug or biologic which must become effective before clinical trials may begin;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug or biologic for each proposed indication;
- demonstration of the consistent manufacturing of drug substance and drug product;
- the submission of a new drug application to the regulatory authority; and
- regulatory review and approval of the application before any commercial marketing, sale or shipment of the drug.

If applicable requirements are not met, regulatory authorities may issue fines, require that a company recall its products, seize products, require that a company totally or partially suspend the production of its products, refuse to approve a marketing application, pursue criminal prosecution and/or revoke previously granted marketing authorizations.

To secure regulatory authority approval, we must submit extensive non-clinical and clinical data, adequate evidence of a product manufactured by a well-controlled process that is safe and effective for its intended use, and other supporting information to the regulatory authority. The number of preclinical studies and clinical trials that will be required for FDA and foreign regulatory agency approvals varies depending on the product candidate, the disease or condition for which the product candidate is in development and regulations applicable to any particular drug candidate. Data obtained from preclinical and clinical activities are susceptible to varying interpretations, which could

delay, limit or prevent regulatory approval or clearance. Further, the results from preclinical testing and early clinical trials may not be predictive of results obtained in later clinical trials. In addition, the development of the drug substance and drug product may require manufacturing modifications to ensure future regulatory acceptance. The approval process takes many years, requires the expenditures of substantial resources, and involves post-marketing surveillance.

Delays experienced during the approval process may materially reduce the period during which we will have exclusive rights to exploit patented products or technologies. Delays can occur at any stage of drug development and as a result of many factors, certain of which are not under our control, including but not limited to the following:

- lack of efficacy, or incomplete or inconclusive results from clinical trials;
- unforeseen safety issues;
- failure by investigators to adhere to protocol requirements, including patient enrollment criteria;
- slower than expected rate of patient recruitment;
- failure by subjects to comply with trial protocol requirements;
- inability to follow patients adequately after treatment;
- inability to qualify and enter into arrangements with third parties to manufacture sufficient quality and quantities of materials for use in clinical trials;
- failure by a contract research organization to fulfill contractual obligations; and
- adverse changes in regulatory policy during the period of product development or the period of review of any application for regulatory approval or clearance.

The FDA or foreign regulatory agency may also require post-marketing testing and surveillance to monitor the effects of approved products or place conditions on any approvals that could restrict the commercial applications of these products. Following approval, we may be required to conduct additional post-marketing studies. The regulatory authority may withdraw product approvals if we do not continue to comply with regulatory standards or if problems occur following initial marketing.

Non-clinical studies involve laboratory evaluation of product characteristics or animal studies to assess the initial efficacy and safety of the product. The FDA or other foreign regulatory agency, under its good laboratory practices regulations, regulates certain non-clinical studies. Research and preclinical studies do not involve the introduction of a product candidate in human subjects. These activities involve identification of potential product candidates, modification of promising candidates to optimize their biological activity, as well as preclinical studies to assess safety and effectiveness in animals. In clinical trials, the product candidate is administered to humans. Violations of these regulations can, in some cases, lead to invalidation of those studies, requiring these studies to be repeated. The results of these tests, together with manufacturing information and analytical data, are submitted to the regulatory authority as part of a clinical application, which must be approved by the regulatory authority before we can commence clinical investigations in humans.

Clinical trials involve the administration of the investigational product to humans under the supervision of a qualified principal investigator. We must conduct our clinical trials in accordance with GCP regulations under protocols submitted to applicable regulatory authorities as part of the clinical application. GCP regulations mandate comprehensive documentation for the clinical protocol, record keeping, training, and facilities including computers. Quality assurance and inspections are designed to ensure that these GCP standards are achieved. Additionally, each clinical trial must be approved and conducted under the auspices of an Institutional Review Board (“IRB”) or Independent Ethics Committee and with patient informed consent. The IRB will consider, among other matters, ethical factors, the safety of human subjects and the possibility of liability of the institution conducting the trial.

The stages of the regulatory process include clinical trials in three sequential phases that may overlap. Phase 1 clinical trials typically involve the administration of a product candidate into a small group of healthy human subjects. These trials are the first attempt to evaluate a drug’s safety, determine a safe dose range and identify side effects. During Phase 2 trials, the product candidate is introduced into patients who suffer from the medical condition that the product candidate is intended to treat. Phase 2 studies are designed to evaluate whether a product candidate shows evidence of effectiveness, to further evaluate dosage, and to identify possible adverse effects and safety risks. When Phase 2 evaluations demonstrate that a product candidate appears to be both safe and effective, Phase 3 trials are undertaken to confirm a product candidate’s effectiveness and to test for safety in an expanded patient population. If the results of Phase 3 trials appear to confirm effectiveness and safety, the data gathered in all phases of clinical trials form the basis for an application for regulatory approval of the product candidate.

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We and all of our contract manufacturers are required to comply with the applicable FDA or foreign regulatory agency current GMP regulations. Manufacturers of biologics also must comply with a regulatory authority's general biological product standards. Failure to comply with the statutory and regulatory requirements subjects the manufacturer to possible legal or regulatory action, such as suspension of manufacturing, seizure of product or voluntary recall of a product. Good manufacturing practice regulations require quality control and quality assurance as well as the corresponding maintenance of records and documentation. Before granting product approval, the regulatory authority must determine that our or our third party contractor's manufacturing facilities meet GMP requirements before we can use them in the commercial manufacture of our products. In addition, our facilities are subject to periodic inspections by the regulatory authority for continued compliance with GMP requirements during clinical development as well as following product approval. Adverse experiences with the product must be reported to the FDA or foreign regulatory agency and could result in the imposition of market restriction through labeling changes or in product removal.

If our products are approved for sale, we will be subject to further regulatory requirements under federal and state provisions such as federal "sunshine" laws, anti-kickback laws, false claims laws and state law equivalents of those and other regulations. We are also subject to various federal, state, local and foreign laws, regulations and recommendations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our research. We cannot accurately predict the extent of government regulation that might result from any future legislation or administrative action.

MANUFACTURING

We rely on our facility in Dusseldorf, Germany and third parties to perform the multiple processes involved in manufacturing our product candidates, including the manufacturing of TLR agonist and inhibitors, antigens, the combination of the TLR agonist and the antigens, and the formulation, fill and finish of these products. The process for manufacturing oligonucleotides is well-established and uses commercially available equipment and raw materials. We have relied on a limited number of suppliers to produce products for clinical trials and a single supplier to produce our 1018 for HEPLISAV-B. To date, we have manufactured only small quantities of TLR agonist and inhibitors ourselves for development purposes. We currently manufacture the HBsAg for HEPLISAV-B at our Dynavax Europe facility.

RESEARCH AND DEVELOPMENT

Conducting a significant amount of research and development has been central to our business model. Our research and development expenses were $50.9 million, $49.1 million and $51.3 million for the years ended December 31, 2013, 2012 and 2011, respectively.

ENVIRONMENT

We have made, and will continue to make, expenditures for environmental compliance and protection. We do not expect that expenditures for compliance with environmental laws will have a material effect on our capital expenditures or results of operations in the future.

EMPLOYEES

As of December 31, 2013, we had 151 full-time employees, including 21 Ph.D.s, 1 M.D. and 17 others with advanced degrees. Of the 151 employees, 122 were dedicated to research and development activities. None of our employees is subject to a collective bargaining agreement and we believe our relations with our employees are good.

ITEM 1A. RISK FACTORS

This Annual Report on Form 10-K contains forward-looking statements concerning our future products, product candidates, timing of development activities, regulatory strategies, intellectual property position, expenses, revenues, liquidity and cash needs, as well as our plans and strategies. These forward-looking statements are based on current expectations and we assume no obligation to update this information. Numerous factors could cause our actual results to differ significantly from the results described in these forward-looking statements, including the following risk factors.

Risks Related to our Business

The success of our product candidates, in particular HEPLISAV-B, depends on regulatory approval. The FDA or foreign regulatory agencies may determine our clinical trials or other data regarding safety, efficacy, consistency of manufacture or compliance with GMP regulations are insufficient for regulatory approval. Failure to obtain regulatory approvals could require us to discontinue operations.

None of our product candidates has been approved for sale by any regulatory agency. Any product candidate we develop is subject to extensive regulation by federal, state and local governmental authorities in the U.S., including the FDA, and foreign regulatory agencies. Our success is primarily dependent on our ability to obtain regulatory approvals for our most advanced product candidates. Approval processes in the U.S. and in other countries are uncertain, can take many years and require the expenditure of substantial resources and we are unable to predict the timing of when regulatory approval may be received, if ever, in any jurisdiction.

For our lead product, HEPLISAV-B, our BLA must be approved by the FDA and corresponding applications to foreign regulatory agencies must be approved by those agencies before we may sell the product in their respective geographic area. Obtaining approval of a BLA and corresponding foreign applications is highly uncertain and we may fail to obtain approval. The BLA review process is extensive, lengthy, expensive and uncertain, and the FDA or foreign regulatory agencies may delay, limit or deny approval of our application for many reasons, including: whether the data from our clinical trials, including the Phase 3 results, or the development program is satisfactory to the FDA or foreign regulatory agency; disagreement with the number, design, size, conduct or implementation of our clinical trials or a conclusion that the data fails to meet statistical or clinical significance; acceptability of data generated at our clinical trial sites that are monitored by third party clinical research organizations; the results of an FDA or other advisory committee that may recommend against approval of our BLA or may recommend that the FDA or other agencies require, as a condition for approval, additional preclinical studies or clinical trials; and deficiencies in our manufacturing processes or facilities or those of our third party contract manufacturers and suppliers, if any. For example, in our 2013 CRL, HEPLISAV-B was not approvable for the proposed indication based on insufficient patient safety data for an indication in adults 18-70 years of age without further evaluation of safety. While we are undertaking a study intended to obtain additional safety data information to the FDA, there can be no assurance that this additional clinical study will support approval, or that the data will provide acceptable immunogenicity data for patients with diabetes. The FDA also requested additional data from our manufacturing process validation program as well as clarifying information on the manufacturing controls and facilities in our Düsseldorf manufacturing facility with respect to quality assurance of commercial product. There can be no assurance that Dynavax can successfully produce the requisite data in a timely manner or that the data will be sufficient for approval in the U.S.

In addition, we recently announced our withdrawal of our Marketing Authorization Application for approval to the EMA based in part upon our determination that in the required timeframe for response under the MAA procedure we would not be able to collect the necessary clinical data in a timely manner to respond to the EMA’s list of outstanding issues regarding the safety database. While we expect to begin shortly an additional HEPLISAV clinical trial, HBV-23, that is intended to provide a safety database sufficient to support licensure, there can be no assurance that we can timely initiate or complete such study in a timely manner, nor that our safety database will be sufficient or acceptable to support MAA approval. Moreover, our withdrawal means that additional questions raised by the EMA in the continuing review process were not completed and there can be no assurance that we would be able to respond sufficiently to satisfy the other outstanding questions from the EMA with respect to our MAA.

In addition, we obtain guidance from regulatory authorities on certain aspects of our clinical development activities and seek to comply with written guidelines provided by the authorities. These discussions and written guidelines are not binding obligations on the part of the regulatory authorities and the regulatory authorities may require additional patient data or studies to be conducted. Regulatory authorities may revise or retract previous guidance during the course of a clinical trial or after completion of the trial. The authorities may also disqualify a clinical trial from consideration in support of approval of a potential product if they deem the guidelines have not been met. The FDA or

foreign regulatory agencies may determine our clinical trials or other data regarding safety, efficacy or consistency of manufacture or compliance with GMP regulations are insufficient for regulatory approval.

Failure to receive approval or significant delay in being able to provide the safety and manufacturing information required for approval of our BLA for HEPLISAV-B would have a material adverse effect on our business and results of operations. Even if approved, the labeling approved by the relevant regulatory authority for a product may restrict to whom we and our potential partners, if any, may market the product or the manner in which our product may be administered and sold, which could significantly limit the commercial opportunity for such product.

Before granting product approval, the FDA must determine that our or our third party contractor's manufacturing facilities meet current GMP requirements before we can use them in the commercial manufacture of our products. We and all of our contract manufacturers are required to comply with the applicable current GMP regulations. Manufacturers of biological products must also comply with the FDA's general biological product standards. In addition, GMP regulations require quality control and quality assurance as well as the corresponding maintenance of records and documentation sufficient to ensure the quality of the approved product. Failure to comply with the statutory and regulatory requirements subjects the manufacturer to possible legal or regulatory action, such as delay of approval, suspension of manufacturing, seizure of product or voluntary recall of a product.

The FDA may require more clinical trials for our product candidate than we currently expect or are conducting before granting regulatory approval, if regulatory approval is granted at all. Our clinical trials may be extended which may lead to substantial delays in the regulatory approval process for our product candidates, which will impair our ability to generate revenues.

Our registration and commercial timelines depend on further discussions with the FDA and corresponding foreign regulatory agencies and requirements and requests they may make for additional data or completion of additional clinical trials. Any such requirements or requests could:

- adversely affect our ability to timely and successfully commercialize or market these product candidates;
- result in significant additional costs;
- potentially diminish any competitive advantages for those products;
- potentially limit the markets for those products;
- adversely affect our ability to enter into collaborations or receive milestone payments or royalties from potential collaborators;
- cause us to abandon the development of the affected product candidate; or
- limit our ability to obtain additional financing on acceptable terms, if at all. Clinical trials for our product candidates are expensive and time consuming, may take longer than we expect or may not be completed at all, and their outcomes are uncertain.

We are undertaking an additional trial of HEPLISAV-B and expect to commence clinical trials for our other product candidates in the future. Each of our clinical trials requires the investment of substantial planning, expense and time and the timing of the commencement, continuation and completion of these clinical trials may be subject to significant delays relating to various causes, including scheduling conflicts with participating clinicians and clinical institutions, difficulties in identifying and enrolling participants who meet trial eligibility criteria, failure of participants to complete the clinical trial, delay or failure to obtain institutional review board, or IRB, or other regulatory approval to conduct a clinical trial at a prospective site, unexpected adverse events and shortages of available drug supply. Participant enrollment is a function of many factors, including the size of the relevant population, the proximity of participants to clinical sites, the eligibility criteria for the trial, the existence of competing clinical trials and the availability of alternative or new treatments.

Failure by us or our clinical research organizations (“CROs”) to conduct a clinical study to GCP standards could result in disqualification of the clinical trial from consideration in support of approval of a potential product.

We are responsible for conducting our clinical trials consistent with GCP standards and for oversight of our vendors to ensure that they comply with such standards. We depend on medical institutions and clinical research organizations, or CROs, to conduct our clinical trials in compliance with GCP. To the extent that they fail to comply with GCP standards, fail to enroll participants for our clinical trials, or are delayed for a significant time in the execution of our trials, including achieving full enrollment, we may be affected by increased costs, program delays or both, which may harm our business.

In addition, we conduct clinical trials in foreign countries which may subject us to further delays and expenses as a result of increased drug shipment costs, additional regulatory requirements and the engagement of foreign CROs, as well as expose us to risks associated with less experienced clinical investigators who are unknown to the FDA, and different standards of medical care. Foreign currency transactions insofar as changes in the relative value of the U.S. dollar to the foreign currency where the trial is being conducted may also unfavorably impact our actual costs.

Clinical trials must be conducted in accordance with FDA or other applicable foreign government guidelines and are subject to oversight by the FDA, other foreign governmental agencies and IRBs at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of our product candidates produced under cGMP and other requirements in foreign countries, and may require large numbers of participants.

The FDA or other foreign governmental agencies or we ourselves could delay, suspend or halt our clinical trials of a product candidate for numerous reasons, including:

- deficiencies in the trial design;
- deficiencies in the conduct of the clinical trial including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols;
- deficiencies in the clinical trial operations or trial sites resulting in the imposition of a clinical hold;

- the product candidate may have unforeseen adverse side effects, including fatalities, or a determination may be made that a clinical trial presents unacceptable health risks;
- the time required to determine whether the product candidate is effective may be longer than expected;
- fatalities or other adverse events arising during a clinical trial that may not be related to clinical trial treatments;
- the product candidate may appear to be no more effective than current therapies;
- the quality or stability of the product candidate may fail to conform to acceptable standards;
- our inability to produce or obtain sufficient quantities of the product candidate to complete the trials;
- our inability to reach agreement on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- our inability to obtain IRB approval to conduct a clinical trial at a prospective site;
- our liability to obtain regulatory approval to conduct a clinical trial;
- lack of adequate funding to continue the clinical trial, including the occurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our CROs and other third parties;
- our inability to recruit and enroll individuals to participate in clinical trials for reasons including competition from other clinical trial programs for the same or similar indications; or
- our inability to retain participants who have initiated a clinical trial but may be prone to withdraw due to side effects from the therapy, lack of efficacy or personal issues, or who are lost to further follow-up.

In addition, we may experience significant setbacks in advanced clinical trials, even after promising results in earlier trials, such as unexpected adverse events that occur when our product candidates are combined with other therapies and drugs or given to larger populations, which often occur in later-stage clinical trials. In addition, clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Also, patient advocacy groups and parents of trial participants may demand additional clinical trials or continued access to drug even if our interpretation of clinical results received thus far leads us to determine that additional clinical trials or continued access are unwarranted. Any disagreement with patient advocacy groups or parents of trial participants may require management's time and attention and may result in legal proceedings being instituted against us, which could be expensive, time-consuming and distracting, and may result in delay of the program. Negative or inconclusive results or adverse medical events, including participant fatalities that may be attributable to our product candidates, during a clinical trial may necessitate that it be redesigned, repeated or terminated. Further, some of our clinical trials may be overseen by an independent data safety monitoring board ("DSMB"), and the DSMB may determine to delay or suspend one or more of these trials due to safety or futility findings based on events occurring during a clinical trial. Any such delay, suspension, termination or request to repeat or redesign a trial could increase our costs and prevent or significantly delay our ability to commercialize our product candidates.

HEPLISAV-B and most of our earlier stage programs rely on oligonucleotide TLR agonists. Serious adverse event data relating to either 1018 or other TLR agonists may require us to reduce the scope of or discontinue our operations.

HEPLISAV-B incorporates 1018, a TLR 9 agonist CPG oligonucleotide, and most of our research and development programs use similar oligonucleotides. If any of our product candidates in clinical trials produce serious adverse event data, we may be required to delay, discontinue or modify our clinical trials or our clinical trial strategy. Most of our clinical product candidates contain oligonucleotides, and if a common safety risk across therapeutic areas were identified, it may hinder our ability to enter into potential collaboration arrangements or commercialize our product candidates. If adverse event data are found to apply to our TLR agonist and/or inhibitor technology as a whole, we may be required to significantly reduce or discontinue our operations.

We have no commercialization experience, and the time and resources to develop sales, marketing and distribution capabilities for HEPLISAV-B are significant. If we fail to achieve and sustain commercial success for HEPLISAV-B, either directly or with a partner, our business would be harmed.

Our lead product candidate, HEPLISAV-B, if approved, would require us to establish sales, marketing and distribution capabilities, or make arrangements with third parties to perform these services. These efforts will require

resources and time and we may not be able to enter into these arrangements on acceptable terms. In particular, significant resources may be necessary to successfully market, sell and distribute HEPLISAV-B to patients with diabetes, a group recently recommended by the CDC and ACIP to receive hepatitis B vaccination. Moreover, our pricing and reimbursement strategies with respect to our initial approval plans for HEPLISAV-B may significantly impact our ability to achieve commercial success in this potential patient population.

If we, or our partners, if any, are not successful in setting our marketing, pricing and reimbursement strategy, recruiting sales and marketing personnel or in building a sales and marketing infrastructure, we will have difficulty commercializing HEPLISAV-B, which would adversely affect our business and financial condition. To the extent we rely on other pharmaceutical or biotechnology companies with established sales, marketing and distribution systems to market HEPLISAV-B, we will need to establish and maintain partnership arrangements, and we may not be able to enter into these arrangements on acceptable terms or at all. To the extent that we enter into co-promotion or other arrangements, certain revenues we receive will depend upon the efforts of third parties, which may not be successful and are only partially in our control.

We rely on our facility in Düsseldorf, Germany and third parties to supply materials or perform processes necessary to manufacture our product candidates. We rely on a limited number of suppliers to produce the oligonucleotide we will require for commercialization. Additionally, we have limited experience in manufacturing our product candidates in commercial quantities.

We rely on our facility in Düsseldorf and third parties to perform the multiple processes involved in manufacturing our product candidates, including 1018, certain antigens, the combination of the oligonucleotide and the antigens, and the formulation, fill and finish. Termination or interruption of these relationships may occur due to circumstances that are outside of our control, resulting in higher cost or delays in our product development or commercialization efforts.

We have relied on a limited number of suppliers to produce oligonucleotides for clinical trials and a single supplier to produce our 1018 ISS for HEPLISAV-B. To date, we have manufactured only small quantities of oligonucleotides ourselves for development purposes. If we were unable to maintain our existing supplier for 1018, we would have to establish an alternate qualified manufacturing capability, which would result in significant additional operating costs and delays in developing and commercializing our product candidates, particularly HEPLISAV-B. We or other third parties may not be able to produce 1018 at a cost, quantity and quality that are available from our current third-party supplier.

We currently utilize our facility in Düsseldorf to manufacture the hepatitis B surface antigen for HEPLISAV-B. The commercial manufacturing of biological products is a time-consuming and complex process, which must be performed in compliance with current GMP regulations. As part of the review of our BLA filing for HEPLISAV-B, the FDA requested additional data regarding our manufacturing process validation program as well as clarifying information on the manufacturing controls and facilities and there can be no assurance that our responses will be sufficient to meet the FDA requirements for GMP manufacturing.

