DYNAVAX TECHNOLOGIES CORP
Form 10-K
March 08, 2013
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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, 2012

¨ **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	*(IRS Employer*

incorporation or organization) *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 ¨ No x

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 29, 2012 as reported on the NASDAQ Capital Market, was approximately $422,877,457. 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, 2013, the registrant had outstanding 182,881,013 shares of common stock.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Definitive Proxy Statement for the registrant s 2013 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

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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 business strategy and regulations, our future research and development and intellectual property position, our product development efforts, our ability to commercialize our product candidates, the timing of the introduction of our products, the effect of GAAP accounting pronouncements, the potential for entry into collaborative arrangements, uncertainty regarding our future operating results and our 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 term 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, discovers and develops novel products to prevent and treat infectious and inflammatory diseases. Our lead product candidate is HEPLISAV™, a Phase 3 investigational adult hepatitis B vaccine.

On February 25, 2013, Dynavax announced that it had received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA or Agency) regarding its Biologic License Application (BLA) for HEPLISAV. In the CRL, the FDA specified that the indication in adults 18-70 years of age cannot be approved without further evaluation of safety in this broad age group. The FDA also expressed concern that novel adjuvants may cause rare autoimmune events, however, the Agency indicated its willingness to continue discussions with us regarding a more restricted use of HEPLISAV.

The FDA also requested additional data from our process validation program as well as clarifying information on the manufacturing controls and facilities with respect to quality assurance of commercial product. Dynavax believes it can provide the information but the exact timeframe for its response cannot be determined until a meeting with the Agency occurs. We plan to meet with the FDA in the near term to discuss the CRL and the steps necessary for potential approval of HEPLISAV.

Dynavax s BLA was accepted for review by the FDA in June 2012. On November 15, 2012, the FDA s Vaccines and Related Biological Products Advisory Committee (Committee) voted 8 to 5 with 1 abstention that there was insufficient data to adequately support the safety of HEPLISAV.

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Dynavax s Marketing Authorization Application (MAA) for HEPLISAV continues to be under review in Europe.

Our pipeline of product candidates includes: HEPLISAV, our autoimmune program partnered with GlaxoSmithKline (GSK) and our therapy for asthma partnered with AstraZeneca AB (AstraZeneca). We compete with pharmaceutical companies, biotechnology companies, academic institutions and research organizations in developing therapies to prevent or treat infectious and inflammatory diseases. Our product candidates are based on our proprietary technology which uses immunostimulatory and immunoregulatory sequences.

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 ethics, corporate governance guidelines, audit committee charter, nominating 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

Immunostimulatory Sequences

Immunostimulatory Sequences (ISS) are short deoxyribonucleic acid (DNA) sequences that enhance the ability of the immune system to fight disease. ISS activate the innate immune response by specifically targeting Toll-like Receptor (TLR) 9, which is found on a specialized subset of immune cells.

ISS work by changing or reprogramming the immune responses that cause disease rather than just by treating the symptoms of the disease. Since TLR9 is found exclusively in a specialized subset of dendritic cells, ISS do not cause a generalized activation of the immune system and redirect the response of only those T-cells involved in a given disease. When linked to or combined with antigens, ISS help generate memory T Helper (Th) 1 cells that can reprogram the immune system to induce long-lasting therapeutic effects.

We have developed a number of proprietary ISS compositions and formulations that make use of the different ways in which the innate immune system responds to ISS. Depending on the indication for which ISS is being explored as a therapy, we use ISS in different ways.

Immunostimulatory Sequences Linked to or Combined with Antigens

For prevention of infectious diseases, ISS can be linked to or combined with antigens to increase the visibility of the antigen and stimulate an immune response that will attack and destroy infected or abnormal cells. This treatment induces a highly specific Th1 immune response and generates memory T-cells for long-term protection. This treatment has the potential to be used synergistically with other therapies.

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Immunostimulatory Sequences Alone

For treatment of viral and respiratory diseases, ISS can be used alone to modify the course of the disease by reprogramming the immune system. ISS suppress the Th2 inflammatory response caused by any number of allergens to modify the underlying cause of inflammation as well as provide symptomatic relief.

Advanced Immunostimulatory Sequences Technologies

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

Immunoregulatory Sequences

Immunoregulatory Sequences (IRS) are short DNA sequences that specifically inhibit TLRs associated with autoimmune and inflammatory diseases. TLRs are key receptors of the innate immune system that can induce strong inflammatory responses. In animal studies as well as *in vitro*, our TLR inhibitors have demonstrated broad potential in multiple autoimmune disease models, such as lupus, inflammatory skin disorders and rheumatoid arthritis.

DEVELOPMENT PROGRAMS

Our pipeline of product candidates includes the following:

Product Candidate	Clinical Indication(s)	Phase	Partnership/Funding Support
HEPLISAV	Hepatitis B prevention	Phase 3	Dynavax
DV1179	Autoimmune and inflammatory diseases	Phase 1	GSK
AZD1419	Asthma	Preclinical	AstraZeneca

HEPLISAV Hepatitis B Vaccine

HEPLISAV is an investigational adult hepatitis B vaccine. In Phase 3 trials, HEPLISAV demonstrated higher and earlier protection with fewer doses than currently licensed vaccines. Dynavax has worldwide commercial rights to HEPLISAV. HEPLISAV combines our first generation ISS, 1018, (1018 ISS) with hepatitis B surface antigen (HBsAg) manufactured in our Dynavax facility in Düsseldorf, Germany (Rhein or Dynavax Europe).

On February 25, 2013, Dynavax announced that it had received a CRL from the FDA regarding its BLA for HEPLISAV. In the CRL, the FDA specified that the indication in adults 18-70 years of age cannot be approved without further evaluation of safety in this broad age group. The FDA also expressed concern that novel adjuvants may cause rare autoimmune events, however, the Agency indicated its willingness to continue discussions with us regarding a more restricted use of HEPLISAV.

The FDA also requested additional data from Dynavax s process validation program as well as clarifying information on the manufacturing controls and facilities with respect to quality assurance of commercial product. Dynavax believes it can provide the information but the exact timeframe for its response cannot be determined until a meeting with the Agency occurs. We plan to meet with the FDA in the near term to discuss the CRL and the steps necessary for potential approval of HEPLISAV.

Dynavax s BLA was accepted for review by the FDA in June 2012. On November 15, 2012, the FDA s Vaccines and Related Biological Products Advisory Committee (Committee) voted 8 to 5 with 1 abstention that there was insufficient data to adequately support the safety of HEPLISAV, although the Committee voted 13 to 1 that HEPLISAV data adequately demonstrated immunogenicity.

