DYNAVAX TECHNOLOGIES CORP
Form 10-K
March 12, 2012
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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, 2011

¨ **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, $.001 Par Value	The NASDAQ Stock Market LLC
Preferred Shares Purchase Rights	

Securities Registered Pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

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

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

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

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

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

The aggregate market value of the voting and non-voting stock held by non-affiliates of the registrant, based upon the closing sale price of the common stock on June 30, 2011 as reported on the NASDAQ Capital Market, was approximately $154,205,000. 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 29, 2012, the registrant had outstanding 155,815,117 shares of common stock.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Definitive Proxy Statement for the registrant s 2012 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, intend, or certain or the negative o variations or comparable terminology.

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

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

PART I

ITEM 1. BUSINESS

OVERVIEW

Dynavax Technologies Corporation (we, our, us, Dynavax or the Company), a clinical-stage biopharmaceutical company, discovers and develops novel products to prevent and treat infectious and inflammatory diseases. Our lead product candidate is HEPLISAV™ (HEPLISAV), a Phase 3 investigational adult hepatitis B vaccine designed to provide higher and earlier protection with fewer doses than currently licensed vaccines.

Our pipeline of product candidates includes: HEPLISAV, our autoimmune program partnered with GlaxoSmithKline (GSK), our therapy for asthma partnered with AstraZeneca AB (AstraZeneca), and clinical-stage programs for our Universal Flu vaccine and hepatitis B therapy. 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.

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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 Th1 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.

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.

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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
Universal Flu vaccine	Influenza prevention	Phase 1b	Novartis (Supply and Option Agreement)
DV-601	Hepatitis B infection	Phase 1b	Dynavax

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 1018 ISS with hepatitis B surface antigen (HBsAg) manufactured in our Dynavax Europe facility in Düsseldorf, Germany.

Clinical Results

Over 4,800 individuals have been vaccinated with HEPLISAV to date. During 2011, we reported topline results from our Phase 3 trial (HBV-16), which demonstrated non-inferiority, superiority and the safety of HEPLISAV. In 2011, we also reported immunogenicity data from the HBV-16 trial for subpopulations known to be hypo-responsive to currently licensed hepatitis B vaccines (males, obese, and smokers) as well as a diabetic subset analysis from the trial. In February 2012, we announced that we had met with the U.S. Food and Drug Administration (FDA) in a Pre-Biologics License Application (pre- BLA) meeting, and had agreed that the initial HEPLISAV BLA submission will be for an indication in healthy adults 18-70 years of age. This agreement represents a significant expansion of the previously anticipated population of healthy adults age 40 and over. In addition, it was confirmed that a supplemental BLA with an indication for patients with chronic kidney disease will be filed when the initial BLA is approved. We are making the required modifications to the BLA to support the expanded indication and plan to submit the BLA by the middle of May 2012. We plan to submit the Marketing Authority Application to the European Medicines Agency for European approval after the submission of our BLA in the U.S.

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, obese, smokers and diabetics, and immunocompromised persons, such as end-stage renal disease (ESRD) 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.

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We estimate the worldwide market for adult hepatitis B vaccines exceeds $700 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 CKD patients, people with multiple sexual partners or injection drug use, healthcare workers and first responders, travelers, and chronic liver disease patients.

In October 2011, the Advisory Committee on Immunization Practices (ACIP) expanded the groups considered to be at increased risk of HBV infection to include adults with diabetes mellitus. The ACIP recommended that all previously unvaccinated adults aged 19 through 59 years with diabetes mellitus (type 1 and type 2) be vaccinated against hepatitis B as soon as possible after a diagnosis of diabetes is made. In addition, the ACIP recommended that hepatitis B vaccination may be administered at the discretion of the treating clinician to unvaccinated adults with diabetes mellitus who are aged 60 and over. There are approximately 18 million people diagnosed with diabetes in the United States.

DV1179 (IRS) for Autoimmune and Inflammatory Diseases

We are developing DV1179, a bifunctional inhibitor of TLR7 and TLR9, under a worldwide strategic alliance with GSK. Our IRS program is focused on novel TLR inhibitors for diseases such as lupus and psoriasis. In October 2011, we announced the expansion of our worldwide strategic alliance to include a new target, TLR8. The activation of TLR8 in myeloid cells yields the production of multiple pro-inflammatory cytokines including tumor necrosis factors (TNF), IL-1, IL-6 and IL-12. Based on preclinical data, we will work with GSK to develop a TLR8 inhibitor for the treatment of multiple autoimmune and inflammatory diseases such as rheumatoid arthritis. We will evaluate the hypothesis that inhibition of TLR8 could prevent the inflammatory cascade these cytokines initiate in many autoimmune conditions.

Clinical Results

During 2011, we initiated the first human clinical trial in our lupus program. DV1179 was shown to be well-tolerated in this Phase 1 trial in healthy subjects. In late 2011, we initiated a proof-of-mechanism clinical trial of DV1179 in systemic lupus erythematosus (SLE) patients. GSK has an exclusive option to obtain a license to the program following completion of this trial.

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 therapy for 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.

In December 2011, we agreed to advance AZD1419 into preclinical toxicology studies. These toxicology studies are scheduled to be the first module of work performed by us under the recently amended collaboration agreement with AstraZeneca.

Universal Flu Vaccine

Our Universal Flu vaccine is designed to offer protection against divergent influenza strains as well as to increase the efficacy and potentially reduce the antigen content of standard flu vaccines. This unique approach is based on our proprietary component N8295, which is a fusion protein comprised of two highly conserved influenza antigens, nucleoprotein (NP) and matrix protein 2 (M2e), covalently linked to proprietary second-generation ISS. N8295 is then combined with a conventional flu vaccine:

Conventional flu vaccines Available flu vaccines typically contain antigens of three flu viruses: two influenza A subtypes and one influenza B subtype. The exact composition changes every year and is

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determined by the World Health Organization (WHO) and FDA based upon surveillance and estimates of which types and strains of viruses are likely to circulate. The goal of existing vaccines is to induce the development of antibodies to provide protection against influenza infection. Our proprietary component could be combined with any flu vaccine, including standard trivalent influenza vaccine (TIV) and vaccines for emerging strains such as H5N1 or H1N1.

Our proprietary second-generation ISS may enhance efficacy and enable antigen-sparing, which could extend the quantity of standard flu vaccine available.

Two highly conserved antigens, NP and M2e, are expected to offer protection against divergent influenza strains Our Universal Flu vaccine includes two conserved antigens, NP and M2e, which are present in all flu strains. NP is highly conserved across human and animal strains, while the extracellular domain of M2e is conserved but with some variations among species. NP induces cytotoxic T-cell protection and M2e induces antibodies that may provide protection against divergent strains.

We have established a worldwide supply and option agreement with Novartis Vaccines and Diagnostics, Inc. (Novartis), under which Novartis is supplying TIV, an essential component of our Universal Flu vaccine.

Clinical Results

In February 2011, we reported data from the Phase 1a and the Phase 1b study reported at the WHO 7th Meeting on Evaluation of Pandemic Influenza Prototype Vaccines, which showed:

N8295 alone or combined with H5N1 vaccine was safe and generally well-tolerated;

The most common adverse events were mild, self-limited injection site reactions;

There were no serious adverse events;

All N8295 dose groups had an antibody response to M2e, and the placebo group did not;

All N8295 dose groups had an antibody response to NP, and the placebo group did not;

All N8295 dose groups had a cellular immune response to NP, and the placebo group did not;

The addition of N8295 to a non-immunogenic dose of H5N1 vaccine resulted in HI responses in all N8295 dose groups.

Commercial Opportunity

Human viral influenza is an acute respiratory disease with high morbidity and mortality that occurs in annual epidemics worldwide. There are an estimated 30,000 to 40,000 viral influenza-associated deaths per year in the United States, primarily in those over 65 years of age. Influenza pandemics occur infrequently, on average every 30 to 40 years, but it is estimated that the next pandemic could result in millions of deaths worldwide. Analysts estimate the current worldwide market opportunity for seasonal influenza vaccines to be approximately $3 billion annually.

Standard flu vaccines can provide protection against the flu strains predicted to be prevalent during a season. The efficacy of these vaccines is often decreased by unpredictable changes in the actual strains causing influenza. Current vaccines are also least effective in those most in need of prevention, the elderly and others with weaker immune systems. Pandemic vaccination is further complicated by the need to produce large

quantities of vaccine in a short time period.

Our Universal Flu vaccine candidate is designed to offer protection against divergent influenza strains, increase the efficacy of standard vaccines and potentially reduce the antigen content of vaccine to extend the quantity available during a pandemic.

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DV-601 Hepatitis B Therapy

DV-601, our proprietary hepatitis B therapy, completed a Phase 1b clinical trial and is part of our portfolio of development programs that are available for partnership. Our treatment approach, originally entered into development by Rhein Biotech prior to its acquisition by Dynavax in 2006, combines both the surface and core HBV antigens with ISCOMATRIX® adjuvant. DV-601 is designed to induce an immune response against HBV-infected cells and, if proven to be safe and effective, may offer an alternative therapeutic option for patients chronically infected with HBV.

The Phase 1b dose escalation study assessed safety and the immunologic and virologic responses in 14 subjects with chronic hepatitis B infection. The therapeutic regimen was safe and generally well-tolerated at all dose levels. No serious adverse events were recorded.

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 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.

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. We are eligible to receive future development milestones payments. GSK can exercise its exclusive option to license each program upon achievement of certain events, and we are eligible to receive option exercise payments. If GSK exercises its option, GSK would carry out further development and commercialization of these products. We are eligible to receive tiered, up to double-digit royalties on sales, if any, and have retained an option to co-develop and co-promote one product under this agreement.

In 2011, we earned $15 million in milestone payments related to the initiation of Phase 1 and proof-of-mechanism clinical trials of DV1179 in SLE patients and the expansion of our collaboration with GSK to develop a TLR8 inhibitor.

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 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. 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 for the development of AZD1419. Development expenses will be funded by AstraZeneca. Under the terms of the amended agreement, AstraZeneca

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will provide us with a total of approximately $20 million in payments to cover the cost of development activities through Phase 2a. 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, if any. 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.

Novartis Vaccines and Diagnostics, Inc.

In July 2008, we entered into a supply and option agreement with Novartis related to our Universal Flu vaccine. Under this agreement, Novartis is supplying TIV, an essential component of our Universal Flu vaccine. We agreed to conduct early-stage development through a defined proof-of-concept. If Novartis exercises the right to negotiate and enter a further agreement for development and commercialization, we would retain co-commercialization rights in the United States and receive product royalties on product sales outside of the United States, if any. If the option is not exercised or we do not enter into a further agreement, Novartis remains committed to providing commercial supply of TIV with pre-agreed commercial terms and we retain the right to independently continue with late-stage development and commercialization, provided we do not partner with a company that produces or markets a TIV product in the United States.

Either we or Novartis may terminate the agreement if (a) the other party commits a material uncured breach, (b) there is change in control of the other party, (c) certain specified clinical or regulatory objectives are not achieved or certain development events or failures occur, or (d) we cease development of the product candidate for a certain length of time.

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.

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 HBV. 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 received $0.5 million in 2011 and $0.1 million in 2010.

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. We also received a $0.6 million grant from the NIH to explore the feasibility of developing a universal vaccine to prevent infection by human papilloma virus (HPV).

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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 in order to further protect the inventions that we or our partners consider important to the development of our foreign business. We also rely on trade secrets and contracts to protect our proprietary information.

As of December 31, 2011, our intellectual property portfolio included 18 issued U.S. patents, over 100 issued or granted foreign patents and over 100 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 2031.

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 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,

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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 hepatitis B surface antigen, a component of HEPLISAV. In addition, the Institut Pasteur also owns or has exclusive licenses to patents covering hepatitis B surface antigen. 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 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 U.S. Patent and Trademark Office 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 in any of these actions or proceedings.

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

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

Under the terms of our license agreements with the Regents of the University of California, we are required to pay license fees, make milestone payments, share a portion of fees from third party partnerships up to a specified amount and pay low single-digit royalties on net sales resulting from successful products originating from the licensed technologies. To date, we have paid the University of California a total of $1.8 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.

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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 in addition to 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 Genentech, Inc. (Genentech), Biogen Idec, Roche, Abbott Laboratories and Human Genome Sciences/GSK. In addition, our product would compete with generic drugs commonly used to treat autoimmune diseases, including corticosteroids, NSAIDs, antimalarials and immunosuppressive agents. Other companies, such as MedImmune, Genentech, Idera, Pfizer and UCB/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, Genentech, Novartis, AstraZeneca and GSK. In addition, directly competing products are in development by Sanofi-Aventis and Idera Pharmaceuticals.

Our Universal Flu vaccine, if developed, approved and commercialized, will compete with traditional and emerging influenza vaccines from companies currently marketing these products, including: GSK, Novartis, Sanofi Pasteur, MedImmune/AstraZeneca and CSL Ltd. In addition, there are several companies developing potentially competing universal vaccines for influenza, including Sanofi Pasteur, VaxInnate, Merck and Vical.

Our hepatitis B therapy, DV-601, if developed, approved and commercialized, will compete directly with existing hepatitis B therapy products, including antiviral drugs and interferon alpha, manufactured by Roche, Merck, Gilead, Bristol-Myers Squibb, GSK, and Novartis. In addition, our hepatitis B therapy faces competition from several companies developing novel antivirals and immunomodulators, including GSK, Achillon, Bukwang and Chongqing Jiachen Biotech.