In addition, we may not be able to comply with ongoing and comparable foreign regulations, and our manufacturing process may be subject to delays, disruptions or quality control/quality assurance problems. Noncompliance with these regulations or other problems with our manufacturing process may limit, delay or disrupt the commercialization of HEPLISAV-B and could result in significant expense. Moreover, depending on the level of market acceptance of HEPLISAV-B, if approved, we may not have the capacity in our existing facility to meet all of our future commercial supply needs. Our current manufacturing capacity could supply up to approximately 2 million doses of hepatitis B surface antigen annually, and our ability to expand Düsseldorf manufacturing capacity by improving utilization in our existing facility, improving upon our current production yields or using a new facility will take time to implement and could result in substantial cost. In the event that demand exceeds our current capacity plans, we may experience a shortage in supply of HEPLISAV-B, which could have a material adverse effect on the success of HEPLISAV-B. Likewise, in the event that HEPLISAV-B is not approved, we would have to consider other alternatives for the facility in Düsseldorf, including its sale or closure, and any such efforts would be complex, expensive, and time-consuming.

If we receive regulatory approval for our product candidates, we will be subject to ongoing FDA and foreign regulatory obligations and continued regulatory review.

We and our third party suppliers are required to comply with applicable current GMP regulations and other international regulatory requirements. The regulations require that our product candidates be manufactured and our records maintained in a prescribed manner with respect to manufacturing, testing and quality control/quality assurance activities. Suppliers of key components and materials must be named in a BLA submitted to the FDA for any product candidate for which we are seeking FDA approval. Additionally, these third parties and our manufacturing facility must undergo a pre-approval inspection before we can obtain marketing authorization for any of our product candidates. Even after a manufacturer has been qualified by the FDA, the manufacturer must continue to expend time, money and effort in the area of production and quality control to ensure full compliance with GMP. Manufacturers are subject to regular, periodic inspections by the FDA following initial approval. Further, to the extent that we contract with third parties for the manufacture of our products, our ability to control third-party compliance with FDA requirements will be limited to contractual remedies and rights of inspection.

If, as a result of their inspections, the FDA determines that the equipment, facilities, laboratories or processes do not comply with applicable FDA regulations and conditions of product approval, the FDA may not approve the product or may suspend the manufacturing operations. If the manufacturing operations of any of the suppliers for our product candidates are suspended, we may be unable to generate sufficient quantities of commercial or clinical supplies of product to meet market demand, which would harm our business. In addition, if delivery of material from our suppliers were interrupted for any reason, we might be unable to ship our approved product for commercial supply or to supply our products in development for clinical trials. Significant and costly delays can occur if the qualification of a new supplier is required.

Any regulatory approvals that we receive for our product candidates are likely to contain requirements for post-marketing follow-up studies, which may be costly. Product approvals, once granted, may be modified based on data from subsequent studies or commercial use. As a result, limitations on labeling indications or marketing claims, or withdrawal from the market may be required if problems occur after commercialization.

Failure to comply with regulatory requirements could prevent or delay marketing approval or require the expenditure of money or other resources to correct. Failure to comply with applicable requirements may also result in warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal of the government to renew marketing applications and criminal prosecution, any of which could be harmful to our ability to generate revenues and our stock price.

We may develop, seek regulatory approval for and market our product candidates outside the U.S., requiring a significant commitment of resources. Failure to successfully manage our international operations could result in significant unanticipated costs and delays in regulatory approval or commercialization of our product candidates.

We may introduce certain of our product candidates, including HEPLISAV-B, in various markets outside the U.S.. Developing, seeking regulatory approval for and marketing our product candidates outside the U.S. could impose substantial burdens on our resources and divert management’s attention from domestic operations. International operations are subject to risk, including:

- the difficulty of managing geographically distant operations, including recruiting and retaining qualified employees, locating adequate facilities and establishing useful business support relationships in the local community;
- compliance with varying international regulatory requirements, laws and treaties;
- securing international distribution, marketing and sales capabilities;
- adequate protection of our intellectual property rights;
- obtaining regulatory and pricing approvals at a level sufficient to justify commercialization;
- legal uncertainties and potential timing delays associated with tariffs, export licenses and other trade barriers;
- diverse tax consequences;
- the fluctuation of conversion rates between foreign currencies and the U.S. dollar; and
- regional and geopolitical risks.

We have withdrawn our MAA in Europe and we may not be able to timely initiate our planned clinical trial or provide sufficient data from such trial or respond to other comments to our previously filed MAA sufficient to obtain foreign regulatory approvals in Europe in a reasonable time period or at all. Any failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in other jurisdictions. If we are unable to successfully manage our international operations, we may incur significant unanticipated costs and delays in regulatory approval or commercialization of our product candidates, which would impair our ability to generate revenues.

If any products we develop are not accepted by the market or if regulatory agencies limit our labeling indications or marketing claims, we may be unable to generate significant revenues, if any.

Even if we obtain regulatory approval for our product candidates and are able to commercialize them, our products may not gain market acceptance among physicians, patients, healthcare payors and the medical community.

The degree of market acceptance of any of our approved products will depend upon a number of factors, including:

- the indication for which the product is approved and its approved labeling;
- the presence of other competing approved therapies;
- the potential advantages of the product over existing and future treatment methods;

- the relative convenience and ease of administration of the product;
- the strength of our sales, marketing and distribution support;
- the price and cost-effectiveness of the product; and
- sufficient third-party reimbursement.

The FDA or other regulatory agencies could limit the labeling indication for which our product candidates may be marketed or could otherwise limit marketing efforts for our products. If we are unable to achieve approval or successfully market any of our product candidates, or marketing efforts are restricted by regulatory limits, our ability to generate revenues could be significantly impaired.

We face uncertainty regarding coverage, pricing and reimbursement and the practices of third party payors, which may make it difficult or impossible to sell our product candidates on commercially reasonable terms.

In both domestic and foreign markets, our ability to achieve profitability will depend in part on the negotiation of a favorable price or the availability of appropriate reimbursement from third party payors, in particular for HEPLISAV-B where existing products are already marketed. Existing laws affecting the pricing and coverage of pharmaceuticals and other medical products by government programs and other third party payors may change before any of our product candidates are approved for marketing. In addition, third party payors are increasingly challenging the price and cost-effectiveness of medical products and services, and pricing and reimbursement decisions may not allow our products to compete effectively with existing or competitive products. Because we intend to offer products, if approved, that involve new technologies and new approaches to treating disease, the willingness of third party payors to reimburse for our products is uncertain. We will have to charge a price for our products that is sufficient to enable us to recover our considerable investment in product development and our operating costs. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to achieve profitability and could harm our future prospects and reduce our stock price.

We are unable to predict what impact the Health Care and Education Reconciliation Act of 2010 or other reform legislation will have on our business or future prospects. The uncertainty as to the nature and scope of the implementation of any proposed reforms limits our ability to forecast changes that may affect our business. In Europe, the success of our products, in particular HEPLISAV-B, will depend largely on obtaining and maintaining government reimbursement because many providers in European countries are unlikely to use medical products that are not reimbursed by their governments. Many countries in Europe have adopted legislation and increased efforts to control prices of healthcare products. We are unable to predict the impact these actions will have on our business or future prospects.

We rely on contract research organizations to conduct our clinical trials. If these third parties do not fulfill their contractual obligations or meet expected deadlines, our planned clinical trials may be delayed and we may fail to obtain the regulatory approvals necessary to commercialize our product candidates.

We rely on third parties to conduct our clinical trials. If these third parties do not perform their obligations or meet expected deadlines our planned clinical trials may be extended, delayed, modified or terminated. While we conduct regular reviews of the data, we are dependent on the processes and quality control efforts of our third party contractors to ensure that detailed, quality records are maintained to support the results of the clinical trials that they are conducting on our behalf. Any extension, delay, modification or termination of our clinical trials or failure to ensure adequate documentation and the quality of the results in the clinical trials could delay or otherwise adversely affect our ability to commercialize our product candidates and could have a material adverse effect on our business and operations.

A key part of our business strategy is to establish collaborative relationships to commercialize and fund development of our product candidates. We may not succeed in establishing and maintaining collaborative relationships, which may significantly limit our ability to develop and commercialize our products successfully, if at all.

We will need to establish collaborative relationships to obtain domestic and international sales, marketing and distribution capabilities for our product candidates, in particular with respect to the commercialization of HEPLISAV-B, if approved. Failure to obtain a collaborative relationship for HEPLISAV-B, particularly in the European Union and for other markets requiring extensive sales efforts, may significantly impair the potential for this product, and our recent withdrawal of our MAA increases the risk that we may be unable to enter into a collaborative relationship prior to regulatory approval. The process of establishing and maintaining collaborative relationships is difficult, time-consuming and involves significant uncertainty, including:

- our partners may seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical results, manufacturing issues, a change in business strategy, a change of control or other reasons;
- our shortage of capital resources may impact the willingness of companies to collaborate with us;

- our contracts for collaborative arrangements are terminable at will on written notice and may otherwise expire or terminate and we may not have alternative funding available;
- our partners may choose to pursue alternative technologies, including those of our competitors;
- we may have disputes with a partner that could lead to litigation or arbitration;
- we have limited control over the decisions of our partners and they may change the priority of our programs in a manner that would result in termination of the agreement or add significant delay in the partnered program;
- our ability to generate future payments and royalties from our partners depends upon the abilities of our partners to establish the safety and efficacy of our drug candidates, obtain regulatory approvals and successfully manufacture and achieve market acceptance of products developed from our drug candidates;
- we or our partners may fail to properly initiate, maintain or defend our intellectual property rights, where applicable, or a party may use our proprietary information in such a way as to invite litigation that could jeopardize or potentially invalidate our proprietary information or expose us to potential liability;
- our partners may not devote sufficient capital or resources towards our product candidates; and
- our partners may not comply with applicable government regulatory requirements.

If any collaborator fails to fulfill its responsibilities in a timely manner, or at all, our research, clinical development, manufacturing or commercialization efforts pursuant to that collaboration could be delayed or terminated, or it may be necessary for us to assume responsibility for expenses or activities that would otherwise have been the responsibility of our collaborator. If we are unable to establish and maintain collaborative relationships on acceptable terms or to successfully transition terminated collaborative agreements, we may have to delay or discontinue further development of one or more of our product candidates, undertake development and commercialization activities at our own expense or find alternative sources of capital.

Many of our competitors have greater financial resources and expertise than we do. If we are unable to successfully compete with existing or potential competitors despite these disadvantages we may be unable to generate revenues and our business will be harmed.

We compete with pharmaceutical companies, biotechnology companies, academic institutions and research organizations, in developing therapies to prevent or treat infectious and inflammatory diseases. For example, if it is approved in the future, HEPLISAV-B will compete in the U.S. with established hepatitis B vaccines marketed by Merck and GSK and outside the U.S. with vaccines from those companies and several additional established pharmaceutical companies. Competitors may develop more effective, more affordable or more convenient products or may achieve earlier patent protection or commercialization of their products. These competitive products may render our product candidates obsolete or limit our ability to generate revenues from our product candidates.

Existing and potential competitors may also compete with us for qualified scientific and management personnel, as well as for technology that would be advantageous to our business. Although certain of our employees have commercialization experience, as a company we currently have limited sales, marketing and distribution capabilities. Our success in developing marketable products and achieving a competitive position will depend, in part, on our ability to attract and retain qualified personnel. If we do not succeed in attracting new personnel and retaining and motivating existing personnel, our operations may suffer and we may be unable to obtain financing, enter into collaborative arrangements, sell our product candidates or generate revenues.

As we evolve from a company primarily involved in research and development to a company potentially involved in commercialization, we may encounter difficulties in managing our growth and expanding our operations successfully.

If we are successful in advancing HEPLISAV-B through the development stage towards commercialization, we will need to expand our organization, including adding marketing and sales capabilities or contracting with third parties to provide these capabilities for us. As our operations expand, we expect that we will also need to manage additional relationships with various collaborative partners, suppliers and other third parties. Future growth will impose significant added responsibilities on our organization, in particular on management. Our future financial performance and our ability to commercialize HEPLISAV-B and to compete effectively will depend, in part, on our ability to

manage any future growth effectively. To that end, we may not be able to manage our growth efforts effectively, and hire, train and integrate additional management, administrative and sales and marketing personnel, and our failure to accomplish any of these activities could prevent us from successfully growing our company.

If we fail to comply with the extensive requirements applicable to biopharmaceutical manufacturers and marketers under the healthcare fraud laws of the jurisdictions in which we conduct our business, we may be subject to significant liability.

Our activities, and the activities of our agents, including some contracted third parties, are subject to extensive government regulation and oversight both in the U.S. and in foreign jurisdictions. If we obtain approval for and commercialize a vaccine or other product, our interactions with physicians and others in a position to prescribe or purchase our products will be subject to a legal regime designed to prevent healthcare fraud and abuse. Relevant U.S. laws include:

- the Anti-Kickback Statute, which prohibits persons from, among other things, 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, 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;
- federal false claims laws which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, claims for payment to the government or its agents that are false or fraudulent;
- laws that require transparency regarding financial arrangements with health care professionals, such as the reporting and disclosure requirements imposed by the Patient Protection and Affordable Care Act ("PPACA") and state laws; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by state health insurance programs or any third-party payer, including commercial insurers.

The Office of Inspector General for the Department of Health and Human Services, the Department of Justice, states' Attorneys General and other governmental authorities actively enforce the laws and regulations discussed above. These entities also coordinate extensively with the FDA, using legal theories that connect violations of the Federal Food, Drug and Cosmetic Act (such as off-label promotion) to the eventual submission of false claims to government healthcare programs. Prosecution of such promotion cases under the healthcare fraud laws provides the potential for private parties (qui tam relators, or "whistleblowers") to initiate cases on behalf of the government and provides for significantly higher penalties upon conviction.

In the U.S., pharmaceutical and biotechnology companies have been the target of numerous government prosecutions and investigations alleging violations of law, including claims asserting impermissible off-label promotion of pharmaceutical products, payments intended to influence the referral of federal or state health care business, submission of false claims for government reimbursement, or submission of incorrect pricing information.

Violations of any of the laws described above or any other applicable governmental regulations and other similar foreign laws may subject us, our employees or our agents to criminal and/or civil sanctions, including fines, civil monetary penalties, exclusion from participation in government health care programs (including Medicare and Medicaid), and the restriction or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. Additionally, whether or not we have complied with the law, an investigation into alleged unlawful conduct may incur significant expense, cause reputational damage, divert management time and attention, and otherwise adversely affect our business. While we have developed and instituted a corporate compliance program, we cannot guarantee that we, our employees, our consultants, contractors, or other agents are or will be in compliance with all applicable U.S. or foreign laws.

We expect there will continue to be federal and state laws and/or regulations, proposed and implemented, that could impact our operations and business. The extent to which future legislation or regulations, if any, relating to health care fraud abuse laws and/or enforcement, may be enacted or what effect such legislation or regulation would have on our business remains uncertain.

The loss of key personnel, including our Chief Executive Officer, could delay or prevent achieving our objectives.

We depend on our senior executive officers, as well as key scientific and other personnel. Our research, product development and business efforts could be adversely affected by the loss of one or more key members of our scientific or management staff, including our Chief Executive Officer. We currently have no key person insurance on any of our employees.

We face product liability exposure, which, if not covered by insurance, could result in significant financial liability.

While we have not experienced any product liability claims to date, the use of any of our product candidates in clinical trials and the sale of any approved products will subject us to potential product liability claims and may raise questions about a product's safety and efficacy. As a result, we could experience a delay in our ability to commercialize one or more of our product candidates or reduced sales of any approved product candidates. In addition, a product liability claim may exceed the limits of our insurance policies and exhaust our internal resources. We have obtained limited clinical trial liability and umbrella insurance coverage for our clinical trials. This coverage may not be adequate or may not continue to be available in sufficient amounts, at an acceptable cost or at all. We also may not be able to obtain commercially reasonable product liability insurance for any product approved for marketing in the future. A product liability claim, product recalls or other claims, as well as any claims for uninsured liabilities or in excess of insured liabilities, would divert our management's attention from our business and could result in significant financial liability.

We are involved in legal actions that are expensive and time consuming, and, if resolved adversely, could harm our business, financial condition, or results of operations.

Two class action complaints brought by purported stockholders and one purported stockholder derivative complaint have been brought against us. Any negative outcome from such lawsuits could result in payments of monetary damages or fines, or adversely affect our products, and accordingly our business, financial condition, or results of operations could be materially and adversely affected.

There can be no assurance that a favorable final outcome will be obtained in these cases, and defending any lawsuit is costly and can impose a significant burden on management and employees. Any litigation to which we are a party may result in an onerous or unfavorable judgment that may not be reversed upon appeal or in payments of monetary damages or fines not covered by insurance, or we may decide to settle lawsuits on unfavorable terms, which could adversely affect our business, financial conditions, or results of operations.

We use hazardous materials in our business. Any claims or liabilities relating to improper handling, storage or disposal of these materials could be time consuming and costly to resolve.

Our research and product development activities involve the controlled storage, use and disposal of hazardous and radioactive materials and biological waste. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials and certain waste products. We believe we are currently in compliance with all government permits that are required for the storage, use and disposal of these materials. However, we cannot eliminate the risk of accidental contamination or injury to persons or property from these materials. In the event of an accident related to hazardous materials, we could be held liable for damages, cleanup costs or penalized with fines, and this liability could exceed the limits of our insurance policies and exhaust our internal resources. We may have to incur significant costs to comply with future environmental laws and regulations.

Risks Related to our Finances and Capital Requirements

We have incurred substantial losses since inception and do not have any commercial products that generate revenue.

We have experienced significant net losses in each year since our inception. Our accumulated deficit was $502.2 million as of December 31, 2013. To date, our revenue has resulted from collaboration agreements, government and private agency grants and services and license fees from our customers, including the customers of Rhein. We anticipate that we will incur substantial additional net losses in future years as a result of our continuing investment in research and development activities and our addition of infrastructure and operations to support further development and regulatory approval of HEPLISAV-B.

We do not have any products that generate revenue. There can be no assurance whether HEPLISAV-B can be successfully developed, financed or commercialized in a timely manner based on our current plans. The 2013 CRL from the FDA for HEPLISAV-B means that our efforts to achieve product revenues are delayed significantly and there can be no assurance that we will be able to achieve approval or generate meaningful sales without significant additional resources. Our ability to generate revenue depends upon obtaining regulatory approvals for our product candidates, generating product sales and entering into and maintaining successful collaborative relationships.

If we are unable to generate significant revenues or achieve profitability, we may be required to reduce or discontinue our current and planned operations, enter into a transaction that constitutes a change in control of the company or raise additional capital on less than favorable terms.

If we are unable to generate significant revenues or achieve profitability, we will require substantial additional capital to continue development of our product candidates and if our most advanced candidate, HEPLISAV-B, is approved, to commence sales and marketing activities.

To continue development of our product candidates and, if it is approved, to launch HEPLISAV-B, we will need significant additional funds. Addressing this need may occur through strategic alliance and licensing arrangements and/or future public or private financings. We expect to continue to spend substantial funds in connection with:

- development, manufacturing and, if approved, commercialization of our product candidates, particularly HEPLISAV-B;
- various human clinical trials for our product candidates; and
- protection of our intellectual property.

We currently estimate that we have sufficient resources to meet our anticipated cash needs through at least the next 12 months based on cash, cash equivalents and marketable securities on hand as well as anticipated revenues and funding from existing agreements.

Sufficient additional financing through future public or private financings, strategic alliance and licensing arrangements or other financing sources may not be available on acceptable terms or at all. Additional equity financings, if completed, could result in significant dilution or otherwise adversely affect the rights of existing stockholders. If adequate funds are not available in the future, we may need to delay, reduce the scope of, or put on hold the HEPLISAV-B program or other development programs while we seek strategic alternatives.

Risks Related to our Intellectual Property

We rely on licenses to intellectual property from third parties. Impairment of these licenses or our inability to maintain them would severely harm our business.

Our current research and development efforts depend in part upon our license arrangements for intellectual property owned by third parties. Our dependence on these licenses subjects us to numerous risks, such as disputes regarding the use of the licensed intellectual property and the creation and ownership of new discoveries under such license agreements. In addition, these license arrangements require us to make timely payments to maintain our licenses and typically contain diligence or milestone-based termination provisions. Our failure to meet any obligations pursuant to these agreements could allow our licensors to terminate our agreements or undertake other remedies such as converting exclusive to non-exclusive licenses if we are unable to cure or obtain waivers for such failures or amend such agreements on terms acceptable to us. In addition, our license agreements may be terminated or may expire by their terms, and we may not be able to maintain the exclusivity of these licenses. If we cannot obtain and maintain licenses that are advantageous or necessary to the development or the commercialization of our product candidates, we may be required to expend significant time and resources to develop or license similar technology or to find other alternatives to maintaining the competitive position of our products. If such alternatives are not available to us in a timely manner or on acceptable terms, we may be unable to continue development or commercialize our product candidates. In addition, we must make timely payments or meet diligence obligations to maintain any such licenses in effect. In the absence of a current license, we may be required to redesign our technology so it does not infringe a third party’s patents, which may not be possible or could require substantial funds and time.

If third parties successfully assert that we have infringed their patents and proprietary rights or challenge our patents and proprietary rights, we may become involved in intellectual property disputes and litigation that would be costly, time consuming and delay or prevent development or commercialization of our product candidates.

We may be exposed to future litigation by third parties based on claims that our product candidates or proprietary technologies infringe their intellectual property rights, or we may be required to enter into litigation to enforce patents issued or licensed to us or to determine the ownership, scope or validity of our or another party’s proprietary rights,

including a challenge as to the validity of our issued and pending claims. From time to time we are involved in various interference and other administrative proceedings related to our intellectual property which has caused us to incur certain legal expenses. If we become involved in any litigation and/or other significant interference proceedings related to our intellectual property or the intellectual property of others, we will incur substantial additional expenses and it will divert the efforts of our technical and management personnel.

