DYNAVAX TECHNOLOGIES CORP
Form 10-K
March 11, 2011
Table of Contents

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, 2010

¨ **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 ¨ 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, 2010 as reported on the NASDAQ Capital Market, was approximately $142,099,406. 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 March 8, 2011, the registrant had outstanding 115,689,769 shares of common stock.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Definitive Proxy Statement for the registrant s 2011 Annual Meeting of Stockholders are incorporated by reference into Part III, Items 10-14 of this Form 10-K.

Table of Contents

INDEX

DYNAVAX TECHNOLOGIES CORPORATION

Table of Contents

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 (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 rapid and superior protection with fewer doses than current licensed vaccines.

Our pipeline of product candidates includes: HEPLISAV; clinical-stage programs for our Universal Flu vaccine and hepatitis C and hepatitis B therapies; and preclinical programs partnered with GlaxoSmithKline (GSK) and AstraZeneca. We compete with pharmaceutical companies, biotechnology companies, academic institutions and research organizations in developing therapies to prevent or treat infectious and inflammatory diseases. Our product candidates are based on the use of immunostimulatory 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 2001. Our principal offices are located at 2929 Seventh Street, Suite 100, Berkeley, California 94710-2753. Our telephone number is (510) 848-5100.

Immunostimulatory Sequences (ISS)

Our proprietary technology platform includes ISS, which are short DNA sequences that enhance the ability of the immune system to fight disease. ISS activate the innate immune response by specifically targeting TLR9, which is found on a specialized subset of immune cells.

Table of Contents

ISS work by changing or reprogramming the immune responses that cause disease rather than just treating the symptoms of the disease. Since TLR9 is found only 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.

ISS 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.

ISS 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 ISS Technologies

For several programs, we use 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 (IRS)

Our proprietary technology platform includes IRS, which 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 diseases models, such as lupus, inflammatory skin disorders, and rheumatoid arthritis.

Development Programs

Our pipeline of product candidates includes:

Product Candidate	Clinical Indication(s)	Phase	Partnership/Funding Support
HEPLISAV	Hepatitis B prevention	Phase 3	Dynavax
Universal Flu vaccine	Influenza prevention	Phase 1b	Novartis (Supply and Option Agreement)
SD-101	Hepatitis C infection	Phase 1b	Dynavax
DV-601	Hepatitis B infection	Phase 1b	Dynavax
AZD1419	Asthma	IND Ready	AstraZeneca AB
DV1179	Autoimmune and inflammatory diseases	IND Ready	GlaxoSmithKline; NIH

Table of Contents

HEPLISAV Hepatitis B Vaccine

Our lead product candidate is HEPLISAV, a Phase 3 investigational adult hepatitis B vaccine designed to enhance protection more rapidly with fewer doses than current licensed vaccines. Our global strategy is to develop HEPLISAV for adults who are at risk of hepatitis B infection, initially in populations that are less responsive to current licensed vaccines, including adults over 40 years of age, individuals with chronic kidney disease, diabetics and others.

Dynavax has worldwide commercial rights to HEPLISAV, which is based on our proprietary ISS that specifically target TLR9 to stimulate an innate immune response. This vaccine combines our first generation 1018 ISS with hepatitis B surface antigen (HBsAg) manufactured in our Dynavax Europe facility in Düsseldorf, Germany.

HEPLISAV is being evaluated in Phase 3 trials that are directed toward fulfilling licensure requirements in the United States, Canada and Europe. The ongoing large-scale Phase 3 lot-to-lot consistency and safety trial is expected to be completed in May 2011, after a 12-month follow-up of these subjects. Enrollment for the Phase 3 trial in chronic kidney disease patients was completed in January 2011. There have been four safety assessments made by an independent data safety monitoring board, all of which have recommended the trials continue without protocol modification. In February 2011 following completion of the fourth planned safety assessment, the DSMB determined that no other formal meetings of the DSMB are required.