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

REGULATORY CONSIDERATIONS

In the United States, pharmaceutical and biological products are subject to rigorous review by the FDA under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and other federal statutes and

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regulations. The steps ordinarily required by the FDA before a new drug or biologic may be marketed in the United States are similar to steps required in most other countries and include but are not limited to the following:

- completion of preclinical laboratory tests, preclinical studies and formulation studies;
- submission to the FDA of an IND 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 (NDA) or a biologics license application (BLA) to the FDA; and
- FDA review and approval of the NDA or BLA before any commercial marketing, sale or shipment of the drug.

If we do not comply with applicable requirements, U.S. regulatory authorities may fine us, require that we recall our products, seize our products, require that we totally or partially suspend the production of our products, refuse to approve our marketing applications, criminally prosecute us, and/or revoke previously granted marketing authorizations.

To secure FDA 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 FDA for each indication. 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. Following approval, we may be required to conduct additional post-marketing studies. The FDA 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. The FDA may withdraw product approvals if we do not continue to comply with regulatory standards or if problems occur following initial marketing. Delays experienced during the approval process may materially reduce the period during which we will have exclusive rights to exploit patented products or technologies. Delays can occur at any stage of drug development and as a result of many factors, certain of which are not under our control, including but not limited to the following:

- lack of efficacy, or incomplete or inconclusive results from clinical trials;
- unforeseen safety issues;
- failure by investigators to adhere to protocol requirements, including patient enrollment criteria;

slower than expected rate of patient recruitment;

failure by subjects to comply with trial protocol requirements;

inability to follow patients adequately after treatment;

inability to qualify and enter into arrangements with third parties to manufacture sufficient quality and quantities of materials for use in clinical trials;

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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.

Non-clinical studies involve laboratory evaluation of product characteristics or animal studies to assess the initial efficacy and safety of the product. The FDA, under its good laboratory practices regulations, regulates certain non-clinical studies. 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 FDA as part of an IND application, which must be approved by the FDA before we can commence clinical investigations in humans. Unless the FDA objects to an IND application, the IND application will become effective 30 days following its receipt by the FDA. 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 FDA as part of the IND 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 FDA regulatory process include clinical trials in three sequential phases that may overlap. 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. 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 FDA regulatory approval of the product candidate.

We and all of our contract manufacturers are required to comply with the applicable FDA current Good Manufacturing Practice (GMP) regulations. Manufacturers of biologics also must comply with FDA 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. Prior to granting product approval, the FDA must determine that our or our third party contractor s manufacturing facilities meet GMP requirements before we can use them in the commercial manufacture of our products. In addition, our facilities are subject to periodic inspections by the FDA 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 and could result in the imposition of market restriction through labeling changes or in product removal.

Outside the United States, our ability to market a product is contingent upon receiving marketing authorization and pricing or reimbursement approval from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, manufacturing, marketing authorization, pricing and reimbursement vary widely from country to country.

At present, foreign marketing authorizations may be applied for at a national level, although within the European Union centralized registration procedures are mandatory for biotechnology and some other drugs and

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are available to companies wishing to market a product in more than one European Union member state. The regulatory authority generally will grant marketing authorization if it is satisfied that we have presented it with adequate evidence of a product manufactured by a well-controlled process that is safe and effective for its intended use.

We are also subject to various federal, state and local 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 a number of third parties for the multiple steps involved in the manufacturing process of our product candidates, including ISS, the production of certain antigens, the combination of the antigens and ISS, and the fill and finish. 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 hepatitis B surface antigen 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 $51.3 million, $53.7 million, and $38.7 million for the years ended December 31, 2011, 2010, and 2009, 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, 2011, we had 150 full-time employees, including 22 Ph.D.s, 8 M.D.s and 28 others with advanced degrees. Of the 150 employees, 116 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 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 $365.5 million as of December 31, 2011. To date, our revenue has resulted from collaboration agreements, services and license fees from our customers and customers of Rhein Biotech GmbH (Rhein or Dynavax Europe), and government and private agency grants. 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 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. Our ability to generate revenue depends upon obtaining regulatory approvals for our product candidates 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.

We 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.

In order to continue development of our product candidates and, if it is approved, to launch HEPLISAV, we still need significant additional funds. This 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 and cash equivalents and marketable securities on hand and 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 would 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 Business

The success of our product candidates depends on regulatory approval. The FDA or foreign regulatory agencies may determine our clinical trials or other data regarding safety, efficacy or consistency of manufacture is 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

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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, we must prepare and submit a BLA to the FDA and corresponding applications to foreign regulatory agencies that must be approved by those agencies before we may sell the product. Obtaining approval of a BLA by the FDA and corresponding foreign applications is highly uncertain and we may fail to obtain approval even if we are able to submit a BLA for HEPLISAV that is acceptable for review. 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 HEPLISAV 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. 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 is insufficient for regulatory approval.

Failure to timely file and receive approval for our BLA 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 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.

Prior to 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 biologics 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 additional clinical trials for our HEPLISAV 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;

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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 is based on 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 collaborations and 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 is significant. If we fail to achieve and sustain commercial success for HEPLISAV, 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. In order 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. 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 October 2011, the Centers for Disease Control and Prevention (CDC) ACIP voted to recommend that hepatitis B vaccine should be administered to unvaccinated adults with diabetes who are less than 60 years of age. This change significantly expands the potential number of persons for whom vaccination is recommended in the U.S. and we believe could significantly expand the revenue potential for HEPLISAV. In order to successfully market, sell and distribute HEPLISAV to patients with diabetes, we will need to establish a sales and marketing infrastructure and/or establish and maintain distribution arrangements. We may not be able to enter into these arrangements on acceptable terms. 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 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 prescribe 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;

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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

unanticipated delays, costs and expenses associated with manufacturing and commercialization of our products, including costs of creating and sustaining an independent sales and marketing organization in various territories.

If we, or our partner, if any, are not successful in setting our marketing, pricing and reimbursement strategy, recruiting sales and marketing personnel or in timely 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 necessary to manufacture our product candidates. We have limited experience in manufacturing sufficient quantities of ISS for our commercial products and rely on limited third parties 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 a number of third parties for the multiple steps involved in the manufacturing process of our product candidates, including ISS, the production of certain antigens, the combination of the antigens and ISS, and the 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 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 source 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.

We currently utilize our facility in Düsseldorf to manufacture the hepatitis B surface antigen for HEPLISAV. The commercial manufacturing of vaccines and other biological products is a time-consuming and complex process that must be performed in compliance with current GMP regulations. We may not be able to comply with these 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 the development or commercialization of our product candidates and could result in significant expense. Moreover, if our HEPLISAV clinical trials are sufficient for approval and depending on the level of market acceptance of the product, we likely would not have the capacity in our existing facility to meet all of our commercial supply needs in the future. For example, the recent ACIP recommendation that hepatitis B vaccine should be administered to unvaccinated adults with diabetes who are less than 60 years of age could significantly increase the market demand for HEPLISAV. Our current manufacturing capacity could supply up to approximately 2 million doses of HEPLISAV annually, which may not be sufficient to meet demand. Our ability to expand 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

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may experience a shortage in our supply of HEPLISAV and our clinical candidates, which could have a material adverse effect on the success of HEPLISAV and our other product candidates. 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, time-consuming and difficult.

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 these 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 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 delays can occur if the qualification of a new supplier is required.

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

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

We may develop, seek regulatory approval for and market our product candidates outside the 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;

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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.

To date, we have not filed for marketing approval for any of our product candidates outside the United States. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory agencies in other foreign countries. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in other jurisdictions, including approval by the FDA. 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, health care payors and the medical community.

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

the indication for which the product is approved and its approved labeling;

the presence of other competing approved therapies;

the potential advantages of the product over existing and future treatment methods;

the relative convenience and ease of administration of the product;

the strength of our sales, marketing and distribution support;

the price and cost-effectiveness of the product; and

sufficient third-party reimbursement.

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

We face uncertainty related to 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

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particular for HEPLISAV where existing products are approved for our target indications. 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 particularly uncertain. We will have to charge a price for our products that is sufficiently high to enable us to recover our considerable investment in product development. 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.

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 which 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 products and could have a material adverse effect on our business and operations.

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

We will need to establish collaborative relationships to obtain domestic and international sales, marketing and distribution capabilities for our product candidates, in particular with respect to the commercialization of HEPLISAV. 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 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;

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- 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, 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 utilize 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 related 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 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 no sales, marketing or

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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 also 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. 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.

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 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.

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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 in order 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 not able 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 in order to maintain any such licenses in effect. In the absence of a current license, we may be required to redesign our technology so it does not infringe a third party s patents, which may not be possible or could require substantial funds and time.

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

We may be exposed to future litigation by third parties based on claims that our product candidates or proprietary technologies infringe their intellectual property rights, or we may be required to enter into litigation to enforce patents issued or licensed to us or to determine the ownership, scope or validity of our or another party s proprietary rights, including a challenge as to the validity of our issued and pending claims. From time to time we are involved in various interference and other administrative proceedings related to our intellectual property which has caused us to incur certain legal expenses. If we become involved in any litigation and/or other significant interference proceedings related to our intellectual property or the intellectual property of others, we will incur substantial additional expenses and it will divert the efforts of our technical and management personnel.

Two of our potential competitors, Merck and GSK, are exclusive licensees of broad patents covering hepatitis B surface antigen, a component of HEPLISAV. In addition, the Institut Pasteur also owns or has exclusive licenses to patents covering hepatitis B surface antigen. 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 (The Regents of the University of California and Biogen Idec), 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.

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One of our potential competitors, Pfizer Inc., has issued patent claims, as well as patent claims pending with the U.S. Patent and Trademark Office 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 in order 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.

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

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

the volume of trading in our common stock.

One or more of these factors could cause a substantial decline in the price of our common stock. In addition, securities class action litigation has often been brought against a company following a decline in the market price of its securities. 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, 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;

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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 the Company s 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 the Common Shares 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 Act of 2010, as well as new rules implemented by the Securities and Exchange Commission and the NASDAQ Stock Market LLC. We may need to continue to implement additional financial and accounting systems, procedures and controls in order 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, 2011, we had 154,625,723 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 registration statements on Form S-8 under the Securities Act of 1933, as amended, to register the shares of our common stock reserved for issuance under our stock option plans, and intend to file additional registration statements on Form S-8 to register the shares automatically added each year to the share reserves under these plans.

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ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

As of December 31, 2011, we leased approximately 44,000 square feet of laboratory and office space in Berkeley, California under agreements expiring in September 2017. 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
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
2010		
First Quarter	$ 1.83	$ 1.19
Second Quarter	$ 2.08	$ 1.28
Third Quarter	$ 2.34	$ 1.58
Fourth Quarter	$ 3.24	$ 1.75

As of February 29, 2012, there were approximately 178 holders of record of our common stock, as shown on the records of our transfer agent. We believe that our stockholders exceed 300 as the number of record holders does not include 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.

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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, 2011 to October 31, 2011				
November 1, 2011 to November 30, 2011	66	$ 2.77		
December 1, 2011 to December 31, 2011				
Total	66	$ 2.77		

(1) In November 2011, we delivered 270,000 shares of common stock to certain holders of vested restricted stock units, which had been awarded in October 2008. 66,024 shares of common stock were surrendered at an average price of $2.77 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, 2011, 2010, and 2009 and the Consolidated Balance Sheets Data as of December 31, 2011 and 2010 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, 2008 and 2007 and the Consolidated Balance Sheets Data as of December 31, 2009, 2008, and 2007 are derived from 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,				
	2011	2010	2009	2008	2007
	(In thousands, except per share data)				
Consolidated Statements of Operations Data:					
Total revenues	$ 21,614	$ 23,950	$ 40,318	$ 37,094	$ 14,093
Operating expenses:					
Research and development	51,322	53,680	38,708	44,771	65,888
General and administrative	17,570	16,879	15,745	15,463	18,293
Amortization of intangible assets	299	980	980	980	1,004
Total operating expenses	69,191	71,539	55,433	61,214	85,185
Loss from operations	(47,577)	(47,589)	(15,115)	(24,120)	(71,092)
Interest income	103	85	178	1,631	3,965
Interest expense	(1,957)	(1,654)	(124)	(9,157)	(1,719)
Other income (expense)[1]	834	(8,150)	(66)	110	200
Loan forgiveness[2]				5,000	
Net loss	(48,597)	(57,308)	(15,127)	(26,536)	(68,646)
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	8,675
Net loss attributable to Dynavax	$ (48,597)	$ (57,308)	$ (30,565)	$ (20,829)	$ (59,971)
Basic and diluted net loss per share attributable to Dynavax common stockholders	$ (0.39)	$ (0.69)	$ (0.76)	$ (0.52)	$ (1.51)
Shares used to compute basic and diluted net loss per share attributable to Dynavax common stockholders	125,101	82,463	40,350	39,819	39,746

(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 and is treated as a deemed dividend for purposes of reporting earnings per share, increasing loss per share for the year ended December 31, 2009. See Note 8 to the

Consolidated Financial Statements.

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	2011	2010	December 31, 2009	2008	2007
			(In thousands)		
Consolidated Balance Sheets Data:					
Cash, cash equivalents and marketable securities	$ 113,961	$ 72,154	$ 36,720	$ 43,367	$ 56,617
Investments held by Symphony Dynamo, Inc.				25,109	31,631
Working capital[1]	97,399	60,598	24,583	36,381	82,262
Total assets	134,102	84,249	50,470	90,623	120,449
Note payable to Symphony Dynamo Holdings LLC[2]	12,810	10,939	9,342		
Noncontrolling interest in Symphony Dynamo, Inc.				2,634	8,341
Accumulated deficit	(365,542)	(316,945)	(259,637)	(248,743)	(227,914)
Total Dynavax stockholders equity	99,880	52,111	6,376	13,522	30,790

(1) We have reclassified deferred rent in all prior years from current accrued liabilities to other long-term liabilities in order to conform to the current year presentation.