Two of our potential competitors, Merck and GSK, are exclusive licensees of broad patents covering methods of production of recombinant HBsAg, a component of HEPLISAV-B. In addition, the Institut Pasteur also owns or has exclusive licenses to patents relating to aspects of production of recombinant HBsAg. While some of these patents have expired or will soon expire outside the U.S., they remain in force in the U.S. To the extent we are able to commercialize HEPLISAV-B in the U.S. while these patents remain in force, Merck, GSK or their respective licensors or the Institut Pasteur may bring claims against us.

If we or our collaborators are unsuccessful in defending or prosecuting our issued and pending claims or in defending potential claims against our products, for example, as may arise in the commercialization of HEPLISAV-B or any similar product candidate, we or our collaborator could be required to pay substantial damages or be unable to commercialize our product candidates or use our proprietary technologies without a license from such third party. A license may require the payment of substantial fees or royalties, require a grant of a cross-license to our technology or may not be available on acceptable terms, if at all. Any of these outcomes could require us to change our business strategy and could materially impact our business and operations.

One of our potential competitors, Pfizer, has issued patent claims, as well as patent claims pending with the PTO and foreign patent offices, that may be asserted against our TLR agonist products and our TLR inhibitor products. We may need to obtain a license to one or more of these patent claims held by Pfizer by paying fees or royalties or offering rights to our own proprietary technologies to commercialize one or more of our formulations other than with respect to HEPLISAV-B, for which we have a license. A license for other uses may not be available to us on acceptable terms, if at all, which could preclude or limit our ability to commercialize our products.

If the combination of patents, trade secrets and contractual provisions that we rely on to protect our intellectual property is inadequate, the value of our product candidates will decrease.

Our success depends on our ability to:

- obtain and protect commercially valuable patents or the rights to patents both domestically and abroad;
- operate without infringing upon the proprietary rights of others; and
- prevent others from successfully challenging or infringing our proprietary rights.

We will be able to protect our proprietary rights from unauthorized use only to the extent that these rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. We try to protect our proprietary rights by filing and prosecuting U.S. and foreign patent applications. However, in certain cases such protection may be limited, depending in part on existing patents held by third parties, which may only allow us to obtain relatively narrow patent protection. In the U.S., legal standards relating to the validity and scope of patent claims in the biopharmaceutical field can be highly uncertain, are still evolving and involve complex legal and factual questions for which important legal principles remain unresolved.

The biopharmaceutical patent environment outside the U.S. is even more uncertain. We may be particularly affected by this uncertainty since several of our product candidates may initially address market opportunities outside the U.S., where we may only be able to obtain limited patent protection.

The risks and uncertainties that we face with respect to our patents and other proprietary rights include the following:

- we may not receive an issued patent for any of our patent applications or for any patent applications that we have exclusively licensed;
- the pending patent applications we have filed or to which we have exclusive rights may take longer than we expect to result in issued patents;
- the claims of any patents that are issued may not provide meaningful protection or may not be valid or enforceable;
- we might not be able to develop additional proprietary technologies that are patentable;
- the patents licensed or issued to us or our collaborators may not provide a competitive advantage;
- patents issued to other parties may limit our intellectual property protection or harm our ability to do business;
- other parties may independently develop similar or alternative technologies or duplicate our technologies and commercialize discoveries that we attempt to patent; and
- other parties may design around technologies we have licensed, patented or developed.

We also rely on trade secret protection and confidentiality agreements to protect our interests in proprietary know-how that is not patentable and for processes for which patents are difficult to enforce. We cannot be certain that we will be

able to protect our trade secrets adequately. Any disclosure of confidential data in the public domain or to third parties could allow our competitors to learn our trade secrets. If we are unable to adequately obtain or enforce proprietary rights we may be unable to commercialize our products, enter into collaborations, generate revenues or maintain any advantage we may have with respect to existing or potential competitors.

Risks Related to an Investment in our Common Stock

Our stock price is subject to volatility, and your investment may suffer a decline in value.

The market prices for securities of biopharmaceutical companies have in the past been, and are likely to continue in the future, to be, very volatile. The market price of our common stock is subject to substantial volatility depending upon many factors, many of which are beyond our control, including:

- progress or results of any of our clinical trials or regulatory or manufacturing efforts, in particular any announcements regarding the progress or results of our planned trials and communications from the FDA or other regulatory agencies;
- our ability to establish and maintain collaborations for the development and commercialization of our product candidates;
- our ability to raise additional capital to fund our operations;
- technological innovations, new commercial products or drug discovery efforts and preclinical and clinical activities by us or our competitors;
- changes in our intellectual property portfolio or developments or disputes concerning the proprietary rights of our products or product candidates;
- our ability to obtain component materials and successfully enter into manufacturing relationships for our product candidates or establish manufacturing capacity on our own;
- our ability to establish and maintain licensing agreements for intellectual property necessary for the development of our product candidates;
- changes in government regulations, general economic conditions or industry announcements;
- issuance of new or changed securities analysts' reports or recommendations;
- actual or anticipated fluctuations in our quarterly financial and operating results;
- our ability to maintain continued listing on the NASDAQ markets or similar exchanges; and
- the volume of trading in our common stock.

One or more of these factors could cause a substantial decline in the price of our common stock. In addition, securities class action litigation has often been brought against a company following a decline in the market price of its securities. We are currently the target of such securities litigation, resulting from the decline in our common stock following the disclosure in 2013 that the FDA would not approve HEPLISAV-B for sale without a significant additional clinical study. We may in the future be the target of additional such litigation. Securities litigation could result in substantial costs, and divert management's attention and resources, which could harm our business, operating results and financial condition.

The anti-takeover provisions of our certificate of incorporation, our bylaws, Delaware law and our share purchase rights plan may prevent or frustrate a change in control, even if an acquisition would be beneficial to our stockholders, which could affect our stock price adversely and prevent attempts by our stockholders to replace or remove our current management.

Provisions of our certificate of incorporation and bylaws may delay or prevent a change in control, discourage bids at a premium over the market price of our common stock and adversely affect the market price of our common stock and the voting or other rights of the holders of our common stock. These provisions include:

- authorizing our Board of Directors to issue additional preferred stock with voting rights to be determined by the Board of Directors;
- limiting the persons who can call special meetings of stockholders;
- prohibiting stockholder actions by written consent;
- creating a classified board of directors pursuant to which our directors are elected for staggered three year terms;
- providing that a supermajority vote of our stockholders is required for amendment to certain provisions of our certificate of incorporation and bylaws; and

· establishing advance notice requirements for nominations for election to our Board of Directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

Our share purchase rights plan may have certain anti-takeover effects. Specifically, the rights issued pursuant to the plan will cause substantial dilution to a person or group that attempts to acquire the Company on terms not approved by our Board of Directors. Although the rights should not interfere with any merger or other business combination approved by the Board of Directors since the rights issued may be amended to permit such acquisition or redeemed by the Company at $0.001 per right prior to the earliest of (i) the time that a person or group has acquired beneficial ownership of 20% or more of our common stock or (ii) the final expiration date of the rights, the effect of the rights plan may deter a potential acquisition of the Company. In addition, we remain subject to the provisions of the Delaware corporation law that, in general, prohibit any business combination with a beneficial owner of 15% or more of our common stock for three years unless the holder's acquisition of our stock was approved in advance by our Board of Directors.

We will continue to incur increased costs and demands upon management as a result of complying with the laws and regulations affecting public companies, which could affect our operating results.

As a public company, we will continue to incur legal, accounting and other expenses associated with reporting requirements and corporate governance requirements, including requirements under the Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, as well as new rules implemented by the Securities and Exchange Commission and the NASDAQ Stock Market LLC. We may need to continue to implement additional financial and accounting systems, procedures and controls to accommodate changes in our business and organization and to comply with new reporting requirements. There can be no assurance that we will be able to maintain a favorable assessment as to the adequacy of our internal control over financial reporting. If we are unable to reach an unqualified assessment, or our independent registered public accounting firm is unable to issue an unqualified attestation as to the effectiveness of our internal control over financial reporting as of the end of our fiscal year, investors could lose confidence in the reliability of our financial reporting which could harm our business and could impact the price of our common stock.

Future sales of our common stock or the perception that such sales may occur 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. As of December 31, 2013, we had 262,796,285 shares of common stock outstanding, all of which shares were eligible for sale in the public market, subject in some cases to the volume limitations and manner of sale requirements under Rule 144 of the Securities Act of 1933, as amended.

In addition, we have filed shelf registration statements on Form S-3 under the Securities Act of 1933, as amended, to register securities that we may choose to issue in the future and on Form S-8 to register the shares of our common stock reserved for issuance under our stock option plans.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

As of December 31, 2013, we leased approximately 55,200 square feet of laboratory and office space in Berkeley, California under agreements expiring in June 2018. We also lease approximately 5,600 square meters of laboratory and office space in Düsseldorf, Germany under lease agreements expiring in March 2023.

ITEM 3. LEGAL PROCEEDINGS

From time to time in the ordinary course of business, we receive claims or allegations regarding various matters, including employment, vendor and other similar situations in the conduct of our operations.

On June 18, 2013, the first of two substantially similar securities class action complaints was filed in the U.S. District Court for the Northern District of California against the Company and certain of its former executive officers. The second was filed on June 26, 2013. On August 22, 2013, these two complaints and all related actions that subsequently may be filed in, or transferred to, the District Court were consolidated into a single case entitled In re Dynavax Technologies Securities Litigation. On September 27, 2013, the Court appointed a lead plaintiff and lead counsel. On November 12, 2013, the Lead Plaintiff in the In re Dynavax Technologies Securities Litigation filed his Consolidated Class Action Complaint ("Complaint"). The Complaint alleges that between April 26, 2012 and June 10, 2013, the Company and certain current and former officers and directors violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, in connection with statements related to our product candidate, HEPLISAV. The Complaint seeks unspecified damages, interest, attorneys' fees, and other costs. On January 10, 2014, the Company filed a motion to dismiss the Complaint. The hearing on the motion is set for May 2, 2014.

Additionally, on July 3, 2013, a purported stockholder derivative complaint was filed in the Superior Court of California for the County of Alameda against certain of our former and current directors. On August 9, 2013, a substantially similar purported stockholder derivative complaint was filed in the U.S. District Court for the Northern District of California. The derivative complaint alleges breaches of fiduciary duties by the defendants and other violations of law. In general, the complaints allege that certain of our current and former executive officers and directors caused or allowed for the dissemination of materially false and misleading statements regarding our product, HEPLISAV-B. Plaintiff is seeking unspecified monetary damages, including restitution from defendants and attorneys' fees and costs, and other relief.

On August 21, 2013, pursuant to a stipulation between the parties, the State Court stayed the state derivative case pending a decision on the Company's motion to dismiss in the In re Dynavax Technologies Securities Litigation. On October 17, 2013, pursuant to a stipulation between the parties, the federal court stayed the federal derivative case pending a decision on the Company's motion to dismiss in the In re Dynavax Technologies Securities Litigation.

The Company believes that it has meritorious defenses and intends to defend these lawsuits vigorously.

ITEM 4. MINE SAFETY DISCLOSURE

Not applicable.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information and Holders

Our common stock is traded on the NASDAQ Capital Market under the ticker symbol DVAX. Public trading of our common stock commenced on February 19, 2004. The following table sets forth for the periods indicated the high and low intra-day sale prices per share of our common stock.

	Common Stock Price	
	High	Low
2013		
First Quarter	$3.39	$1.74
Second Quarter	$2.68	$0.98
Third Quarter	$1.46	$1.02
Fourth Quarter	$2.05	$1.10
2012		
First Quarter	$5.08	$3.24
Second Quarter	$5.34	$3.33
Third Quarter	$4.99	$3.48
Fourth Quarter	$5.10	$2.22

As of February 28, 2014, there were approximately 84 holders of record of our common stock, as shown on the records of our transfer agent. We believe that our stockholders exceed 14,200 as the number of record holders excludes shares held in "street name" through brokers.

Dividends

We have never paid any cash dividends on our common stock. We currently expect to retain future earnings, if any, for use in the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future.

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

(a)	(c) Total Number of Shares	(d) Maximum Number (or Approximate Dollar Value) of Shares (or Units) that

Period	Total Number of Shares (or Units) Purchased[1] (In thousands)	(b) Average Price Paid per Share (or Unit)	(or Units) Purchased as Part of Publicly Announced Plans or Programs	May Yet Be Purchased Under the Plans or Programs
October 1, 2013 to October 31, 2013	-	$ -	-	-
November 1, 2013 to November 30, 2013	-	-	-	-
December 1, 2013 to December 31, 2013	-	-	-	-
Total	-	$ -	-	-

(1) During the 3 months ended December 31, 2013, no securities were purchased by the Company.

ITEM 6. SELECTED FINANCIAL DATA

The following selected financial data should be read in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations, and with the Consolidated Financial Statements and Notes thereto which are included elsewhere in this Form 10-K. The Consolidated Statements of Operations Data for the years ended December 31, 2013, 2012 and 2011 and the Consolidated Balance Sheets Data as of December 31, 2013 and 2012 are derived from the audited Consolidated Financial Statements included elsewhere in this Form 10-K. The Consolidated Statements of Operations Data for the years ended December 31, 2010 and 2009 and the Consolidated Balance Sheets Data as of December 31, 2011, 2010 and 2009 are derived from audited Consolidated Financial Statements that are not included in this Form 10-K. Historical results are not necessarily indicative of results to be anticipated in the future.

	Year Ended December 31,				
	2013	2012	2011	2010	2009
	(In thousands, except per share data)				
Consolidated Statements of Operations Data:					
Total revenues	$11,251	$9,714	$21,614	$23,950	$40,318
Operating expenses:					
Research and development	50,870	49,146	51,322	53,680	38,708
General and administrative	25,943	28,164	17,570	16,879	15,745
Unoccupied facility expense	926	-	-	-	-
Amortization of intangible assets	-	-	299	980	980
Total operating expenses	77,739	77,310	69,191	71,539	55,433
Loss from operations	(66,488)	(67,596)	(47,577)	(47,589)	(15,115)
Other income (expense):					
Interest income	116	291	103	85	178
Interest expense	-	(2,351)	(1,957)	(1,654)	(124)
Other income (expense)[1]	(348)	(293)	834	(8,150)	(66)
Net loss	(66,720)	(69,949)	(48,597)	(57,308)	(15,127)
Consideration paid in excess of carrying value of the noncontrolling interest in Symphony Dynamo, Inc. ("SDI")[2]	-	-	-	-	(19,671)
Add: Losses attributable to noncontrolling interest in SDI	-	-	-	-	4,233
Net loss attributable to Dynavax	(66,720)	(69,949)	(48,597)	(57,308)	(30,565)
Preferred stock deemed dividend[3]	(8,469)	-	-	-	-
Net loss allocable to Dynavax common stockholders	$(75,189)	$(69,949)	$(48,597)	$(57,308)	$(30,565)
Basic and diluted net loss per share allocable to Dynavax common stockholders	$(0.38)	$(0.41)	$(0.39)	$(0.69)	$(0.76)
Shares used to compute basic and diluted net loss per share allocable to Dynavax common stockholders	196,275	170,469	125,101	82,463	40,350

(1) Includes the impact of the anti-dilution provision associated with the common stock and warrants issued to Symphony Capital Partners, L.P. and Symphony Strategic Partners, LLC (collectively, "Symphony") and the change in fair value of the Symphony-related long-term contingent and warrant liabilities for the year ended December 31, 2010. See Note 8 to the Consolidated Financial Statements.

(2) Represents the consideration paid in excess of the carrying value of the noncontrolling interest in SDI that was treated as a deemed dividend for purposes of reporting earnings per share, increasing net loss per share for the year ended December 31, 2009. See Note 8 to the Consolidated Financial Statements.

(3) Deemed dividend related to beneficial conversion feature of convertible preferred stock. The fair value of the common stock into which the Series B Preferred Stock is convertible exceeded the allocated purchase price of the

Series B Preferred Stock by $8.5 million on the date of issuance, resulting in a deemed dividend. The Company recognized the deemed dividend as a one-time, non-cash, deemed dividend to the holders of Series B Preferred Stock on the date of issuance, which is the date the stock first became convertible.

	December 31,				
	2013	2012	2011	2010	2009
	(In thousands)				
Consolidated Balance Sheets Data:					
Cash, cash equivalents and marketable securities	$189,376	$125,130	$113,961	$72,154	$36,720
Working capital	176,186	109,173	97,399	60,598	24,583
Total assets	204,622	139,752	134,102	84,249	50,470
Note payable to Symphony Dynamo Holdings LLC[(1)]	-	-	12,810	10,939	9,342
Accumulated deficit	(502,211)	(435,491)	(365,542)	(316,945)	(259,637)
Total Dynavax stockholders' equity	186,294	114,826	99,880	52,111	6,376

(1) The note payable to Symphony Dynamo Holdings LLC ("Holdings") was paid in cash on December 31, 2012.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following Management's Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements that involve a number of risks and uncertainties. Our actual results could differ materially from those indicated by forward-looking statements as a result of various factors, including but not limited to, the period for which we estimate our cash resources are sufficient, the availability of additional funds, as well as those set forth under "Risk Factors" and those that may be identified from time to time in our reports and registration statements filed with the Securities and Exchange Commission.

The following discussion and analysis is intended to provide an investor with a narrative of our financial results and an evaluation of our financial condition and results of operations. The discussion should be read in conjunction with "Item 6—Selected Financial Data" and the Consolidated Financial Statements and the related notes thereto set forth in "Item 8—Financial Statements and Supplementary Data."

Overview

Dynavax Technologies Corporation ("we," "our," "us," "Dynavax" or the "Company"), a clinical-stage biopharmaceutical company, develops products to prevent and treat infectious and inflammatory diseases and cancer based on Toll-like Receptor ("TLR") biology and its ability to modulate the innate immune system. Our lead product candidate is HEPLISAV-B™ (also known as "HEPLISAV"), an investigational adult hepatitis B vaccine in Phase 3 clinical development. HEPLISAV-B combines our proprietary TLR 9 agonist adjuvant and hepatitis B surface antigen ("HBsAg") to elicit an immune response after two doses. In the spring of 2014 we expect to initiate a Phase 3 study of HEPLISAV-B compared with Engerix-B® in adults 18-70 years of age in order to provide a sufficiently-sized safety database for the U.S. Food and Drug Administration ("FDA") to complete its review of Dynavax's Biologics License Application ("BLA").

In addition to HEPLISAV-B, we are conducting clinical and preclinical programs that utilize our expertise in TLR biology. Our product candidates include both TLR agonists and TLR inhibitors. Our clinical stage programs include our autoimmune program partnered with GlaxoSmithKline ("GSK"), our asthma therapeutic program partnered with AstraZeneca AB ("AstraZeneca"), and our cancer immunotherapy program. We also are advancing preclinical development programs in adjuvant technology and TLR 7, 8, and 9 inhibition. We compete with pharmaceutical companies, biotechnology companies, academic institutions and research organizations in developing therapies to prevent or treat infectious and inflammatory diseases and cancer.

Our revenues consist of amounts earned from collaborations, grants and fees from services and licenses. Product revenue will depend on our ability to receive regulatory approvals for, and successfully market, our drug candidates. We have yet to generate any revenues from product sales and have recorded an accumulated deficit of $502.2 million at December 31, 2013. These losses have resulted principally from costs incurred in connection with research and development activities, compensation and other related personnel costs and general corporate expenses. Research and development activities include costs of outside contracted services including clinical trial costs, manufacturing and process development costs, research costs and other consulting services. Salaries and other personnel-related costs include non-cash stock-based compensation associated with options and other equity awards granted to employees. General corporate expenses include outside services such as accounting, consulting, business development, investor relations, insurance services and legal costs. Our operating results may fluctuate substantially from period to period principally as a result of the timing of preclinical activities and other activities related to clinical trials for our drug candidates.

As of December 31, 2013, we had $189.4 million in cash, cash equivalents and marketable securities. Since our inception, we have relied primarily on the proceeds from public and private sales of our equity securities and revenues from collaboration agreements to fund our operations. We expect to continue to spend substantial funds in connection with the development and manufacturing of our product candidates, particularly HEPLISAV-B, human clinical trials for our product candidates and additional applications and advancement of our technology. In order to continue these activities, we may need to raise additional funds. This may occur through strategic alliance and licensing arrangements and/or future public or private financings. If adequate funds are not available in the future, we may need to delay, reduce the scope of or put on hold the HEPLISAV-B program or other development programs while we seek strategic alternatives.

Recent Developments

On February 25, 2013, we received a complete response letter ("CRL") from the FDA indicating that it would not approve HEPLISAV-B for the indication proposed in our BLA. Following extensive discussions with the FDA, we finalized the design of an additional clinical study of HEPLISAV-B that is intended to provide a sufficiently-sized safety database for the FDA to complete its review of our BLA and make a final determination regarding the safety and immunogenicity of the product. The planned study will be a Phase 3, observer-blinded, randomized, active-controlled, multicenter trial of the safety and immunogenicity of HEPLISAV-B compared with Engerix-B in adults 18 to 70 years of age. The study will include 5,500 HEPLISAV-B subjects and 2,500 Engerix-B subjects, stratified by age and diabetes diagnosis. HEPLISAV-B subjects will receive two doses at 0 and 1 month, while Engerix-B subjects will receive three doses at 0, 1 and 6 months.

The primary objectives of the study will be: (1) to evaluate the overall safety of HEPLISAV-B with respect to clinically significant adverse events and (2) to demonstrate the noninferiority of the peak seroprotection rate ("SPR") induced by HEPLISAV-B versus Engerix-B in subjects with type 2 diabetes mellitus. All HEPLISAV-B subjects will be evaluated for safety for one year following the second dose, all potential autoimmune events will be adjudicated by a Safety Evaluation and Adjudication Committee and safety will be monitored by a Data and Safety Monitoring Board. We intend to initiate this study in the first quarter of 2014 and conclude subject visits by the end of 2015. We estimate the external costs of the study to be in the range of $50-55 million.