Clinical Results

Over 4,000 individuals have been vaccinated with HEPLISAV to date. In the largest completed clinical trial, known as PHAST (Phase 3 HeplisAv Short-regimen Trial), HEPLISAV met its primary endpoint. The multi-center PHAST trial evaluated more than 2,000 subjects from 11 to 55 years of age in Canada and Germany. This Phase 3 trial evaluated a two-dose regimen of HEPLISAV administered at 0 and 1 month, compared to a three-dose regimen of Engerix-B® administered at 0, 1, and 6 months. The primary endpoint was the proportion of subjects who developed protective antibody to hepatitis B after receiving a full course of vaccination.

Immunogenicity results from this trial demonstrated that subjects receiving HEPLISAV were seroprotected with fewer doses and at an earlier time point than subjects receiving Engerix-B. Results showed 95% of subjects who received two doses of HEPLISAV at 0 and 1 month developed protective antibody to hepatitis B by 12 weeks, compared to 81% of subjects who received three doses of Engerix-B at 0, 1, and 6 months at 28 weeks. Data from this trial also demonstrate that subjects over 40 years of age receiving two doses of HEPLISAV over one month achieved a seroprotection rate of 92%, compared to 75% of subjects receiving 3 doses of Engerix-B over six months.

Overall safety results in the PHAST trial showed the profile of 2 doses of HEPLISAV appeared similar to 3 doses of Engerix-B, with the exception that subjects who received HEPLISAV had a higher risk of developing injection site swelling, redness, and pain compared to those who received Engerix-B. The incidence of Adverse Events (AE) was 81.9% for the HEPLISAV group, compared to 81.4% for the Engerix-B group. The incidence of Serious Adverse Events (SAEs) was 1.5% for the HEPLISAV group, compared to 2.1% for the Engerix-B group. There were two cases of systemic vasculitis reported as SAEs in this trial, a case of Wegener s granulomatosis, or c-ANCA vasculitis, in the HEPLISAV group and a case of p-ANCA systemic vasculitis in the Engerix-B group. From March 2008 until September 2009, the two Investigational New Drug (IND) applications for HEPLISAV were placed on clinical hold by the U.S. Food and Drug Administration (the FDA) following the Wegener s granulomatosis SAE that occurred in the HEPLISAV group of the PHAST trial. In September 2009, the FDA removed the clinical hold on the IND application for individuals with chronic kidney disease.

In October 2010, we reported that HEPLISAV given as two doses over four weeks demonstrated superior seroprotection in persons with diabetes mellitus compared to Engerix-B given as three doses over 24 weeks. The subset analysis of 62 adults with diabetes in our previously reported PHAST Phase 3 multicenter study showed

Table of Contents

that at 12 weeks, 84% of adult diabetics treated with HEPLISAV achieved seroprotection as compared to 0% of adult diabetics treated with Engerix-B. At week 28, 93% of the HEPLISAV-treated group versus 35% in the Engerix-B group achieved seroprotection. HEPLISAV s significantly higher rate of seroprotection was achieved without further immunization past four weeks while the Engerix-B group received a third immunization at 24 weeks.

Commercial Opportunity

Hepatitis B is a chronic disease which can lead to cirrhosis of the liver and hepatocellular carcinoma. 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 low responders current vaccines provide less seroprotection to persons over 40 years of age and to 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 current vaccines by providing rapid and superior protection with fewer doses than currently licensed vaccines.

We estimate the current worldwide market for adult monovalent hepatitis B vaccines exceeds $400 million annually. This market is primarily comprised of GSK s Engerix-B and Merck s Recombivax-HB. Over an estimated $400 million in additional sales are generated by GSK s combined Hepatitis A / Hepatitis B vaccine, Twinrix. Key market segments include chronic kidney disease (CKD) patients, healthcare workers and first responders, travelers, people with multiple sexual partners or injection drug use, and chronic liver disease patients.

HEPLISAV is being developed initially for patients less responsive to current licensed vaccines, including patients over 40 years of age, individuals with CKD, HIV, and chronic liver disease. The CKD market is large, growing rapidly, and is recommended for vaccination. In 2008, there were approximately 750,000 ESRD patients in the United States and major European markets and approximately 150,000 new patients are added annually. Because these patients typically do not respond well to current vaccines, a typical regimen calls for 8 doses of Engerix-B (versus 3 doses in the general population). Even with this regimen, approximately 35% of these immunocompromised ESRD patients do not respond to vaccination and approximately 27-43% require boosters. As vaccination for these patients occurs regularly at dialysis centers, this is a concentrated, renewable market that can be served by cost-effective, targeted sales distribution networks.