(2) The note payable to Symphony Dynamo Holdings LLC was reclassified from long-term to short-term as of December 31, 2011 because the note matures 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 designed to provide higher and earlier protection with fewer doses than currently licensed vaccines.

Our pipeline of product candidates includes: HEPLISAV, our autoimmune program partnered with GlaxoSmithKline (GSK), our therapy for asthma partnered with AstraZeneca AB (AstraZeneca), and clinical-stage programs for our Universal Flu vaccine and hepatitis B therapy. 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.

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Recent Developments

In February 2012, we announced that we had met with the FDA in a Pre-Biologics License Application (pre-BLA) meeting, and had agreed that the initial HEPLISAV BLA submission will be for an indication in healthy adults 18-70 years of age. This agreement represents a significant expansion of the previously anticipated population of healthy adults age 40 and over. In addition, it was confirmed that a supplemental BLA with an indication for patients with chronic kidney disease (CKD) will be filed when the initial BLA is approved. We are making the required modifications to the BLA to support the expanded indication and plan to submit the BLA by the middle of May 2012. We plan to submit the Marketing Authorization Application to the European Medicines Agency for European approval after the submission of our BLA in the U.S.

In late 2011, we initiated a proof-of-mechanism clinical trial of DV1179 in systemic lupus erythematosus patients. GSK has an exclusive option to obtain a license to the program following completion of this trial.

In late 2011, we agreed to advance AZD1419 into preclinical toxicology studies. These toxicology studies are scheduled to be the first module of work performed by us under our recently amended collaboration agreement with AstraZeneca.

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 are derived from collaborative and service agreements as well as grants. 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, 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) issued 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. The adoption of the

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standard did not impact our financial position or results of operations as of and for the year ended December 31, 2011. However, the adoption of this standard may result in revenue recognition patterns for future agreements that are different from those recognized for our existing multiple-element arrangements.

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 Issued 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 management s performance or a specific outcome resulting from management s performance and (iii) if achieved, the event would result in additional payments being due to management.

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 was substantial uncertainty whether any such milestones would be achieved at the time we entered into these agreements. In addition, we evaluated whether the development milestones met the criteria to be considered substantive, when all of the conditions are met. The conditions include: (1) the development work is commensurate on either of the following: (a) the vendor s performance to achieve the milestone and (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; (2) it relates solely to past performance and (3) it is reasonable relative to all the deliverable and payment terms within the arrangement. As a result of our analysis, we considered 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. The election to adopt the milestone method did not impact our financial position or results of operations as of and for the year ended December 31, 2011.

Milestone payments that were contingent upon the achievement of substantive at-risk performance criteria were recognized in full upon achievement of those milestone events in accordance with the terms of the agreement and assuming all other revenue recognition criteria were 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 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.

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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, 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

Determining the appropriate fair value model and calculating the fair value of stock-based awards at the grant date requires judgment and estimates. The fair value of each option is amortized on a straight-line basis over the option s vesting period, assuming an annual forfeiture rate of 15% for both the executive level and non-executive level employee groups, and is estimated on the date of grant using the Black-Scholes option valuation model, which requires the input of highly subjective assumptions, including the expected life of the option and expected stock price volatility. The expected life of options granted is estimated based on historical option exercise and employee termination data. Executive level and non-executive level employees were grouped and considered separately for valuation purposes. The expected life of the options for both groups of employees is 4 years. Expected volatility is based on historical volatility of our stock over the life of the options granted to executive and non-executive level employees.

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Results of Operations

Revenues

Revenues consist of amounts earned from collaborations, grants, 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, 2011, 2010 and 2009 (in thousands, except for percentages):

	Years Ended December 31,			Increase (Decrease) from 2010 to 2011		Increase (Decrease) from 2009 to 2010	
Revenues:	**2011**	**2010**	**2009**	**$**	**%**	**$**	**%**
Collaboration revenue	$ 17,190	$ 19,535	$ 35,534	$ (2,345)	(12)%	$ (15,999)	(45)%
Grant revenue	3,110	3,940	3,477	(830)	(21)%	463	13%
Service and license revenue	1,314	475	1,307	839	177%	(832)	(64)%
Total revenues	$ 21,614	$ 23,950	$ 40,318	$ (2,336)	(10)%	$ (16,368)	(41)%

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 $15.0 million from GSK for milestones earned in 2011, compared to collaboration revenue for the year ended December 31, 2010 which included recognition of a $10.0 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, and a one-time $4.0 million payment from Merck& Co. (Merck) in satisfaction of its obligations to us following termination of our collaboration. 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 National Institute of Health s National Institute of Allergy and Infectious Diseases (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 Biotech GmbH (Rhein or Dynavax Europe).

Total revenues for the year ended December 31, 2010 decreased by $16.4 million, or 41%, as compared to 2009 primarily due to the reduction in collaboration revenue following the termination of our collaboration with Merck. Collaboration revenue for the year ended December 31, 2010 included recognition of the $10.0 million upfront payment received from AstraZeneca in 2006 following the amendment to the collaboration agreement, $4.1 million of other revenue related to our collaboration with AstraZeneca, and a $4.0 million payment from Merck in satisfaction of its obligations. Grant revenue for the year ended December 31, 2010 increased from the same period in 2009 primarily due to the increase in revenue recognized for the NIAID contract. Service and license revenue for the year ended December 31, 2010 decreased as compared to 2009 as a result of a decline in royalty revenue and manufacturing services from 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 relate to our preclinical experiments and clinical trials, regulatory filings, and manufacturing our product candidates.

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

	Years Ended December 31,			Increase (Decrease) from 2010 to 2011		Increase (Decrease) from 2009 to 2010	
Research and Development:	**2011**	**2010**	**2009**	**$**	**%**	**$**	**%**
Compensation and related personnel costs	$ 18,654	$ 14,867	$ 15,601	$ 3,787	25%	$ (734)	(5)%
Outside services	24,811	31,372	14,985	(6,561)	(21)%	16,387	109%
Facility costs	5,754	6,809	6,983	(1,055)	(15)%	(174)	(2)%
Non-cash stock-based compensation	2,103	632	1,139	1,471	233%	(507)	(45)%
Total research and development	$ 51,322	$ 53,680	$ 38,708	$ (2,358)	(4)%	$ 14,972	39%

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 $1.1 million as compared to 2010, as a result of lower rent expense from reduced leased space.

Research and development expense for the year ended December 31, 2010 increased by $15.0 million, or 39%, as compared to 2009. The increase in outside services during 2010 is primarily due to continued clinical and manufacturing activities associated with HEPLISAV. The increase in outside services expense was partially offset by a decrease in compensation and related personnel costs and stock-based compensation over the same period primarily due to a decline in employee headcount.

We expect research and development expenses in 2012 to be in line with 2011 expenses.

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 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):

	Years Ended December 31,			Increase (Decrease) from 2010 to 2011		Increase (Decrease) from 2009 to 2010	
General and Administrative:	**2011**	**2010**	**2009**	**$**	**%**	**$**	**%**
Compensation and related personnel costs	$ 7,271	$ 6,318	$ 5,886	$ 953	15%	$ 432	7%
Outside services	4,548	4,207	4,033	341	8%	174	4%
Legal costs	1,894	3,622	3,003	(1,728)	(48)%	619	21%
Facility costs	809	971	927	(162)	(17)%	44	5%
Non-cash stock-based compensation	3,048	1,761	1,896	1,287	73%	(135)	(7)%
Total general and administrative	$ 17,570	$ 16,879	$ 15,745	$ 691	4%	$ 1,134	7%

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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General and administrative expenses for the year ended December 31, 2010 increased by $1.1 million, or 7%, compared to the same period in 2009. The increase is primarily due to an increase in legal costs related to patent activities, as well as personnel costs for travel and recruitment to support HEPLISAV development and other business efforts.

We expect general and administrative expenses in 2012 to be in line with 2011 expenses.

Amortization of Intangible Assets

Intangible assets, which consisted primarily of the manufacturing process and customer relationships resulting from our April 2006 acquisition of Rhein, were amortized over five years from the date of acquisition through the first half of 2011. Amortization of intangible assets was $0.3 million, $1.0 million and $1.0 million for each of the three years ended December 31, 2011, 2010, and 2009, respectively.

Interest Income, Interest Expense, and Other Income (Expense)

Interest income is reported net of amortization of premiums and discounts on marketable securities and realized gains and losses on investments. Interest expense relates to the note payable issued to Symphony Dynamo Holdings LLC (Holdings) in connection with our acquisition of SDI on December 30, 2009. Other income (expense) includes gains and losses on foreign currency transactions, gains and losses on disposals of property and equipment and the change in fair value of financial assets and liabilities such as the warrants and contingent consideration liabilities assumed in connection with the acquisition of SDI. 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 2010 to 2011		Increase (Decrease) from 2009 to 2010	
	2011	2010	2009	$	%	$	%
Interest income	$ 103	$ 85	$ 178	$ 18	21%	$ (93)	(52)%
Interest expense	$ (1,957)	$ (1,654)	$ (124)	$ 303	18%	$ 1,530	1234%
Other income (expense)	$ 834	$ (8,150)	$ (66)	$ 8,984	110%	$ 8,084	12248%

Interest income for the year ended December 31, 2011 increased by $18 thousand, or 21%, compared to the same period in 2010 due primarily to higher cash equivalents and marketable securities balances. Interest income for the year ended December 31, 2010 decreased by $0.1 million, or 52%, compared to the same period in 2009 due primarily to lower returns on our investment portfolio resulting from market conditions.

Interest expense for the year ended December 31, 2011 increased by $0.3 million compared to the same period in 2010 due to interest from the accretion of the discount on the note payable to Holdings. Interest expense for the year ended December 31, 2010 increased by $1.5 million compared to the same period in 2009 due to interest from the accretion of the discount on the note payable to Holdings.

Other income (expense) for the year ended December 31, 2011 includes a gain of $0.8 million for the change in fair value of the long-term contingent liability to Holdings. 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 in April 2010 (April 2010 Warrants) and the remeasurement of the warrant liability through June 30, 2010, which 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. Following the expiration date of Symphony s anti-dilution protection on June 30, 2010, the value of the April 2010 Warrants was reclassified into stockholders equity in the consolidated balance sheets. 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.

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Losses Attributable to Noncontrolling Interest in Symphony Dynamo, Inc.

Pursuant to the agreements that we entered into with SDI (a variable interest entity) in April 2006, the results of operations of SDI were included in our consolidated financial statements from the date of formation on April 18, 2006. We deducted the losses attributed to the noncontrolling interest in the determination of net loss in our consolidated statements of operations through December 30, 2009, the date we acquired all the outstanding equity of SDI. For the fiscal year ended December 31, 2009, the losses attributable to the noncontrolling interest were $4.2 million.

Consideration Paid in Excess of Carrying Value of the Noncontrolling Interest in Symphony Dynamo, Inc.

Upon the closing of the acquisition of all of the outstanding equity of SDI on December 30, 2009, we recorded the acquisition as a capital transaction that did not affect our net loss. However, because the acquisition was accounted for as a capital transaction, the excess consideration transferred over the carrying value of the noncontrolling interest in SDI was treated as a deemed dividend for purposes of reporting net loss and net loss per share attributable to us, increasing net loss and net loss per share attributable to our common stockholders by $19.7 million or $0.49 per share for the year ended December 31, 2009.

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 IFRSs*. 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 U.S. 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 U.S. GAAP and International Financial Reporting Standards, which could change how fair value measurement guidance in ASC 820 is applied. ASU No. 2011-04 is effective on a prospective basis for us on January 1, 2012. We are currently evaluating whether this new guidance will have a material impact on our consolidated financial statements.

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. ASU No. 2011-05 is effective on a retrospective basis for us on January 1, 2012. We do not expect that this new guidance will have a material impact on our consolidated financial statements.

Accounting Standards Update 2011-08

In September 2011, the FASB issued ASU No. 2011-08, *Testing Goodwill for Impairment*. This ASU will allow 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 is effective for us on January 1, 2012. We do not expect that this new guidance will have a material impact on our consolidated financial statements.

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Liquidity and Capital Resources

As of December 31, 2011, we had $114.0 million in cash, cash equivalents and marketable securities. Our funds are currently invested in short-term money market funds, U.S. government agency securities and corporate obligations.

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 operating activities during the year ended December 31, 2010 was $51.4 million compared to $33.6 million for the same period in 2009. The increase in cash usage compared to 2009 was due to our net loss and changes in working capital, particularly an increase in spending for HEPLISAV development.

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 used in investing activities during the year ended December 31, 2010 was $50.5 million compared to cash provided by investing activities of $19.9 million for 2009. The change was primarily due to higher purchases of marketable securities in 2010.

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 of 27,600,000 shares of our common stock, including 3,600,000 shares sold pursuant to the full exercise of an overallotment option in November 2011, which resulted in aggregate net proceeds of $64.6 million, after deducting underwriting discounts and commissions and other offering expenses payable to us, and funding from Aspire Capital. Cash provided by financing activities during the year ended December 31, 2010 was $87.6 million compared to $22.1 million for the same period in 2009. The increase was primarily attributed to the completion of public offerings in April and November 2010, which resulted in aggregated net proceeds of $87.4 million. Additionally, prior to the termination of our equity distribution agreement with Wedbush Morgan Securities on September 14, 2010, we sold 900,860 shares of common stock for net proceeds of $1.2 million during fiscal year 2010.