We submitted our Marketing Authorization Application ("MAA") for HEPLISAV-B to the European Medicines Agency's ("EMA") in July of 2012. In late 2012 we received the Day 120 List of Questions issued by the Committee for Medicinal Products for Human Use of the EMA regarding our MAA, which related primarily to the suitability of different patient populations, the safety database size, and Good Manufacturing Practices ("GMP") and Good Clinical Practices ("GCP") matters. In the early summer of 2013, EMA added to the list of questions, resetting the clock for our response. EMA also inspected several study sites, Dynavax and our clinical contract research organization. The focus of the GCP inspection was HBV-17, a 500 patient study in CKD patients that is part of the EMA application but not the U.S. application. In the fourth quarter of 2013, we submitted our responses to the 120-Day Questions. The Day 180 List of Outstanding Issues ("LOI") provided by the EMA in February 2014 indicated that, based primarily on the GCP inspection findings, HBV-17 was not acceptable and because some of the findings were related to the Dynavax's overall systems, the other pivotal HEPLISAV-B studies (HBV-10 and HBV-16) were questioned. The LOI also noted that the HEPLISAV-B safety database was considered to be too small to rule out a risk of less common serious adverse events, particularly in light of the GCP concerns. On February 18, 2014 we announced the withdrawal of the MAA for HEPLISAV-B under review by the EMA. We withdrew the application, in part, because the required time frame for response under the MAA procedure was not long enough to permit the collection of the necessary clinical data. The Phase 3 study to be initiated in the U.S. in 2014 is expected to provide additional data to support the safety of HEPLISAV-B.

Critical Accounting Policies and the Use of Estimates

The accompanying discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements and the related disclosures, which have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of these financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the balance sheet dates and the reported amounts of revenues and expenses for the periods presented. On an ongoing basis, we evaluate our estimates, assumptions and judgments described below that have the greatest potential impact on our consolidated financial statements, including those related to revenue recognition, research and development activities and stock-based compensation. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Accounting assumptions and estimates are inherently uncertain and actual results may differ materially from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 to the Consolidated Financial Statements, we believe the following critical accounting policies reflect the more significant judgments and estimates used in the preparation of our financial statements.

Revenue Recognition

Our revenues consist of amounts earned from collaborations, grants and fees from services and licenses. We enter into license and manufacturing agreements and collaborative research and development arrangements with pharmaceutical and biotechnology partners that may involve multiple deliverables. Our arrangements may include one or more of the following elements: upfront license payments, cost reimbursement for the performance of research and development activities, milestone payments, other contingent payments, contract manufacturing service fees, royalties and license fees. Each deliverable in the arrangement is evaluated to determine whether it meets the criteria to be accounted for as a separate unit of accounting or whether it should be combined with other deliverables. In order to account for the multiple-element arrangements, the Company identifies the deliverables included within the arrangement and evaluates which deliverables represent separate units of accounting. Analyzing the arrangement to identify deliverables requires the use of judgment, and each deliverable may be an obligation to deliver services, a right or license to use an asset, or another performance obligation. We recognize revenue when there is persuasive evidence that an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable and collectability is reasonably assured.

On January 1, 2011, we adopted on a prospective basis Financial Accounting Standards Board (“FASB”) Accounting Standards Update (“ASU”) 2009-13, Multiple-Deliverable Revenue Arrangements, which amends the criteria related to identifying separate units of accounting and provides guidance on whether multiple deliverables exist, how an arrangement should be separated and the consideration allocated.

Non-refundable upfront fees received for license and collaborative agreements entered into prior to January 1, 2011 and other payments under collaboration agreements where we have continuing performance obligations related to the payments are deferred and recognized over our expected performance period. Revenue is recognized on a ratable basis, unless we determine that another method is more appropriate, through the date at which our performance obligations are completed. Management makes its best estimate of the period over which we expect to fulfill our performance obligations, which may include clinical development activities. Given the uncertainties of research and development collaborations, significant judgment is required to determine the duration of the performance period. We recognize cost reimbursement revenue under collaborative agreements as the related research and development costs are incurred, as provided for under the terms of these agreements.

Under the milestone method, contingent consideration received for the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved. A milestone is defined as an event having all of the following characteristics: (i) there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved, (ii) the event can only be achieved based in whole or in part on either the entity’s performance or a specific outcome resulting from the entity’s performance and (iii) if achieved, the event would result in additional payments being due to the entity.

Our license and collaboration agreements with our partners provide for payments to be paid to us upon the achievement of development milestones. Given the challenges inherent in developing biologic products, there is substantial uncertainty whether any such milestones will be achieved at the time we entered into these agreements. In addition, we evaluate whether the development milestones meet the criteria to be considered substantive. The conditions include: (i) the development work is contingent on either of the following: (a) the vendor’s performance to achieve the milestone or (b) the enhancement of the value of the deliverable item or items as a result of a specific outcome resulting from the vendor’s performance to achieve the milestone; (ii) it relates solely to past performance and (iii) it is reasonable relative to all the deliverable and payment terms within the arrangement. As a result of our analysis, we consider our development milestones to be substantive and, accordingly, we expect to recognize as revenue future payments received from such milestones as we achieve each milestone.

Milestone payments that are contingent upon the achievement of substantive at-risk performance criteria are recognized in full upon achievement of those milestone events in accordance with the terms of the agreement and

assuming all other revenue recognition criteria have been met. All revenue recognized to date under our collaborative agreements has been nonrefundable.

Our license and collaboration agreements with certain partners also provide for contingent payments to be paid to us based solely upon the performance of our partner. For such contingent payments we expect to recognize the payments as revenue upon receipt and when the other revenue recognition criteria have been satisfied.

Revenues from manufacturing services are recognized upon meeting the criteria for substantial performance and acceptance by the customer.

Revenue from royalty payments is contingent on future sales activities by our licensees. As a result, we recognize royalty revenue when reported by our licensees and when collection is reasonably assured.

Revenue from government and private agency grants are recognized as the related research expenses are incurred and to the extent that funding is approved. Additionally, we recognize revenue based on the facilities and administrative cost rate reimbursable per the terms of the grant awards.

Research and Development Expenses and Accruals

Research and development expenses include personnel and facility-related expenses, outside contracted services including clinical trial costs, manufacturing and process development costs, research costs and other consulting services and non-cash stock-based compensation. Research and development costs are expensed as incurred. Amounts due under such arrangements may be either fixed fee or fee for service, and may include upfront payments, monthly payments and payments upon the completion of milestones or receipt of deliverables. Non-refundable advance payments under agreements are capitalized and expensed as the related goods are delivered or services are performed.

We contract with third parties to perform various clinical trial activities in the on-going development of potential products. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows to our vendors. Payments under the contracts depend on factors such as the achievement of certain events, successful enrollment of patients, completion of portions of the clinical trial or similar conditions. Our accruals for clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with clinical trial centers and clinical research organizations. We may terminate these contracts upon written notice and we are generally only liable for actual effort expended by the organizations to the date of termination, although in certain instances we may be further responsible for termination fees and penalties. The Company makes estimates of its accrued expenses as of each balance sheet date based on the facts and circumstances known to the Company at that time. There have been no material adjustments to the Company’s prior period accrued estimates for clinical trial activities through December 31, 2013.

Stock-Based Compensation

Stock-based compensation expense for stock options and other stock awards is estimated at the grant date based on the award’s fair value-based measurement and is recognized on a straight-line basis over the award’s vesting period, assuming appropriate forfeiture rates. Our determination of the fair value-based measurement of stock options on the date of grant using an option-pricing model is affected by our stock price, as well as assumptions regarding a number of highly complex and subjective variables. These variables include, but are not limited to, our expected stock price volatility over the term of the awards, and actual and projected employee stock option exercise behaviors. In the future, as additional empirical evidence regarding these input estimates becomes available, we may change or refine our approach of deriving these input estimates. These changes could impact our fair value-based measurement of stock options granted in the future. Changes in the fair value-based measurement of stock awards could materially impact our operating results.

We selected the Black-Scholes option pricing model as the most appropriate method for determining the estimated fair value-based measurement of our stock options. The Black-Scholes model requires the use of highly subjective and complex assumptions which determine the fair value-based measurement of stock options, including the option’s expected term and the price volatility of the underlying stock. Our current estimate of volatility is based on the historical volatility of our stock price. To the extent volatility in our stock price increases in the future, our estimates of the fair value of options granted in the future could increase, thereby increasing stock-based compensation cost recognized in future periods. We derive the expected term assumption primarily based on our historical settlement experience, while giving consideration to options that have not yet completed a full life cycle. Stock-based compensation cost is recognized only for awards ultimately expected to vest. Our estimate of the forfeiture rate is based primarily on our historical experience. To the extent we revise this estimate in the future, our share-based compensation cost could be materially impacted in the quarter of revision, as well as in the following quarters.

Results of Operations

Revenues

Revenues consist of amounts earned from collaborations, grants and services and license fees. Collaboration revenue includes amounts recognized under our collaboration agreements. Grant revenue includes amounts earned under government and private agency grants. Service and license fees include revenues related to research and development and contract manufacturing services, license fees and royalty payments.

The following is a summary of our revenues for the years ended December 31, 2013, 2012 and 2011 (in thousands, except for percentages):

	Year Ended December 31,			Increase (Decrease) from 2012 to 2013		Increase (Decrease) from 2011 to 2012	
Revenues:	2013	2012	2011	$	%	$	%
Collaboration revenue	$4,929	$4,610	$17,190	$ 319	7 %	$(12,580)	(73)%
Grant revenue	5,138	3,939	3,110	1,199	30 %	829	27 %
Service and license revenue	1,184	1,165	1,314	19	2 %	(149)	(11)%
Total revenues	$11,251	$9,714	$21,614	$ 1,537	16 %	$(11,900)	(55)%

2013 versus 2012

Total revenues for the year ended December 31, 2013, increased by $1.5 million, or 16%, as compared to the same period in 2012 principally due to an increase in grant revenue. Grant revenue for the year ended December 31, 2013, increased by $1.2 million from the same period in 2012 primarily due to an increase in revenue recognized from our National Institute of Health's National Institute of Allergy and Infectious Diseases ("NIAID") contract for adjuvant development and other programs funded by grants.

2012 versus 2011

Total revenues for the year ended December 31, 2012, decreased by $11.9 million, or 55%, as compared to the same period in 2011 primarily due to a reduction in collaboration revenue. Collaboration revenue for the year ended December 31, 2012, included $3.2 million earned from our partnership with AstraZeneca for work on asthma therapies, compared to $0.8 million earned for the year ended December 31, 2011. Additionally, total collaboration revenue for the year ended December 31, 2011, included recognition of $15 million from GSK for milestones earned in 2011. Grant revenue for the year ended December 31, 2012, increased by $0.8 million from the same period in 2011 primarily due to an increase in revenue recognized from our NIAID contract related to adjuvant development.

Research and Development

Research and development expense consists primarily of compensation and related personnel costs, which include benefits, recruitment, travel and supply costs, outside services, allocated facility costs and non-cash stock-based compensation. Outside services relate to our preclinical experiments and clinical trials, regulatory filings and manufacturing of our product candidates. For the years ended December 31, 2013, 2012 and 2011, approximately 73%, 73% and 79%, respectively, of our total research and development expense, excluding non-cash stock-based compensation, is related to our lead product candidate, HEPLISAV-B. The remainder of our research and development expense results primarily from earlier-stage programs. The following is a summary of our research and development expense (in thousands, except for percentages):

	Year Ended December 31,	Increase (Decrease) from 2012 to 2013	Increase (Decrease) from 2011 to 2012

Research and Development:	2013	2012	2011	$	%	$	%
Compensation and related personnel costs	$20,649	$21,134	$19,106	$(485)	(2)%	$2,028	11 %
Outside services	20,247	19,371	24,811	876	5 %	(5,440)	(22)%
Facility costs	5,746	5,127	5,302	619	12%	(175)	(3)%
Non-cash stock-based compensation	4,228	3,514	2,103	714	20%	1,411	67 %
Total research and development	$50,870	$49,146	$51,322	$1,724	4 %	$(2,176)	(4)%

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2013 versus 2012

Research and development expense for the year ended December 31, 2013, increased by $1.7 million, or 4%, as compared to 2012. Outside services increased by $0.9 million compared to 2012 primarily due to additional development work related to our adjuvant studies and collaboration with AstraZeneca. Facility costs increased by $0.6 million compared to 2012 primarily due to repairs and maintenance of our manufacturing facility and depreciation on recently purchased manufacturing equipment. Non-cash stock-based compensation expense increased by $0.7 million due to accelerated vesting of stock options and modifications of stock options related to management continuity and severance agreements. Compensation and related personnel costs decreased by $0.5 million primarily due to a decrease in employee headcount.

2012 versus 2011

Research and development expense for the year ended December 31, 2012, decreased by $2.2 million, or 4%, as compared to 2011. The decrease in costs was primarily due to the decline in outside services during 2012 as compared to 2011 due to lower HEPLISAV-B clinical trial expenses, partially offset by an increase in compensation and related personnel costs, including non-cash stock-based compensation, from an increase in employee headcount and related expense incurred for option grants.

General and Administrative

General and administrative expense consists primarily of compensation and related personnel costs; outside services such as accounting, consulting, business development, investor relations and insurance services; legal costs that include corporate and patent-related expenses; allocated facility costs and non-cash stock-based compensation.

The following is a summary of our general and administrative expenses (in thousands, except for percentages):

	Year Ended December 31,			Increase (Decrease) from 2012 to 2013		Increase (Decrease) from 2011 to 2012	
General and Administrative:	2013	2012	2011	$	%	$	%
Compensation and related personnel costs	$10,521	$9,468	$7,398	$1,053	11 %	$2,070	28 %
Outside services	4,319	8,730	4,548	(4,411)	(51)%	4,182	92 %
Legal costs	2,361	2,437	1,894	(76)	(3)%	543	29 %
Facility costs	630	604	644	26	4 %	(40)	(6)%
Non-cash stock-based compensation	8,112	6,925	3,086	1,187	17 %	3,839	124 %
Total general and administrative	$25,943	$28,164	$17,570	$(2,221)	(8)%	$10,594	60 %

2013 versus 2012

General and administrative expenses for the year ended December 31, 2013, decreased by $2.2 million, or 8%, compared to the same period in 2012. Outside services expense decreased $4.4 million due to reduced marketing expenses. Compensation costs and non-cash stock-based compensation increased due to severance expense and other one-time compensation costs as well as accelerated vesting of stock options related to the transition of our former Chief Executive Officer and certain other employees and executive officers.

2012 versus 2011

General and administrative expenses for the year ended December 31, 2012, increased by $10.6 million, or 60%, compared to the same period in 2011. This increase is primarily due to higher legal and outside costs, including

consulting costs for corporate development activities and market research for HEPLISAV-B. Compensation costs and non-cash stock-based compensation increased due to growth in the number of administrative employees to support the organization and an amended management continuity and severance agreement with one of our executive officers.

Amortization of Intangible Assets

Intangible assets consisted of the manufacturing process and customer relationships resulting from our April 2006 acquisition of Rhein and were amortized over five years from the date of acquisition through the second quarter of 2011. Amortization of intangible assets was $0.3 million for the year ended December 31, 2011.

Interest Income, Interest Expense and Other Income (Expense)

Interest income is reported net of amortization of premiums and discounts on marketable securities, realized gains and losses on investments, and fees related to investment portfolio management. Interest expense in 2012 was related to the $15 million note payable held by Symphony Dynamo Holdings LLC ("Holdings"), which was paid in cash on December 31, 2012. Other expense includes gains and losses on foreign currency transactions as well as gains and losses on disposals of property and equipment.

The following is a summary of our interest income, interest expense and other income (expense) (in thousands, except for percentages):

	Year Ended December 31,			Increase (Decrease) from 2012 to 2013		Increase (Decrease) from 2011 to 2012	
	2013	2012	2011	$	%	$	%
Interest income	$116	$291	$103	$(175)	(60)%	$188	183 %
Interest expense	$-	$(2,351)	$(1,957)	$(2,351)	(100)%	$394	20 %
Other income (expense)	$(348)	$(293)	$834	$55	19 %	$(1,127)	(135)%

Interest income for the year ended December 31, 2013, decreased by $0.2 million, or 60%, compared to the same period in 2012 due to lower average marketable securities balance. Interest income for the year ended December 31, 2012, increased by $0.2 million, or 183%, compared to the same period in 2011 due to higher investment balances primarily as a result of our May 2012 common stock offering which resulted in net proceeds of approximately $69.6 million.

Interest expense for the year ended December 31, 2013 decreased compared to the same period in 2012 due to the interest recorded for the note payable to Holdings which was repaid in cash on December 31, 2012. Interest expense for the year ended December 31, 2012 increased over the same period in 2012 due to the accretion of interest expense related to the note payable to Holdings.

Other income (expense) for the year ended December 31, 2013 increased by 19%, compared to the same period in 2012 due to losses on foreign currency transactions in 2013 related to fluctuations in the value of the Euro compared to the U.S. dollar. Other income (expense) for the year ended December 31, 2012 decreased by $1.1 million, or 135%, compared to the same period in 2011 due to losses on foreign currency transactions in 2012 related to fluctuations in the value of the Euro compared to the U.S. dollar and the recognition of a one-time gain of $0.8 million for the change in fair value of the long-term contingent and warrant liabilities to Holdings in 2011.

Liquidity and Capital Resources

As of December 31, 2013, we had $189.4 million in cash, cash equivalents and marketable securities. Since our inception, we have relied primarily on the proceeds from public and private sales of our equity securities and revenues from collaboration agreements to fund our operations. Our funds are currently invested in short-term money market funds, U.S. government agency securities and U.S. treasury securities.

On October 30, 2013, we sold 79,570,000 shares of our common stock and 43,430 shares of the Company's Series B Convertible Preferred Stock ("Series B"), resulting in aggregate net proceeds to us of $125.1 million after deducting commissions and offering expenses.

On March 29, 2013, we entered into an At Market Issuance Sales Agreement (the "Agreement") with MLV & Co. LLC ("MLV") under which we may offer and sell our common stock having aggregate sales proceeds of up to $50 million from time to time through MLV as our sales agent. Sales of our common stock through MLV, if any, will be made by means of ordinary brokers' transactions on The NASDAQ Capital Market or otherwise at market prices prevailing at the time of sale, in block transactions, or as otherwise agreed upon by us and MLV. MLV will use commercially reasonable efforts to sell our common stock from time to time, based upon instructions from us (including any price, time or size limits or other customary parameters or conditions we may impose). We will pay MLV a commission of up to 3.0% of the gross sales proceeds of any common stock sold through MLV under the Agreement. No sales of our common stock have taken place under this Agreement as of December 31, 2013.

During the year ended December 31, 2013, we used $58.7 million of cash for our operations and had a net loss of $66.7 million, of which $15.5 million consisted of non-cash charges such as stock-based compensation, depreciation and amortization, accretion and amortization on marketable securities and unoccupied facility expense. By comparison, during the year ended December 31, 2012, we used $43.8 million of cash for our operations with a net loss of $69.9 million, of which $15.1 million consisted of non-cash charges such as stock-based compensation, depreciation and amortization, accretion and amortization on marketable securities and non-cash interest on borrowings. Cash used in our operations during 2013 increased by $14.9 million, totaling $58.7 million for the year ended December 31, 2013 compared to $43.8 million for the same period in 2012. The increase was primarily due to a $9.1 million change in accounts receivable related to a decrease in payments received from our collaborations with GSK and AstraZeneca in the prior year and an increase in stock based compensation of $1.9 million related to employee severance arrangements and awards for non-employees.

During the year ended December 31, 2013, we used $51.4 million of cash in investing activities compared to $39.7 million for the year ended December 31, 2012. Cash provided by investing activities during 2013 included $49.7 million of net purchases of marketable securities versus $36.8 million of net purchases of marketable securities during 2012. Cash used in investing activities decreased an additional $1.3 million compared to the prior year due to purchases of property and equipment which totaled $1.6 million and $2.9 million in 2013 and 2012, respectively.

During the year ended December 31, 2013, cash provided by financing activities increased by $66.4 million, totaling $125.4 million, compared to $59.0 million for the year ended December 31, 2012. Cash provided by financing activities in 2013 included the sale of 79,570,000 shares of common stock and 43,430 shares of Series B Convertible Preferred Stock in separate underwritten public offerings for net proceeds of $125.1 million. Cash provided by financing activities for the year ended December 31, 2012 included net proceeds of $69.6 million from a public stock offering of common stock. These proceeds were partially offset by our $15.0 million repayment of the note payable to Holdings on December 31, 2012. Additionally, proceeds from stock option and warrant exercises for the year ended December 31, 2013 decreased $1.8 million as compared to the same period in 2012.

During the year ended December 31, 2012, we used $43.8 million of cash for our operations and had a net loss of $69.9 million, of which $15.1 million consisted of non-cash charges such as depreciation and amortization, non-cash interest expense related to our long-term note payable to Holdings and stock based compensation. By comparison, during the year ended December 31, 2011, we used $47.1 million of cash, and had a net loss of $48.6 million, of which $9.0 million consisted of non-cash charges such as depreciation and amortization, non-cash interest expense related to our long-term note payable to Holdings and stock based compensation. Cash used in operating activities for the year ended December 31, 2012, decreased by $3.3 million compared to cash used for year ended December 31, 2011, due primarily to a decrease in accounts receivable in 2012 related to payments received from our collaborations with GSK and AstraZeneca.

During the year ended December 31, 2012, we used $39.7 million of cash in investing activities which was a $5.1 million increase compared to $34.6 million used during the year ended December 31, 2011. Cash used in investing activities during the year ended December 31, 2012, primarily related to $36.8 million of cash used for net purchases of marketable securities compared to $33.5 million in the prior year, a $3.3 million increase. Cash used in investing activities increased an additional $1.8 million compared to the prior year due to purchases of property and equipment which totaled $2.9 million and $1.1 million in 2012 and 2011, respectively.