In addition to the CKD market, we believe that the potentially differentiating characteristics of HEPLISAV can address key unmet needs in adult hepatitis B vaccination, and may provide an opportunity for growth in under-served market segments such as HIV and chronic liver disease. The HIV positive market segment shares similar characteristics to the ESRD market. Vaccination is critical due to substantially increased morbidity and mortality from co-infection with HIV and HBV and similar modes of transmission. Because these patients typically do not respond well to current vaccines, aggressive vaccination regimens and boosters are common. There are approximately two million adults living with HIV in the United States and Europe, with approximately 150,000 new cases annually. Chronic liver disease can be caused by hepatitis C infection, alcohol or genetics. These patients are also recommended for vaccination, but vaccine coverage rates are low, representing a future opportunity for hepatitis B vaccines to grow.

Table of Contents

We also believe that the profile of HEPLISAV has potential benefits for individuals who need rapid protection against hepatitis B, including healthcare workers, first responders, travelers and diabetics because HEPLISAV provides higher levels of protection following 30 days of treatment compared to 6 months for current licensed vaccines.

Universal Flu Vaccine

Our Universal Flu vaccine is designed to offer protection against divergent strains as well as 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 TLR9 agonist. N8295 is then combined with a conventional flu vaccine:

Conventional flu vaccines Currently 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 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.

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, or nucleoprotein, is highly conserved across human and animal strains, while M2e, the extracellular domain of the matrix 2 protein, 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.

Our proprietary second-generation TLR9 agonist may enhance efficacy and enable antigen-sparing, which could extend the quantity of standard flu vaccine available.

Dynavax has established a worldwide supply and option agreement with Novartis Vaccines and Diagnostics, Inc., under which Novartis is supplying trivalent influenza vaccine, an essential component of our Universal Flu vaccine.

Clinical Results

In early December 2010, we reported safety and immunogenicity data from our Phase 1a clinical trial of N8295. The trial assessed three dose levels of N8295 in a total study population of 39 subjects. The Phase 1a data showed that all doses were safe and generally well tolerated. There were no dose limiting toxicities, subjects demonstrated positive antibody responses to M2e and NP, and positive T-cell mediated responses to NP were seen. Based on preliminary safety data for the Phase 1a trial, we initiated a Phase 1b study in September 2010 to evaluate the safety of the combination of N8295 and an investigational H5N1 avian influenza vaccine. The Phase 1b study evaluated 54 subjects, including 39 from the Phase 1a dose escalation study of N8295 and 15 from the Phase 1b dose escalation study of H5N1/N8295. Data from the Phase 1a and the Phase 1b study reported at the World Health Organization 7th Meeting on Evaluation of Pandemic Influenza Prototype Vaccines in February 2011 showed:

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

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

There were no SAEs;

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;

Table of Contents

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 H1 responses in all N8295 dose groups.[1]

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 who need prevention the most, 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.

SD-101 Hepatitis C Therapy

SD-101, our hepatitis C therapy, has completed a Phase 1b clinical trial and is part of the portfolio of development programs that are available for partnership. This therapy utilizes a novel Type C TLR9 agonist based on our second-generation ISS. SD-101 is designed to be used in combination with current or emerging therapies to reduce hepatitis C virus (HCV) viral replication and induce a long-lasting immune response. In December 2009, we completed the acquisition of Symphony Dynamo, Inc., which provided us with full development and commercialization rights to SD-101.

Data from a Phase 1b trial and from an *in vitro* study of SD-101 s mechanism of action show that SD-101 is safe and well-tolerated, and induces both IFN-lambda and IFN-alpha at concentrations producing antiviral activity.

DV-601 Hepatitis B Therapy

DV-601, our proprietary hepatitis B therapy, is completing a Phase 1b clinical trial and is part of the portfolio of development programs that are available for partnership. Our treatment approach combines both the surface and core HBV antigens with ISCOMATRIX® adjuvant originally entered into development by Rhein Biotech prior to its acquisition by Dynavax in 2006. 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. We have retained all commercial rights to this product.

