DYNAVAX TECHNOLOGIES CORP
Form S-3/A
April 23, 2010
Table of Contents

As filed with the Securities and Exchange Commission on April 23, 2010

Registration No. 333-164254

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 1

TO

FORM S-3

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

Dynavax Technologies Corporation

(Exact name of registrant as specified in its charter)

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

2929 Seventh Street, Suite 100

Berkeley, CA 94710-2753

(510) 848-5100

(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

Jennifer Lew

Vice President, Finance

Dynavax Technologies Corporation

2929 Seventh Street, Suite 100

Berkeley, CA 94710-2753

(510) 848-5100

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Robert L. Jones, Esq.

Glen Sato, Esq.

Cooley Godward Kronish LLP

Five Palo Alto Square

3000 El Camino Real

Palo Alto, California 94306-2155

(650) 843-5000

Approximate date of proposed sale to the public: From time to time after this Registration Statement becomes effective.

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. ¨

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. þ

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. ¨

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. ¨

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

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities To Be Registered	Amount to be Registered(1)	Proposed Maximum Offering Price Per Share(2)	Proposed Maximum Aggregate Offering Price(2)	Amount of Registration Fee(3)(4)
Common Stock, $0.001 par value per share	21,114,630	$1.42	$29,982,774.60	$2,138.00

(1) Includes 7,038,210 shares of common stock issuable upon the exercise of warrants. Pursuant to Rule 416 under the Securities Act, the shares being registered hereunder include such indeterminate number of shares of common stock as may be issuable with respect to the shares being registered hereunder as a result of stock splits, stock dividends or similar transactions.

(2) Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457 under the Securities Act. The price per share and aggregate offering price are based on the average of the high and low prices of the Registrant s common stock on April 21, 2010,

as reported on the Nasdaq Capital Market.

(3) The Registrant previously paid a registration fee of $1,557 in connection with the initial filing of this registration statement (File No. 333-164254) filed with the Commission on January 8, 2010. Accordingly, after application of this credit, $581 is due.

(4) Includes warrants to purchase the registrant s common stock for which no fee is payable pursuant to Rule 457(g) under the Securities Act as the warrants are registered for distribution in the same registration statement as the securities offered hereunder.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

Table of Contents

EXPLANATORY NOTE

This Pre-Effective Amendment No. 1 (this Amendment) to the Registration Statement on Form S-3 (File No. 333-164254) of Dynavax Technologies Corporation (Dynavax), filed with the Securities and Exchange Commission (the SEC) on January 8, 2010 (the Registration Statement) is being filed to (a) include information in the section of the Registration Statement titled Where You Can Find More Information About Dynavax And This Offering that incorporates by reference all of our filings pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended (the Exchange Act), filed with the SEC after the date of initial filing of the Registration Statement and prior to effectiveness of the Registration Statement, (b) list all filings specified in (a) as of the filing date of this Amendment, (c) update the section of the Registration Statement titled Risk Factors by incorporating by reference the section of the same title in our Annual Report on Form 10-K for year ended December 31, 2009, filed with the SEC on March 16, 2010, (d) make other conforming changes in Part I such as updating the price per share of our common stock, (e) include warrants to purchase our common stock as a registered security hereunder, (f) increase the number of shares registered under the Registration Statement and (g) update the list of exhibits under Item 16 of Part II.

Table of Contents

The information in this prospectus is not complete and may be changed. The Selling Securityholders may not sell these securities until the Securities and Exchange Commission declares our registration statement effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion, Dated April 23, 2010

PRELIMINARY PROSPECTUS

21,114,630 Shares

(includes 7,038,210 Shares issuable upon exercise of the Warrants)

14,076,420 Warrants

DYNAVAX TECHNOLOGIES CORPORATION

Common Stock

Warrants

This prospectus relates to the disposition from time to time of up to 21,114,630 shares of our common stock, which includes 7,038,210 shares of our common stock issuable upon the exercise of warrants and 14,076,420 warrants to purchase our common stock. We are not selling any common stock or warrants under this prospectus and will not receive any of the proceeds from the sale of shares by the Selling Securityholders. We provide more information about the Selling Securityholders in the section entitled Selling Securityholders on page 12.

The Selling Securityholders may sell the shares of common stock or the warrants described in this prospectus in a number of different ways and at varying prices. We provide more information about how the Selling Securityholders may sell their shares of common stock or their warrants in the section entitled Plan of Distribution on page 15. We will not be paying any underwriting discounts or commissions in this offering.

Our common stock is traded on the Nasdaq Capital Market under the symbol DVAX. On April 21, 2010, the reported closing price of the common stock was $1.41 per share.