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Dynavax s MAA for HEPLISAV continues to be under review in Europe.

Commercial Opportunity

Hepatitis B can be a chronic disease which can lead to cirrhosis of the liver, hepatocellular carcinoma and death. There is no cure for hepatitis B, 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 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 people with diabetes mellitus (type 1 and type 2).

DV1179 (IRS) for Autoimmune and Inflammatory Diseases

Our IRS program is focused on novel inhibitors of TLR7, TLR8 and TLR9 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, a bifunctional inhibitor of TLR7 and TLR9, in systemic lupus erythematosus patients. GSK has an exclusive option to obtain a license to this program following completion of this trial. We also are developing inhibitors of TLR8 for the treatment of multiple autoimmune and inflammatory diseases in this collaboration. The activation of TLR8 in myeloid cells yields the production of multiple pro-inflammatory cytokines including tumor necrosis factors, Interleukin-1, Interleukin-6 and Interleukin-12.

AZD1419 Asthma Therapy

We are developing AZD1419, a novel candidate drug for asthma, under our collaboration agreement with AstraZeneca. AZD1419 utilizes our proprietary second-generation ISS and represents a new 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. We are preparing to advance AZD1419 into Phase 1 clinical trials after completion of remaining preclinical activities.

PHARMACEUTICAL 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 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.

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GlaxoSmithKline

In December 2008, we entered into a worldwide strategic alliance with GSK to discover, develop and commercialize TLR inhibitors. We received an initial payment of $10 million and agreed to conduct research and early clinical development in up to four programs. In 2011, we earned $15 million in milestone payments for the initiation of Phase 1 and proof-of-mechanism clinical trials of DV1179 in systemic lupus erythematosus patients and expansion of our collaboration with GSK to develop a TLR8 inhibitor. We are eligible to receive future development milestone payments which we have determined to be substantive milestones. GSK can exercise its exclusive option to license each program upon achievement of certain events and we are eligible to receive contingent option exercise payments. If GSK exercises an option, GSK would carry out further development and commercialization of the corresponding products. We are eligible to receive tiered, up to double-digit royalties on sales of any products originating from the collaboration and have retained an option to co-develop and co-promote one product under this agreement.

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 TLR9 agonist-based therapies for the treatment of asthma and chronic obstructive pulmonary disease for which we received an upfront payment of $10 million. In 2008, we received a milestone payment of $4.5 million for the nomination of the first candidate drug, AZD1419, for asthma. The research term of this agreement was extended through July 2010.

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. 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. 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 United States 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 ISS technology using TLR9 agonists as vaccine adjuvants. This five-year contract was awarded by the National Institute of Health s (NIH) National Institute of Allergy and Infectious Diseases (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.

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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 $0.3 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, we were awarded a $0.6 million grant from the NIH that will be used to fund research to characterize the role of the phosphoinositide 3-kinase in preclinical models of skin autoimmune inflammation.

During 2012, we were awarded a $0.4 million grant from the NIH to fund research in screening for inhibitors of TLR8 for treatment of rheumatoid arthritis and a $0.6 million grant to fund development of TLR8 inhibitors for treatment of autoimmune diseases.

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 United States, 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, 2012, our intellectual property portfolio included 25 issued U.S. patents, over 150 issued or granted foreign patents and over 50 additional pending U.S. and foreign patent applications claiming compositions and formulations of ISS and IRS, 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 ISS contained in our HEPLISAV investigational vaccine that will expire in 2018, unless extended, and corresponding 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 United States 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 2032.

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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 United States 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 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. In addition, the Institut Pasteur also owns or has exclusive licenses to patents covering HBsAg. While some of these patents have expired or will soon expire outside the United States, they remain in force in the United States. To the extent we are able to commercialize HEPLISAV in the United States 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 ISS other than with respect to HEPLISAV, 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

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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 $1.8 million in license fees, 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, 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 United States. In addition, HEPLISAV will compete against a number of multivalent vaccines that simultaneously protect against hepatitis B and other diseases.

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, Abbott Laboratories 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.

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

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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 United States, 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 United States 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;

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- 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 good clinical practice under protocols submitted to the regulatory authority as part of the clinical application. This includes the requirement that each clinical trial must be approved and conducted under the auspices of an investigational review board and with patient informed consent. The investigational review board will consider, among other things, 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.

We and all of our contract manufacturers are required to comply with the applicable FDA or foreign regulatory agency current Good Manufacturing Practice (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

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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 ISS, certain antigens, the combination of the ISS and the antigens and the formulation, fill and finish of these products. The process for manufacturing oligonucleotides such as ISS is well-established and uses commercially available equipment and raw materials. We have relied on a limited number of suppliers to produce ISS for clinical trials and a single supplier to produce our 1018 ISS for HEPLISAV. To date, we have manufactured only small quantities of ISS and 1018 ISS ourselves for development purposes. We currently manufacture the HBsAg for HEPLISAV 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 $49.1 million, $51.3 million and $53.7 million for the years ended December 31, 2012, 2011 and 2010, 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, 2012, we had 167 full-time employees, including 22 Ph.D.s, 6 M.D.s and 13 others with advanced degrees. Of the 167 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.

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Risks Related to our Business

The success of our product candidates, in particular HEPLISAV, 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 United States, 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 United States and in other countries are uncertain, can take many years and require the expenditure of substantial resources.

For our lead product, HEPLISAV, 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 by the FDA 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; 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 recent Complete Response Letter from the FDA received in February 2013 (the Complete Response Letter), HEPLISAV 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 in this broad age group. The FDA also expressed concern that novel adjuvants may cause rare autoimmune events. While the Agency indicated its willingness to continue discussions with us regarding a more restricted use of HEPLISAV, there can be no assurance that further FDA guidance will not require us to conduct additional clinical studies or that our data will support approval.

The FDA also requested additional data from our process validation program as well as clarifying information on the manufacturing controls and facilities 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.

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 based on the Complete Response Letter from the FDA 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.

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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 before granting regulatory approval, if 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. Any extension of our clinical trials 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.

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

HEPLISAV incorporates our 1018 ISS compound and most of our research and development programs use ISS-based technology. 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 ISS, 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 ISS-based 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 are significant. If we fail to achieve and sustain commercial success for HEPLISAV, either directly or with a partner, our business would be harmed.