The Phase 1b dose escalation study assessed safety and the immunologic and virologic responses in 14 subjects with chronic hepatitis B infection, including six patients that were HBeAg negative and eight patients who were HBeAg positive, and found:

The therapeutic regimen was safe and generally well tolerated at all dose levels;

Most common systemic reactions were fatigue and malaise. No SAEs were recorded;

[1] The Journal of Infectious Diseases 2008; 198:1309-16 and Vaccine 28 (2010) 840-848

Table of Contents

DV601 was found to elicit immune responses at all dose levels, and anti-HBe antibodies were elicited in two of eight (2/8) patients;

Anti-HBs antibodies were elicited in four of 14 (4/14) patients;

Amongst the eight HBeAg positive patients, two had HBeAg clearance, and one of those individuals also had HBsAg clearance;

Three patients are still in the follow-up observation period.

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, psoriasis, and rheumatoid arthritis. We plan to initiate a Phase 1 clinical study with GSK in 2011.

AZD1419 Asthma Therapy

We have developed AZD1419, a novel candidate drug for asthma, under our worldwide collaboration with AstraZeneca. AZD1419 utilizes our proprietary second-generation ISS and represents a new strategy for the treatment of allergic respiratory diseases such as asthma. This therapy is designed to modify the course of these diseases by changing the basic immune response to environmental allergens, such as house dust and pollens, leading to prolonged reduction in asthma symptoms.

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 endosomal TLR inhibitors for diseases such as lupus, psoriasis, and rheumatoid arthritis. 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 potential development and commercialization milestones totaling approximately $200 million per program. GSK can exercise its exclusive option to license each program upon achievement of proof-of-concept or earlier upon certain circumstances. After exercising its option, GSK would carry out further development and commercialization of these products. We are eligible to receive royalties from the mid-single digits up to the high-teens based on product sales and have retained an option to co-develop and co-promote one specified product under the 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.

Table of Contents

AstraZeneca AB

In September 2006, we entered into a worldwide research and license agreement with AstraZeneca to discover and develop TLR9 agonist products for asthma and COPD. We are eligible to receive a total of $136 million in payments and, upon commercialization of these products, royalties up to the high-teens based on product sales, if any. AstraZeneca has the right to sublicense its rights with our prior consent. We also have the opportunity to co-promote in the United States. In September 2008, we received a $4.5 million milestone payment from AstraZeneca for the nomination of the first candidate drug, AZD1419, for asthma and have completed IND-enabling studies.

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 trivalent influenza vaccine, 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 the parties do not enter into a further agreement, Novartis remains committed to providing commercial supply of trivalent influenza vaccine 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 trivalent influenza vaccine product in the United States.

Either party 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) Dynavax ceases development of the product candidate for a certain length of time.

National Institutes of Health (NIH) 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 NIH s 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 the Company defaults in performing and fails to cure after notice.

During 2010, we announced a grant from the NIAID to take a systems biology approach to study the differences between individuals that do or do not respond to vaccination against the HBV. This study will be one of several projects covered in a five-year, $17.6 million grant to the Baylor Institute of Immunology Research in Dallas as part of the Human Immune Phenotyping Centers program.

We also received the award of 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). In contrast to the two approved HPV vaccines that target approximately 70% of HPV strains, our goal is to develop a vaccine that provides immunity to nearly all cancer-causing strains of HPV. Each year, 470,000 new cases of cervical cancers are diagnosed worldwide, and 250,000 deaths are attributable to cervical cancers.

Table of Contents

Finally, $0.7 million in grants under The Patient Protection and Affordable Care Act of 2010 were awarded to us to cover research and development costs from 2009 and 2010 for our qualified therapeutic discovery projects including HEPLISAV.

For our TLR inhibitor programs, since 2004 we have been awarded $2.8 million in grants from the NIH and Alliance for Lupus Research.

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, 2010, our intellectual property portfolio included 16 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. Some of these patents and applications are exclusively licensed to us under two agreements with 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 2030.

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

Table of Contents

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, including Pfizer, Inc., 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 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.