During the year ended December 31, 2012, cash provided by financing activities was $59.0 million compared to $91.4 million for the same period in 2011. Cash provided for the year ended December 31, 2012 included net proceeds of $69.6 million from a public stock offering as well as proceeds from stock option and warrant exercises of $4.1 million. These proceeds were partially offset by our $15 million repayment of our note payable to Holdings on December 31, 2012. By comparison, during the year ended December 31, 2011, we completed a public offering which resulted in aggregate net proceeds of $64.5 million, and raised additional funding from Aspire Capital totaling $26.7 million.

We currently estimate that we have sufficient cash resources to meet our anticipated cash needs through at least the next 12 months based on cash and cash equivalents and marketable securities on hand as of December 31, 2013 and anticipated revenues and funding from existing agreements. We expect to continue to spend substantial funds in connection with the development and manufacturing of our product candidates, particularly HEPLISAV-B, human clinical trials for our other product candidates and additional applications and advancement of our technology. In order to continue these activities, we may need to raise additional funds. This may occur through strategic alliance and licensing arrangements and/or future public or private financings. Sufficient funding may not be available, or if available, may be on terms that significantly dilute or otherwise adversely affect the rights of existing stockholders. If adequate funds are not available in the future, we may need to delay, reduce the scope of or put on hold the HEPLISAV-B program or other development programs while we seek strategic alternatives.

Contractual Obligations

The following summarizes our significant contractual obligations at December 31, 2013 and the effect those obligations are expected to have on our liquidity and cash flows in future periods (in thousands):

Contractual Obligations:	Total	2014	2015-2016	2017-2018	2019 and Thereafter
Future minimum payments under our operating leases	$13,080	$2,233	$ 4,615	$ 3,733	$ 2,499
Total	$13,080	$2,233	$ 4,615	$ 3,733	$ 2,499

We lease our facilities in Berkeley, California (the "Berkeley Lease"), and Düsseldorf, Germany (the "Düsseldorf Lease") under operating leases that expire in June 2018 and March 2023, respectively.

During September 2013, we decided not to occupy a portion of our facility in Berkeley, California. As a result, we recorded a one-time estimated unoccupied facility expense of $0.9 million, representing the present value of the rent payments and other costs associated with the lease, net of estimated sublease income, for the remaining life of the operating lease.

During the fourth quarter of 2004, we established a letter of credit with Silicon Valley Bank as security for the Berkeley Lease in the amount of $0.4 million. The letter of credit remained outstanding as of December 31, 2013 and is collateralized by a certificate of deposit for $0.4 million which has been included in restricted cash in the consolidated balance sheets as of December 31, 2013 and 2012. Under the terms of the Berkeley Lease, if the total amount of our cash, cash equivalents and marketable securities falls below $20 million for a period of more than 30 consecutive days during the lease term, the amount of the required security deposit will increase to $1.1 million, until such time as our projected cash and cash equivalents will exceed $20 million for the remainder of the lease term, or until our actual cash and cash equivalents remains above $20 million for a period of 12 consecutive months.

We established a letter of credit with Deutsche Bank as security for our Düsseldorf Lease in the amount of approximately 0.2 million Euros. The letter of credit remained outstanding through December 31, 2013 and is collateralized by a certificate of deposit for 0.2 million Euros which has been included in restricted cash in the consolidated balance sheets as of December 31, 2013 and 2012.

In addition to the non-cancelable commitments included above, we have entered into contractual arrangements that obligate us to make payments to the contractual counterparties upon the occurrence of future events. Also, in the normal course of operations, we have entered into license and other agreements and intend to continue to seek additional rights relating to compounds or technologies in connection with our discovery, manufacturing and development programs. Under the terms of the agreements, we may be required to pay future upfront fees, milestones, royalties on net sales of products originating from the licensed technologies or other payments contingent upon the occurrence of an event that cannot reasonably be estimated.

We rely on research institutions, contract research organizations, clinical investigators and clinical material manufacturers. As of December 31, 2013, under the terms of our agreements, we are obligated to make future payments as services are provided of approximately $4.5 million through 2015. These agreements are terminable by us upon written notice. Generally, we are liable only for actual effort expended by the organizations at any point in time during the contract through the notice period.

Under the terms of our exclusive license agreements with The Regents of the University of California, as amended, for certain technology and related patent rights and materials, we pay annual license or maintenance fees and will be required to pay milestones and royalties on net sales of certain products, if any, originating from the licensed technologies.

Off-balance Sheet Arrangements

We do not have any off-balance sheet arrangements as defined by rules enacted by the SEC and accordingly, no such arrangements are likely to have a current or future effect on our financial position.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK
Quantitative and Qualitative Disclosure About Market Risk

Interest Rate Risk

We are subject to interest rate risk. Our investment portfolio is maintained in accordance with our investment policy, which defines allowable investments, specifies credit quality standards and limits the credit exposure of any single issuer. The primary objective of our investment activities is to preserve principal and, secondarily, to maximize income we receive from our investments without significantly increasing risk. Some of the securities that we invest in may have market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate. To minimize this risk, we maintain our portfolio of cash equivalents and investments in a variety of securities, including short-term money market funds, U.S. government agency securities, U.S. treasury securities and municipal securities. We do not invest in auction rate securities or securities collateralized by home mortgages, mortgage bank debt or home equity loans. We do not have derivative financial instruments in our investment portfolio. To assess our risk, we calculate that if interest rates were to rise or fall from current levels by 100 basis points or by 125 basis points, the pro forma change in fair value of our net unrealized loss on investments would be $2.1 million or $2.6 million, respectively.

Due to the short duration and conservative nature of our cash equivalents and marketable securities, as well as our intention to hold the investments to maturity, we do not expect any material loss with respect to our investment portfolio.

Foreign Currency Risk

We have certain investments outside the U.S. for the operations of Dynavax Europe with exposure to foreign exchange rate fluctuations. The cumulative translation adjustment reported in the consolidated balance sheet as of December 31, 2013 was $0.1 million primarily related to translation of Dynavax Europe assets, liabilities and operating results from Euros to U.S. dollars. As of December 31, 2013, the effect of our exposure to these exchange rate fluctuations has not been material, and we do not expect it to become material in the foreseeable future. We do not hedge our foreign currency exposures and have not used derivative financial instruments for speculation or trading purposes.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Dynavax Technologies Corporation

We have audited the accompanying consolidated balance sheets of Dynavax Technologies Corporation as of December 31, 2013 and 2012, and the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2013. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Dynavax Technologies Corporation at December 31, 2013 and 2012, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2013, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Dynavax Technologies Corporation's internal control over financial reporting as of December 31, 2013, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992 Framework) and our report dated March 10, 2014 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Redwood City, California

March 10, 2014

DYNAVAX TECHNOLOGIES CORPORATION

CONSOLIDATED BALANCE SHEETS

(In thousands, except per share amounts)

	December 31,	
	2013	2012
Assets		
Current assets:		
Cash and cash equivalents	$23,122	$7,599
Marketable securities available-for-sale	166,254	117,531
Accounts receivable	1,627	1,005
Prepaid expenses and other current assets	1,375	2,052
Total current assets	192,378	128,187
Property and equipment, net	8,706	7,965
Goodwill	2,579	2,475
Restricted cash	662	652
Other assets	297	473
Total assets	$204,622	$139,752
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$1,901	$2,166
Accrued liabilities	8,166	10,063
Deferred revenues	6,125	6,785
Total current liabilities	16,192	19,014
Deferred revenues, net of current portion	1,173	5,283
Other long-term liabilities	963	629
Total liabilities	18,328	24,926
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock: $0.001 par value		
Authorized: 5,000 shares; Issued and outstanding:	-	-
Series B Convertible Preferred Stock — 43 shares at December 31, 2013 and zero shares at December 31, 2012	-	-
Common stock: $0.001 par value; 350,000 and 250,000 shares authorized at December 31, 2013 and 2012, respectively; 262,796 and 182,792 shares issued and outstanding at December 31, 2013 and 2012, respectively	263	183
Additional paid-in capital	688,390	550,729
Total accumulated other comprehensive loss	(148)	(595)
Accumulated deficit	(502,211)	(435,491)
Total stockholders' equity	186,294	114,826
Total liabilities and stockholders' equity	$204,622	$139,752

See accompanying notes.

DYNAVAX TECHNOLOGIES CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

	Year Ended December 31,		
	2013	2012	2011
Revenues:			
Collaboration revenue	$4,929	$4,610	$17,190
Grant revenue	5,138	3,939	3,110
Service and license revenue	1,184	1,165	1,314
Total revenues	11,251	9,714	21,614
Operating expenses:			
Research and development	50,870	49,146	51,322
General and administrative	25,943	28,164	17,570
Unoccupied facility expense	926	-	-
Amortization of intangible assets	-	-	299
Total operating expenses	77,739	77,310	69,191
Loss from operations	(66,488)	(67,596)	(47,577)
Other income (expense):			
Interest income	116	291	103
Interest expense	-	(2,351)	(1,957)
Other income (expense)	(348)	(293)	834
Net loss	(66,720)	(69,949)	(48,597)
Preferred stock deemed dividend	(8,469)	-	-
Net loss allocable to common stockholders	$(75,189)	$(69,949)	$(48,597)
Net loss per share allocable to common stockholders - basic and diluted	$(0.38)	$(0.41)	$(0.39)
Weighted average shares outstanding used to compute basic and diluted net loss per share allocable to common stockholders	196,275	170,469	125,101

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

	Year Ended December 31,		
	2013	2012	2011
Net loss	$(66,720)	$(69,949)	$(48,597)
Other comprehensive income (loss):			
Unrealized (loss) gain on marketable securities available-for-sale	(76)	48	14
Cumulative translation adjustment	523	366	(277)
Total other comprehensive income (loss)	447	414	(263)
Total comprehensive loss	$(66,273)	$(69,535)	$(48,860)

See accompanying notes.

DYNAVAX TECHNOLOGIES CORPORATION

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(In thousands)

	Common Stock		Preferred Stock			Accumulated		
	Shares	Par Amount	Shares	Par Amount	Additional Paid-In Capital	Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balances at December 31, 2010	115,611	$ 116	-	-	$ 369,686	$ (746)	$ (316,945)	$ 52,111
Issuance of common stock upon exercise of stock options and restricted stock awards	308	-	-	-	10	-	-	10
Issuance of common stock under Employee Stock Purchase Plan	106	-	-	-	132	-	-	132
Proceeds from issuances of common stock and warrants, net of issuance costs	38,601	39	-	-	91,259	-	-	91,298
Stock compensation expense	-	-	-	-	5,189	-	-	5,189
Total other comprehensive income (loss)	-	-	-	-	-	(263)	-	(263)
Net loss	-	-	-	-	-	-	(48,597)	(48,597)
Balances at December 31, 2011	154,626	155	-	-	466,276	(1,009)	(365,542)	99,880
Issuance of common stock upon exercise of stock options and restricted stock awards	1,222	1	-	-	1,954	-	-	1,955
Issuance of common stock under Employee Stock Purchase Plan	141	-	-	-	307	-	-	307
Proceeds from issuances of common stock and warrants, net of issuance costs	26,803	27	-	-	71,753	-	-	71,780
Stock compensation expense	-	-	-	-	10,439	-	-	10,439
Total other comprehensive income (loss)	-	-	-	-	-	414	-	414
Net loss	-	-	-	-	-	-	(69,949)	(69,949)
Balances at December 31, 2012	182,792	183	-	-	550,729	(595)	(435,491)	114,826
Issuance of common stock upon exercise of stock options and restricted stock awards	106	-	-	-	112	-	-	112
Issuance of common stock under Employee stock purchase plan	129	-	-	-	224	-	-	224
	115	-	-	-		-	-	-

Restricted stock award delivered								
Issuance of common stock, net of issuance costs	79,570	80	-		80,919	-	-	80,999
Issuance of Series B convertible preferred stock, net of issuance costs	-	-	43	-	44,209	-	-	44,209
Beneficial conversion feature of Series B convertible preferred stock	-	-	-	-	-	-	-	-
Deemed dividend to holders of Series B convertible preferred stock	-	-	-	-	-	-	-	-
Initial expenses related to ATM agreement	-	-	-	-	(143)	-	-	(143)
Warrants exercised	84	-	-	-	-	-	-	-
Stock compensation expense	-	-	-	-	12,340	-	-	12,340
Total other comprehensive income (loss)	-	-	-	-	-	447	-	447
Net loss	-	-	-	-	-	-	(66,720)	(66,720)
Balances at December 31, 2013	262,796	$ 263	43	$ -	$ 688,390	$ (148)	$ (502,211)	$ 186,294

See accompanying notes.

DYNAVAX TECHNOLOGIES CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Year Ended December 31,		
	2013	2012	2011
Operating activities			
Net loss	$(66,720)	$(69,949)	$(48,597)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,327	1,207	1,303
Amortization of intangible assets	-	-	299
Loss (gain) on disposal of property and equipment	18	8	20
Accretion of discounts and amortization of premiums of marketable securities	923	1,298	1,172
Interest associated with long-term note payable to Symphony Dynamo Holdings LLC (“Holdings)	-	2,190	1,871
Fair value adjustment of the warrant and contingent liabilities to Holdings, including the impact of the anti-dilution provision associated with the common stock and warrants issued to Symphony Capital Partners, L.P. and Symphony Strategic Partners, LLC (collectively, “Symphony”)	-	-	(843)
Unoccupied facility expense	926	-	-
Stock compensation expense	12,340	10,439	5,189
Changes in operating assets and liabilities:			
Accounts receivable	(622)	8,522	(8,526)
Prepaid expenses and other current assets	677	(922)	230
Restricted cash and other assets	176	(116)	(290)
Accounts payable	(657)	126	(289)
Accrued liabilities and other long term liabilities	(2,291)	1,916	(2,167)
Deferred revenues	(4,770)	1,472	3,512
Net cash used in operating activities	(58,673)	(43,809)	(47,116)
Investing activities			
Purchases of marketable securities	(192,044)	(206,149)	(111,205)
Proceeds from maturities of marketable securities	142,321	169,387	77,729
Purchases of property and equipment, net	(1,629)	(2,931)	(1,142)
Net cash used in investing activities	(51,352)	(39,693)	(34,618)
Financing activities			
Proceeds from issuances of common stock	80,856	71,780	91,298
Proceeds from issuances of preferred stock	44,209	-	-
Proceeds from issuances of warrants	-	-	-
Proceeds from exercise of stock options and restricted stock awards	112	1,955	10
Proceeds from employee stock purchase plan	224	307	132
Payment of notes payable to Holdings	-	(15,000)	-
Net cash provided by financing activities	125,401	59,042	91,440
Effect of exchange rate changes on cash and cash equivalents	147	118	(218)
Net increase (decrease) in cash and cash equivalents	15,523	(24,342)	9,488
Cash and cash equivalents at beginning of year	7,599	31,941	22,453
Cash and cash equivalents at end of year	$23,122	$7,599	$31,941
Supplemental disclosure of cash flow information			

Non-cash investing and financing activities:			
Disposal of fully depreciated property and equipment	$86	$169	$1,181
Net change in unrealized (loss) gain on marketable securities	$(76)	$48	$14

See accompanying notes.

DYNAVAX TECHNOLOGIES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization

Dynavax Technologies Corporation ("we," "our," "us," "Dynavax" or the "Company"), a clinical-stage biopharmaceutical company, develops products to prevent and treat infectious and inflammatory diseases and cancer based on Toll-like Receptor ("TLR") biology and its ability to modulate the innate immune system. Our lead product candidate is HEPLISAV-B™ (also known as "HEPLISAV"), an investigational adult hepatitis B vaccine in Phase 3 clinical development.

In addition to HEPLISAV-B, we are conducting clinical and preclinical programs that utilize our expertise in TLR biology. Our product candidates include both TLR agonists and TLR inhibitors. Our clinical stage programs include our autoimmune program partnered with GlaxoSmithKline ("GSK"), our asthma therapeutic program partnered with AstraZeneca AB ("AstraZeneca"), and our cancer immunotherapy program. We also are advancing preclinical development programs in adjuvant technology and TLR 7, 8, and 9 inhibition. We compete with pharmaceutical companies, biotechnology companies, academic institutions and research organizations in developing therapies to prevent or treat infectious and inflammatory diseases and cancer. We were incorporated in California in August 1996 under the name Double Helix Corporation, and we changed our name to Dynavax Technologies Corporation in September 1996. We reincorporated in Delaware in 2000.

Subsidiaries

In April 2006, we completed the acquisition of Rhein Biotech GmbH ("Rhein" or "Dynavax Europe"), a wholly-owned subsidiary in Düsseldorf, Germany. In October 2011, we formed Dynavax International, B.V., a wholly-owned subsidiary in Amsterdam, Netherlands.

2. Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements include our accounts and those of our wholly-owned subsidiaries. All significant intercompany accounts and transactions among the entities have been eliminated from the consolidated financial statements.

Liquidity and Financial Condition

We have incurred significant operating losses and negative cash flows from operations since our inception. As of December 31, 2013, we had cash, cash equivalents and marketable securities of $189.4 million. We currently estimate that we have sufficient cash resources to meet our anticipated cash needs through at least the next 12 months based on cash, cash equivalents and marketable securities on hand as of December 31, 2013 and anticipated revenues and funding from existing agreements.

We expect to continue to spend substantial funds in connection with the development and manufacturing of our product candidates, particularly HEPLISAV-B, human clinical trials for our product candidates and additional applications and advancement of our technology. In order to continue these activities, we may need to raise additional funds. This may occur through strategic alliance and licensing arrangements and/or future public or private financings. Sufficient additional funding may not be available on acceptable terms, or at all. If adequate funds are not available in the future, we may need to delay, reduce the scope of or put on hold the HEPLISAV-B program or our other development programs while we seek strategic alternatives.

Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles ("U.S. GAAP") requires management to make informed estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results may differ materially from these estimates.

Foreign Currency Translation

We consider the local currency to be the functional currency for our international subsidiary, Rhein. Accordingly, assets and liabilities denominated in foreign currencies are translated into U.S. dollars using the exchange rate in effect on the balance sheet date. Revenues and expenses are translated at average exchange rates prevailing throughout the year. Currency translation adjustments arising from period to period are charged or credited to accumulated other comprehensive income (loss) in stockholders' equity. For the years ended December 31, 2013, 2012 and 2011, we reported an unrealized gain of $0.5 million, an unrealized gain of $0.4 million and an unrealized loss of $0.3 million, respectively. Realized gains and losses resulting from currency transactions are included in the consolidated statements of operations. For the years ended December 31, 2013, 2012 and 2011, we reported a loss of $0.2 million, a loss of $0.2 million and a gain of $0.2 million, respectively, resulting from currency transactions in our consolidated statements of operations.

Cash, Cash Equivalents and Marketable Securities

We consider all highly liquid investments purchased with an original maturity of three months or less and that can be liquidated without prior notice or penalty, to be cash equivalents. Management determines the appropriate classification of marketable securities at the time of purchase. We invest in short-term money market funds, U.S. government agency securities, U.S. treasury securities and municipal securities. We believe these types of investments are subject to minimal credit and market risk. We do not invest in auction rate securities or securities collateralized by home mortgages, mortgage bank debt, or home equity loans.

We have classified our entire investment portfolio as available-for-sale and available for use in current operations and accordingly have classified all investments as short-term. Available-for-sale securities are carried at fair value based on inputs that are observable, either directly or indirectly, such as quoted market prices for similar securities; 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 securities, with unrealized gains and losses included in accumulated other comprehensive income (loss) in stockholders' equity. Realized gains and losses and declines in value, if any, judged to be other than temporary on available-for-sale securities are included in interest income or expense. The cost of securities sold is based on the specific identification method. Management assesses whether declines in the fair value of investment securities are other than temporary. In determining whether a decline is other than temporary, management considers the following factors:

- Whether the investment has been in a continuous realized loss position for over 12 months;
- the duration to maturity of our investments;
- our intention and ability to hold the investments to maturity and if it is not more likely than not that we will be required to sell the investment before recovery of the amortized cost bases;
- the credit rating, financial condition and near-term prospects of the issuer; and
- the type of investments made.

To date, there have been no declines in fair value that have been identified as other than temporary.

Concentration of Credit Risk and Other Risks and Uncertainties

We operate in one business segment, which is the discovery and development of biopharmaceutical products. We determine our segments based on the way we organize our business by making operating decisions and assessing performance. In fiscal years 2013, 2012 and 2011, 89%, 88% and 94% of our revenues were earned in the United States, respectively, and the remaining revenues were earned in Germany. As of December 31, 2013 and 2012, 9% and 10%, respectively, of our long-lived assets were located in the United States and the remaining long-lived assets were located in Germany.

Financial instruments that are subject to concentration of credit risk consist primarily of cash equivalents, marketable securities and accounts receivable. Our policy is to invest cash in institutional money market funds and marketable securities of U.S. government and corporate issuers with high credit quality to limit the amount of credit exposure. We currently maintain a portfolio of cash equivalents and marketable securities in a variety of securities, including short-term money market funds, U.S. government agency securities, U.S. treasury securities and municipal securities. We have not experienced any losses on our cash equivalents and marketable securities.

Accounts receivable are recorded at invoice value. We review our exposure to accounts receivable, including the requirement for allowances based on management’s judgment. We have not historically experienced any significant losses. We do not currently require collateral for any of our accounts receivable.

Our products will require approval from the U.S. Food and Drug Administration ("FDA") and foreign regulatory agencies before commercial sales can commence. There can be no assurance that our products will receive any of these required approvals. The denial or delay of such approvals would have a material adverse impact on our business.

We have relied on a limited number of suppliers to produce oligonucleotides for clinical trials and a single contract manufacturer to produce our first generation TLR 9 agonist, 1018 for HEPLISAV-B. The loss of our current supplier would have a significant effect on our ability to produce HEPLISAV-B for commercialization and development of our other product candidates. To date, we have manufactured only small quantities of oligonucleotides and 1018 ourselves for development purposes.