Although certain of our employees have commercialization experience, as a company we currently have no sales, marketing or distribution capabilities. HEPLISAV product sales are currently expected to generate a substantial portion of our future revenue, if HEPLISAV is approved. To commercialize HEPLISAV, we must either develop sales, marketing and distribution capabilities, or make arrangements with third parties to perform these services, which will require resources and time and we may not be able to enter into these arrangements on acceptable terms. If we decide to market HEPLISAV directly, we must commit significant resources to develop a marketing and sales force with technical expertise and

with supporting distribution capabilities. In particular, significant resources may be necessary to successfully market, sell and distribute HEPLISAV to patients with

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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 may significantly impact our ability to achieve commercial success in this potential patient population.

Factors that may inhibit our efforts to commercialize HEPLISAV directly or indirectly with a partner if approved include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to administer our products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- our inability to expand and sustain qualified manufacturing capacity to meet demand, in particular if there is a significant increase in demand due to the recommendation to vaccinate persons with diabetes if we should obtain approval to market to those patients;
- our inability to determine appropriate pricing and reimbursement strategies for HEPLISAV in the potential patient populations that may use HEPLISAV, particularly in the diabetes market; and
- possible claims against us, including enjoining sales of HEPLISAV, based on the patent rights of others; and
- unanticipated delays, costs and expenses associated with manufacturing and commercialization of our products, including costs of maintaining and scaling up manufacturing capabilities and creating and sustaining an independent sales and marketing organization in various territories.

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, 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, 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 ISS 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 ISS, certain antigens, the combination of ISS 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 ISS for clinical trials and a single supplier to produce our 1018 ISS for HEPLISAV. To date, we have manufactured only small quantities of ISS and 1018 ISS ourselves for development purposes. If we were unable to maintain our existing supplier for 1018 ISS, 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. We or other third parties may not be able to produce 1018 ISS at a cost, quantity and quality that are available from our current third-party supplier.

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We currently utilize our facility in Düsseldorf to manufacture the hepatitis B surface antigen for HEPLISAV. The commercial manufacturing of biological products is a time-consuming and complex process, which must be performed in compliance with current GMP regulations.

As indicated in the Complete Response Letter from the FDA, we will be required to provide additional data from our process validation program as well as clarifying information on the manufacturing controls and facilities with respect to quality assurance of commercial product, and there can be no assurance as to the timing and if we can provide the data and information necessary to secure product approval.

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 or delay or disrupt the commercialization of HEPLISAV and could result in significant expense. Moreover, depending on the level of market acceptance of HEPLISAV, 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, which could have a material adverse effect on the success of HEPLISAV. Likewise, in the event that HEPLISAV 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.

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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 United States, 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, in various markets outside the United States. Developing, seeking regulatory approval for and marketing our product candidates outside the United States 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 submitted HEPLISAV for marketing approval in Europe. The Complete Response Letter from the FDA may result in further consideration of our MAA in Europe and we may not obtain foreign regulatory approvals on a timely basis, if at all. Specifically, a 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;

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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 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, 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.

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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, if approved. The recent FDA Complete Response Letter for HEPLISAV may negatively impact the potential for a collaborative relationship and failure to obtain a collaborative relationship for HEPLISAV, particularly in the European Union and for other markets requiring extensive sales efforts, may significantly impair the potential for this product. We also will need to enter into or maintain collaborative relationships to provide funding to support our other research and development programs. 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.

The financial terms of future collaborative licensing or financing arrangements could result in dilution of our share value.

Funding from collaboration partners and other parties may in the future involve issuance of our equity securities. Because we do not currently have any such arrangements, we cannot be certain how the terms under

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which such shares are issued will be determined or when such determinations will be made. The current market for financing or collaborative arrangements often involves the issuance of warrants as additional consideration in establishing the purchase price of the equity securities issued. Any such issuance could result in dilution in the value of our issued and outstanding shares.

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, HEPLISAV will compete in the United States with established hepatitis B vaccines marketed by Merck and GSK and outside the United States 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.

As we advance HEPLISAV 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. In addition, we expect to enhance our senior management group as we prepare to become a commercial organization. Our future financial performance and our ability to commercialize HEPLISAV 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 development 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

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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 or our President, could delay or prevent achieving our objectives.

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, Dr. Dino Dina, or our President, Dr. J. Tyler Martin. We currently have no key person insurance on any of our employees. We intend to strengthen our senior management group as we prepare to become a commercial organization, and during the second quarter 2012, our Board of Directors initiated a process for Dr. Dina s succession.

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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 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 $435.5 million as of December 31, 2012. 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 regulatory approval and commercialization of HEPLISAV.

We do not have any products that generate revenue. There can be no assurance whether HEPLISAV can be further developed, financed or commercialized in a timely manner without significant additional studies or patient data or significant expense; whether current development efforts will be sufficient to support approval of HEPLISAV; or if approved, whether the market for HEPLISAV will be sufficient for us to reach profitability. The recent Complete Response Letter from the FDA for HEPLISAV means that our efforts to achieve product revenues are delayed 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.

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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, is approved, to commence sales and marketing activities.

To continue development of our product candidates and, if it is approved, to launch HEPLISAV, we may 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 commercialization of our product candidates, particularly HEPLISAV;

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 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

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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. 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 United States, they remain in force in the United States. To the extent we are able to commercialize HEPLISAV in the United States 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 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 ISS 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 of ISS other than with respect to HEPLISAV, 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 United States, 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 United States 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 United States, where we may only be able to obtain limited patent protection.

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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, for example as evidenced by our stock decline of over 30% following our February 2013 announcement of a Complete Response Letter from the FDA;
- 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;

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- 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. This risk may be particularly relevant for us because we have experienced greater than average stock price volatility. We may in the future be the target of 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

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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, 2012, we had 182,791,521 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, 2012, we leased approximately 40,700 square feet of laboratory and office space in Berkeley, California under agreements expiring in June 2018. On December 17, 2012, we entered into a new lease of approximately 14,500 square feet of additional office space in Berkeley, California under an agreement 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. We do not believe any of the current claims or allegations are material to our current business or operations.

ITEM 4. MINE SAFETY DISCLOSURE

Not applicable.

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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 sale prices per share of our common stock.

	Common Stock Price	
	High	Low
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
2011		
First Quarter	$ 3.59	$ 2.48
Second Quarter	$ 2.94	$ 2.42
Third Quarter	$ 3.16	$ 1.80
Fourth Quarter	$ 3.39	$ 1.75

As of February 28, 2013, there were approximately 86 holders of record of our common stock, as shown on the records of our transfer agent. We believe that our stockholders exceed 17,800 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

Period	(a) Total Number of Shares (or Units) Purchased[1] (In thousands)	(b) Average Price Paid per Share (or Unit)	(c) Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	(d) Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs
October 1, 2012 to October 31, 2012	28	$ 4.81		

November 1, 2012 to November 30, 2012			
December 1, 2012 to December 31, 2012			
Total	28	$	4.81

(1) In October 2012, we delivered 75,000 shares of common stock to certain holders of vested restricted stock units, which had been awarded in November 2010. Of this amount, 27,510 shares of common stock were surrendered at an average price of $4.81 per share to the Company in satisfaction of tax obligations related to the shares of common stock delivered.