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. 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 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 $1.6 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

Table of Contents

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 royalty payments, meet diligence requirements, produce required reports or fund internal research and we do not cure such breach within 60 days after being notified of the breach. Otherwise, the agreements generally continue in effect until the last patent claiming a product licensed under the agreement or its manufacture or use expires, or in the absence of patents, until the date the last patent application claiming a licensed product is abandoned.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. Many of our competitors, including biotechnology and pharmaceutical companies, academic institutions and other research organizations, are actively engaged in the discovery, research and development of products 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 three-dose marketed vaccines produced by GSK and Merck & Co. (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 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 C therapy, SD-101, if developed, approved, and commercialized, may compete directly with interferon alpha, products currently marketed by Roche and Merck. Other companies, such as Vertex Pharmaceuticals, Inc./Tibotec Pharmaceuticals, Gilead Sciences, Inc. (Gilead), Merck, Bristol-Myers Squibb, and Roche/Pharmasset, Inc./InterMune, Inc. are developing direct acting antiviral therapy, including NS5A inhibitors, protease inhibitors and polymerase inhibitors, and long-acting interferons. As these products may enter the market potentially within the next one to five years, combination therapy is likely to evolve. Novel therapies aim to improve the efficacy, safety and convenience of current hepatitis C treatment and may compete both directly and indirectly with SD-101.

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 Pharmasset and LG Life Sciences, Cytheis and Phytrix, as well as companies developing therapeutic vaccines, including Genexine Co., Ltd.

Our therapy for autoimmune and inflammatory diseases, DV1179, is a bifunctional inhibitor of TLR7 and TLR9 that 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

Table of Contents

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.

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 for 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

The advertising, labeling, storage, record-keeping, safety, efficacy, research, development, testing, manufacture, promotion, marketing and distribution of our potential products are subject to extensive regulation by numerous governmental authorities in the United States and other countries. 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 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 a 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, involves post-marketing surveillance and may involve requirements for 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

14

Table of Contents

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

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

Non-clinical studies involve laboratory evaluation of product characteristics and animal studies to assess the initial efficacy and safety of the product. The FDA, under its good laboratory practices regulations, regulates 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 the non-clinical 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. In addition, 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 research and preclinical studies and 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

Table of Contents

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 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.

Research and Development

Conducting a significant amount of research and development has been central to our business model. Our research and development expenses were $53.6 million, $38.7 million and $44.8 million for the years ended December 31, 2010, 2009 and 2008, 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, 2010, we had 128 full-time employees, including 21 Ph.D.s, 5 M.D.s and 10 others with advanced degrees. Of the 128 employees, 100 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.

Available Information and Website Address

Our website address is www.dynavax.com. We make available free of charge through our website, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to these reports as soon as reasonably practicable after filing, by providing a hyperlink to the SEC s website directly to our reports. The contents of our website are not incorporated by reference into this report.

Table of Contents

ITEM 1A. RISK FACTORS

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

Risks Related to our 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 $316.9 million as of December 31, 2010. To date, our revenue has resulted from collaboration agreements, services and license fees from customers of Dynavax Europe, and government and private agency grants. The grants are subject to annual review based on the achievement of milestones and other factors. We anticipate that we will incur substantial additional net losses in future years as a result of our investment in research and development activities.

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 development efforts will be sufficient to support approval of HEPLISAV; or whether the market for HEPLISAV will be sufficient for us to reach profitability.

Clinical trials for certain of our other product candidates are ongoing, and our other product candidates may never be commercialized or achieve profitability. Our ability to generate revenue depends upon demonstrating in clinical trials that our product candidates are safe and effective, 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. Additionally, if we continue to incur substantial additional net losses without additional equity funding, we will continue to deplete our stockholders equity, and if such equity balance falls below the listing requirement threshold of $2.5 million for the NASDAQ Capital Market, we may be delisted.

We require substantial additional capital to continue development of our product candidates, in particular our most advanced candidate, HEPLISAV. We cannot be certain that funds will be available and, if they are not available, we may not be able to continue as a going concern which may result in actions that could adversely impact our stockholders.

In order to continue development of our product candidates, particularly HEPLISAV, we still need to raise significant additional funds. This may occur through our September 2010 Purchase Agreement (the Purchase Agreement) with Aspire Capital Fund, LLC (Aspire Capital), future public or private financings and/or strategic alliance and licensing arrangements. 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.