We are subject to risks common to companies in the biopharmaceutical industry, including, but not limited to, new technological innovations, clinical development risk, establishing appropriate commercial partnerships, protection of proprietary technology, compliance with government and environmental regulations, uncertainty of market acceptance of products, product liability, the volatility of our stock price and the need to obtain additional financing.

Long-Lived Assets

Property and equipment are recorded at cost. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets. Repair and maintenance costs are charged to expense as incurred. Leasehold improvements in both of our facilities are amortized over the remaining life of the initial lease term or the estimated useful lives of the assets, whichever is shorter.

We evaluate the carrying value of long-lived assets, including intangible assets, whenever events or changes in business circumstances or our planned use of long-lived assets indicate, based on undiscounted future operating cash flows, that their carrying amounts may not be fully recoverable or that their useful lives are no longer appropriate. When an indicator of impairment exists, long-lived assets are written down to their respective fair values. Fair value is determined primarily using the anticipated cash flows discounted at a rate commensurate with the risk involved. Significant management judgment is required in the forecast of future operating results that are used in the preparation of expected undiscounted cash flows. No impairments of purchased intangible assets have been identified during the years presented.

Goodwill

Our goodwill balance relates to our April 2006 acquisition of Rhein. Goodwill was recorded as the excess purchase price over tangible and intangible assets acquired and liabilities assumed based on their estimated fair value, by applying the acquisition method of accounting. Goodwill is not amortized but is subject to an annual impairment test which consists of a comparison of the fair value of the related reporting unit against its carrying amount including goodwill. If the carrying amount exceeds the fair value, impairment is calculated and recorded as a charge in the consolidated statements of operations. We determined that we have only one operating segment and there are no components of that operating segment that are deemed to be separate reporting units such that we have one reporting unit for purposes of our goodwill impairment testing. We evaluate goodwill for impairment on an annual basis and on an interim basis if events or changes in circumstances between annual impairment tests indicate that the asset might be impaired.

Revenue Recognition

Our revenues consist of amounts earned from collaborations, grants and fees from services and licenses. We enter into license and manufacturing agreements and collaborative research and development arrangements with pharmaceutical and biotechnology partners that may involve multiple deliverables. Our arrangements may include one or more of the

following elements: upfront license payments, cost reimbursement for the performance of research and development activities, milestone payments, other contingent payments, contract manufacturing service fees, royalties and license fees. Each deliverable in the arrangement is evaluated to determine whether it meets the criteria to be accounted for as a separate unit of accounting or whether it should be combined with other deliverables. In order to account for the multiple-element arrangements, the Company identifies the deliverables included within the arrangement and evaluates which deliverables represent separate units of accounting. Analyzing the arrangement to identify deliverables requires the use of judgment, and each deliverable may be an obligation to deliver services, a right or license to use an asset, or another performance obligation. We recognize revenue when there is persuasive evidence that an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable and collectability is reasonably assured.

On January 1, 2011, we adopted on a prospective basis Financial Accounting Standards Board (“FASB”) Accounting Standards Update (“ASU”) 2009-13, Multiple-Deliverable Revenue Arrangements, which amends the criteria related to identifying separate units of accounting and provides guidance on whether multiple deliverables exist, how an arrangement should be separated and the consideration allocated.

Non-refundable upfront fees received for license and collaborative agreements entered into prior to January 1, 2011 and other payments under collaboration agreements where we have continuing performance obligations related to the payments are deferred and recognized over our expected performance period. Revenue is recognized on a ratable basis, unless we determine that another method is more appropriate, through the date at which our performance obligations are completed. Management makes its best estimate of the period over which we expect to fulfill our performance obligations, which may include clinical development activities. Given the uncertainties of research and development collaborations, significant judgment is required to determine the duration of the performance period. We recognize cost reimbursement revenue under collaborative agreements as the related research and development costs are incurred, as provided for under the terms of these agreements.

Contingent consideration received for the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved. A milestone is defined as an event having all of the following characteristics: (i) there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved, (ii) the event can only be achieved based in whole or in part on either the entity's performance or a specific outcome resulting from the entity's performance and (iii) if achieved, the event would result in additional payments being due to the entity.

Our license and collaboration agreements with our partners provide for payments to be paid to us upon the achievement of development milestones. Given the challenges inherent in developing biologic products, there is substantial uncertainty whether any such milestones will be achieved at the time we entered into these agreements. In addition, we evaluate whether the development milestones meet the criteria to be considered substantive. The conditions include: (i) the development work is contingent on either of the following: (a) the vendor's performance to achieve the milestone or (b) the enhancement of the value of the deliverable item or items as a result of a specific outcome resulting from the vendor's performance to achieve the milestone; (ii) it relates solely to past performance and (iii) it is reasonable relative to all the deliverable and payment terms within the arrangement. As a result of our analysis, we consider our development milestones to be substantive and, accordingly, we expect to recognize as revenue future payments received from such milestones as we achieve each milestone.

Milestone payments that are contingent upon the achievement of substantive at-risk performance criteria are recognized in full upon achievement of those milestone events in accordance with the terms of the agreement and assuming all other revenue recognition criteria have been met. All revenue recognized to date under our collaborative agreements has been nonrefundable.

Our license and collaboration agreements with certain partners also provide for contingent payments to be paid to us based solely upon the performance of our partner. For such contingent payments we expect to recognize the payments as revenue upon receipt, provided that collection is reasonably assured and the other revenue recognition criteria have been satisfied.

Revenues from manufacturing services are recognized upon meeting the criteria for substantial performance and acceptance by the customer.

Revenue from royalty payments is contingent on future sales activities by our licensees. As a result, we recognize royalty revenue when reported by our licensees and when collection is reasonably assured.

Revenue from government and private agency grants are recognized as the related research expenses are incurred and to the extent that funding is approved. Additionally, we recognize revenue based on the facilities and administrative cost rate reimbursable per the terms of the grant awards.

Research and Development Expenses and Accruals

Research and development expenses include personnel and facility-related expenses, outside contracted services including clinical trial costs, manufacturing and process development costs, research costs and other consulting services and non-cash stock-based compensation. Research and development costs are expensed as incurred. Amounts due under such arrangements may be either fixed fee or fee for service, and may include upfront payments, monthly payments and payments upon the completion of milestones or receipt of deliverables. Non-refundable advance payments under agreements are capitalized and expensed as the related goods are delivered or services are performed.

We contract with third parties to perform various clinical trial activities in the on-going development of potential products. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows to our vendors. Payments under the contracts depend on factors such as the achievement of certain events, successful enrollment of patients, completion of portions of the clinical trial or similar conditions. Our accruals for clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with clinical trial centers and clinical research organizations. We may terminate these contracts upon written notice and we are generally only liable for actual effort expended by the organizations to the date of termination, although in certain instances we may be further responsible for termination fees and penalties. The Company makes estimates of its accrued expenses as of each balance sheet date based on the facts and circumstances known to the Company at that time. There have been no material adjustments to the Company's prior period accrued estimates for clinical trial activities through December 31, 2013.

Stock-Based Compensation

Stock-based compensation expense for stock options and other stock awards is estimated at the grant date based on the award's fair value-based measurement and is recognized on a straight-line basis over the award's vesting period, assuming appropriate forfeiture rates. Our determination of the fair value-based measurement of stock options on the date of grant using an option-pricing model is affected by our stock price, as well as assumptions regarding a number of highly complex and subjective variables. These variables include, but are not limited to, our expected stock price volatility over the term of the awards, and actual and projected employee stock option exercise behaviors. In the future, as additional empirical evidence regarding these input estimates becomes available, we may change or refine our approach of deriving these input estimates. These changes could impact our fair value-based measurement of stock options granted in the future. Changes in the fair value-based measurement of stock awards could materially impact our operating results.

We selected the Black-Scholes option pricing model as the most appropriate method for determining the estimated fair value-based measurement of our stock options. The Black-Scholes model requires the use of highly subjective and complex assumptions which determine the fair value-based measurement of stock options, including the option's expected term and the price volatility of the underlying stock. Our current estimate of volatility is based on the historical volatility of our stock price. To the extent volatility in our stock price increases in the future, our estimates of the fair value of options granted in the future could increase, thereby increasing stock-based compensation cost recognized in future periods. We derive the expected term assumption primarily based on our historical settlement experience, while giving consideration to options that have not yet completed a full life cycle. Stock-based compensation cost is recognized only for awards ultimately expected to vest. Our estimate of the forfeiture rate is based primarily on our historical experience. To the extent we revise this estimate in the future, our share-based compensation cost could be materially impacted in the quarter of revision, as well as in the following quarters.

Income Taxes

We account for income taxes using the asset and liability method, under which deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Additionally, we assess the likelihood that deferred tax assets will be recovered as deductions from future taxable income. We have provided a full valuation allowance on our deferred tax assets at December 31, 2013 and 2012 because we believe it is more likely than not that our deferred tax assets will not be realized as of December 31, 2013, and 2012.

We have no unrecognized tax benefits as of December 31, 2013, including no accrued amounts for interest and penalties. We do not anticipate that total unrecognized tax benefits will significantly change prior to December 31, 2014. Our policy will be to recognize interest and penalties related to income taxes, if any, as a component of general

and administrative expense. We are subject to income tax examinations for U.S. federal and state income taxes from 1996 forward. We are subject to tax examination in Germany from 2010 forward.

Recent Accounting Pronouncements

Accounting Standards Update 2013-02

In February 2013, the FASB issued ASU 2013-02, “Reporting of Amounts Reclassified out of Accumulated Other Comprehensive Income.” This ASU expands the presentation of changes in accumulated other comprehensive income. The new guidance requires an entity to disaggregate the total change of each component of other comprehensive income either on the face of the statement of operations or as a separate disclosure in the financial statement footnotes. ASU 2013-02 is effective for fiscal years beginning after December 15, 2012. The Company adopted this guidance on a prospective basis in the first quarter of 2013 and the adoption did not have any impact on our financial position, results of operations or cash flows as there were no amounts reclassified out of accumulated other comprehensive (loss) income during the year ended December 31, 2013.

3. Fair Value Measurements

The Company defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (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 accounting standard describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

- Level 1—Observable inputs, such as quoted prices in active markets for identical assets or liabilities;
- Level 2—Inputs other than Level 1 that are observable, either directly or indirectly, 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; and
- 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, therefore requiring an entity to develop its own assumptions.

Recurring Fair Value Measurements

The following table represents the fair value hierarchy for our financial assets (cash equivalents and marketable securities) measured at fair value on a recurring basis as of December 31, 2013 and 2012 (in thousands):

	Level 1	Level 2	Level 3	Total
December 31, 2013				
Money market funds	$20,013	$-	$ -	$20,013
U.S. government agency securities	-	167,597	-	167,597
Total	$20,013	$167,597	$ -	$187,610

	Level 1	Level 2	Level 3	Total
December 31, 2012				
Money market funds	$3,140	$-	$ -	$3,140
U.S. government agency securities	-	119,233	-	119,233
U.S. treasury securities	-	500	-	500
Municipal securities	-	715	-	715
Total	$3,140	$120,448	$ -	$123,588

Money market funds are highly liquid investments and are actively traded. The pricing information on these investment instruments are readily available and can be independently validated as of the measurement date. This approach results in the classification of these securities as Level 1 of the fair value hierarchy.

U.S. Government agency securities, U.S. treasury securities and municipal securities are measured at fair value using Level 2 inputs. We review trading activity and pricing for these investments as of each measurement date. When sufficient quoted pricing for identical securities is not available, we use market pricing and other observable market inputs for similar securities obtained from various third party data providers. These inputs represent quoted prices for similar assets in active markets or these inputs have been derived from observable market data. This approach results in the classification of these securities as Level 2 of the fair value hierarchy.

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4. Cash, Cash Equivalents and Marketable Securities

The following is a summary of cash, cash equivalents and marketable securities as of December 31, 2013, and 2012 (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
December 31, 2013				
Cash and cash equivalents:				
Cash	$ 1,766	$ -	$ -	$ 1,766
Money market funds	20,013	-	-	20,013
U.S. government agency securities	1,343	-	-	1,343
Total cash and cash equivalents	23,122	-	-	23,122
Marketable securities available-for-sale:				
U.S. government agency securities	166,285	16	(47)	166,254
Total marketable securities available-for-sale	166,285	16	(47)	166,254
Total cash, cash equivalents and marketable securities	$ 189,407	$ 16	$ (47)	$ 189,376
December 31, 2012				
Cash and cash equivalents:				
Cash	$ 1,542	$ -	$ -	$ 1,542
Money market funds	3,140	-	-	3,140
Municipal securities	715	-	-	715
U.S. government agency securities	2,202	-	-	2,202
Total cash and cash equivalents	7,599	-	-	7,599
Marketable securities available-for-sale:				
U.S. government agency securities	116,986	46	(1)	117,031
U.S. treasury securities	500	-	-	500
Total marketable securities available-for-sale	117,486	46	(1)	117,531
Total cash, cash equivalents and marketable securities	$ 125,085	$ 46	$ (1)	$ 125,130

The maturities of our marketable securities available-for-sale are as follows (in thousands)

	December 31, 2013	
	Amortized Cost	Estimated Fair Value
Mature in one year or less	$ 93,691	$ 93,701
Mature after one year through two years	72,594	72,553
	$ 166,285	$ 166,254

We invest in short-term money market funds, U.S. government agency securities, U.S treasury securities and municipal securities.

There were no realized gains or losses from the sale of marketable securities in the years ended December 31, 2013, 2012 and 2011. All of our investments are classified as short-term and available-for-sale, as we may not hold our investments until maturity.

5. Property and Equipment

Property and equipment as of December 31, 2013, and 2012 consist of the following (in thousands):

	Estimated Useful Life (In years)	December 31, 2013	2012
Manufacturing equipment	5-14	$8,968	$7,574
Lab equipment	5-13	7,227	6,755
Computer equipment	3	1,962	1,807
Furniture and fixtures	3	1,056	983
Leasehold improvements	5-7	6,048	5,445
Assets in progress		762	1,047
		26,023	23,611
Less accumulated depreciation and amortization		(17,317)	(15,646)
Total		$8,706	$7,965

Depreciation and amortization expense on property and equipment was $1.3 million, $1.2 million and $1.3 million for the years ended December 31, 2013, 2012 and 2011, respectively.

6. Intangible Assets

Intangible assets consisted primarily of manufacturing process and customer relationships related to our 2006 acquisition of Rhein. The manufacturing process derives from the methods for making proteins in Hansenula yeast, which is a process we use to make a key component in the production of hepatitis B vaccine. The customer relationships derive from Rhein's ability to sell existing, in-process and future products to its existing customers. Purchased intangible assets other than goodwill are amortized on a straight-line basis over their respective useful lives. The manufacturing process and customer relationships were amortized over their estimated useful lives of five years. Both the manufacturing process and customer relationships intangible assets were fully amortized as of the year ended December 31, 2011. Amortization of intangible assets was zero for the years ended December 31, 2013 and 2012, and $0.3 million for the year ended December 31, 2011.

7. Current Accrued Liabilities

Current accrued liabilities as of December 31, 2013, and 2012 consist of the following (in thousands):

	December 31, 2013	2012
Payroll and related expenses	$3,639	$4,538
Legal expenses	338	396
Third party research and development expenses	2,403	3,207
Other accrued liabilities	1,786	1,922
Total	$8,166	$10,063

8. Symphony Dynamo, Inc.

On April 18, 2006, we, Symphony and Holdings entered into a transaction involving a series of related agreements providing for the advancement of certain of our immunostimulatory sequences-based programs for cancer, hepatitis B and hepatitis C therapy (collectively, the “Programs”). Pursuant to these agreements, Symphony formed SDI and invested $50 million to fund the Programs, and we licensed to Holdings our intellectual property rights related to the Programs, which were assigned to SDI. As a result of these agreements, Symphony owned 100% of the equity of Holdings, which owned 100% of the equity of SDI.

In connection with the transaction described above, Holdings granted to us an exclusive purchase option that gave us the right, but not the obligation, to acquire the outstanding equity securities of SDI, which would result in our reacquisition of the intellectual property rights that we licensed to Holdings (the "Original Purchase Option"). In exchange for the Original Purchase Option, we granted Holdings five-year warrants to purchase up to 2,000,000 shares of our common stock at an exercise price of $7.32 per share pursuant to a warrant purchase agreement (the "Original Warrants"), and granted certain registration rights to Holdings pursuant to a registration rights agreement. We also received an exclusive option to purchase either the hepatitis B or hepatitis C therapy program (the "Program Option") during the first year of the arrangement. In April 2007, we exercised the Program Option for the hepatitis B program which resulted in the recognition of a $15 million liability to Symphony. We remained primarily responsible for the development of the cancer and hepatitis C therapy programs in accordance with a development plan and related development budgets that we agreed to with Holdings.

Prior to the acquisition of all of the outstanding equity of SDI on December 30, 2009, we consolidated the financial position and results of operations of SDI. In November 2009, we entered into an agreement with Holdings to modify the provisions of and to exercise the Original Purchase Option (the "Amended Purchase Option"). We completed the acquisition of all of the outstanding equity of SDI on December 30, 2009. In exchange for all of the outstanding equity of SDI, we issued to Symphony and certain of its co-investors: (i) 13,000,000 shares of common stock (the "Shares"); (ii) 5-year warrants to purchase 2,000,000 shares of common stock with an exercise price of $1.94 per share (the "Warrants"); and (iii) a non-interest bearing note in the principal amount of $15 million, due December 31, 2012, payable in cash, our common stock or a combination thereof at our discretion, which obligation was previously payable solely in cash on April 18, 2011 (the "Note"). In addition, we agreed to contingent cash payments from us equal to 50% of the first $50 million from any upfront, pre-commercialization milestone or similar payments received by us from any agreement with any third party with respect to the development and/or commercialization of the cancer and hepatitis C therapies originally licensed to SDI. The Original Warrants held by Symphony were cancelled as part of this transaction.

We were obligated to make future contingent cash payments to the former Holdings shareholders related to certain payments received by us, if any, from future partnering agreements pertaining to our hepatitis C and cancer therapy programs. We estimated the valuation of this contingent liability using a discounted cash flow model. The discounted cash flow model was derived from management's assumptions regarding the timing, amounts, and probability of potential upfront and milestone payments for the development and/or commercialization of the hepatitis C program based on transactions for similar stage programs by other companies. These cash flows were discounted at a rate of 16% for the fiscal year ended December 31, 2010.

Changes in the fair value of the contingent consideration liability were recognized in "other income (expense)" in the consolidated statements of operations in the period of the change. During the fiscal year ended December 31, 2010, we reduced the assumed probability of our receipt of upfront and milestone payments from a potential partnership and extended the timing of when these expected receipts would occur. In addition, based on our assumptions regarding our beta and risk free interest rate used in the discounted cash flow model, the change in fair value of the contingent consideration liability resulted in other income of $2.2 million for the fiscal year ended December 31, 2010. During the year ended December 31, 2011, we determined that we would not receive any upfront or milestone payments from a potential partnership for our hepatitis C therapy program and, therefore, estimated the fair value of the liability to be zero as of December 31, 2011 resulting in other income of $0.8 million. These fair value measurements were based on significant inputs not observed in the market and thus represented a Level 3 measurement.

We recorded the acquisition of all of the outstanding equity of SDI pursuant to the Amended Purchase Option as a return of equity to the noncontrolling interest. The acquisition was accounted for as a capital transaction that did not affect our consolidated net loss. However, because the acquisition was accounted for as a capital transaction, the consideration paid in excess of the carrying value of the noncontrolling interest in SDI is treated as a deemed dividend

at the time for purposes of reporting net loss and earnings per share.

The estimated fair values of the warrants transferred were calculated using the Black-Scholes valuation model.

We estimated the fair value of the Note using a net present value model with a discount rate of 17%. Imputed interest was recorded as interest expense over the term of the loan using the interest rate method. We paid in cash the $15 million principal balance of the Note on December 31, 2012.

The Shares and Warrants were subject to certain anti-dilution protection in the event that we issued other equity securities within six months from December 30, 2009. As a result of an equity offering completed in April 2010 prior to the expiration of the anti-dilution provision, Symphony received an additional 1,076,420 shares of common stock (“April 2010 Shares”) and warrants to purchase 7,038,210 shares of common stock (“April 2010 Warrants”) having the same terms as the warrants sold in the offering, which have an exercise price of $1.50 per share and a term of five years. The Warrants issued on December 30, 2009 were cancelled upon the issuance of the April 2010 Warrants.

The fair value of the April 2010 Shares and incremental fair value of the April 2010 Warrants provided to Symphony, as measured upon issuance and remeasured at June 30, 2010, resulted in non-operating expense of $11.1 million in the second quarter of 2010. This also resulted in an increase of $9.5 million to the warrant liability and an increase of $1.6 million to additional paid in capital as of June 30, 2010. Following the expiration date of Symphony's anti-dilution protection, on June 30, 2010, the value of the April 2010 Warrants of $12.0 million was reclassified into stockholders' equity in the consolidated balance sheets. As of December 31, 2013, warrants to purchase 6,765,128 shares remained outstanding.

9. Commitments and Contingencies

We lease our facilities in Berkeley, California ("Berkeley Lease") and Düsseldorf, Germany ("Düsseldorf Lease") under operating leases that expire in June 2018 and March 2023, respectively. The Berkeley Lease provides for periods of escalating rent. The total cash payments over the life of the lease are divided by the total number of months in the lease period and the average rent is charged to expense each month during the lease period. We entered into sublease agreements under the Düsseldorf Lease for a certain portion of the leased space. The sublease income is offset against our rent expense.

During September 2013, we decided not to occupy a portion of our facility in Berkeley, California. As a result, we recorded a one-time estimated unoccupied facility expense of $0.9 million for the year ended December 31, 2013, representing the present value of the rent payments and other costs associated with the lease, net of estimated sublease income, for the remaining life of the operating lease.