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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, 2012, 2011 and 2010 and the Consolidated Balance Sheets Data as of December 31, 2012 and 2011 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, 2009 and 2008 and the Consolidated Balance Sheets Data as of December 31, 2010, 2009 and 2008 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.

	Years Ended December 31,				
	2012	2011	2010	2009	2008
	(In thousands, except per share data)				
Consolidated Statements of Operations Data:					
Total revenues	$ 9,714	$ 21,614	$ 23,950	$ 40,318	$ 37,094
Operating expenses:					
Research and development	49,146	51,322	53,680	38,708	44,771
General and administrative	28,164	17,570	16,879	15,745	15,463
Amortization of intangible assets		299	980	980	980
Total operating expenses	77,310	69,191	71,539	55,433	61,214
Loss from operations	(67,596)	(47,577)	(47,589)	(15,115)	(24,120)
Interest income	291	103	85	178	1,631
Interest expense	(2,351)	(1,957)	(1,654)	(124)	(9,157)
Other income (expense)[1]	(293)	834	(8,150)	(66)	110
Loan forgiveness[2]					5,000
Net loss	(69,949)	(48,597)	(57,308)	(15,127)	(26,536)
Consideration paid in excess of carrying value of the noncontrolling interest in Symphony Dynamo, Inc. (SDI[3])				(19,671)	
Add: Losses attributable to noncontrolling interest in SDI				4,233	5,707
Net loss attributable to Dynavax	$ (69,949)	$ (48,597)	$ (57,308)	$ (30,565)	$ (20,829)
Basic and diluted net loss per share attributable to Dynavax common stockholders	$ (0.41)	$ (0.39)	$ (0.69)	$ (0.76)	$ (0.52)
Shares used to compute basic and diluted net loss per share attributable to Dynavax common stockholders	170,469	125,101	82,463	40,350	39,819

(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 a $5.0 million portion of a loan from Deerfield that was forgiven upon termination of a loan agreement during the year ended December 31, 2008.

(3) 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.

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	2012	2011	December 31, 2010	2009	2008
			(In thousands)		
Consolidated Balance Sheets Data:					
Cash, cash equivalents and marketable securities	$ 125,130	$ 113,961	$ 72,154	$ 36,720	$ 43,367
Investments held by Symphony Dynamo, Inc.					25,109
Working capital	109,173	97,399	60,598	24,583	36,381
Total assets	139,752	134,102	84,249	50,470	90,623
Note payable to Symphony Dynamo Holdings LLC[(1)]		12,810	10,939	9,342	
Noncontrolling interest in Symphony Dynamo, Inc.					2,634
Accumulated deficit	(435,491)	(365,542)	(316,945)	(259,637)	(248,743)
Total Dynavax stockholders equity	114,826	99,880	52,111	6,376	13,522

(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, discovers and develops novel products to prevent and treat infectious and inflammatory diseases. Our lead product candidate is HEPLISAV , a Phase 3 investigational adult hepatitis B vaccine.

Our pipeline of product candidates includes: HEPLISAV, our autoimmune program partnered with GlaxoSmithKline (GSK) and our therapy for asthma partnered with AstraZeneca AB (AstraZeneca). We compete with pharmaceutical companies, biotechnology companies, academic institutions and research organizations, in developing therapies to prevent or treat infectious and inflammatory diseases. Our product candidates are based on our proprietary technology which uses immunostimulatory and immunoregulatory sequences.

Recent Developments

On February 25, 2013, Dynavax announced that it had received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA or Agency) regarding its Biologic License Application (BLA) for HEPLISAV. In the CRL, the FDA specified that the indication in adults 18-70 years of age cannot be approved without further evaluation of safety in this broad age group. Furthermore, the FDA requested

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additional data from Dynavax s process validation program and clarifying information on the manufacturing controls and facilities related to the assurance of the quality of the commercial product. We plan to meet with the FDA in the near term to discuss the CRL and the steps necessary for potential approval of HEPLISAV.

Dynavax s Marketing Authorization Application for HEPLISAV continues to be under review in Europe.

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 (U.S. 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, including those related to revenue recognition, research and development activities, stock-based compensation, asset impairment, contingencies and the valuation of certain liabilities. 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. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 to 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, 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. 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.

On January 1, 2011, we elected to prospectively adopt the milestone method as described in FASB ASU 2010-17, *Milestone Method of Revenue Recognition.* Under the milestone method, contingent consideration

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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

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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.

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 an annual forfeiture rate of 5% for our senior management group and 13% for all other employees. 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. See Note 13, Stockholder s Equity to the Consolidated Financial Statements for further information on our equity incentive plans.

Results of Operations

Revenues

Revenues consist of amounts earned from collaborations, grants and services and license fees. Collaboration revenue includes revenue recognized under our collaboration agreements. Grant revenue includes amounts earned under government and private agency grants. Service and license fees include 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, 2012, 2011 and 2010 (in thousands, except for percentages):

	Years Ended December 31,			Increase (Decrease) from 2011 to 2012		Increase (Decrease) from 2010 to 2011	
Revenues:	**2012**	**2011**	**2010**	**$**	**%**	**$**	**%**
Collaboration revenue	$ 4,610	$ 17,190	$ 19,535	$ (12,580)	(73)%	$ (2,345)	(12)%
Grant revenue	3,939	3,110	3,940	829	27%	(830)	(21)%
Service and license revenue	1,165	1,314	475	(149)	(11)%	839	177%
Total revenues	$ 9,714	$ 21,614	$ 23,950	$ (11,900)	(55)%	$ (2,336)	(10)%

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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 the 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 the increase in revenue recognized from our National Institute of Health s National Institute of Allergy and Infectious Diseases (NIAID) contract related to adjuvant development.

2011 versus 2010

Total revenues for the year ended December 31, 2011, decreased by $2.3 million, or 10%, as compared to 2010 primarily due to the reduction in collaboration revenue. Collaboration revenue for the year ended December 31, 2011, included recognition of $15 million from GSK for milestones earned in 2011, $1.4 million in revenue from our collaboration with GSK and $0.8 million in other revenue related to our collaboration with AstraZeneca, compared to collaboration revenue for the year ended December 31, 2010, which included recognition of a $10 million upfront payment received from AstraZeneca in 2006 following an amendment to the collaboration agreement, $4.1 million of other revenue related to our collaboration with AstraZeneca, a one-time $4 million payment from Merck & Co. in satisfaction of its obligations to us following termination of our collaboration and $1.4 million in revenue from our collaboration with GSK. Grant revenue for the year ended December 31, 2011, decreased by $0.8 million from the same period in 2010 primarily due to the decrease in revenue recognized from our NIAID contract. Service and license revenue for the year ended December 31, 2011, increased by $0.8 million as compared to 2010 as a result of an increase in royalty revenue and manufacturing service revenue earned by Rhein.