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

We currently estimate that we have sufficient cash resources to meet our anticipated cash needs through at least the next 12 months based on cash and cash equivalents and marketable securities on hand at December 31, 2011 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. In order to continue development of our product candidates and if it is approved, to launch HEPLISAV, we will 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 as of December 31, 2011 and the effect those obligations are expected to have on our liquidity and cash flows in future periods (in thousands):

		Payments due by Period			
Contractual Obligations:	**Total**	**1 Year**	**2-3 Years**	**4-5 Years**	**More Than 5 Years**
Future minimum payments under our operating leases, excluding payments from sublease agreements	$ 13,438	$ 1,783	$ 3,570	$ 3,643	$ 4,442
Note payable to Symphony Dynamo Holdings	15,000	15,000			
Total	$ 28,438	$ 16,783	$ 3,570	$ 3,643	$ 4,442

We lease our facilities in Berkeley, California (the Berkeley Lease), and Düsseldorf, Germany (the Düsseldorf Lease) under operating leases that expire in September 2017 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 $0.1 million 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, 2011 and is collateralized by a certificate of deposit which has been included in restricted cash in the consolidated balance sheets as of December 31, 2011 and 2010. Under the terms of the Berkeley Lease, if the total amount of our cash, cash equivalents and marketable securities falls below $20.0 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 $20.0 million for the remainder of the lease term, or until our actual cash and cash equivalents remains above $20.0 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, 2011 and is collateralized by a certificate of deposit which has been included in restricted cash in the consolidated balance sheets as of December 31, 2011 and 2010.

In connection with the exercise of our purchase of all of the outstanding equity of SDI on December 30, 2009, we issued a note to Holdings in the principal amount of $15 million. The note is due on December 31, 2012 and is payable in cash, our common stock or a combination thereof at our discretion. If we elect to pay all or a portion of the note in shares of our common stock, the number of shares issued will be equal to the portion of the outstanding principal amount of the note to be repaid using our common stock, divided by the average closing price of our common stock for the thirty (30) trading days immediately preceding (but not including) the second trading day prior to the date of such payment multiplied by 1.15.

As part of the consideration we transferred to Holdings for the acquisition of SDI, we are obligated to make contingent cash payments equal to 50% of the first $50 million from any upfront, pre-commercialization milestone or similar payments received by us from any agreement with any third party with respect to the development and/or commercialization of the cancer and hepatitis C therapies. During 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 contingent liability to be zero as of December 31, 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,

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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, 2011, under the terms of our agreements, we are obligated to make future payments as services are provided of approximately $14.8 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.

Off-balance Sheet Arrangements

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

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Quantitative and Qualitative Disclosure About Market Risk

Interest Rate Risk. 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 investments in a variety of securities, including money market funds, government agency securities and corporate obligations, some of which are government-secured. 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 our recent 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 or fall from current levels by 100 basis points and by 125 basis points, the change in our net unrealized loss on investments would be $0.5 million and $0.6 million, respectively. We do not utilize derivative financial instruments to manage interest rate risks.

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, 2011 was $1.0 million primarily related to translation of Dynavax Europe assets, liabilities and operating results from Euros to U.S. dollars. As of December 31, 2011 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, 2011 and 2010, and the related consolidated statements of operations, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2011. 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, 2011 and 2010, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2011, 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, 2011, 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 12, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Redwood City, California

March 12, 2012

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DYNAVAX TECHNOLOGIES CORPORATION

CONSOLIDATED BALANCE SHEETS

(In thousands, except per share amounts)

	December 31, 2011	December 31, 2010
Assets		
Current assets:		
Cash and cash equivalents	$ 31,941	$ 22,453
Marketable securities	82,020	49,701
Accounts receivable	9,527	1,001
Prepaid expenses and other current assets	1,130	1,360
Total current assets	124,618	74,515
Property and equipment, net	6,163	6,404
Goodwill	2,312	2,312
Other intangible assets, net		299
Restricted cash	647	652
Other assets	362	67
Total assets	$ 134,102	$ 84,249
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 2,040	$ 2,329
Accrued liabilities	8,159	10,159
Deferred revenues	4,210	1,429
Note payable to Symphony Dynamo Holdings LLC (Holdings)	12,810	
Total current liabilities	27,219	13,917
Deferred revenues, noncurrent	6,386	5,655
Long-term note payable to Holdings		10,939
Long-term contingent liability to Holdings		843
Other long-term liabilities	617	784
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, 2011 and 2010		
Common stock: $0.001 par value; 250,000 and 150,000 shares authorized at December 31, 2011 and 2010, respectively; 154,626 and 115,611 shares issued and outstanding at December 31, 2011 and 2010, respectively	155	116
Additional paid-in capital	466,276	369,686
Accumulated other comprehensive loss:		
Unrealized gain on marketable securities available-for-sale	(3)	(17)
Cumulative translation adjustment	(1,006)	(729)
Total accumulated other comprehensive loss	(1,009)	(746)
Accumulated deficit	(365,542)	(316,945)
Total stockholders equity	99,880	52,111

Total liabilities and stockholders equity	$ 134,102	$ 84,249

See accompanying notes.

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DYNAVAX TECHNOLOGIES CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

	Years Ended December 31,		
	2011	**2010**	**2009**
Revenues:			
Collaboration revenue	$ 17,190	$ 19,535	$ 35,534
Grant revenue	3,110	3,940	3,477
Service and license revenue	1,314	475	1,307
Total revenues	21,614	23,950	40,318
Operating expenses:			
Research and development	51,322	53,680	38,708
General and administrative	17,570	16,879	15,745
Amortization of intangible assets	299	980	980
Total operating expenses	69,191	71,539	55,433
Loss from operations	(47,577)	(47,589)	(15,115)
Interest income	103	85	178
Interest expense	(1,957)	(1,654)	(124)
Other income (expense)	834	(8,150)	(66)
Net loss	(48,597)	(57,308)	(15,127)
Consideration paid in excess of carrying value of the noncontrolling interest in Symphony Dynamo, Inc. (SDI)			(19,671)
Add: Losses attributable to noncontrolling interest in SDI			4,233
Net loss attributable to Dynavax	$ (48,597)	$ (57,308)	$ (30,565)
Basic and diluted net loss per share attributable to Dynavax common stockholders	$ (0.39)	$ (0.69)	$ (0.76)
Shares used to compute basic and diluted net loss per share attributable to Dynavax common stockholders	125,101	82,463	40,350

See accompanying notes.

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DYNAVAX TECHNOLOGIES CORPORATION

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

(In thousands)

	Common Stock							
	Shares	Par Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Dynavax Stockholders Equity	Noncontrolling Interest in SDI	Total Stockholders Equity
Balances at December 31, 2008	39,854	40	262,579	(354)	(248,743)	13,522	2,634	16,156
Issuance of common stock upon financing	13,000	13	18,577			18,590		18,590
Issuance of common stock upon exercise of stock options and restricted stock awards	8		13			13		13
Issuance of common stock under Employee Stock Purchase Plan	136		72			72		72
Proceeds from issuance of common stock, net of issuance costs	1,281	1	2,241			2,242		2,242
Modification of warrants in conjunction with Deerfield agreement			84			84		84
Reclassification of warrant liability issued in conjunction with the SDI transaction			(2,567)			(2,567)		(2,567)
Issuance of warrants in conjunction with SDI agreements			1,764			1,764		1,764
Excess consideration paid for the noncontrolling interest in SDI			(19,671)			(19,671)		(19,671)
Stock compensation expense			3,035			3,035		3,035
Dividends paid to SDI shareholders							(335)	(335)
Dividends paid to SDI shareholders							1,934	1,934
Comprehensive loss:								
Change in unrealized gain on marketable securities				(49)		(49)		(49)
Cumulative translation adjustment				235		235		235
Net loss					(10,894)	(10,894)	(4,233)	(15,127)
Total comprehensive loss						(10,708)	(4,233)	(14,941)
Balances at December 31, 2009	54,279	54	266,127	(168)	(259,637)	6,376		6,376
Issuance of common stock upon exercise of stock options and restricted stock awards	141	1	159			160		160
Issuance of common stock under Employee Stock Purchase Plan	121		72			72		72
Proceeds from issuances of common stock and warrants, net of issuance costs	59,994	59	87,340			87,399		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		13,580
Stock compensation expense			2,410			2,410		2,410
Comprehensive loss:								
Change in unrealized gain on marketable securities				(17)		(17)		(17)
Cumulative translation adjustment				(561)		(561)		(561)
Net loss					(57,308)	(57,308)		(57,308)
Total comprehensive loss						(57,886)		(57,886)
Balances at December 31, 2010	115,611	116	369,686	(746)	(316,945)	52,111		52,111
	308		10			10		10

Issuance of common stock upon exercise of stock options and restricted stock awards								
Issuance of common stock under Employee Stock Purchase Plan	106		132			132		132
Proceeds from issuances of common stock and warrants, net of issuance costs	38,601	39	91,259			91,298		91,298
Stock compensation expense			5,189			5,189		5,189
Comprehensive loss:								
Change in unrealized gain on marketable securities				14		14		14
Cumulative translation adjustment				(277)		(277)		(277)
Net loss					(48,597)	(48,597)		(48,597)
Total comprehensive loss						(48,860)		(48,860)
Balances at December 31, 2011	154,626	$ 155	$ 466,276	$ (1,009)	$ (365,542)	$ 99,880	$	$ 99,880

See accompanying notes.

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DYNAVAX TECHNOLOGIES CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Years Ended December 31,		
	2011	**2010**	**2009**
Operating activities			
Net loss attributable to Dynavax	$ (48,597)	$ (57,308)	$ (30,565)
Adjustments to reconcile net loss to net cash used in operating activities:			
Consideration paid in excess of carrying value of the noncontrolling interest in SDI			19,671
Amount attributed to noncontrolling interest in SDI			(4,233)
Depreciation and amortization	1,303	1,415	1,857
Amortization of intangible assets	299	980	980
(Gain) loss on disposal of property and equipment	20	(36)	12
Accretion of discounts and amortization of premiums of marketable securities	1,172	367	4
Non-cash interest associated with long-term note payable to Holdings	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	(843)	8,816	
Interest associated with Deerfield financing agreement			84
Stock compensation expense	5,189	2,410	3,035
Changes in operating assets and liabilities:			
Accounts receivable	(8,526)	(106)	5,512
Prepaid expenses and other current assets	230	(774)	405
Restricted cash and other assets	(290)	(38)	(13)
Accounts payable	(289)	643	781
Accrued liabilities and other long term liabilities	(2,167)	3,381	762
Deferred revenues	3,512	(12,717)	(31,844)
Net cash used in operating activities	(47,116)	(51,370)	(33,552)
Investing activities			
Change in investments held by SDI			5,041
Purchases of marketable securities	(111,205)	(80,835)	(14,289)
Proceeds from maturities of marketable securities	77,729	30,750	29,500
Purchases of property and equipment, net	(1,142)	(420)	(377)
Net cash provided by (used in) investing activities	(34,618)	(50,505)	19,875
Financing activities			
Cash acquired from the purchase of noncontrolling interest in SDI			19,732
Proceeds from issuances of common stock and warrants, net of issuance costs	91,298	87,399	2,242
Proceeds from exercise of stock options and restricted stock awards	10	160	13
Proceeds from employee stock purchase plan	132	72	72
Net cash provided by financing activities	91,440	87,631	22,059
Effect of exchange rate on cash and cash equivalents	(218)	(23)	235
Net increase (decrease) in cash and cash equivalents	9,488	(14,267)	8,617
Cash and cash equivalents at beginning of year	22,453	36,720	28,103
Cash and cash equivalents at end of year	$ 31,941	$ 22,453	$ 36,720
Supplemental disclosure of cash flow information			
Non-cash investing and financing activities:			
Shares issued to Aspire Capital in conjunction with purchase agreement	$	$ 1,200	$

Note payable issued to Holdings from purchase option exercised under the SDI collaboration	$	$	$ 9,342
Shares issued in conjunction with the SDI transaction	$	$ 1,551	$ 18,590
Liability from program option exercised under the SDI collaboration	$	$	$ (15,000)
Warrants issued in conjunction with the SDI transaction	$	$ 6,638	$ 1,764
Modification of warrants previously issued to Deerfield	$	$	$ 84
Disposal of fully depreciated property and equipment	$ 1,181	$ 42	$ 1,215

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 designed to provide higher and earlier protection with fewer doses than currently licensed vaccines.

Our pipeline of product candidates includes: HEPLISAV, our autoimmune program partnered with GlaxoSmithKline (GSK), our therapy for asthma partnered with AstraZeneca AB (AstraZeneca), and clinical-stage programs for our Universal Flu vaccine and hepatitis B therapy. We compete with pharmaceutical companies, biotechnology companies, academic institutions and research organizations in developing therapies to prevent or treat infectious diseases, asthma and inflammatory and autoimmune 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 December 2009, we completed the acquisition of Symphony Dynamo, Inc. (SDI), which became a wholly-owned subsidiary (see Note 8). In April 2006, we completed the acquisition of Rhein Biotech GmbH (Rhein), 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. Prior to December 30, 2009, Dynavax also consolidated the financial results of SDI, as SDI was deemed a variable interest entity and we were deemed the primary beneficiary. All significant intercompany accounts and transactions have been eliminated. We have reclassified the prior year deferred rent balance of $0.8 million from current accrued liabilities to other long-term liabilities in order to conform to the current year presentation. 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 for making operating decisions and assessing performance. In fiscal years 2011, 2010 and 2009, 94%, 98% and 97% of our revenues were earned in the United States, respectively, and the remaining revenues were earned in Europe. As of December 31, 2011 and 2010, 14% and 17%, respectively, of our long-lived assets were located in the United States and the remaining 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, 2011, we had cash, cash equivalents and marketable securities of $114 million. We currently estimate that we have sufficient cash resources to meet our anticipated cash needs through at least the next 12 months based on cash and cash equivalents and marketable securities on hand as of December 31, 2011 and anticipated revenues and funding from existing agreements.