Table of Contents

We currently estimate that we will have sufficient resources to meet our anticipated cash needs through the next twelve months based on cash and cash equivalents and marketable securities on hand at December 31, 2010, anticipated revenues from existing agreements and the funding available to us under the Purchase Agreement.

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 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.

The sale of our common stock to Aspire Capital may cause dilution to our existing stockholders and the sale of the shares of common stock acquired by Aspire Capital could cause the price of our common stock to decline.

Shares offered to Aspire Capital under the Purchase Agreement may be sold over a period of up to 25 months from the date of the Purchase Agreement subject to the limitations and conditions of the agreement. The number of our shares ultimately offered for sale by Aspire Capital is dependent upon the number of shares we elect to sell to Aspire Capital under the Purchase Agreement and the number of authorized shares we have available for sale. Aspire Capital may ultimately purchase all, some or none of the remaining common stock provided for in the Purchase Agreement. As of December 31, 2010, we have issued 2,350,000 shares of common stock under the Purchase Agreement. After Aspire Capital has acquired shares pursuant to the Purchase Agreement, it may sell all, some or none of those shares.

On any business day on which the closing sale price of our common stock exceeds $1.00 per share, we have a right to sell up to a maximum of 150,000 shares per day under the Purchase Agreement, which total may be increased by mutual agreement up to an additional 1,000,000 shares per day. The capital available under the Purchase Agreement may not be sufficient to fund our current need for capital. The extent to which we rely on Aspire Capital as a source of funding will depend on a number of factors, including the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources.

Depending upon market liquidity at the time, sales of shares of our common stock by Aspire Capital may cause the trading price of our common stock to decline. In addition, sales to Aspire Capital by us pursuant to the Purchase Agreement may result in dilution to the interests of other holders of our common stock. The sale of a substantial number of shares of our common stock to Aspire Capital, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales. However, we have the right to control the timing and amount of any sales of our shares to Aspire Capital and the Purchase Agreement may be terminated by us at any time at our discretion without any cost to us.

Our independent registered public accountants have indicated that our financial condition raises substantial doubt as to our ability to continue as a going concern.

Our independent registered public accounting firm has included in their audit opinion on our consolidated financial statements for the year ended December 31, 2010 a statement with respect to substantial doubt regarding our ability to continue as a going concern. Our consolidated financial statements have been prepared assuming the Company will continue to operate as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. If we became unable to continue as a going concern, we may have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our consolidated financial statements.

Table of Contents

Risks Related to our Business

The success of our product candidates depends on timely achievement of successful clinical results, adequate evidence of a product manufactured by a well-controlled process that is safe and effective for its intended use and regulatory approval. Failure to obtain regulatory approvals could require us to discontinue operations.

None of our product candidates have 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 U.S. Food and Drug Administration (FDA) and by foreign regulatory agencies. Our success is primarily dependent on our ability to timely enroll patients in clinical trials, achieve successful clinical results, provide adequate evidence of a product manufactured by a well-controlled process that is safe and effective for its intended use, and 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.

We will need to demonstrate in clinical trials that a product candidate is safe and effective before we can obtain the necessary approvals from the FDA and foreign regulatory agencies. If we identify any safety issues associated with our product candidates, we may be restricted from initiating further trials for those products. Moreover, we may not see sufficient signs of efficacy in those studies.

The FDA or foreign regulatory agencies may require us to conduct additional clinical trials prior to approval. Despite the time and money expended, regulatory approvals are uncertain. In addition, failure to timely and successfully complete clinical trials and show that our products are safe and effective 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 may market the product, 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 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 FDA GMP current 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.

Our clinical trials may be extended, suspended, delayed or terminated at any time. Even short delays in the commencement and progress of our trials may lead to substantial delays in the regulatory approval process for our product candidates, which will impair our ability to generate revenues.

We may extend, suspend or terminate clinical trials at any time for various reasons, including regulatory actions by the FDA or foreign regulatory agencies, actions by institutional review boards, failure to comply with good clinical practice requirements, concerns regarding health risks to test subjects, failure to enroll patients in a timely manner, or delays due to manufacturing an inadequate supply of the product candidate. Even a short delay in a trial for any product candidate could require us to delay commencement or continuation of a trial until the target population is available for testing, which could result in a delay of a year or more. The FDA may require larger or additional clinical trials for our HEPLISAV product candidate than we currently expect before granting regulatory approval, if at all.