Research and Development

Research and development expenses consist 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 are incurred for our preclinical experiments and clinical trials, regulatory filings and manufacturing of our product candidates.

The following is a summary of our research and development expense (in thousands, except for percentages):

	Years Ended December 31,			Increase (Decrease) from 2011 to 2012		Increase (Decrease) from 2010 to 2011	
Research and Development:	**2012**	**2011**	**2010**	**$**	**%**	**$**	**%**
Compensation and related personnel costs	$ 21,134	$ 19,106	$ 15,221	$ 2,028	11%	$ 3,885	26%
Outside services	19,371	24,811	31,372	(5,440)	(22)%	(6,561)	(21)%
Facility costs	5,127	5,302	6,455	(175)	(3)%	(1,153)	(18)%
Non-cash stock-based compensation	3,514	2,103	632	1,411	67%	1,471	233%
Total research and development	$ 49,146	$ 51,322	$ 53,680	$ (2,176)	(4)%	$ (2,358)	(4)%

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

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as compared to 2011 from lower HEPLISAV 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.

2011 versus 2010

Research and development expense for the year ended December 31, 2011, decreased by $2.4 million, or 4%, as compared to 2010. The decrease in costs was primarily due to the decline in outside services during 2011 as compared to 2010 from lower HEPLISAV 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. In addition, during 2011, facility costs decreased by $1.2 million as compared to 2010, as a result of lower rent expense from reduced leased space.

General and Administrative

General and administrative expenses primarily consist 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):

				Increase (Decrease) from 2011 to 2012		Increase (Decrease) from 2010 to 2011	
	Years Ended December 31,						
General and Administrative:	**2012**	**2011**	**2010**	**$**	**%**	**$**	**%**
Compensation and related personnel costs	$ 9,468	$ 7,398	$ 6,436	$ 2,070	28%	$ 962	15%
Outside services	8,730	4,548	4,207	4,182	92%	341	8%
Legal costs	2,437	1,894	3,622	543	29%	(1,728)	(48)%
Facility costs	604	644	836	(40)	(6)%	(192)	(23)%
Non-cash stock-based compensation	6,925	3,086	1,778	3,839	124%	1,308	74%
Total general and administrative	$ 28,164	$ 17,570	$ 16,879	$ 10,594	60%	$ 691	4%

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. 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.

2011 versus 2010

General and administrative expenses for the year ended December 31, 2011, increased by $0.7 million, or 4%, compared to the same period in 2010. This increase is primarily due to higher compensation and related personnel costs, including non-cash stock-based compensation, from growth in the number of administrative employees to support the overall organization, partially offset by a decline in legal costs related to patent activities.

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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 and $1.0 million for the years ended December 31, 2011, and 2010, respectively.

Interest Income, Interest Expense and Other Income (Expense)

Interest income is reported net of amortization of premiums and includes accretion of discounts on marketable securities and realized gains and losses on marketable securities. Interest expense relates to the note payable issued to Symphony Dynamo Holdings LLC (Holdings). Other income (expense) includes gains and losses on foreign currency transactions, changes in the fair value of contingent and warrant liabilities 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):

	Years Ended December 31,			Increase (Decrease) from 2011 to 2012		Increase (Decrease) from 2010 to 2011	
	2012	2011	2010	$	%	$	%
Interest income	$ 291	$ 103	$ 85	$ 188	183%	$ 18	21%
Interest expense	$ (2,351)	$ (1,957)	$ (1,654)	$ 394	20%	$ 303	18%
Other income (expense)	$ (293)	$ 834	$ (8,150)	$ (1,127)	(135)%	$ 8,984	110%

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, 2012 and 2011 is related to interest from the accretion of the discount on the note payable to Holdings that was paid in cash on December 31, 2012.

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. Other income (expense) for the year ended December 31, 2010 primarily 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) in April 2010 and the remeasurement of the warrant liability through June 30, 2010, that resulted in non-operating expense of $11.1 million, partially offset by a gain of $2.2 million for the change in fair value of the long-term contingent liability to Holdings. Additionally, in 2010 we received a one-time payment of $0.7 million under The Patient Protection and Affordable Care Act of 2010, awarded to us to cover research and development costs from 2009 and 2010 for our qualified therapeutic discovery projects including HEPLISAV.

Liquidity and Capital Resources

As of December 31, 2012, we had $125.1 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 to fund our operations. We raised $69.6 million, $91.3 million and $87.4 million in the years ended December 31, 2012, 2011 and 2010, respectively, from public and private sales of our securities. Our funds are currently invested in short-term money market funds, U.S. government agency securities, U.S. treasury securities and municipal securities.

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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.

Cash used in operating activities during the year ended December 31, 2011, was $47.1 million compared to $51.4 million for the same period in 2010. The decrease in cash usage compared to the prior year was due to the decline in spending for HEPLISAV clinical development and the receipt of milestone payments from our pharmaceutical partners.

Cash used in investing activities during the year ended December 31, 2011, was $34.6 million compared to $50.5 million for 2010. The change was primarily due to the decrease in the net purchases of marketable securities in 2011.

Cash provided by financing activities during the year ended December 31, 2011, was $91.4 million compared to $87.6 million for the same period in 2010. The increase was primarily attributed to the completion of a public offering, which resulted in aggregate net proceeds of $64.5 million, after deducting offering expenses, and an additional $26.7 million in and funding from Aspire Capital, compared to $87.4 million raised in public offerings during 2010.

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 at December 31, 2012 and anticipated revenues and funding from existing agreements. We expect to continue to spend substantial funds in connection with development and manufacturing of our product candidates, particularly HEPLISAV; various human clinical trials for our product candidates; and protection of our intellectual property. To continue development of our product candidates and if it is approved, to launch HEPLISAV, 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 shareholders. If adequate funds are not available in the future, we would need to delay, reduce the scope of, or put on hold the HEPLISAV program or other development programs while we seek strategic alternatives.