In order to continue development of our product candidates and if it is approved, to launch HEPLISAV, we will need to raise significant additional funds. This may occur through strategic alliance and licensing

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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 would need to delay, reduce the scope of, or put on hold the HEPLISAV program or our other development programs while we seek strategic alternatives.

Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles (U.S. GAAP) requires management to make 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, 2011, 2010 and 2009, we reported a loss of $0.3 million, a loss of $0.6 million, and a gain of $0.2 million, respectively. Realized gains and losses resulting from currency transactions are included in the consolidated statements of operations. We reported a $0.2 million gain resulting from currency transactions in our consolidated statements of operations for the year ended December 31, 2011.

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, government agency securities and corporate obligations, some of which are government-secured. 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:

- Length of time and the extent to which the market value has been less than cost;
- The financial condition and near-term prospects of the issuer; and
- Our intent and ability to retain our investment in the issuer for a period of time sufficient to allow for any anticipated recovery in market value.

When determining if there are any other-than-temporary impairments on our investments, we evaluate: (i) whether the investment has been in a continuous realized loss position for over 12 months, (ii) the duration to

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maturity of our investments, (iii) 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, (iv) the credit rating of each investment, and (v) the type of investments made. Through December 31, 2011, we have not recognized any other-than-temporary losses on our investments.

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

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that are subject to concentration of credit risk consist primarily of cash and 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 in order to limit the amount of credit exposure. We currently maintain a portfolio of cash equivalents and investments in a variety of securities, including money market funds, government agency securities and corporate obligations, some of which are government-secured. 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 and cash equivalents and marketable securities.

Trade 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 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 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. The assets held in our Berkeley facility have estimated useful lives of three years for computer equipment and furniture, and five years for laboratory equipment. The assets in our Düsseldorf, Germany facility have estimated useful lives of three years for computer equipment and thirteen years for furniture and laboratory equipment. Leasehold improvements in both facilities are amortized over the remaining life of the initial lease term or the estimated useful lives of the assets, whichever is shorter. Repair and maintenance costs are charged to expense as incurred.

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

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fully recoverable or that their useful lives are no longer appropriate. Intangible assets are subject to amortization and are 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

Goodwill is recorded as the excess purchase price over tangible assets, liabilities and intangible assets acquired based on their estimated fair value, by applying the acquisition method of accounting. Goodwill is not amortized but is subject to an annual impairment test which consists of a comparison of the fair value of a reporting unit against its carrying amount. If the carrying value 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 reporting units. Since we are one reporting unit, we have allocated goodwill to that one reporting unit based on the relative fair value of the reporting unit. The ongoing evaluation for impairment of goodwill requires significant management estimates and judgment. 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 are derived from collaborative and service agreements as well as grants. 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, 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) issued 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. The adoption of the standard did not impact our financial position or results of operations as of and for the year ended December 31, 2011. However, the adoption of this standard may result in revenue recognition patterns for future agreements that are different from those recognized for our existing multiple-element arrangements.

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 Issued ASU 2010-17, *Milestone Method of Revenue Recognition.* Under the milestone method, contingent consideration

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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 management s performance or a specific outcome resulting from management s performance and (iii) if achieved, the event would result in additional payments being due to management.

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 was substantial uncertainty whether any such milestones would be achieved at the time we entered into these agreements. In addition, we evaluated whether the development milestones met the criteria to be considered substantive, when all of the conditions are met. The conditions include: (1) the development work is commensurate on either of the following: (a) the vendor s performance to achieve the milestone and (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; (2) it relates solely to past performance and (3) it is reasonable relative to all the deliverable and payment terms within the arrangement. As a result of our analysis, we considered 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. The election to adopt the milestone method did not impact our financial position or results of operations as of and for the year ended December 31, 2011.

Milestone payments that were contingent upon the achievement of substantive at-risk performance criteria were recognized in full upon achievement of those milestone events in accordance with the terms of the agreement and assuming all other revenue recognition criteria were 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

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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.

Consolidation of Variable Interest Entities

Arrangements that are not controlled through voting or similar rights are accounted for as variable interest entities (VIEs). An enterprise is required to consolidate a VIE if it is the primary beneficiary of the VIE. The enterprise that is deemed to absorb a majority of the expected losses or receive a majority of expected residual returns of the VIE is considered the primary beneficiary.

We have concluded that under certain circumstances when we enter into agreements that contain an option to purchase assets or equity securities from an entity, or enter into an arrangement with a financial partner for the formation of joint ventures which engage in research and development projects, a VIE may be created. For each VIE created, we compute expected losses and residual returns based on the probability of future cash flows. If we are determined to be the primary beneficiary of the VIE, the assets, liabilities and operations of the VIE will be consolidated with our financial statements. Prior to the acquisition of all of the outstanding equity of SDI pursuant to the Amended Purchase Option on December 30, 2009, our consolidated financial statements include the accounts of SDI, a VIE, of which we were the primary beneficiary (refer to Note 8 below).

Stock-Based Compensation

Determining the appropriate fair value model and calculating the fair value of stock-based awards at the grant date requires judgment and estimates. The fair value of each option is amortized on a straight-line basis over the option s vesting period, assuming an annual forfeiture rate of 15% for both the executive level and non-executive level employee groups, and is estimated on the date of grant using the Black-Scholes option valuation model, which requires the input of highly subjective assumptions, including the expected life of the option and expected stock price volatility. The expected life of options granted is estimated based on historical option exercise and employee termination data. Executive level and non-executive level employees were grouped and considered separately for valuation purposes. The expected life of the options for both groups of employees is 4 years. Expected volatility is based on historical volatility of our stock over the life of the options granted to executive and non-executive level employees. See Note 13, Stockholder s Equity for further information on our equity incentive plans.

Income Taxes

We account for income taxes using the liability method under FASB issued Accounting Standards Codification (ASC) 740, *Income Taxes*. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial statements 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 because we believe it is more likely than not that our deferred tax assets will not be realized as of the year ended in 2011 and 2010.

We have no provision for income taxes as we have incurred losses for the years ended December 31, 2011, 2010 and 2009.

We have no unrecognized tax benefits as of December 31, 2011, including no accrued amounts for interest and penalties. We do not anticipate that total unrecognized tax benefits will significantly change prior to

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December 31, 2012. 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 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 IFRSs*. 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 U.S. GAAP, it expands 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 U.S. GAAP and International Financial Reporting Standards, which could change how fair value measurement guidance in ASC 820 is applied. ASU No. 2011-04 is effective on a prospective basis for us on January 1, 2012. We are currently evaluating whether this new guidance will have a material impact on our consolidated financial statements.

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. ASU No. 2011-05 is effective on a retrospective basis for us on January 1, 2012. We do not expect that this new guidance will have a material impact on our consolidated financial statements.

Accounting Standards Update 2011-08

In September 2011, the FASB issued ASU No. 2011-08, *Testing Goodwill for Impairment*. This ASU will allow 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 is effective for us on January 1, 2012. We do not expect that this new guidance will have a material impact on our consolidated financial statements.

3. Fair Value Measurements

ASC 820 defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles and enhances disclosures about fair value measurements. Fair value is defined under ASC 820 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 under ASC 820 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;

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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.

The following table represents the fair value hierarchy for our financial assets (cash equivalents and marketable securities) and liabilities measured at fair value on a recurring basis as of December 31, 2011 and 2010 (in thousands):

	Level 1	Level 2	Level 3	Total
December 31, 2011				
Assets:				
Money market funds	$ 17,171	$	$	$ 17,171
U.S. government agency securities		28,495		28,495
Corporate debt securities		58,580		58,580
Total assets	$ 17,171	$ 87,075	$	$ 104,246

	Level 1	Level 2	Level 3	Total
December 31, 2010				
Assets:				
Money market funds	$ 18,980	$	$	$ 18,980
U.S. government agency securities		49,039		49,039
Corporate debt securities		1,764		1,764
Total assets	$ 18,980	$ 50,803	$	$ 69,783
Liabilities:				
Long-term contingent consideration liability to Holdings	$	$	$ 843	$ 843
Total liabilities	$	$	$ 843	$ 843

Financial Assets

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.

Marketable securities are primarily comprised of U.S. Government sponsored and corporate debt securities which 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.

When determining if there are any other-than-temporary impairments on our investments, we evaluate: (i) whether the investment has been in a continuous realized loss position for over 12 months, (ii) the duration to maturity of our investments, (iii) our intention to hold the investments to maturity and if it is not more likely than not that the Company will be required to sell the investment before recovery of the amortized cost bases, (iv) the credit rating of each investment, and (v) the type of investments made. Through December 31, 2011, we have not recognized any other-than-temporary losses on our investments.

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Financial Liabilities

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. Refer to Note 8, Symphony Dynamo Inc. for further discussion. 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 rates of 16% and 18% for the fiscal years ended December 31, 2010 and 2009, respectively.

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. This fair value measurement was based on significant inputs not observed in the market and thus represents a Level 3 measurement.

The following table represents the changes in the fair value measurement of the contingent liability for the year ended December 31, 2011 (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	$

In connection with our purchase of all of the outstanding equity of 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 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 represents 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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The following table represents the changes in the fair value measurement of the warrant liability (in thousands):

Warrant Liability to Holdings	Amount
Acquisition date fair value measurement at December 30, 2009	$ 2,567
Adjustment to fair value measurement	9,462
Reclassification of warranty liability into equity	(12,029)
Balance as of December 31, 2010	$

4. Available-for-Sale Securities

The following is a summary of available-for-sale securities included in cash and cash equivalents and marketable securities as of December 31, 2011 and 2010 (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
December 31, 2011				
Certificates of deposit and money market funds	$ 25,243	$	$	$ 25,243
U.S. Government agency securities	28,501		(6)	28,495
Corporate debt securities	58,577	9	(6)	58,580
Total	$ 112,321	$ 9	$ (12)	$ 112,318
December 31, 2010				
Certificates of deposit and money market funds	$ 19,797	$	$	$ 19,797
U.S. Government agency securities	49,056		(17)	49,039
Corporate debt securities	1,764			1,764
Total	$ 70,617	$	$ (17)	$ 70,600

There were no realized gains or losses from the sale of marketable securities in the years ended December 31, 2011, 2010 and 2009. As of December 31, 2011, all of our investments have a stated maturity date that is within one year of the current balance sheet date. All of our investments are classified as short-term and available-for-sale, as we may not hold our investments until maturity.

5. Property and Equipment

Property and equipment as of December 31, 2011 and 2010 consist of the following (in thousands):

	December 31, 2011	2010
Laboratory equipment	$ 13,735	$ 14,173
Computer equipment	1,498	1,341
Furniture and fixtures	1,001	1,518
Leasehold improvements	4,345	3,872
	20,579	20,904
Less accumulated depreciation and amortization	(14,416)	(14,500)

Total	$ 6,163	$ 6,404

Depreciation and amortization expense on property and equipment was $1.3 million, $1.4 million and $1.9 million for the years ended December 31, 2011, 2010 and 2009, respectively.

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6. Intangible Assets

Intangible assets consist primarily of manufacturing process and customer relationships. The manufacturing process derives from the methods for making proteins in Hansenula yeast, which is a process we use to make a key component in the production of hepatitis B vaccine. The customer relationships derive from Rhein s ability to sell existing, in-process and future products to its existing customers. Purchased intangible assets other than goodwill are amortized on a straight-line basis over their respective useful lives. The following tables present details of the purchased intangible assets at December 31, 2011 and December 31, 2010 (in thousands):

	Estimated Useful Life (In years)	December 31, 2011			December 31, 2010		
		Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Intangible Assets							
Manufacturing process	5	$ 3,670	$ (3,670)	$	$ 3,670	$ (3,446)	$ 224
Customer relationships	5	1,230	(1,230)		1,230	(1,155)	75
Total		$ 4,900	$ (4,900)	$	$ 4,900	$ (4,601)	$ 299

7. Current Accrued Liabilities

Current accrued liabilities as of December 31, 2011 and 2010 consist of the following (in thousands):

	December 31,	
	2011	2010
Payroll and related expenses	$ 3,224	$ 2,485
Legal expenses	220	596
Third party research and development expenses	3,903	6,130
Other accrued liabilities	812	948
Total	$ 8,159	$ 10,159

8. Symphony Dynamo, Inc.

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

In connection with the transaction described above, Holdings granted to us an exclusive purchase option that gave us the right, but not the obligation, to acquire the outstanding equity securities of SDI, which would result in our reacquisition of the intellectual property rights that we licensed to Holdings (the Original Purchase Option). In exchange for the Original Purchase Option, we granted Holdings five-year warrants to purchase up to 2,000,000 shares of our common stock at an exercise price of $7.32 per share pursuant to a warrant purchase agreement (the Original Warrants), and granted certain registration rights to Holdings pursuant to a registration rights agreement. We also received an exclusive option to purchase either the hepatitis B or hepatitis C therapy program (the Program Option) during the first year of the arrangement. In April 2007, we exercised the Program Option for the hepatitis B program which resulted in the recognition of a $15.0 million liability to Symphony. We remained primarily responsible for the development of the cancer and hepatitis C therapy programs in accordance with a development plan and related development budgets that we agreed to with Holdings.