Table of Contents

Our registration and commercial timelines depend on successful completion of current and planned clinical trials, successful results from such trials, and further discussions with the FDA and corresponding foreign regulatory agencies. Any extension, suspension, modification, termination or unanticipated delays of our clinical trials could:

- adversely affect our ability to timely and successfully commercialize or market these product candidates;
- result in significant additional costs;
- potentially diminish any competitive advantages for those products;
- potentially limit the markets for those products;
- adversely affect our ability to enter into collaborations, 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.

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. Any extension, delay, modification or termination of our 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.

HEPLISAV and most of our earlier stage programs rely on ISS-based technology. Serious adverse safety 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 safety data, we may be required to delay, discontinue or modify our clinical trials or our clinical trial strategy. For example, from March 2008 until September 2009, the two investigational new drug (IND) applications for HEPLISAV were placed on clinical hold by the FDA following a serious adverse event that occurred in one of our clinical trials. In September 2009, the FDA removed the clinical hold on the IND application for individuals with chronic kidney disease but the other IND application for HEPLISAV remains on clinical hold. In addition, 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 safety 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 rely on our facility in Düsseldorf, Germany and third parties to supply materials necessary to manufacture our clinical product candidates. We have limited experience in manufacturing sufficient quantities of ISS for our clinical trials and rely on limited third parties to produce the ISS we need for our clinical trials. Additionally, we have limited experience in manufacturing our product candidates in commercial quantities. If we reduce our clinical product candidates, we may not require this manufacturing capacity.

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.

Table of Contents

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, which 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 may not have the capacity in our existing facility to meet all of our commercial supply needs in the future.

If HEPLISAV cannot be successfully developed or is not commercially viable, we will have to use the Düsseldorf facility for alternative manufacturing or research activities that may not fully utilize the facility s capacity, resulting in continued operating costs that may not be offset by corresponding revenues. We may also consider other alternatives for the Düsseldorf facility, including its sale or closure, which would result in certain costs of disposal or discontinuation of operations. Discontinuation of operations in Düsseldorf would be complex, expensive, time-consuming and difficult to execute without significant additional costs due to, among other things, international legal and tax considerations related to those operations. As a result, we may not realize cost savings associated with closure of the Düsseldorf operations, if at all.

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 may 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.

Table of Contents

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 in various markets outside the United States. Developing, seeking regulatory approval for and marketing our product candidates outside the United States could impose substantial burdens on our resources and divert management s attention from domestic operations. International operations are subject to risk, including:

- the difficulty of managing geographically distant operations, including recruiting and retaining qualified employees, locating adequate facilities and establishing useful business support relationships in the local community;
- compliance with varying international regulatory requirements, laws and treaties;
- securing international distribution, marketing and sales capabilities;
- adequate protection of our intellectual property rights;
- 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.

Table of Contents

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. For example, in connection with the removal of the clinical hold on HEPLISAV in September 2009 and related discussions with the FDA, it is expected that further development of HEPLISAV in the United States initially will be limited to individuals who are less responsive to current licensed vaccines, including adults over 40 years of age and individuals with chronic kidney disease. 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 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.

Table of Contents

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, may significantly impair the potential for this product and our ability to successfully develop, manufacture and commercialize HEPLISAV as a product candidate. 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;
- 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 event 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

Table of Contents

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. 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. Many of the companies developing competing technologies and products have significantly greater financial resources and expertise in research and development, general and administrative support, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and marketing than we do.

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. Our success in developing marketable products and achieving a competitive position will depend, in part, on our ability to attract and retain qualified scientific, manufacturing, sales, marketing, general and administrative and management 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 implement our current initiatives. If we are unable to compete successfully, we may not be able to obtain financing, enter into collaborative arrangements, sell our product candidates or generate revenues.

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.

Table of Contents

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

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

Risks Related to our 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 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. 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

Table of Contents

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.