Total net rent expense related to our operating leases for the years ended December 31, 2013, 2012 and 2011, was $1.9 million, $1.7 million and $1.7 million, respectively. Deferred rent was $0.6 million as of December 31, 2013 and 2012.

Future minimum payments under the non-cancelable portion of our operating leases at December 31, 2013, excluding payments from sublease payments, are as follows (in thousands):

Years ending December 31,	
2014	$2,233
2015	2,282
2016	2,333
2017	2,382
2018	1,351
Thereafter	2,499
Total	$13,080

During the fourth quarter of 2004, we established a letter of credit with Silicon Valley Bank as security for our Berkeley Lease in the amount of $0.4 million. The letter of credit remained outstanding as of December 31, 2013, and is collateralized by a certificate of deposit for $0.4 million, which has been included in restricted cash in the consolidated balance sheets as of December 31, 2013 and 2012. Under the terms of the Berkeley Lease, if the total amount of our cash, cash equivalents and marketable securities falls below $20 million for a period of more than 30 consecutive days during the lease term, the amount of the required security deposit will increase to $1.1 million, until such time as our projected cash and cash equivalents will exceed $20 million for the remainder of the lease term, or until our actual cash and cash equivalents remains above $20 million for a period of 12 consecutive months.

We established a letter of credit with Deutsche Bank as security for our Düsseldorf Lease in the amount of approximately 0.2 million Euros. The letter of credit remained outstanding through December 31, 2013 and is collateralized by a certificate of deposit for 0.2 million Euros, which has been included in restricted cash in the consolidated balance sheets as of December 31, 2013 and 2012.

In addition to the non-cancelable commitments included above, we have entered into contractual arrangements that obligate us to make payments to the contractual counterparties upon the occurrence of future events. In addition, in the normal course of operations, we have entered into license and other agreements and intend to continue to seek additional rights relating to compounds or technologies in connection with our discovery, manufacturing and development programs. Under the terms of the agreements, we may be required to pay future up-front fees, milestones and royalties on net sales of products originating from the licensed technologies, if any, or other payments contingent upon the occurrence of future events that cannot reasonably be estimated.

We rely on research institutions, contract research organizations, clinical investigators as well as clinical and material manufacturers of our product candidates. As of December 31, 2013, under the terms of our agreements, we are obligated to make future payments as services are provided of approximately $4.5 million through 2015. These agreements are terminable by us upon written notice. Generally, we are liable only for actual effort expended by the organizations at any point in time during the contract through the notice period.

Under the terms of our exclusive license agreements with the Regents of the University of California, as amended, for certain technology and related patent rights and materials, we pay annual license or maintenance fees and will be required to pay milestones and royalties on net sales, if any, of certain products originating from the licensed technologies.

10. Collaborative Research, Development and License Agreements
GlaxoSmithKline

In December 2008, we entered into a worldwide strategic alliance with GSK to discover, develop and commercialize TLR inhibitors. Under the terms of the arrangement, we agreed to conduct research and early clinical development in up to four programs: the Lead TLR 7/9 program, a Follow-On TLR 7/9 program, and up to two other TLR programs. In 2011 we began development of a TLR 8 program as one of the two additional programs under the collaboration. GSK subsequently returned all rights to this program to us.

We are currently conducting a Phase 1 clinical trial in the Lead TLR 7/9 program with DV1179 in systemic lupus erythematosus patients. The Company is not currently performing any activities on the Follow-On TLR 7/9 program. GSK has not yet chosen to initiate development of the remaining program under the agreement. In December 2013, we amended our agreement with GSK to extend the research term until conclusion of the ongoing phase 1 study of DV1179. In addition, the exclusivity provisions of the agreement were modified, giving us rights to immediately begin preclinical and clinical research on inhibitors of TLR 7 and 9 (other than DV1179) for oncology indications.

GSK can exercise its exclusive option to license each program. If GSK exercises an option, GSK would carry out further development and commercialization of the corresponding products. If GSK exercises their option on the Lead TLR 7/9 program, then we are eligible to receive payments of up to approximately $125 million, comprised of contingent option exercise payments and additional payments based on GSK’s achievement of certain development, regulatory and commercial objectives.

We are also eligible to receive up to $60 million if aggregate worldwide annual net sales milestones are achieved and tiered royalties ranging from the mid–single digit to mid-teens on sales of any products originating from the collaboration. We have retained an option to co-develop and co-promote one product under this agreement.

We received an initial payment of $10 million in 2008. The deliverables under this arrangement did not have stand-alone value and so did not qualify as separate units of accounting. In 2011, we earned and recognized $12 million in substantive development milestone payments related to the initiation of Phase I and proof-of-mechanism clinical trials of DV1179 in systemic lupus erythematosus patients. In 2011, we earned and recognized $3 million in

substantive development milestone payments related to the initiation of development of the TLR 8 program.

Revenue from the initial payment from GSK was deferred and is being recognized over the expected period of performance under the agreement, initially estimated to be seven years. In the fourth quarter of 2013 we reevaluated and revised the expected period of performance under the agreement from seven years to six years resulting in the recognition of $0.3 million of additional revenue in 2013.

The following table summarizes the revenues recognized under our agreement with GSK (in thousands):

	Year ended December 31,		
	2013	2012	2011
Initial payment	$1,702	$1,428	$1,428
Milestone revenue	-	-	15,000
Total	$1,702	$1,428	$16,428

As of December 31, 2013 and 2012, deferred revenue relating to the initial payment was $2.5 million and $4.2 million, respectively.

Absent early termination, the agreement will expire when all of GSK's payment obligations expire. Either party may terminate the agreement early upon written notice if the other party commits an uncured material breach of the agreement. Either party may terminate the agreement in the event of insolvency of the other party. GSK also has the option to terminate the agreement without cause upon prior written notice within a specified window of time dependent upon the stage of clinical development of the programs.

AstraZeneca

In September 2006, we entered into a three-year research collaboration and license agreement with AstraZeneca for the discovery and development of TLR 9 agonist-based therapies for the treatment of asthma and chronic obstructive pulmonary disease.

In October 2011, we amended our agreement with AstraZeneca to provide that we will conduct initial clinical development of AZD1419. Under the terms of the amended agreement, AstraZeneca will fund all program expenses to cover the cost of development activities through Phase 2a, estimated to total approximately $20 million. We received an initial payment of $3 million to begin the clinical development program. In the first quarter of 2012, we received a $2.6 million payment to advance AZD1419 into preclinical toxicology studies and these toxicology studies were completed in the third quarter of 2012. We and AstraZeneca have agreed to advance AZD1419 towards a Phase 1 clinical trial, which resulted in a development funding payment of $6 million, received in the fourth quarter of 2012. If AstraZeneca chooses to advance the program following completion of Phase 2a, we will receive a $20 million milestone payment and AstraZeneca will retain its rights to develop the candidate therapy and to commercialize the resulting asthma product. We are eligible to receive additional milestone payments, which we have determined to be substantive milestones, of up to approximately $100 million, based on the achievement of certain development and regulatory objectives. Additionally, upon commercialization, we are eligible to receive tiered royalties ranging from the mid to high single-digits based on product sales of any products originating from the collaboration. We have the option to co-promote in the United States products arising from the collaboration, if any. AstraZeneca has the right to sublicense its rights upon our prior consent.

Revenue from the initial payment was deferred and is being recognized over the expected period of performance under the agreement, which is approximately 50 months. Revenue from the development funding payment is being recognized as the development work is performed.

The following table summarizes the revenues earned under our agreement with AstraZeneca (in thousands):

	Year ended December 31,		
	2013	2012	2011
Initial payments	$720	$720	$120
Performance of research activities	2,507	2,462	642
Total	$3,227	$3,182	$762

As of December 31, 2013 and 2012, total deferred revenue from the initial payment and development funding payments was $4.8 million and $7.7 million, respectively.

Absent early termination, the agreement will expire when all of AstraZeneca's payment obligations expire. AstraZeneca has the right to terminate the agreement at any time upon prior written notice and either party may terminate the agreement early upon written notice if the other party commits an uncured material breach of the agreement.

National Institutes of Health ("NIH") and Other Funding

We have been awarded various grants from the NIH and the NIH's National Institute of Allergy and Infectious Disease ("NIAID") in order to fund research. The awards are related to specific research objectives and we earn revenue as the related research expenses are incurred. We have earned revenue during the periods ended December 31, 2013 and 2012 from the following awards:

- September 2013, NIH awarded us $0.2 million to fund research in developing TLR antagonists for therapy of hepatic fibrosis and cirrhosis.
- June 2012, NIH awarded us $0.6 million to fund research in screening for inhibitors of TLR 8 for treatment of autoimmune diseases.
- May 2012, NIH awarded us $0.4 million to fund development of TLR 8 inhibitors for treatment of rheumatoid arthritis.
- July 2011, NIH awarded us $0.6 million to fund research in preclinical models of skin autoimmune inflammation.
- August 2010, NIAID awarded us a grant to take a systems biology approach to study the differences between individuals who do or do not respond to vaccination against the hepatitis B virus. This study will be one of several projects conducted under a grant to the Baylor Institute of Immunology Research in Dallas as part of the Human Immune Phenotyping Centers program. We have been awarded a total of $1.4 million under this grant.
- July 2010, NIH awarded us $0.6 million to explore the feasibility of developing a universal vaccine to prevent infection by human papilloma virus.
- September 2008, NIAID awarded us a five-year $17 million contract to develop our oligonucleotide technology using TLR 9 agonists as vaccine adjuvants. The contract supports adjuvant development for anthrax as well as other disease models.

The following table summarizes the revenues recognized under the various arrangements with the NIH and NIAID (in thousands):

	Year ended December 31,		
	2013	2012	2011
NIAID contracts	$4,103	$3,571	$2,730
All other NIH contracts	1,035	368	380
Total grant revenue	$5,138	$3,939	$3,110

11. Net Loss Per Share

Basic net loss per share allocable to common stockholders is calculated by dividing the net loss allocable to common stockholders by the weighted-average number of common shares outstanding during the period. Diluted net loss per share allocable to common stockholders is computed by dividing the net loss allocable to common stockholders by the weighted-average number of common shares outstanding during the period and giving effect to all potentially dilutive common shares using the treasury-stock method. For purposes of this calculation, common stock subject to repurchase by us, outstanding stock options, stock awards, warrants and Series B Convertible Preferred Stock are considered to be potentially dilutive common shares and are only included in the calculation of diluted net loss per share allocable to common stockholders when their effect is dilutive.

December 31,

	2013	2012	2011
Basic and diluted net loss per share (in thousands, except per share amounts):			
Numerator:			
Net loss	(66,720)	(69,949)	(48,597)
Preferred stock deemed dividend	(8,469)	-	-
Net loss allocable to common stockholders	$(75,189)	$(69,949)	$(48,597)
Denominator for basic and diluted net loss per share allocable to common stockholders:			
Weighted-average common shares outstanding	196,275	170,469	125,101
Basic and diluted net loss per share allocable to common stockholders	$(0.38)	$(0.41)	$(0.39)

Outstanding warrants, stock options, Series B Convertible Preferred Stock and stock subject to repurchase by us under stock awards were excluded from the calculation of net loss per share allocable to common stockholders as the effect of their inclusion would have been anti-dilutive.

	December 31,		
	2013	2012	2011
Outstanding securities not included in diluted net loss per share calculation (in thousands):			
Stock options and stock awards	17,040	15,561	11,101
Series B Convertible Preferred Stock (as converted to common stock)	43,430	-	-
Warrants	12,464	12,714	25,729
	72,934	28,275	36,830

12. Preferred Stock, Common Stock and Warrants

Authorized Shares

On May 29, 2013 the stockholders approved an increase in the number of authorized shares of common stock from 250,000,000 to 350,000,000. The increase in authorized shares was effected pursuant to a Certificate of Amendment to the Sixth Amended and Restated Certificate of Incorporation (the "Certificate of Amendment"), filed with the Secretary of State of the State of Delaware on May 30, 2013.

Preferred Stock Outstanding

As of December 31, 2013 there were 5,000,000 shares of preferred stock authorized and 43,430 shares outstanding.

In October 2013 the Company sold 43,430 shares of $0.001 par value Series B Convertible Preferred Stock for a purchase price of $1,075 per share and gross proceeds of approximately $46.7 million in an underwritten public offering. After issuance costs of approximately $2.5 million, the net proceeds from the offering were approximately $44.2 million.

Each share of Series B Convertible Preferred Stock is convertible into 1,000 shares of common stock at any time at the holder’s option. However, the holder is prohibited from converting the Series B Convertible Preferred Stock into shares of common stock if, as a result of such conversion, the holder and its affiliates would own more than 9.98% of the total number of shares of common stock then issued and outstanding. In the event of the Company’s liquidation, dissolution, or winding up, holders of Series B Convertible Preferred Stock will receive a payment equal to $0.001 per share before any proceeds are distributed to the common stockholders. Shares of Series B Convertible Preferred Stock generally have no voting rights, except as required by law and except that the consent of holders of a majority of the outstanding Series B Convertible Preferred Stock is required to amend the terms of the Series B Convertible Preferred Stock. Holders of Series B Convertible Preferred Stock are not entitled to receive any dividends, unless and until specifically declared by the Company’s board of directors. The Series B Convertible Preferred Stock ranks senior to the Company’s common stock as to distributions of assets upon the Company’s liquidation, dissolution or winding up, whether voluntarily or involuntarily. The Series B Convertible Preferred Stock may rank senior to, on parity with or junior to any class or series of the Company’s capital stock created in the future depending upon the specific terms of such future stock issuance.

The fair value of the common stock into which the Series B Convertible Preferred Stock is convertible exceeded the allocated purchase price of the Series B Convertible Preferred Stock by $8.5 million on the date of issuance, for which the Company recorded a deemed dividend. The Company recognized the deemed dividend equal to the number of shares of Series B Convertible Preferred Stock sold on October 30, 2013 multiplied by the difference between the value of the common stock and the Series B Convertible Preferred Stock conversion price per share on that date. The dividend was reflected as a one-time, non-cash, deemed dividend to the holders of Series B Convertible Preferred Stock on the date of issuance, which is the date the stock first became convertible.

Preferred Stock Rights

On November 4, 2008, our Board of Directors declared a dividend of one preferred share purchase right (a "Right") for each outstanding share of our Common Stock, par value $0.001 per share (the "Common Shares"). The dividend was payable on November 17, 2008 to the stockholders of record on that date. Each Right entitles the registered holder to purchase from us one one-hundredth of a share of Series A Junior Participating Preferred Stock, par value $0.001 per share (the "Preferred Shares"), at a price of $6.00 per one one-hundredth of a Preferred Share, subject to adjustment. Upon the acquisition of, or announcement of the intent to acquire, 20 percent or more of our outstanding Common Shares by a person, entity or group of affiliated or associated persons ("Acquiring Person"), each holder of a Right, other than Rights held by the Acquiring Person, will have the right to purchase that number of Common Shares having a market value of two times the exercise price of the Right. If we are acquired in a merger or other business combination transaction or 50 percent or more of our assets or earning power are sold to an Acquiring Person, each holder of a Right will thereafter have the right to purchase, at the then current exercise price of the Right, that number of shares of common stock of the acquiring company which at the time of such transaction will have a market value of two times the exercise price of the Right. The Rights plan is intended to maximize the value of the Company in the event of an unsolicited attempt to take over the Company in a manner or on terms not approved by the Company's Board of Directors. The Rights will expire on November 17, 2018, unless the Rights are earlier redeemed or exchanged by the Company.

Common Stock Outstanding

In October 2013 we completed an underwritten public offering of 79,570,000 shares of our common stock to the public at $1.075 per share. The gross proceeds to us from this offering were approximately $85.5 million. After deducting issuance costs of approximately $4.5 million, the net proceeds from the offering were approximately $80.9 million.

On March 29, 2013, we entered into an At Market Issuance Sales Agreement (the "Agreement") with MLV & Co. LLC ("MLV") under which we may offer and sell our common stock having aggregate sales proceeds of up to $50,000,000 from time to time through MLV as our sales agent. Sales of our common stock through MLV, if any, will be made by means of ordinary brokers' transactions on the NASDAQ Capital Market or otherwise at market prices prevailing at the time of sale, in block transactions, or as otherwise agreed upon by us and MLV. MLV will use commercially reasonable efforts to sell our common stock from time to time, based upon instructions from us (including any price, time or size limits or other customary parameters or conditions we may impose). We will pay MLV a commission of up to 3.0% of the gross sales proceeds of any common stock sold through MLV under the Agreement. No sales of our common stock have taken place under this Agreement as of December 31, 2013.

On May 9, 2012, we completed an underwritten public offering of 17,500,000 shares of our common stock to the public at $4.25 per share. The net proceeds to us from this offering were $69.6 million, after deducting offering expenses.

On November 3, 2011, we completed an underwritten public offering of 27,600,000 shares of our common stock including 3,600,000 shares sold pursuant to the full exercise of an overallotment option previously granted to the underwriters at a price to the public of $2.50 per share. The net proceeds to us from this offering were $64.5 million, after deducting offering expenses.

On November 2, 2010, we completed an underwritten public offering of 26,450,000 shares of our common stock including 3,450,000 shares sold pursuant to the full exercise of an overallotment option previously granted to the underwriters at a price to the public of $1.70 per share. The net proceeds to us from this offering were $42.0 million, after deducting offering expenses.

On September 20, 2010, we entered into a Purchase Agreement with Aspire Capital, which provided that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital was committed to purchase up to an aggregate of $30.0 million of shares of our common stock (the “Purchase Shares”) over the 25-month term of the Purchase Agreement. Under the Purchase Agreement, we agreed to pay Aspire Capital a commitment fee equal to 4% of $30 million in consideration for Aspire Capital’s obligation to purchase up to $30 million of our common stock. We paid this commitment fee of $1.2 million by the issuance of 600,000 shares of our common stock and this fee was recorded as a cost of raising capital and netted against the gross proceeds from the Purchase Agreement in September 2010. During 2010, we sold 2,350,000 shares of common stock to Aspire Capital for $3.3 million and during 2011 we sold 10,995,210 shares of common stock for $26.7 million, which totaled the proceeds available to us of $30 million under the Purchase Agreement.

On April 16, 2010, we completed an underwritten public offering resulting in net proceeds of $41.1 million, after deducting offering expenses of approximately $3.0 million, from the sale of 30,293,000 units at a per unit price of $1.4525. Each unit consisted of one share of common stock and one warrant to purchase 0.5 of a share of common stock. Each warrant has an exercise price of $1.50 per share, and is exercisable for a period of five years from the date of issuance. From this offering, warrants to purchase an aggregate of 10,913,873 shares of our common stock were outstanding as of December 31, 2013 (including the warrants to purchase 6,765,128 shares provided to Symphony as described in Note 8 “Symphony Dynamo, Inc.”).

Warrants

In connection with a 2007 loan agreement that was subsequently terminated in 2008, we issued warrants to purchase up to 3,550,000 shares of our common stock as follows:

Warrant Issuance Date	Shares Issuable (in thousands)	Expiration Date	Exercise Price per Share	Outstanding as of December 31, 2013 (in thousands)
July 18, 2007	1,250	2/26/2014	$ 5.13	1,250
October 18, 2007	1,300	2/26/2014	$ 1.68	-
December 27, 2007	300	2/26/2014	$ 5.65	300
December 27, 2007	700	2/26/2014	$ 1.68	-
Total	3,550			1,550

As of December 31, 2013, warrants to purchase an aggregate of approximately 12,500,000 shares of our common stock were outstanding. The warrants are exercisable at a weighted average price of $1.96 per share. During the years ended December 31, 2013, and 2012, warrants were exercised to purchase an aggregate of approximately 250,000 and 13,000,000 shares, respectively, of our common stock.

13. Equity Plans and Stock-Based Compensation
Stock Plans

As of December 31, 2013, we had three share-based compensation plans.

2004 Stock Incentive Plan (“2004 Plan”)

The 2004 Plan was adopted in January 2004 by the Board of Directors and stockholders and became effective on February 11, 2004. This plan provided for the issuance of up to 3,500,000 shares of our common stock plus an annual increase. Subsequently, we discontinued granting stock options under the 1997 Plan. Options under the 2004 Plan were granted for periods of up to ten years and the exercise price of all stock options granted under the 2004 Plan was at least equal to 100% of the fair market value of the common stock on the date of grant. If, however, incentive stock options were granted to an employee who owns stock possessing more than 10% of the voting power of all classes of the Company’s stock or the stock of any parent or subsidiary of the Company, the exercise price of any incentive stock option granted must equal at least 110% of the fair market value on the grant date and the maximum term of these incentive stock options must not exceed five years. The maximum term of an incentive stock option granted to any other participant must not exceed ten years. The 2004 Plan authorizes the issuance of various forms of stock-based awards including stock options, restricted stock, restricted stock units and other equity awards to employees, consultants and members of the board of directors. As of December 31, 2013, options to purchase 4,066,277 shares of common stock remained outstanding under the 2004 Plan.

2010 Employment Inducement Award Plan (“Inducement Plan”)

The Inducement Plan was adopted in January 2010 by our Board of Directors to induce qualified individuals to join Dynavax. This Inducement Plan provided for the issuance of up to 1,500,000 shares of our common stock and became effective on January 8, 2010. Stockholder approval of the Inducement Plan is not required under NASDAQ Marketplace Rule 5635(c)(4). As of December 31, 2013, options to purchase 743,625 shares of common stock remained outstanding under the Inducement Plan.