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Prior to the acquisition of all of the outstanding equity of SDI pursuant to the Amended Purchase Option on December 30, 2009, as described below, we consolidated the financial position and results of operations of SDI. Net losses incurred by SDI and charged to Symphony s noncontrolling interest were $4.2 million for the year ended December 31, 2009. In November 2009, we entered into an agreement with Holdings to modify the provisions of and to exercise the Original Purchase Option. We completed the acquisition of all of the outstanding equity of SDI on December 30, 2009. In exchange for all of the outstanding equity of SDI, we issued to Symphony and certain of its co-investors: (i) 13,000,000 shares of common stock (the Shares); (ii) 5-year warrants to purchase 2,000,000 shares of common stock with an exercise price of $1.94 per share (the Warrants); and (iii) a note in the principal amount of $15.0 million, due December 31, 2012, payable in cash, our common stock or a combination thereof at our discretion, which obligation was previously payable solely in cash on April 18, 2011. In addition, we agreed to contingent cash payments from us equal to 50% of the first $50 million from any upfront, pre-commercialization milestone or similar payments received by us from any agreement with any third party with respect to the development and/or commercialization of the cancer and hepatitis C therapies originally licensed to SDI. The Original Warrants held by Symphony were cancelled as part of this transaction.

We recorded the acquisition of all of the outstanding equity of SDI pursuant to the Amended Purchase Option as a return of equity to the noncontrolling interest. The acquisition was accounted for as a capital transaction that did not affect our consolidated net loss. However, because the acquisition was accounted for as a capital transaction, the consideration paid in excess of the carrying value of the noncontrolling interest in SDI is treated as a deemed dividend for purposes of reporting net loss and earnings per share, increasing net loss and net loss per share attributable to us for the year ended December 31, 2009. We ceased to charge net losses incurred by SDI against the noncontrolling interest upon our acquisition of SDI on December 30, 2009.

The fair value of our common stock issued to the Symphony investors was based on the closing sales price of our common stock on the NASDAQ Capital Market on December 30, 2009, the date the transaction was completed. The estimated fair values of the warrants transferred were calculated using the Black-Scholes valuation model.

The principal amount of the non-interest bearing note payable to Holdings of $15 million is due on December 31, 2012 and is payable in cash, our common stock or a combination thereof at our discretion. As of December 31, 2011, the estimated fair value of the note payable was $12.8 million and was classified as a short term liability. We estimated the fair value using a net present value model with a discount rate of 17%. Imputed interest was recorded as interest expense over the term of the loan using the interest rate method. If we elect to pay all or a portion of the note in shares of our common stock, the number of shares issued will be equal to the portion of the outstanding principal amount of the note to be repaid using our common stock, divided by the average closing price of our common stock for the thirty (30) trading days immediately preceding (but not including) the second trading day prior to the date of such payment multiplied by 1.15.

We estimated the fair value of the contingent consideration liability for potential future payments 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%. Changes in the fair value of the acquisition-related contingent consideration liability subsequent to the December 30, 2009 acquisition date are recognized in other income and expense on our consolidated statement of operations in the period of the change.

The Shares and Warrants were subject to certain anti-dilution protection in the event that we issued other equity securities within six months from December 30, 2009. 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 the Company s own stock and therefore were recorded as a liability at fair value, which was estimated at the issuance date using the Black-Scholes Model. As a result of an equity offering completed in April 2010 prior to the expiration of the anti-dilution provision, Symphony received an additional 1,076,420 shares of common stock (April 2010 Shares) and warrants to purchase 7,038,210 shares of common stock (April 2010 Warrants) having the same

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terms as the warrants sold in the offering, which have an exercise price of $1.50 per share and a term of five years. The Warrants issued on December 30, 2009 were cancelled upon the issuance of the April 2010 Warrants.

The fair value of the April 2010 Shares and incremental fair value of the April 2010 Warrants provided to Symphony, as measured upon issuance and remeasured at June 30, 2010, resulted in non-operating expense of $11.1 million in the second quarter of 2010. This also resulted in an increase of $9.5 million to the warrant liability and an increase of $1.6 million to additional paid in capital as of June 30, 2010. Following the expiration date of Symphony s anti-dilution protection, on July 1, 2010, the value of the April 2010 Warrants of $12.0 million was reclassified into stockholders equity in the consolidated balance sheets. The April 2010 Warrants remained outstanding as of December 31, 2011.

9. Financing Agreements

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

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

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

On April 16, 2010, we completed an underwritten public offering resulting in net proceeds of $41.1 million, after deducting the underwriting discount and offering expenses of approximately $3.0 million, from the sale of 30,293,000 units at a per unit price of $1.4525. Each unit consisted of one share of common stock and one warrant to purchase 0.5 of a share of common stock. Each warrant has an exercise price of $1.50 per share, and is exercisable for a period of five years from the date of issuance. From this offering, warrants to purchase an aggregate of 15,141,165 shares of our common stock were outstanding as of December 31, 2011.

On August 17, 2009, we entered into an equity distribution agreement with Wedbush Morgan Securities, Inc. (Wedbush) pursuant to which we could offer and sell shares of our common stock having an aggregate offering price of up to $15 million from time to time through Wedbush as our sales agent or to Wedbush as a principal. During the fiscal year ended December 31, 2009, we sold 1,281,100 shares of common stock under the agreement with Wedbush as our sales agent for aggregate net proceeds of $2.3 million after deducting commissions paid to Wedbush and offering expenses. On September 14, 2010, the Company terminated the agreement with Wedbush. Prior to the termination of the agreement on September 14, 2010, during the year ended December 31, 2010 we sold 900,860 shares of common stock under the agreement with Wedbush as our sales agent for net proceeds of $1.2 million.

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

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

Such warrants remained outstanding as of December 31, 2011.

10. Commitments and Contingencies

We lease our facilities in Berkeley, California (the Berkeley Lease), and Düsseldorf, Germany (the Düsseldorf Lease), under operating leases that expire in September 2017 and March 2023, respectively. Total net rent expense related to our operating leases for the years ended December 31, 2011, 2010 and 2009, was $1.7 million, $2.6 million and $2.5 million, respectively. Deferred rent was $0.6 million and $0.8 million as of December 31, 2011 and 2010, respectively.

Future minimum payments under the non-cancelable portion of our operating leases at December 31, 2011, excluding payments from sublease agreements of $0.1 million, are as follows (in thousands):

Years ending December 31,	
2012	$ 1,783
2013	1,804
2014	1,766
2015	1,803
2016	1,840
Thereafter	4,442
Total	$ 13,438

During the fourth quarter of 2004, we established a letter of credit with Silicon Valley Bank as security for our Berkeley Lease in the amount of $0.4 million. The letter of credit remained outstanding as of December 31, 2011 and is collateralized by a certificate of deposit which has been included in restricted cash in the consolidated balance sheets as of December 31, 2011 and 2010. Under the terms of the Berkeley Lease, if the total amount of our cash, cash equivalents and marketable securities falls below $20.0 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 $20.0 million for the remainder of the lease term, or until our actual cash and cash equivalents remains above $20.0 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 as of December 31, 2011 and is collateralized by a certificate of deposit which has been included in restricted cash in the consolidated balance sheets as of December 31, 2011 and 2010.

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

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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, 2011, under the terms of our agreements, we are obligated to make future payments as services are provided of approximately $14.8 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 originating from the licensed technologies.

11. Collaborative Research, Development, and License Agreements

GlaxoSmithKline

In December 2008, we entered into a worldwide strategic alliance with GSK to discover, develop, and commercialize toll-like receptor (TLR) inhibitors. We received an initial payment of $10 million and agreed to conduct research and early clinical development in up to four programs. 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 its option, GSK would carry out further development and commercialization of these products. We are eligible to receive tiered, up to double-digit royalties on sales, if any, and have retained an option to co-develop and co-promote one product under this agreement.

In 2011, we earned $15 million in milestone payments related to the initiation of Phase 1 and proof-of-mechanism clinical trials of DV1179 in systemic lupus erythematosus patients and the expansion of our collaboration with GSK to develop a TLR8 inhibitor. Revenue from the initial payment is deferred and is being recognized over the expected period of performance which is estimated to be seven years. For the years ended December 31, 2011, 2010 and 2009, we recognized revenue of $16.4 million, $1.4 million and $1.4 million, respectively, from this collaboration.

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 stage of clinical development of the programs.

AstraZeneca

In September 2006, we entered into a three-year research collaboration and license agreement with AstraZeneca for the discovery and development of TLR9 agonist-based therapies for the treatment of asthma and chronic obstructive pulmonary disease. 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 for the development of AZD1419. Development expenses will be funded by AstraZeneca and we received an initial payment of $3.0 million to begin the clinical program. In December 2011, we agreed to advance AZD1419 into preclinical toxicology studies, which entitled us to receive a $2.6 million payment. Under the terms of the amended agreement, AstraZeneca will provide us with a total of approximately $20 million in payments to cover the cost of clinical development activities through Phase 2a. If AstraZeneca chooses to advance the program following completion

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of Phase 2a, we will receive a $20 million substantive 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, if any. We have the option to co-promote in the United States products arising from the collaboration, if any. AstraZeneca has the right to sublicense its rights upon our prior consent.

Revenue from the upfront payment had been deferred until certain contractual obligations were amended in September 2010 when the $10 million was recognized. Revenue from the milestone payment for the nomination of the candidate drug was deferred and recognized ratably over the estimated performance period of the original research term through July 2010. Revenue from the 2011 amendment has been deferred and is being recognized as the development work is performed over the estimated performance period of approximately five years. For the years ended December 31, 2011, 2010, and 2009, we recognized revenue of $0.8 million, $14.1 million, and $5.1 million, respectively, from this collaboration.

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

National Institutes of Health (NIH) and Other Funding

In July 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 (PI3K) in preclinical models of skin autoimmune inflammation. For the year ended December 31, 2011 we recognized revenue of approximately $0.1 million related to this grant.

In August 2010, we were awarded a grant from the NIH s National Institute of Allergy and Infectious Disease (NIAID) to take a systems biology approach to study the differences between individuals who do or do not respond to vaccination against the hepatitis B virus. This study will be one of several projects conducted under a grant to the Baylor Institute of Immunology Research in Dallas as part of the Human Immune Phenotyping Centers program, from which we received $0.5 million in 2011 and $0.1 million in 2010. For the years ended December 31, 2011 and December 31, 2010, we recognized revenue of approximately $0.5 million and $40 thousand, respectively, related to this grant.

In July 2010, we were awarded a $0.6 million grant from the NIH to explore the feasibility of developing a universal vaccine to prevent infection by human papilloma virus. For the years ended December 31, 2011 and December 31, 2010, we recognized revenue of approximately $0.2 million for each of the years, related to this grant.

In September 2008, we were awarded a five-year $17 million contract to develop our ISS technology using TLR9 agonists as vaccine adjuvants. The contract was awarded by NIAID to develop novel vaccine adjuvant candidates that signal through receptors of the innate immune system. The contract supports adjuvant development for anthrax as well as other disease models. NIAID is funding 100% of the total $17 million cost of our program under Contract No. HHSN272200800038C. For the years ended December 31, 2011, 2010, and 2009, we recognized revenue related to this program of approximately $2.3 million, $3.2 million and $1.6 million, respectively.

In July 2008, we were awarded a two-year $1.8 million grant from the NIH to develop a therapy for systemic lupus erythematosus, an autoimmune disease. For the years ended December 31, 2011, 2010, and 2009, we recognized revenue related to this program of approximately $0.1 million, $0.2 million, and $0.9 million, respectively.

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Merck & Co., Inc. (Merck)

In October 2007, we entered into a global license and development collaboration agreement and a related manufacturing agreement with Merck to jointly develop HEPLISAV, our novel investigational hepatitis B vaccine. Under the terms of the agreement, Merck received worldwide exclusive rights to HEPLISAV, and agreed to fund future vaccine development and be responsible for commercialization. We received a non-refundable upfront payment of $31.5 million. Revenue from the initial payment was deferred and recognized ratably over the estimated performance period of the collaboration agreement. On December 18, 2008, Merck provided notice of its termination of the collaboration, at which time all development, manufacturing and commercialization rights to HEPLISAV reverted to us. As a result of Merck s termination, we accelerated the applicable performance period over which we ratably recognized revenue from the upfront fee through the effective date of termination, which was in June 2009. For the year ended December 31, 2009, we recognized revenue of $28.5 million related to the upfront fee. Cost reimbursement revenue under this collaboration agreement totaled $0.3 million for the year ended December 31, 2009. Additionally, in March 2010, Merck agreed to make a $4.0 million payment to us in satisfaction of its obligations for the wind down period following Merck s written notice of termination, which was recorded as collaboration revenue upon receipt.

12. Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss attributable to us by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing the net loss attributable to us by the weighted-average number of common shares outstanding during the period and dilutive potential common shares using the treasury-stock method. For purposes of this calculation, common stock subject to repurchase by us, options and warrants are considered to be dilutive potential common shares and are only included in the calculation of diluted net loss per share when their effect is dilutive.

	Years Ended December 31,		
	2011	2010	2009
Basic and diluted net loss per share (in thousands, except per share amounts):			
Numerator:			
Net loss attributable to Dynavax	$ (48,597)	$ (57,308)	$ (30,565)
Denominator for basic and diluted net loss per share attributable to Dynavax common stockholders:			
Weighted-average common shares outstanding	125,101	82,463	40,350
Basic and diluted net loss per share attributable to Dynavax common stockholders	$ (0.39)	$ (0.69)	$ (0.76)

	December 31,		
	2011	2010	2009
Outstanding securities not included in diluted net loss per share calculation (in thousands):			
Options to purchase common stock	7,882	7,288	5,561
Warrants	25,729	25,734	5,550
	33,611	33,022	11,111

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13. Stockholders Equity

Stock Plans

As of December 31, 2011, we had four share-based compensation plans: the 1997 Equity Incentive Plan; the 2004 Stock Incentive Plan, which includes the 2004 Non-Employee Director Option Program and the 2004 Employee Stock Purchase Plan; the 2010 Employment Inducement Award Plan; and the 2011 Equity Incentive Plan.