An investment in the shares offered hereby involves a high degree of risk. See Risk Factors beginning on page 2 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is [_____], 2010.

Table of Contents

TABLE OF CONTENTS

ABOUT THIS PROSPECTUS

You should rely only on the information contained or incorporated by reference in this prospectus. We have not, and the Selling Securityholders have not, authorized anyone to provide you with information different from that contained in this prospectus. The Selling Securityholders may offer to sell, and seek offers to buy, shares of our common stock or warrants to purchase our common stock only in jurisdictions where it is lawful to do so. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of our common stock or warrants to purchase our common stock.

Table of Contents

PROSPECTUS SUMMARY

Dynavax Technologies Corporation

Dynavax Technologies Corporation (Dynavax or the Company), a clinical-stage biopharmaceutical company, discovers and develops novel products to prevent and treat infectious diseases, asthma and inflammatory and autoimmune diseases. The Company s lead product candidate is HEPLISAV™, a Phase 3 investigational adult hepatitis B vaccine designed to enhance protection more rapidly and with fewer doses than current licensed vaccines.

Our pipeline of product candidates includes: HEPLISAV; our universal flu vaccine; clinical-stage programs for hepatitis C and hepatitis B therapies; and preclinical programs partnered with AstraZeneca and GlaxoSmithKline (GSK). We compete with pharmaceutical companies, biotechnology companies, academic institutions and research organizations, in developing therapies to prevent or treat infectious diseases, asthma and inflammatory and autoimmune diseases.

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. Our Internet address is www.dynavax.com. We do not incorporate the information on our website into this prospectus, and you should not consider it part of this prospectus.

Dynavax and HEPLISAV are registered trademarks of the Company. Each of the other trademarks, trade names or service marks appearing in this prospectus belongs to its respective holder. For further information regarding us and our financial information, you should refer to our recent filings with the Securities and Exchange Commission (the SEC). See Where You Can Find More Information and Incorporation of Certain Documents by Reference.

Recent Developments

On April 16, 2010, we completed an underwritten public offering of resulting in gross proceeds of $44 million, before deducting estimated offering expenses. 30,293,000 units were sold at a per unit price of $1.4525. Each unit consisted of one share of common stock and one warrant to purchase 0.5 of a share of common stock. Each warrant has an exercise price of $1.50 per share and is exercisable for a period of five years from the date of issuance.

Under the terms of the Amended and Restated Purchase Option Agreement and the Warrant Purchase Agreement we entered into with Symphony Dynamo Holdings LLC (Holdings) in connection with a November 2009 exercise of our option to purchase all of the outstanding equity securities of Symphony Dynamo, Inc. (SDI) (the Acquisition) from Holdings, we issued to the Selling Securityholders an aggregate of 13,000,000 shares of our common stock, warrants to purchase up to 2,000,000 shares of our common stock for $1.94 per share and a promissory note in the principal amount of $15 million in consideration of approximately $20 million in cash held by SDI and the reacquisition of the exclusive rights to our proprietary technology for hepatitis C and cancer therapies. Holdings, on behalf of itself and its affiliates, was entitled as a result of the public offering to a post-closing adjustment to the securities it received in the Acquisition (the Equivalent Value Right). As a result, on April 16, 2010, we replaced the warrants initially issued at the time of the Acquisition with newly issued warrants to purchase up to 7,038,210 shares of our common stock at an exercise price of $1.50 per share and on August 20, 2010, we issued to Holdings and its affiliates an additional 1,076,420 shares of our common stock.

The Offering

This prospectus relates to the resale by the Selling Securityholders listed in this prospectus, which include entities affiliated with Symphony Capital Partners, L.P., of up to 21,114,630 shares of our common stock, 7,038,210 shares of common stock which are issuable upon the exercise of warrants held by the Selling Securityholders, and warrants to purchase our common stock. All of the shares, if sold, will be sold by the Selling Securityholders. Such Selling Securityholders may sell their shares of our common stock or their warrants to purchase our common stock from time to time at market prices prevailing at the time of sale, at prices related to the prevailing market price, or at negotiated prices. The Company will not receive any of the proceeds from the sale of the shares or the warrants by the Selling Securityholders. However, in the case of the warrants issued to the Selling Securityholders upon a cash exercise of the warrants by the Selling Securityholders, the Company will receive $1.50 per share of common stock issued in connection with such exercise. If the warrants are exercised in a cashless exercise, the Company will not receive any proceeds from the exercise of the warrants.