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Contractual Obligations

The following summarizes our significant contractual obligations at December 31, 2012 and the effect those obligations are expected to have on our liquidity and cash flows in future periods (in thousands):

Contractual Obligations:	Total	2013	2014-2015	2016-2017	2018 and Thereafter
Future minimum payments under our operating leases	$ 14,932	$ 2,064	$ 4,470	$ 4,671	$ 3,727
Total	$ 14,932	$ 2,064	$ 4,470	$ 4,671	$ 3,727

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. We have also entered into two sublease agreements under the Düsseldorf Lease for certain portions of the leased space with total remaining scheduled payments of $41 thousand due to us through July 2013.

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, 2012 and is collateralized by a certificate of deposit which has been included in restricted cash in the consolidated balance sheets as of December 31, 2012 and 2011. 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, 2012 and is collateralized by a certificate of deposit which has been included in restricted cash in the consolidated balance sheets as of December 31, 2012 and 2011.

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 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. We consider these potential obligations to be contingent and have summarized all significant arrangements below.

We rely on research institutions, contract research organizations, clinical investigators and clinical material manufacturers. As of December 31, 2012, under the terms of our agreements, we are obligated to make future payments as services are provided of approximately $9.9 million through 2015. These agreements are terminable by us upon written notice. We are generally only liable for actual effort expended by the organizations at any point in time during the contract, subject to certain termination fees and penalties.

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 products covered by patents and patent applications originating from the licensed technologies, if any.

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.

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

Interest Rate Risk

The primary objective of our investment activities is to preserve principal while at the same time maximize the 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 currently maintain our portfolio of cash equivalents and marketable securities in a variety of securities, including money market funds, U.S. government agency securities, U.S. treasury securities, municipal securities and corporate obligations secured by the Federal Deposit Insurance Corporation through the Temporary Liquidity Guarantee Program. We do not invest in auction rate securities or securities collateralized by home mortgages, mortgage bank debt, or home equity loans. Our investment portfolio approach has been consistent for several fiscal years.

In addition, if interest rates rise, the market value of our investment portfolio may decline, which could result in a loss if we choose or are forced to sell an investment before its scheduled maturity. If interest rates were to rise from current levels by 100 basis points and by 125 basis points, the change in our net unrealized loss on investments would be $1.4 million and $1.8 million, respectively. We do not utilize derivative financial instruments to manage interest rate risk.

Foreign Currency Risk

We have certain investments outside the United States for the operations of Dynavax Europe and have some exposure to foreign exchange rate fluctuations. The cumulative translation adjustment reported in the consolidated balance sheet as of December 31, 2012 was $0.6 million primarily related to translation of Dynavax Europe assets, liabilities and operating results from Euros to U.S. dollars. Through December 31, 2012 the effect of our exposure to 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.

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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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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, 2012 and 2011, 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, 2012. 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, 2012 and 2011, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2012, 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, 2012, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 8, 2013 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Redwood City, California

March 8, 2013

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DYNAVAX TECHNOLOGIES CORPORATION

CONSOLIDATED BALANCE SHEETS

(In thousands, except per share amounts)

	December 31, 2012	December 31, 2011
Assets		
Current assets:		
Cash and cash equivalents	$ 7,599	$ 31,941
Marketable securities available-for-sale	117,531	82,020
Accounts receivable	1,005	9,527
Prepaid expenses and other current assets	2,052	1,130
Total current assets	128,187	124,618
Property and equipment, net	7,965	6,163
Goodwill	2,475	2,312
Restricted cash	652	647
Other assets	473	362
Total assets	$ 139,752	$ 134,102
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 2,166	$ 2,040
Accrued liabilities	10,063	8,159
Deferred revenues	6,785	4,210
Note payable to Symphony Dynamo Holdings LLC (Holdings)		12,810
Total current liabilities	19,014	27,219
Deferred revenues, noncurrent	5,283	6,386
Other long-term liabilities	629	617
Total liabilities	24,926	34,222
Commitments and contingencies (Note 10)		
Stockholders equity:		
Preferred stock: $0.001 par value; 5,000 shares authorized and no shares issued and outstanding at December 31, 2012 and 2011		
Common stock: $0.001 par value; 250,000 shares authorized at December 31, 2012 and 2011, respectively; 182,792 and 154,626 shares issued and outstanding at December 31, 2012 and 2011, respectively	183	155
Additional paid-in capital	550,729	466,276
Accumulated other comprehensive loss:		
Unrealized gain (loss) on marketable securities available-for-sale	45	(3)
Cumulative translation adjustment	(640)	(1,006)
Total accumulated other comprehensive loss	(595)	(1,009)
Accumulated deficit	(435,491)	(365,542)
Total stockholders equity	114,826	99,880
Total liabilities and stockholders equity	$ 139,752	$ 134,102

See accompanying notes.

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DYNAVAX TECHNOLOGIES CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

	Years Ended December 31,		
	2012	2011	2010
Revenues:			
Collaboration revenue	$ 4,610	$ 17,190	$ 19,535
Grant revenue	3,939	3,110	3,940
Service and license revenue	1,165	1,314	475
Total revenues	9,714	21,614	23,950
Operating expenses:			
Research and development	49,146	51,322	53,680
General and administrative	28,164	17,570	16,879
Amortization of intangible assets		299	980
Total operating expenses	77,310	69,191	71,539
Loss from operations	(67,596)	(47,577)	(47,589)
Interest income	291	103	85
Interest expense	(2,351)	(1,957)	(1,654)
Other income (expense)	(293)	834	(8,150)
Net loss	$ (69,949)	$ (48,597)	$ (57,308)
Basic and diluted net loss per share	$ (0.41)	$ (0.39)	$ (0.69)
Shares used to compute basic and diluted net loss per share	170,469	125,101	82,463

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

	Years Ended December 31,		
	2012	2011	2010
Net loss	$ (69,949)	$ (48,597)	$ (57,308)
Other comprehensive income (loss):			
Unrealized gain (loss) on marketable securities available-for-sale	48	14	(17)
Cumulative translation adjustment	366	(277)	(561)
Total other comprehensive income (loss)	414	(263)	(578)
Total comprehensive loss	$ (69,535)	$ (48,860)	$ (57,886)

See accompanying notes.

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DYNAVAX TECHNOLOGIES CORPORATION

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

(In thousands)

	Common Stock			Accumulated Other Comprehensive Income (Loss)		
	Shares	Par Amount	Additional Paid-In Capital		Accumulated Deficit	Total Stockholders Equity
Balances at December 31, 2009	54,279	$ 54	$ 266,127	$ (168)	$ (259,637)	$ 6,376
Issuance of common stock upon exercise of stock options and restricted stock awards	141	1	159			160
Issuance of common stock under Employee Stock Purchase Plan	121		72			72
Proceeds from issuances of common stock and warrants, net of issuance costs	59,994	59	87,340			87,399
Reclassification of the warrant liability to Holdings into equity and the impact of the anti-dilution provision associated with the common stock and warrants issued to Holdings	1,076	2	13,578			13,580
Stock compensation expense			2,410			2,410
Total comprehensive income (loss)				(578)		(578)
Net loss					(57,308)	(57,308)
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 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 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

See accompanying notes.