In January 1997, we adopted the 1997 Equity Incentive Plan (the 1997 Plan). The 1997 Plan provides for the granting of stock options to employees and non-employees of the Company. Options granted under the 1997 Plan may be either incentive stock options (ISOs) or nonqualified stock options (NSOs). ISOs may be granted to employees, including directors who are also considered employees. NSOs may be granted to employees and non-employees. Options under the 1997 Plan may be granted for periods of up to ten years and at prices no less than 85% of the estimated fair value of the shares on the date of grant as determined by the Board of Directors, provided, however, that (i) the exercise price of an ISO shall not be less than 100% of the estimated fair value of the shares on the date of grant, and (ii) the exercise price of an ISO granted to a 10% stockholder shall not be less than 110% of the estimated fair value of the shares on the date of grant. The options are exercisable immediately and generally vest over a four-year period (generally 25% after one year and in monthly ratable increments thereafter) for stock options issued to employees, directors and scientific advisors, and quarterly vesting over a four-year period or immediate vesting for stock options issued to all other non-employees. All unvested shares issued under the 1997 Plan are subject to repurchase rights by the Company under such conditions as agreed to by the Company and the optionee. The 1997 Plan expired in the first quarter of 2007. Upon expiration of the 1997 Plan, 273,188 shares previously available for grant expired. Any outstanding options under the 1997 Plan that are cancelled in future periods will automatically expire and will no longer be available for grant. As of December 31, 2011, options to purchase approximately 729,000 shares of common stock remained outstanding under the 1997 Plan.

In January 2004, the Board of Directors and stockholders adopted the 2004 Stock Incentive Plan (the 2004 Plan) which became effective on February 11, 2004. Subsequently, we discontinued granting stock options under the 1997 Plan. The exercise price of all incentive stock options granted under the 2004 Plan is at least equal to 100% of the fair market value of the common stock on the date of grant. If, however, incentive stock options are granted to an employee who owns stock possessing more than 10% of the voting power of all classes of the Company s stock or the stock of any parent or subsidiary of the Company, the exercise price of any incentive stock option granted must equal at least 110% of the fair market value on the grant date and the maximum term of these incentive stock options must not exceed five years. The maximum term of an incentive stock option granted to any other participant must not exceed ten years. The 2004 Stock Incentive Plan authorizes the issuance of various forms of stock-based awards including stock options, restricted stock, restricted stock units, and other equity awards to employees, consultants and members of the board of directors. As of December 31, 2011, options to purchase approximately 5.0 million shares of common stock remained outstanding under the 2004 Plan.

In January 2010, our Board of Directors adopted a 2010 Employment Inducement Award Plan (the Inducement Plan) to induce qualified individuals to join Dynavax. This Inducement Plan provides for the issuance of up to 1,500,000 shares of Dynavax Common Stock and became effective on January 8, 2010. Stockholder approval of the Inducement Plan is not required under NASDAQ Marketplace Rule 5635(c)(4). As of December 31, 2011, options to purchase approximately 850,000 shares of common stock remained outstanding under the Inducement Plan.

In January 2011, the Company s stockholders approved the 2011 Equity Incentive Plan (the 2011 Plan). The 2011 Plan provides for the issuance of up to 15,000,000 shares of our common stock to employees and non-employees of the Company and became effective on January 6, 2011. The 2011 Plan is administered by our Board of Directors (the Board), or a designated committee of the Board, and awards granted under the 2011

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Plan have a term of 10 years unless earlier terminated by the Board. Under the 2011 Plan, no additional awards will be granted under either the 2004 Plan or the 2010 Inducement Plan. As of January 6, 2011, all shares subject to awards outstanding under the 1997 Plan, 2004 Plan or 2010 Inducement Plan that expire or are forfeited will be included in the reserve for the 2011 Plan to the extent such shares would otherwise return to such plans. As of December 31, 2011, options to purchase approximately 4.4 million shares of common stock remained outstanding under the 2011 Plan.

Activity under our stock plans is set forth below (in thousands, except price per share):

	Options and Awards Available for Grant	Options Outstanding	Weighted-Average Price Per Share
Balance at December 31, 2010	646	6,868	$ 3.05
2011 Plan options authorized	15,000		
2011 Plan options granted	(4,573)	4,573	$ 3.08
2010 Plan options exercised		(44)	$ 1.36
2004 Plan options exercised		(25)	$ 1.55
2004 Plan RSUs paid to the Company in settlement of taxes	66		$ 2.77
Options cancelled:			
2011 Plan options	148	(148)	$ 2.88
2010 Plan options	185	(185)	$ 1.50
2004 Plan options	36	(36)	$ 2.12
1997 Plan options	16	(16)	$ 6.12
Balance at December 31, 2011	11,524	10,987	$ 3.10

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Stock option activity is summarized as follows:

	Number of Options (In thousands)	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Life (In years)	Aggregate Intrinsic Value (In thousands)
Outstanding as of December 31, 2008 (2,536 exercisable at $5.09 weighted average price per share)	4,823	$ 5.04	5.19	
Granted	1,398	$ 0.96		
Cancelled and expired	(942)	$ 5.14		
Exercised	(3)	$ 1.50		$ 1
Outstanding as of December 31, 2009 (2,848 exercisable at $4.78 weighted average exercise price per share)	5,276	$ 3.94	5.63	
Granted	2,699	$ 1.64		
Cancelled and expired	(968)	$ 4.21		
Exercised	(139)	$ 1.14		$ 84
Outstanding as of December 31, 2010 (3,409 exercisable at $4.28 weighted average exercise price per share)	6,868	$ 3.05	6.82	
Granted	4,573	$ 3.08		
Cancelled and expired	(385)	$ 2.33		
Exercised	(69)	$ 1.43		$ 95
Outstanding as of December 31, 2011	10,987	$ 3.10	7.27	
Outstanding options vested and expected to vest as of December 31, 2011	10,169	$ 3.14	7.15	$ 7,633
Options exercisable as of December 31, 2011	4,219	$ 3.94	5.01	$ 2,919

Options outstanding as of December 31, 2011 are summarized as follows:

	Options Outstanding			Options Exercisable	
Exercise Price Range	Number of Options (In thousands)	Weighted Average Remaining Contractual Life (In Years)	Weighted Average Exercise Price	Number of Options (In thousands)	Weighted Average Exercise Price
$0.54 - $1.48	1,341	7.46	$ 0.86	538	$ 0.71
1.50 - 1.59	1,150	7.40	$ 1.58	315	$ 1.56
1.65 - 2.33	1,238	8.10	$ 1.93	575	$ 2.04
2.40 - 3.00	1,171	5.14	$ 2.85	639	$ 2.99
3.14 - 3.14	3,789	8.98	$ 3.14	50	$ 3.14
3.20 - 9.85	2,298	4.92	$ 5.85	2,102	$ 5.95
	10,987	7.27	$ 3.10	4,219	$ 3.94

The fair value of options vested in 2011, 2010 and 2009 was $2.8 million, $4.6 million, and $4.1 million, respectively.

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Restricted stock units activity is summarized as follows:

	Number of Shares (In thousands)	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Life (In years)	Aggregate Intrinsic Value (In thousands)
Outstanding units as of December 31, 2010	420	$ 2.54	0.94	
Granted				
Released	(305)	$ 2.75		
Forfeited or expired				
Outstanding units as of December 31, 2011	115	$ 1.98	0.58	$ 382

Employee Stock Purchase Plan

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

As of December 31, 2011, 996,000 shares were reserved and approved for issuance under the Purchase Plan, subject to adjustment for a stock split, or any future stock dividend or other similar change in our common stock or capital structure. To date, employees have acquired 558,140 shares of our common stock under the Purchase Plan. At December 31, 2011, 437,860 shares of our common stock remained available for future purchases.

Preferred Stock Rights

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

Stock-Based Compensation

Under our stock-based compensation plans, option awards generally vest over a 4-year period contingent upon continuous service and expire 10 years from the date of grant (or earlier upon termination of continuous service). The Company has also granted performance-based equity awards to certain of our employees under the 2011 Plan, 2004 Plan and Inducement Plan. As of December 31, 2011, 1,269,832 shares related to outstanding

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options and restricted stock units were subject to performance-based vesting criteria. The fair value of each option is estimated on the date of grant using the Black-Scholes option valuation model and the following weighted-average assumptions:

	Stock Options Years Ended December 31,			Employee Stock Purchase Plan Years Ended December 31,		
	2011	2010	2009	2011	2010	2009
Weighted-average fair value	$ 2.76	$ 1.49	$ 0.55	$ 2.09	$ 1.47	$ 0.88
Risk-free interest rate	1.3%	1.7%	1.7%	0.3%	0.4%	0.7%
Expected life (in years)	4.0	4.0	4.0	1.2	0.9	1.1
Volatility	1.6	1.6	1.6	1.6	1.6	1.6

Expected volatility is based on historical volatility of our stock. The expected life of options granted is estimated based on historical option exercise and employee termination data. Executive level employees, who hold a majority of the options outstanding, and non-executive level employees were grouped and considered separately for valuation purposes. In 2009, based on employee termination data we adjusted the expected life of the options for both groups of employees to 4 years and this has remained consistent through the year ended December 31, 2011. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant. The dividend yield is 0% for all years and is based on our history and expectation of dividend payouts.

Compensation expense is based on awards ultimately expected to vest and reflects estimated forfeitures. For equity awards with time-based vesting, the fair value is amortized to expense on a straight-line basis over the vesting periods. For equity awards with performance-based vesting criteria, the fair value is amortized to expense when the achievement of the vesting criteria becomes probable. As of December 31, 2011, the unrecognized compensation cost related to non-vested stock options, net of estimated forfeitures, amounted to $7.6 million, which is expected to be recognized over the remaining weighted-average vesting period of 1.8 years. As of December 31, 2011, the unrecognized compensation cost related to non-vested restricted stock units was nominal.

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

	Years Ended December 31,		
	2011	2010	2009
Employees and directors stock-based compensation expense	$ 5,185	$ 2,378	$ 3,014
Non-employees stock-based compensation expense	4	32	21
Total	$ 5,189	$ 2,410	$ 3,035

	Years Ended December 31,		
	2011	2010	2009
Research and development	$ 2,103	$ 632	$ 1,139
General and administrative	3,086	1,778	1,896
Total	$ 5,189	$ 2,410	$ 3,035

14. Employee Benefit Plan

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

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15. Income Taxes

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

	Years Ended December 31,		
	2011	2010	2009
U.S.	$ (49,990)	$ (56,379)	$ (11,369)
Non U.S.	1,393	(929)	475
Total	$ (48,597)	$ (57,308)	$ (10,894)

For the year ended December 31, 2009, the U.S. loss included losses attributable to the noncontrolling interest in SDI but did not include $19.7 million of consideration paid in excess of carrying value of the noncontrolling interest in SDI.

No income tax expense was recorded for the years ended December 31, 2011, 2010 and 2009 due to net operating losses and valuation allowances to offset the net income at Dynavax Europe. The difference between the consolidated income tax benefit and the amount computed by applying the federal statutory income tax rate to the consolidated loss before income taxes was as follows (in thousands):

	Years Ended December 31,		
	2011	2010	2009
Income tax benefit at federal statutory rate	$ (16,523)	$ (19,486)	$ (3,722)
State tax	(2,586)	(1,617)	(1,727)
Tax credits	(1,394)	(2,172)	(1,473)
Deferred compensation charges	595	318	439
Change in valuation allowance	18,099	19,863	6,873
Change in foreign tax rates	(34)	22	11
Change in NOL			(1,439)
Change in the fair value measurements	286	2,997	
Non-deductible debt discount	509	420	
Deemed dividend	273		
Limitation of NOLs			628
Other	775	(345)	410
	$	$	$

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Deferred tax assets and liabilities as of December 31, 2011 and 2010 consisted of the following (in thousands):

	December 31, 2011	2010
Deferred tax assets:		
Net operating loss carry forwards	$ 103,119	$ 92,253
Research tax credit carry forwards	17,477	15,664
Accruals and reserves	6,818	5,492
Capitalized research costs	17,278	12,415
Deferred revenue	2,189	2,726
Other	1,455	1,732
	148,336	130,282
Less valuation allowance	(148,266)	(130,167)
Total deferred tax assets	70	115
Deferred tax liabilities:		
Acquired intangible assets.	(27)	(115)
Other	(43)	
Total deferred tax liabilities	(70)	(115)
Net deferred tax assets	$	$

ASC 740, *Income Taxes*, requires that the tax benefit of net operating losses, temporary differences and credit carryforwards be recorded as an asset to the extent that management assesses that realization is more likely than not. Realization of the future tax benefits is dependent on our ability to generate sufficient taxable income within the carryforward period. Because of our recent history of operating losses, management believes that recognition of the deferred tax assets arising from the above-mentioned future tax benefits is currently not likely to be realized and, accordingly, has provided a full valuation allowance. The valuation allowance increased by $18.1 million, $19.9 million and $6.9 million during the years ended December 31, 2011, 2010 and 2009, respectively. The amount of the valuation allowance for deferred tax assets associated with excess tax deductions from stock based compensation arrangements that will be allocated to contributed capital if the future tax benefits are subsequently recognized is $0.4 million.

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

As of December 31, 2011, we had federal net operating loss carryforwards of approximately $259.0 million, which will expire in the years 2016 through 2031 and federal research and development tax credits of approximately $11.2 million, which expire in the years 2018 through 2031.