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

One of our potential competitors, Pfizer 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 in 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;

Table of Contents

- the patents licensed or issued to us or our collaborators may not provide a competitive advantage;
- patents issued to other parties may limit our intellectual property protection or harm our ability to do business;
- other parties may independently develop similar or alternative technologies or duplicate our technologies and commercialize discoveries that we attempt to patent; and
- other parties may design around technologies we have licensed, patented or developed.

We also rely on trade secret protection and confidentiality agreements to protect our interests in proprietary know-how that is not patentable and for processes for which patents are difficult to enforce. We cannot be certain that we will be able to protect our trade secrets adequately. Any disclosure of confidential data in the public domain or to third parties could allow our competitors to learn our trade secrets. If we are unable to adequately obtain or enforce proprietary rights we may be unable to commercialize our products, enter into collaborations, generate revenues or maintain any advantage we may have with respect to existing or potential competitors.

Risks Related to an Investment in our Common Stock

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

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

- progress or results of any of our clinical trials or regulatory 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.

Table of Contents

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;
- 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.

Table of Contents

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, 2010, we had 115,611,069 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.

We also have filed registration statements on Form S-3 under the Securities Act of 1933, as amended, to register the shares of our common stock reserved for issuance under the Purchase Agreement, the warrants issued as part of our public offering closed in April 2010, the warrants issued to Symphony Dynamo Holdings LLC (Holdings) in connection with our acquisition of SDI in December 2009, and warrants issued to Deerfield Management in connection with the July 2007 Loan Agreement.

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.

Symphony Capital Partners, L.P. and Symphony Strategic Partners, LLC collectively control a substantial percentage of the voting power of our outstanding common stock as well as $15 million of our debt.

Symphony Capital Partners, L.P. and Symphony Strategic Partners, LLC (collectively, Symphony) currently collectively control approximately 9,031,431 shares of our common stock and warrants to purchase approximately 4,515,717 shares of our common stock. Based on the number of shares of our common stock that are outstanding as of December 31, 2010, Symphony owns approximately 8% of our total outstanding shares of our common stock. If Symphony exercises all of the warrants held by it and assuming no other issuances of our common stock, Symphony would own approximately 11% of our total outstanding shares of common stock. In addition, Holdings, an affiliate of Symphony, holds a promissory note in the principal amount of $15 million, which may be satisfied in cash, Dynavax common stock or a combination of cash and Dynavax common stock, at our election. Finally, under the terms of the Standstill and Corporate Governance Letter Agreement we entered into with Holdings on December 30, 2009, for as long as Holdings and its affiliates, which include Symphony, beneficially own 10% or more of our outstanding common stock, we agreed to use our commercially reasonable efforts to cause to be elected and remain as directors on our Board of Directors one individual designated by Holdings and a second individual who shall be an independent third party designated by Holdings and reasonably acceptable to us. Holdings designated Mark Kessel, a partner of Symphony Capital LLC, as its designee and Mr. Kessel has been appointed to our Board of Directors. On July 22, 2010, the Board of Directors nominated Daniel L. Kisner, M.D. to the Board of Directors as the independent third party designee. As a result, Symphony, Holdings and their affiliates will be able to exercise substantial influence over the direction of the Company.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

As of December 31, 2010, we lease approximately 44,000 square feet of laboratory and office space in Berkeley, California (the Berkeley Lease) under agreements expiring in September 2017. Additionally, approximately 3,000 square feet of the leased premises under the Berkeley Lease is subleased through February 2011. We also lease approximately 5,600 square meters of laboratory and office space in Düsseldorf, Germany under lease agreements expiring in March 2023.

Table of Contents

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. (REMOVED AND RESERVED)

Table of Contents

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 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
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
2009		
First Quarter	$ 1.04	$ 0.50
Second Quarter	$ 2.19	$ 0.64
Third Quarter	$ 3.35	$ 1.15
Fourth Quarter	$ 1.94	$ 1.11

As of March 8, 2011, there were approximately 180 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.

Table of Contents

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, 2010, 2009 and 2008 and the Consolidated Balance Sheets Data as of December 31, 2010 and 2009 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, 2007 and 2006 and the Consolidated Balance Sheets Data as of December 31, 2008, 2007 and 2006 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,				
	2010	2009	2008	2007	2006