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DYNAVAX TECHNOLOGIES CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Years Ended December 31,		
	2012	2011	2010
Operating activities			
Net loss	$ (69,949)	$ (48,597)	$ (57,308)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,207	1,303	1,415
Amortization of intangible assets		299	980
Loss (gain) on disposal of property and equipment	8	20	(36)
Accretion of discounts and amortization of premiums of marketable securities	1,298	1,172	367
Interest associated with long-term note payable to Holdings	2,190	1,871	1,597
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)	8,816
Stock compensation expense	10,439	5,189	2,410
Changes in operating assets and liabilities:			
Accounts receivable	8,522	(8,526)	(106)
Prepaid expenses and other current assets	(922)	230	(774)
Restricted cash and other assets	(116)	(290)	(38)
Accounts payable	126	(289)	643
Accrued liabilities and other long term liabilities	1,916	(2,167)	3,381
Deferred revenues	1,472	3,512	(12,717)
Net cash used in operating activities	(43,809)	(47,116)	(51,370)
Investing activities			
Purchases of marketable securities	(206,149)	(111,205)	(80,835)
Proceeds from maturities of marketable securities	169,387	77,729	30,750
Purchases of property and equipment, net	(2,931)	(1,142)	(420)
Net cash used in investing activities	(39,693)	(34,618)	(50,505)
Financing activities			
Proceeds from issuances of common stock and warrants, net of issuance costs	71,780	91,298	87,399
Proceeds from exercise of stock options and restricted stock awards	1,955	10	160
Proceeds from employee stock purchase plan	307	132	72
Payment of notes payable to Holdings	(15,000)		
Net cash provided by financing activities	59,042	91,440	87,631
Effect of exchange rate on cash and cash equivalents	118	(218)	(23)
Net increase (decrease) in cash and cash equivalents	(24,342)	9,488	(14,267)
Cash and cash equivalents at beginning of year	31,941	22,453	36,720
Cash and cash equivalents at end of year	$ 7,599	$ 31,941	$ 22,453
Supplemental disclosure of cash flow information			
Non-cash investing and financing activities:			
Shares issued to Aspire Capital in conjunction with purchase agreement	$	$	$ 1,200
Shares issued in conjunction with the Symphony Dynamo, Inc. (SDI) transaction	$	$	$ 1,551

Warrants issued in conjunction with the SDI transaction	$	$	$ 6,638
Disposal of fully depreciated property and equipment	$ 169	$ 1,181	$ 42
Net change in unrealized gain (loss) on marketable securities	$ 48	$ 14	$ (17)

See accompanying notes.

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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, discovers and develops novel products to prevent and treat infectious and inflammatory diseases. Our lead product candidate is HEPLISAV , a Phase 3 investigational adult hepatitis B vaccine.

Our pipeline of product candidates includes: HEPLISAV, our autoimmune program partnered with GlaxoSmithKline (GSK) and our therapy for asthma partnered with AstraZeneca AB (AstraZeneca). We compete with pharmaceutical companies, biotechnology companies, academic institutions and research organizations in developing therapies to prevent or treat infectious and inflammatory diseases. Our product candidates are based on the use of immunostimulatory sequences (ISS) and immunoregulatory sequences. 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 have been eliminated. 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 2012, 2011 and 2010, 88%, 94% and 98% of our revenues were earned in the United States, respectively, and the remaining revenues were earned in Germany. As of December 31, 2012, and 2011, 10% and 14%, respectively, of our long-lived assets were located in the United States and the remaining long-lived assets were located in Germany.

Liquidity and Financial Condition

We have incurred significant operating losses and negative cash flows from operations since our inception. As of December 31, 2012, we had cash, cash equivalents and marketable securities of $125.1 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, 2012 and anticipated revenues and funding from existing agreements.

If we are unable to generate significant revenues from HEPLISAV, if it is approved, and to continue development of our product candidates, 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. Additional equity financings, if completed, could result in significant dilution or otherwise adversely affect the rights of existing shareholders. If adequate funds are not available in the future, we may need to delay, reduce the scope of or put on hold the HEPLISAV program or our other development programs while we seek strategic alternatives.

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Use of Estimates

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

Foreign Currency

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 on the balance sheet date. Revenues and expenses are translated at average exchange rates prevailing throughout the year. Currency translation adjustments are charged or credited to accumulated other comprehensive income (loss) in the consolidated balance sheets. For the years ended December 31, 2012, 2011 and 2010, we reported an unrealized gain of $0.4 million, an unrealized loss of $0.3 million and an unrealized loss of $0.6 million, respectively. Realized gains and losses resulting from currency transactions are included in the consolidated statements of operations. For the years ended December 31, 2012, 2011 and 2010, we reported a loss of $0.2 million, a gain of $0.2 million and a loss of $0.1 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 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, municipal securities and corporate obligations secured by the Federal Deposit Insurance Corporation through the Temporary Liquidity Guarantee Program. 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. We view our available-for-sale portfolio as 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 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.

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Concentration of Credit Risk and Other Risks and Uncertainties

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 money market funds, U.S. government agency securities, U.S. treasury securities and municipal securities secured by the Federal Deposit Insurance Corporation through the Temporary Liquidity Guarantee Program. We do not invest in auction rate securities or securities collateralized by home mortgages, mortgage bank debt, or home equity loans. 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 potential 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 trade accounts receivable.

Our future 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 ISS for clinical trials and a single contract manufacturer to produce our first generation ISS, 1018 (1018 ISS) for HEPLISAV. The loss of our current supplier would have a significant effect on our ability to produce HEPLISAV for commercialization and development of our other product candidates. To date, we have manufactured only small quantities of ISS and 1018 ISS 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.

Property and Equipment

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.

Valuation of Long-Lived Assets and Intangible Assets

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 that their carrying amounts may not be fully recoverable or that their useful lives are no longer appropriate. Intangible assets were subject to amortization and amortized over their estimated period of benefit of five years. 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 is 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 assets, liabilities and intangible assets acquired based on their estimated fair value,

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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. 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 methodology 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.

On January 1, 2011, we elected to prospectively adopt the milestone method as described in FASB ASU 2010-17, *Milestone Method of Revenue Recognition.* Under the milestone method, contingent consideration received from 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

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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 and 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, the 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.