As of December 31, 2011, we had net operating loss carryforwards for California state income tax purposes of approximately $180.3 million, which expire in the years 2012 through 2031, and California state research and development tax credits of approximately $9.5 million which do not expire.

As of December 31, 2011, we had net operating loss carryforwards for foreign income tax purposes of approximately $29 million, which do not expire.

The Tax Reform Act of 1986 limits the annual use of net operating loss and tax credit carryforwards in certain situations where changes occur in stock ownership of a company. In the event the Company has a change

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in ownership, as defined, the annual utilization of such carryforwards could be limited. Due to past equity issuances and changes in ownership of Dynavax common stock, we believe that our ability to use some our net operating losses and tax credits in the future may be limited. We are conducting an analysis under Sections 382 and 383 of the Internal Revenue Code as enacted by the Tax Reform Act of 1986, and if necessary, we will reduce our net operating losses and tax credits by any applicable limitation when our analysis is complete.

We concluded a limited scope audit by the Internal Revenue Service (IRS) for the tax year 2008 which resulted in a no change report. The IRS also examined our 2009 amended return and issued a no change report. Additionally, we concluded an audit in Germany for the tax years 2005 to 2009 and there were no material differences as a result of the audit.

In November 2010, we received a one-time $0.7 million payment under The Patient Protection and Affordable Care Act of 2010 covering research and development costs from 2009 and 2010 for three of our qualified therapeutic discovery projects including HEPLISAV. The funds received as a result of this award were recorded as other income in the year ended December 31, 2010.

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

	Year Ended December 31, 2011				Year Ended December 31, 2010			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Revenues	$ 1,744	$ 7,269	$ 1,174	$ 11,427	$ 8,344	$ 2,191	$ 11,649	$ 1,766
Net loss attributable to Dynavax	$ (18,466)	$ (10,635)	$ (15,229)	$ (4,267)	$ (9,184)	$ (28,004)	$ (4,998)	$ (14,953)
Basic and diluted net loss per share attributable to Dynavax common stockholders	$ (0.16)	$ (0.09)	$ (0.12)	$ (0.03)	$ (0.17)	$ (0.34)	$ (0.06)	$ (0.14)
Shares used to compute basic and diluted net loss per share	115,726	117,864	124,069	142,482	54,364	82,012	86,826	106,035

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

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures

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

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

(b) Management s Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our management, with the participation of our Chief Executive Officer and Principal Financial Officer, conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on that evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2011. The Company s independent registered public accountants, Ernst & Young LLP, audited the consolidated financial statements included in this Annual Report on Form 10-K and have issued an attestation report on the Company s internal control over financial reporting. The report on the audit of internal control over financial reporting appears below.

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Dynavax Technologies Corporation

We have audited Dynavax Technologies Corporation s internal control over financial reporting as of December 31, 2011, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Dynavax Technologies Corporation s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management s Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company s internal control over financial reporting based on our audit.

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

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

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

In our opinion, Dynavax Technologies Corporation maintained, in all material respects, effective internal control over financial reporting as of December 31, 2011, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the 2011 consolidated financial statements of Dynavax Technologies Corporation and our report dated March 12, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Redwood City, California

March 12, 2012

(c) Changes in Internal Control Over Financial Reporting

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

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ITEM 9B. OTHER INFORMATION

None.

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PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information required by this Item is incorporated by reference to the sections entitled Proposal 1 Elections of Directors, Executive Officers, Corporate Governance and Section 16(a) Beneficial Ownership Reporting Compliance in our Definitive Proxy Statement in connection with the 2011 Annual Meeting of Stockholders (the Proxy Statement) which will be filed with the Securities and Exchange Commission within 120 days after the fiscal year ended December 31, 2011.

We have adopted the Dynavax Code of Business Conduct and Ethics, a code of ethics that applies to our employees, including our Chief Executive Officer, Principal Financial Officer and to our non-employee directors. We will provide a written copy of the Dynavax Code of Business Conduct and Ethics to anyone without charge, upon request written to Dynavax, Attention: Jennifer Lew, 2929 Seventh Street, Suite 100, Berkeley, CA 94710-2753, (510) 848-5100.

ITEM 11. EXECUTIVE COMPENSATION

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

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

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

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

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

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

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

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) Documents filed as part of this report:

1. Financial Statements

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets

Consolidated Statements of Operations

Consolidated Statements of Stockholders Equity

Consolidated Statements of Cash Flows

Notes to Consolidated Financial Statements

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2. Financial Statement Schedules

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

(b) Exhibits

Exhibit Number	Document
3.1(1)	Sixth Amended and Restated Certificate of Incorporation
3.2(1)	Amended and Restated Bylaws
3.3(2)	Form of Certificate of Designation of Series A Junior Participating Preferred Stock
3.4(12)	Certificate of Amendment of Amended and Restated Certificate of Incorporation
3.5(13)	Certificate of Amendment of Amended and Restated Certificate of Incorporation
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3, 3.4 and 3.5 above
4.2(3)	Registration Rights Agreement
4.3(3)	Form of Warrant
4.4(4)	Form of Specimen Common Stock Certificate
4.5(2)	Rights Agreement dated as of November 5, 2008, by and between the Company and Mellon Investor Services LLC
4.6(2)	Form of Rights Certificate
4.7(6)	Form of Restricted Stock Unit Award Agreement
4.8(14)	Form of Amended Warrant
4.9(15)	Form of Warrant
4.10(17)	Registration Rights Agreement dated as of September 20, 2010, by and between the Company and Aspire Capital Fund, LLC
10.30(16)	Agreement dated September 1, 2006, by and between the Company and AstraZeneca AB.
10.32(5)	License Agreement, dated June 26, 2007, between Coley Pharmaceuticals Group, Inc. and Dynavax Technologies Corporation
10.37(6)+	Amended Management Continuity Agreement, dated as of October 3, 2008, between Dynavax Technologies Corporation and Dino Dina
10.38(6)+	Form of Amended Management Continuity Agreement between Dynavax Technologies Corporation and each of its executive officers
10.39(6)	Research and Development Collaboration and License Agreement, dated December 15, 2008, between Glaxo Group Limited and Dynavax Technologies Corporation
10.40(7)	Amendment No. 2 to the Agreement dated September 1, 2006 by and between the Company and AstraZeneca AB (AZ) (the Agreement) dated February 3, 2009
10.41(8)+	Amended Management Continuity Agreement, dated as of April 22, 2009, between Dynavax Technologies Corporation and Zbigniew Janowicz
10.42(8)	Amendment No. 4, dated June 1, 2009, to the Exclusive License Agreement, dated October 2, 1998, between Dynavax Technologies Corporation and the Regents of the University of California.

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Exhibit Number	Document
10.43[9]	Equity Distribution Agreement, dated August 17, 2009, between Dynavax Technologies Corporation and Wedbush Morgan Securities, Inc.
10.44[10]	Amendment to Equity Distribution Agreement, dated September 10, 2009, between Dynavax Technologies Corporation and Wedbush Morgan Securities, Inc.
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10.60[22]+	Amendment, dated January 6, 2011, to Management Service Contract between Dynavax Technologies Corporation and Zbigniew Janowicz
10.61[23]+	Form of amendment to Management Continuity Agreement between Dynavax Technologies Corporation and each of its executive officers
10.62[24]+	2011 Equity Incentive Plan
10.63[25]+	Form of Restricted Stock Unit Award Notice and Restricted Stock Unit Award Agreement
10.64[26]+	Form of Stock Option Grant Notice and Option Agreement
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10.67	Amendment No. 4 to the Agreement dated 1 September 2006 by and between AstraZeneca AB and Dynavax Technologies Corporation dated September 23, 2011
10.68[20]	Underwriting Agreement, dated November 3, 2011, by and among Dynavax Technologies Corporation, Cowen and Company, LLC and William Blair & Company, L.L.C.
21.1	List of Subsidiaries
23.1	Consent of Independent Registered Public Accounting Firm
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
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(1) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax s Amendment No. 4 to Registration Statement on Form S-1/A, as filed with the SEC on February 5, 2004 (File No. 000- 50577).

(2) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax s Current Report on Form 8-K, as filed with the SEC on November 6, 2008.

(3) Incorporated by reference to Dynavax Technologies Corporation s Registration Statement (File No. 333-145836) on Form S-3 filed on August 31, 2007.

(4) Incorporated by reference to Dynavax Technologies Corporation s Registration Statement (File No. 333-109965) on Form S-1 filed on January 16, 2004.

(5) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax s Quarterly Report on Form 10-Q for the quarter ended June 30, 2007, as filed with the SEC.

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(22) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax s Current Report on Form 8-K, as filed with the SEC on January 7, 2011.

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(24) Incorporated by reference from such document filed with the SEC as exhibit 99.1 to Dynavax Technologies Corporation s Registration Statement (File No. 333-171552) on Form S-8, as filed with the SEC on January 6, 2011.

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101*** The following materials from Registrant s Annual Report on Form 10-K for the year ended December 31, 2011, formatted in Extensible Business Reporting Language (XBRL) includes: (i) Consolidated Balance Sheets as of December 31, 2011 and December 31, 2010, (ii) Consolidated Statements of Operations for the years ended December 31, 2011, December 31, 2010, and December 31, 2009, (iii) Consolidated Statements of Shareholders Equity for the years ended December 31, 2011, December 31, 2010, and December 31, 2009 (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2011, December 31, 2010, and December 31, 2009, and (iv) Notes to Consolidated Financial Statements, tagged as blocks of text.

We have been granted confidential treatment with respect to certain portions of this agreement. Omitted portions have been filed separately with the Securities and Exchange Commission.

+ Indicates management contract or compensatory plan.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has caused this report to be signed on its behalf by the undersigned, thereunto due authorized, in the City of Berkeley, State of California.

DYNAVAX TECHNOLOGIES CORPORATION

By: /s/ DINO DINA, M.D.
Dino Dina, M.D.

Chief Executive Officer

(Principal Executive Officer)

Date: March 12, 2012

By: /s/ JENNIFER LEW
Jennifer Lew

Vice President, Finance

(Principal Accounting and Financial Officer)

Date: March 12, 2012

Signature	Title	Date
/s/ DINO DINA, M.D. **Dino Dina, M.D.**	Chief Executive Officer *(Principal Executive Officer)*	March 12, 2012
/s/ JENNIFER LEW **Jennifer Lew**	Vice President, Finance *(Principal Accounting and Financial Officer)*	March 12, 2012
/s/ ARNOLD L. ORONSKY, PH.D. **Arnold L. Oronsky, Ph.D.**	Chairman of the Board	March 12, 2012
/s/ DENNIS A. CARSON, M.D. **Dennis A. Carson, M.D.**	Director	March 12, 2012
/s/ FRANCIS R. CANO, PH.D. **Francis R. Cano, Ph.D.**	Director	March 12, 2012
/s/ DENISE M. GILBERT, PH.D.	Director	March 12, 2012

	Denise M. Gilbert, Ph.D.		
/s/	MARK KESSEL	Director	March 12, 2012
	Mark Kessel		
/s/	DANIEL L. KISNER, M.D.	Director	March 12, 2012
	Daniel L. Kisner, M.D.		
/s/	J. TYLER MARTIN, M.D.	Director	March 12, 2012
	`J. Tyler Martin, M.D.		

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Signature	Title	Date
/s/ PEGGY V. PHILLIPS **Peggy V. Phillips**	Director	March 12, 2012
/s/ STANLEY A. PLOTKIN, M.D. **Stanley A. Plotkin, M.D.**	Director	March 12, 2012

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EXHIBIT INDEX

Exhibit Number	Document
3.1[1]	Sixth Amended and Restated Certificate of Incorporation
3.2[1]	Amended and Restated Bylaws
3.3[2]	Form of Certificate of Designation of Series A Junior Participating Preferred Stock
3.4[12]	Certificate of Amendment of Amended and Restated Certificate of Incorporation
3.5[13]	Certificate of Amendment of Amended and Restated Certificate of Incorporation
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3, 3.4 and 3.5 above
4.2[3]	Registration Rights Agreement
4.3[3]	Form of Warrant
4.4[4]	Form of Specimen Common Stock Certificate
4.5[2]	Rights Agreement dated as of November 5, 2008, by and between the Company and Mellon Investor Services LLC
4.6[2]	Form of Rights Certificate
4.7[6]	Form of Restricted Stock Unit Award Agreement
4.8[14]	Form of Amended Warrant
4.9[15]	Form of Warrant
4.10[17]	Registration Rights Agreement dated as of September 20, 2010, by and between the Company and Aspire Capital Fund, LLC
10.30[16]	Agreement dated September 1, 2006, by and between the Company and AstraZeneca AB.
10.32[5]	License Agreement, dated June 26, 2007, between Coley Pharmaceuticals Group, Inc. and Dynavax Technologies Corporation
10.37[6]+	Amended Management Continuity Agreement, dated as of October 3, 2008, between Dynavax Technologies Corporation and Dino Dina
10.38[6]+	Form of Amended Management Continuity Agreement between Dynavax Technologies Corporation and each of its executive officers
10.39[6]	Research and Development Collaboration and License Agreement, dated December 15, 2008, between Glaxo Group Limited and Dynavax Technologies Corporation
10.40[7]	Amendment No. 2 to the Agreement dated September 1, 2006 by and between the Company and AstraZeneca AB (AZ) (the Agreement) dated February 3, 2009
10.41[8]+	Amended Management Continuity Agreement, dated as of April 22, 2009, between Dynavax Technologies Corporation and Zbigniew Janowicz
10.42[8]	Amendment No. 4, dated June 1, 2009, to the Exclusive License Agreement, dated October 2, 1998, between Dynavax Technologies Corporation and the Regents of the University of California.
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