2011 Equity Incentive Plan ("2011 Plan")

The 2011 Plan was approved by the Company's stockholders and adopted in January 2011. On May 29, 2013, the stockholders of the Company approved an amendment to the 2011 Plan to increase the number of shares of common stock authorized for issuance under the plan by 10,000,000. The 2011 Plan, as amended, provides for the issuance of up to 25,000,000 shares of our common stock to employees and non-employees of the Company and became effective on January 6, 2011. The 2011 Plan is administered by our Board of Directors, or a designated committee of the Board of Directors, and awards granted under the 2011 Plan have a term of 10 years unless earlier terminated by the Board of Directors. After the adoption of the 2011 Plan, no additional awards were granted under either the 2004 Plan or the Inducement Plan. As of January 6, 2011, all shares subject to awards outstanding under the 2004 Plan and Inducement Plan that expire or are forfeited will be included in the reserve for the 2011 Plan to the extent such shares would otherwise return to such plans. As of December 31, 2013, options to purchase 10,954,940 shares of common stock remained outstanding under the 2011 Plan. As of December 31, 2013, there were 13,666,964 shares of common stock reserved for issuance under the 2011 Plan.

Activity under our stock plans is set forth below:

	Shares Underlying Outstanding Options (in thousands)	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Balance at December 31, 2012	13,806	$ 3.38		
Options granted	5,614	2.69		
Options exercised	(131)	1.43		
Options cancelled:				
Options forfeited (unvested)	(2,555)	3.31		
Options cancelled (vested)	(969)	3.34		
Balance at December 31, 2013	15,765	3.17	5.26	$ 1,427
Vested and expected to vest at December 31, 2013	15,765	3.17	5.26	$ 1,427
Exercisable at December 31, 2013	10,628	3.36	3.61	$ 1,289

The total intrinsic value of stock options exercised during the years ended December 31, 2013, 2012 and 2011 was, $0.3 million, $2.7 million and $0.1 million, respectively. The total intrinsic value of exercised stock options is calculated based on the difference between the exercise price and the quoted market price of our common stock as of the close of the exercise date.

The total fair value of stock options vested during the years ended December 31, 2013, 2012 and 2011 was, $12.1 million, $9.6 million and $2.8 million, respectively.

Our non-vested stock awards are comprised of restricted stock units granted with performance-based vesting criteria. A summary of the status of non-vested restricted stock units as of December 31, 2013, and activities during 2013 is summarized as follows:

	Number of Shares (In thousands)	Weighted-Average Grant-Date Fair Value
Non-vested as of December 31, 2012	1,755	$ 4.23
Granted	250	$ 1.23
Vested	(115)	$ 1.10
Forfeited or expired	(615)	$ 4.23
Non-vested as of December 31, 2013	1,275	$ 3.93

Stock-based compensation expense related to restricted stock units was approximately $0.1 million for the year ended December 31, 2013. The aggregate intrinsic value of the restricted stock units outstanding as of December 31, 2013, based on our stock price on that date, was $2.5 million.

The weighted average grant-date fair value of restricted stock units granted during the years ended December 31, 2013 and 2012 was, $1.23 and $4.23, respectively. No restricted stock units were granted during 2011. The total fair value of restricted stock units vested during the years ended December 31, 2013, 2012, and 2011 was, $0.1 million, $0.2 million, and $0.8 million, respectively.

Stock-Based Compensation

Under our stock-based compensation plans, option awards generally vest over a four-year period contingent upon continuous service and expire ten years from the date of grant (or earlier upon termination of continuous service). The Company has also granted performance-based equity awards to certain of our employees under the 2011 Plan, the 2004 Plan and the Inducement Plan. As of December 31, 2013, 1,922,466 shares were outstanding related to options and restricted stock units subject to these performance-based vesting criteria. The fair value of each option is estimated on the date of grant using the Black-Scholes option valuation model and the following weighted-average assumptions:

	Stock Options Year Ended December 31,			Employee Stock Purchase Plan Year Ended December 31,		
	2013	2012	2011	2013	2012	2011
Weighted-average fair value	$2.41	$3.30	$2.76	$0.93	$3.54	$2.09
Risk-free interest rate	1.1 %	0.5 %	1.3 %	0.2 %	0.2 %	0.3 %
Expected life (in years)	5.9	4.2	4.0	1.3	1.1	1.2
Volatility	1.4	1.6	1.6	0.8	1.6	1.6

Expected volatility is based on historical volatility of our stock price. The expected life of options granted is estimated based on historical option exercise and employee termination data, while giving consideration to options that have not yet completed a full life cycle. Our senior management, who hold a majority of the options outstanding, and other employees were grouped and considered separately for valuation purposes. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant. The dividend yield is zero percent for all years and is based on our history and expectation of dividend payouts.

Compensation expense is based on awards ultimately expected to vest and reflects estimated forfeitures. For equity awards with time-based vesting, the fair value is amortized to expense on a straight-line basis over the vesting periods. For equity awards with performance-based vesting criteria, the fair value is amortized to expense when the achievement of the vesting criteria becomes probable.

We recognized the following amounts of stock-based compensation expense (in thousands):

	Year Ended December 31,		
	2013	2012	2011
Employees and directors stock-based compensation expense	$11,828	$10,439	$5,185
Non-employees stock-based compensation expense	512	-	4
Total	$12,340	$10,439	$5,189

	Year Ended December 31,		
	2013	2012	2011
Research and development	$4,228	$3,514	$2,103
General and administrative	8,112	6,925	3,086
Total	$12,340	$10,439	$5,189

Stock based compensation expense recognized in 2013 and 2012 includes $4.9 million related to employee severance arrangements and $0.5 million for awards to non-employees for the year ended December 31, 2013 and $1.5 million related to employee severance arrangements for the same period in 2012. During the year ended December 31, 2013, we recognized $1.3 million in additional stock-based compensation expense due to the modification of the terms of stock options for five employees. During the year ended December 31, 2012, we recognized $0.7 million in additional stock-based compensation expense due to the modification of the terms of stock options for one employee.

As of December 31, 2013, the total unrecognized compensation cost related to non-vested stock options deemed probable of vesting, including all stock options with time-based vesting, net of estimated forfeitures, amounted to $10.3 million, which is expected to be recognized over the remaining weighted-average vesting period of 2.8 years. As of December 31, 2013, the total unrecognized compensation cost related to non-vested stock options not deemed probable of vesting, net of estimated forfeitures, amounted to $3.8 million.

As of December 31, 2013, the total unrecognized compensation cost related to shares of our common stock under the Purchase Plan, amounted to $0.1 million, which is expected to be recognized over the remaining weighted-average vesting period of 1.4 years.

Employee Stock Purchase Plan

In January 2004, the Board of Directors and stockholders adopted the 2004 Employee Stock Purchase Plan (the "Purchase Plan"). The Purchase Plan provides for the purchase of common stock by eligible employees and became effective on February 11, 2004. The purchase price per share is the lesser of (i) 85% of the fair market value of the common stock on the commencement of the offer period (generally, the fifteenth day in February or August) or (ii) 85% of the fair market value of the common stock on the exercise date, which is the last day of a purchase period (generally, the fourteenth day in February or August).

As of December 31, 2013, 996,000 shares were approved for issuance under the Purchase Plan, subject to adjustment for a stock split, or any future stock dividend or other similar change in our common stock or capital structure. To date, employees have acquired 828,414 shares of our common stock under the Purchase Plan. As of December 31, 2013, 167,586 shares of our common stock remained available for future purchases.

14. Employee Benefit Plan

We maintain a 401(k) Plan, which qualifies as a deferred salary arrangement under Section 401(k) of the Internal Revenue Code. Under the 401(k) Plan, participating employees may defer a portion of their pretax earnings. We may, at our discretion, contribute for the benefit of eligible employees. To date, we have not contributed to the 401(k) Plan.

15. Income Taxes

Consolidated income (loss) before provision for income taxes consisted of the following (in thousands):

	Year Ended December 31,		
	2013	2012	2011
U.S.	$(67,004)	$(70,792)	$(49,990)
Non U.S.	284	843	1,393
Total	$(66,720)	$(69,949)	$(48,597)

No income tax expense was recorded for the years ended December 31, 2013, 2012 and 2011 due to net operating loss carryforwards to offset the net income at Dynavax Europe and a valuation allowance which offsets the deferred tax assets. The difference between the consolidated income tax benefit and the amount computed by applying the federal statutory income tax rate to the consolidated loss before income taxes was as follows (in thousands):

	Year Ended December 31,		
	2013	2012	2011
Income tax benefit at federal statutory rate	$(22,678)	$(23,650)	$(16,523)
State tax	(178)	(89)	(2,586)
Business credits	(2,515)	-	(1,394)
Deferred compensation charges	3,072	1,002	595
Change in valuation allowance	22,354	21,966	18,099
Change in foreign tax rates	-	-	(34)
Change in the fair value measurements	-	-	286
Non-deductible debt discount	-	-	509
Deemed dividend	-	-	273
Prior year true up	-	-	-
Other	(55)	771	775
Total income tax expense	$-	$-	$-

Deferred tax assets and liabilities as of December 31, 2013 and 2012 consisted of the following (in thousands):

	December 31,	
	2013	2012
Deferred tax assets:		
Net operating loss carry forwards	$147,655	$127,529
Research tax credit carry forwards	21,336	18,163
Accruals and reserves	9,501	8,529
Capitalized research costs	10,662	12,757
Deferred revenue	2,486	2,180
Other	1,222	1,221
	192,862	170,379
Less valuation allowance	(192,733)	(170,232)
Total deferred tax assets	129	147
Deferred tax liabilities:		
Fixed Assets	(162)	(86)
Other	33	(61)
Total deferred tax liabilities	(129)	(147)
Net deferred tax assets	$-	$-

The tax benefit of net operating losses, temporary differences and credit carryforwards is required to be recorded as an asset to the extent that management assesses that realization is “more likely than not.” Realization of the future tax benefits is dependent on our ability to generate sufficient taxable income within the carryforward period. Because of

our recent history of operating losses, management believes that recognition of the deferred tax assets arising from the above-mentioned future tax benefits is currently not likely to be realized and, accordingly, has provided a full valuation allowance. The valuation allowance increased by $22.5 million, $22.0 million and $18.1 million during the years ended December 31, 2013, 2012 and 2011, respectively. The amount of the valuation allowance for deferred tax assets associated with excess tax deductions from stock based compensation arrangements that will be allocated to contributed capital if the future tax benefits are subsequently recognized is $0.3 million.

We have not recorded deferred income taxes applicable to undistributed earnings of a foreign subsidiary that are indefinitely reinvested in foreign operations. Generally, such earnings become subject to U.S. tax upon the remittance of dividends and under certain other circumstances. It is not practicable to estimate the amount of the deferred tax liability on such undistributed earnings.

As of December 31, 2013, we had federal net operating loss carryforwards of approximately $384.1 million, which will expire in the years 2018 through 2033 and federal research and development tax credits of approximately $13.8 million, which expire in the years 2018 through 2033.

As of December 31, 2013, we had potential net operating loss carryforwards for California state income tax purposes of approximately $219.7 million, which expire in the years 2014 through 2033, and California state research and development tax credits of approximately $11.5 million which do not expire.

As of December 31, 2013, we had net operating loss carryforwards for foreign income tax purposes of approximately $27.8 million, which do not expire.

The Tax Reform Act of 1986 limits the annual use of net operating loss and tax credit carryforwards in certain situations where changes occur in stock ownership of a company. In the event the Company has a change in ownership, as defined, the annual utilization of such carryforwards could be limited. Due to past equity issuances and changes in ownership of Dynavax common stock, we believe that our ability to use some of our net operating losses and tax credits in the future may be limited.

16. Selected Quarterly Financial Data (Unaudited; in thousands, except per share amounts)

	Year Ended December 31, 2013			
	Q1	Q2	Q3	Q4
Revenues	$2,085	$3,392	$2,927	$2,847
Net loss	$(20,825)	$(17,164)	$(15,675)	$(13,056)
Net loss allocable to common stockholders	$(20,825)	$(17,164)	$(15,675)	$(21,525)
Basic and diluted net loss per share allocable to common stockholders	$(0.11)	$(0.09)	$(0.09)	$(0.09)
Shares used to compute basic and diluted net loss per share allocable to common stockholders	182,847	182,913	183,022	235,879

	Year Ended December 31, 2012			
	Q1	Q2	Q3	Q4
Revenues	$2,350	$2,684	$2,874	$1,806
Net loss	$(16,505)	$(15,110)	$(17,791)	$(20,543)
Net loss allocable to common stockholders	$(16,505)	$(15,110)	$(17,791)	$(20,543)
Basic and diluted net loss per share allocable to common stockholders	$(0.11)	$(0.09)	$(0.10)	$(0.11)
Shares used to compute basic and diluted net loss per share allocable to common stockholders	155,431	167,697	177,870	180,685

17. Subsequent Events

In March, 2014 we announced a $5.4 million milestone payment and amendment of our AstraZeneca agreement to transfer responsibility for all clinical development to AstraZeneca following conclusion of the ongoing Phase 1 clinical trial of AZD1419.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 ("the Exchange Act")) that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Principal Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can only provide reasonable, not absolute, assurance of achieving the desired control objectives.

Based on their evaluation as of the end of the period covered by this report, our management, with the participation of our Chief Executive Officer and our Principal Financial Officer, concluded that our disclosure controls and procedures are effective at the reasonable assurance level to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms.

(b) 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 defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our management, with the participation of our Chief Executive Officer and Principal Financial Officer, conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992 Framework). Based on that evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2013. The Company's independent registered public accountants, Ernst & Young LLP, audited the consolidated financial statements included in this Annual Report on Form 10-K and have issued an attestation report on the Company's internal control over financial reporting. The report on the audit of internal control over financial reporting appears below.

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Dynavax Technologies Corporation

We have audited Dynavax Technologies Corporation's internal control over financial reporting as of December 31, 2013, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992 Framework) (the COSO criteria). Dynavax Technologies Corporation's management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's 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 generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Dynavax Technologies Corporation maintained, in all material respects, effective internal control over financial reporting as of December 31, 2013, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Dynavax Technologies Corporation as of December 31, 2013 and 2012, and the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2013 of Dynavax Technologies Corporation and our report dated March 10, 2014 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Redwood City, California

March 10, 2014

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(c) Changes in Internal Control Over Financial Reporting

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

ITEM 9B. OTHER INFORMATION
None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information required by this Item is incorporated by reference to the sections entitled “Proposal 1—Elections of Directors,” “Executive Officers,” “Corporate Governance” and “Section 16(a) Beneficial Ownership Reporting Compliance” in our Definitive Proxy Statement in connection with the 2014 Annual Meeting of Stockholders (the “Proxy Statement”) which will be filed with the Securities and Exchange Commission within 120 days after the fiscal year ended December 31, 2013.

We have adopted the Dynavax Code of Conduct, a code of ethics that applies to our employees, including our Chief Executive Officer, Principal Financial Officer and to our non-employee directors. The Code of Conduct is publicly available on our website under the Investor Relations section at www.dynavax.com. This website address is intended to be an inactive, textual reference only; none of the material on this website is part of this report. If any substantive amendments are made to the Code of Conduct or any waiver granted, including any implicit waiver, from a provision of the Code of Conduct to our Chief Executive Officer or Principal Financial Officer, we will disclose the nature of such amendment or waiver on that website or in a report on Form 8-K. We will provide a written copy of the Dynavax Code of Conduct to anyone without charge, upon request written to Dynavax, Attention: Corporate Secretary, 2929 Seventh Street, Suite 100, Berkeley, CA 94710-2753, (510) 848-5100.

ITEM 11. EXECUTIVE COMPENSATION

Information required by this Item is incorporated by reference to the section entitled “Executive Compensation,” “Director Compensation,” “Compensation Discussion and Analysis,” “Report of the Compensation Committee of the Board of Directors,” and “Compensation Committee Interlocks and Insider Participation” in the Proxy Statement.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Information regarding security ownership of certain beneficial owners and management is incorporated by reference to the section entitled “Security Ownership of Certain Beneficial Owners and Management” in the Proxy Statement. Information regarding our stockholder approved and non-approved equity compensation plans are incorporated by reference to the section entitled “Equity Compensation Plans” in the Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Information required by this Item is incorporated by reference to the sections entitled “Transactions with Related Persons” and “Independence of the Board of Directors” in the Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Information required by this Item is incorporated by reference to the section entitled “Audit Fees” in the Proxy Statement.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES
(a) Documents filed as part of this report:

1. Financial Statements

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets

Consolidated Statements of Operations

Consolidated Statements of Comprehensive Loss

Consolidated Statements of Stockholders' Equity

Consolidated Statements of Cash Flows

Notes to Consolidated Financial Statements

2. Financial Statement Schedules

None, as all required disclosures have been made in the Consolidated Financial Statements and notes thereto or are not applicable.

(b) Exhibits

Exhibit Number	Document
3.1[(1)]	Sixth Amended and Restated Certificate of Incorporation.
3.2[(1)]	Amended and Restated Bylaws
3.3[(2)]	Form of Certificate of Designation of Series A Junior Participating Preferred Stock
3.4[(3)]	Certificate of Amendment of Amended and Restated Certificate of Incorporation
3.5[(4)]	Certificate of Amendment of Amended and Restated Certificate of Incorporation

3.6[5]	Certificate of Amendment of Amended and Restated Certificate of Incorporation
3.7[6]	Certificate of Designation of Series B Convertible Preferred Stock
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3, 3.4, 3.5, 3.6 and 3.7 above
4.2[7]	Registration Rights Agreement, dated as of July 18, 2007, by and between the Company and Deerfield Entities
4.3[7]	Form of Warrant to Purchase Common Stock
4.4[8]	Form of Specimen Common Stock Certificate
4.5[2]	Rights Agreement, dated as of November 5, 2008, by and between the Company and Mellon Investor Services LLC
4.6[2]	Form of Right Certificate
4.7[9]	Form of Restricted Stock Unit Award Agreement under the 2004 Stock Incentive Plan
4.8[10]	Form of Warrant to Purchase Common Stock
4.9[11]	Form of Warrant to Purchase Common Stock
4.11[6]	Form of Specimen Preferred Stock Certificate

Exhibit Number	Document
10.30[13]†	Research Collaboration and License Agreement, dated September 1, 2006, by and between the Company and AstraZeneca AB
10.32[14]†	License Agreement, dated June 26, 2007, between Coley Pharmaceuticals Group, Inc. and the Company
10.38[9]+	Form of Amended Management Continuity Agreement between the Company and certain of its executive officers
10.39†	Research and Development Collaboration and License Agreement, dated December 15, 2008, between Glaxo Group Limited and the Company
10.40[15]	Amendment No. 2 to the Research Collaboration and License Agreement, dated September 1, 2006, by and between the Company and AstraZeneca AB, dated February 3, 2009
10.43[17]	Equity Distribution Agreement, dated August 17, 2009, between the Company and Wedbush Morgan Securities, Inc.
10.44[18]	Amendment to Equity Distribution Agreement, dated September 10, 2009, between the Company and Wedbush Morgan Securities, Inc.
10.47[10]	Amended and Restated Purchase Option Agreement, dated November 9, 2009, between the Company and Symphony Dynamo Holdings LLC and Symphony Dynamo, Inc.
10.48[10]	Warrant Purchase Agreement, dated as of November 9, 2009, between the Company and Symphony Dynamo Holdings LLC
10.49[10]	Amended and Restated Registration Rights Agreement, dated as of November 9, 2009, between the Company and Symphony Dynamo Holdings LLC
10.50[10]	Standstill and Corporate Governance Agreement, dated as of December 30, 2009, between the Company and Symphony Dynamo Holdings LLC
10.54[20]	Amendment No. 3 to the Research Collaboration and License Agreement, dated September 1, 2006, by and between the Company and AstraZeneca AB, dated September 30, 2010

10.55[21]	First Amendment to Lease, dated as of May 21, 2004, between the Company and 2929 Seventh Street, LLC
10.56[21]	Second Amendment to Lease, dated as of October 12, 2010, between the Company and 2929 Seventh Street, LLC
10.58[22]+	Amended and Restated Management Continuity and Severance Agreement, dated as of November 12, 2010, by and between the Company and Dino Dina, M.D.
10.59[22]+	Amended and Restated Management Continuity and Severance Agreement, dated as of November 12, 2010 by and between the Company and J. Tyler Martin, M.D.
10.61[23]+	Form of Amended to Amended Management Continuity Agreement between the Company and certain of its executive officers
10.62[24]+	2011 Equity Incentive Plan
10.63[24]+	Form of Restricted Stock Unit Award Notice and Restricted Stock Unit Award Agreement under the 2011 Equity Incentive Plan
10.64[24]+	Form of Stock Option Grant Notice and Option Agreement under the 2011 Equity Incentive Plan
10.65[25]	Third Amendment to Lease, dated as of April 1, 2011, between the Company and 2929 Seventh Street, LLC
10.66[25]	Amended and Restated 2004 Non-Employee Director Option Program and Amended and Restated 2005 Non-Employee Director Cash Compensation Program, effective April 14, 2005, and amended April 6, 2011
10.67[26]†	Amendment No. 4 to the Research Collaboration and License Agreement, dated September 1, 2006, by and between AstraZeneca AB and the Company, dated September 23, 2011
10.69[27]	Amended and Restated 2004 Non-Employee Director Option Program and Amended and Restated 2005 Non-Employee Director Cash Compensation Program, amended April 17, 2012

Exhibit Number	Document
10.70[28] +	Employment Offer Letter to Christine R. Larson, dated August 1, 2012
10.72[29]	Fourth Amendment to Lease, dated as of December 14, 2012, between the Company and 2929 Seventh Street, LLC
10.73[29]	New Lease, dated as of December 14, 2012, between the Company and 2929 Seventh Street, LLC
10.74[29]	Consulting Agreement, dated as of November 14, 2012, by and between the Company and Stanley A. Plotkin
10.75[29]+	Amended and Restated Management Continuity and Severance Agreement, dated October 31, 2012, between the Company and J. Tyler Martin.
10.77[30]	Consulting Agreement, dated as of March 29, 2013, by and between Solutio Partners and the Company
10.78[30]+	