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. The fair value-based measurement of stock options is calculated using the Black-Scholes option valuation model and is recognized on a straight-line basis over the option s vesting period, assuming an annual forfeiture rate of 5% for our senior management group and 13% for

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all other employees. Determining the appropriate fair value-based measurement requires the input of highly subjective assumptions, including the expected life of the option and expected stock price volatility. The senior management group and all other employees were grouped and considered separately for valuation purposes. See Note 13, Stockholder s Equity for further information on our equity incentive plans.

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, 2012 and 2011 because we believe it is more likely than not that our deferred tax assets will not be realized as of December 31, 2012, and 2011.

We have no unrecognized tax benefits as of December 31, 2012, including no accrued amounts for interest and penalties. We do not anticipate that total unrecognized tax benefits will significantly change prior to December 31, 2013. 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. See Note 15, Income Taxes for further information on our tax position.

Recent Accounting Pronouncements

Accounting Standards Update 2011-04

In May 2011, the FASB issued ASU No. 2011-04, *Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRS*. This ASU is the result of joint efforts by the FASB and International Accounting Standards Board to develop a single, converged fair value framework. While this ASU is largely consistent with existing fair value measurement principles in GAAP, it expands Accounting Standards Codification (ASC) Topic 820, *Fair Value Measurement* existing disclosure requirements for fair value measurements and makes other amendments. Many of these amendments were made to eliminate unnecessary wording differences between GAAP and International Financial Reporting Standards, which could change how fair value measurement guidance in ASC 820 is applied. We adopted the disclosure requirements in 2012 and included the required disclosure in Note 3 Fair Value Measurements.

Accounting Standards Update 2011-05

In June 2011, the FASB issued ASU No. 2011-05, *Presentation of Comprehensive Income*. This ASU gives an entity the option to present the total of comprehensive income, the components of net income and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. We adopted this presentation of comprehensive income in 2012.

Accounting Standards Update 2011-08

In September 2011, the FASB issued ASU No. 2011-08, *Testing Goodwill for Impairment*. This ASU allows an entity to first assess qualitative factors to determine whether it is necessary to perform the two-step quantitative goodwill impairment test. Under this ASU, an entity would not be required to calculate the fair value of a reporting unit unless the entity determines, based on a qualitative assessment, that it is more likely than not that its fair value is less than its carrying amount. This ASU includes a number of events and circumstances for an entity to consider in conducting the qualitative assessment. ASU No. 2011-08 was effective for us in 2012. The adoption of this ASU did not have a material impact on the Company s financial position or results of operations.

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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 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 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.

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, 2012 and 2011 (in thousands):

	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

	Level 1	Level 2	Level 3	Total
December 31, 2011				
Money market funds	$ 17,171	$	$	$ 17,171
U.S. government agency securities		28,495		28,495
U.S. treasury securities		7,425		7,425
Corporate debt securities, secured by the U.S. government		58,580		58,580
Total	$ 17,171	$ 94,500	$	$ 111,671

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, municipal securities and corporate debt securities are measured at fair value using Level 2 inputs. We review trading activity and pricing for these investments as of the 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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We are 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 are 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. There was no change in this determination during 2012. These fair value measurements were based on significant inputs not observed in the market and thus represented a Level 3 measurement.

The following table represents the changes in the fair value measurement of the contingent liability (in thousands):

Contingent liability to Holdings	**Amount**
Acquisition date fair value measurement at December 30, 2009	$ 3,040
Adjustment to fair value measurement	(2,197)
Balance as of December 31, 2010	843
Adjustment to fair value measurement	(843)
Balance as of December 31, 2011 and 2012	$

In connection with our purchase of all of the outstanding equity of Symphony Dynamo, Inc. (SDI) on December 30, 2009, we issued warrants to Holdings that were subject to certain anti-dilution protection in the event that we issued other equity securities within six months from December 30, 2009. Due to this adjustment provision, the warrants did not meet the criteria set forth in ASC 815, *Derivatives and Hedging*, to be considered indexed to our own stock and therefore were recorded as a liability at fair value, which was estimated at the issuance date using the Black-Scholes Model. This fair value measurement was based on significant inputs not observed in the market and thus represented a Level 3 measurement. In connection with an equity offering completed in April 2010 prior to the expiration of the anti-dilution provision, Holdings received warrants to purchase 7,038,210 shares of common stock (April 2010 Warrants). The warrants issued on December 30, 2009 were cancelled upon the issuance of the April 2010 Warrants.

The incremental fair value of the April 2010 Warrants was remeasured at June 30, 2010, and resulted in an increase of $9.5 million to the warrant liability, which was reported as other expense in the consolidated statement of operations. Following the expiration of Symphony s anti-dilution protection on June 30, 2010, the value of the April 2010 Warrants of $12 million was reclassified into stockholders equity in the consolidated balance sheet.

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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, 2012, and 2011 (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
December 31, 2012				
Cash and cash equivalents:				
Cash	$ 1,542	$	$	$ 1,542
Money market funds	3,140			3,140
U.S. government agency securities	715			715
Municipal 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
December 31, 2011				
Cash and cash equivalents:				
Cash	$ 2,290	$	$	$ 2,290
Money market funds	17,171			17,171
U.S. government agency securities	2,013			2,013
U.S. treasury securities	7,425			7,425
Corporate debt securities, secured by the U.S. government	3,044		(2)	3,042
Total cash and cash equivalents	31,943		(2)	31,941
Marketable securities available-for-sale:				
U.S. government agency securities	26,488		(5)	26,483
Corporate debt securities, secured by the U.S. government	55,533	9	(5)	55,537
Total marketable securities available-for-sale	82,021	9	(10)	82,020
Total cash, cash equivalents and marketable securities	$ 113,964	$ 9	$ (12)	$ 113,961

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

	December 31, 2012	
	Amortized Cost	Estimated Fair Value
Mature in one year or less	$ 79,743	$ 79,772
Mature after one year through two years	37,743	37,759

	$ 117,486	$ 117,531

We invest in short-term money market funds, U.S. government agency securities, U.S treasury securities, municipal securities and corporate obligations secured by the Federal Deposit Insurance Corporation through the Temporary Liquidity Guarantee Program.

There were no realized gains or losses from the sale of marketable securities in the years ended December 31, 2012, 2011 and 2010. All of our investments are classified as short-term and available-for-sale, as we may not hold our investments until maturity.

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5. Property and Equipment

Property and equipment as of December 31, 2012, and 2011 consist of the following (in thousands):

	Estimated Useful Life (In years)	December 31, 2012	2011
Manufacturing equipment	5-14	$	