1

Table of Contents

RISK FACTORS

Various statements in this Prospectus are forward-looking statements concerning our future products, timing of development activities, expenses, revenues, liquidity and cash needs, as well as our plans and strategies. These forward-looking statements are based on current expectations and we assume no obligation to update this information. Numerous factors could cause our actual results to differ significantly from the results described in these forward-looking statements, including the following risk factors.

Risks Related to Our Business

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

We have experienced significant net losses in each year since our inception. Our accumulated deficit was $259.6 million as of December 31, 2009. 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 for the foreseeable future as the 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 our future development efforts will be sufficient to support product approval; or whether the market for HEPLISAV will be substantial enough for us to reach profitability.

Clinical trials for certain of our other product candidates are ongoing. These and our other product candidates may never be commercialized, and we may never achieve profitability. Our ability to generate revenue depends upon:

- demonstrating in clinical trials that our product candidates are safe and effective, in particular, in the current and planned trials for our product candidates;
- obtaining regulatory approvals for our product candidates; and
- entering into and maintaining successful collaborative relationships.

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

We require substantial additional capital to continue development of our product candidates, 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 will have to raise significant additional funds. 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.

We will need to raise additional capital through a combination of public and private equity offerings and strategic alliance and licensing arrangements. We are also exploring various initiatives to reduce costs across our operations in order to preserve our cash resources.

We currently estimate that we will have sufficient cash resources to meet our cash needs through the next twelve months based on cash and cash equivalents on hand at December 31, 2009, anticipated revenues and reductions in spending levels.

Sufficient funding may not be available, or if available, may be on terms that significantly dilute or otherwise adversely affect the rights of existing shareholders. If adequate funds are not available, we would need to delay, reduce the scope of, or put on hold the HEPLISAV program, and potentially our other development programs while we seek strategic alternatives. In any event, we may be required to reduce costs and expenses within our control, including potentially significant personnel-related costs and other expenditures that are part of our current operations.

Table of Contents

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, 2009 a statement with respect to our ability to continue as a going concern. However, 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. The reaction of investors to the inclusion of a going concern statement by our independent auditors, may materially adversely affect our share price and our ability to raise new capital or to enter into strategic alliances.

We may not realize the expected benefits of our initiatives to reduce costs across our operations.

We may pursue a number of initiatives to reduce costs across our operations, including workforce reductions and renegotiation of our leases and other long-term obligations. We may incur some amount of restructuring charges as we implement these cost reduction initiatives and may not realize some or all of the expected benefits of our future initiatives to reduce costs. In addition to restructuring or other charges, the changes may result in significant disruptions in our operations now and in the future as a result of these initiatives.

The success of our product candidates depends on timely achievement of successful clinical results and regulatory approval. Failure to obtain regulatory approvals could require us to discontinue operations.

None of our product candidates have been approved for sale. Any product candidate we develop is subject to extensive regulation by federal, state and local governmental authorities in the U.S., including the FDA, and by foreign regulatory agencies. Our success is primarily dependent on our ability to timely enroll patients in clinical trials, achieve successful clinical results and obtain regulatory approvals for our most advanced product candidates. Approval processes in the U.S. and in other countries are uncertain, 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 of the product may significantly limit the commercial opportunity for such product.

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 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.

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.

Table of Contents

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

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 long-term use. As a result, limitations on labeling indications or marketing claims, or withdrawal from the market may be required if problems occur after commercialization.

In addition, we or our contract manufacturers will be required to adhere to federal regulations setting forth current good manufacturing practice. 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 activities. Furthermore, we or our contract manufacturers will be subject to periodic inspection by the FDA and corresponding foreign regulatory agencies under reciprocal agreements with the FDA. 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.

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.

Our most advanced product candidate and most of our earlier stage programs rely on Immunostimulatory Sequences (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.

Our most advanced product candidate in clinical trials 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 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 a common safety risk across therapeutic areas 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 for our clinical trials. If we reduce our clinical product candidates, we may not require this manufacturing capacity. We have limited experience in manufacturing our product candidates in commercial quantities. Failure to comply with applicable regulatory requirements or loss of these suppliers or key employees in Düsseldorf, or failure to timely replace them may delay our clinical trials and research and development efforts and may result in additional costs, delays or significantly higher costs in manufacturing our product candidates.

We rely on our facility in Düsseldorf and a number of third parties for the multiple steps involved in the manufacturing process of our product candidates, including, for example, ISS, a key component material that is necessary for our product candidates, the production of certain antigens, the combination of the antigens and ISS, and the fill and finish. Termination or interruption of these relationships may occur due to circumstances that are outside of our control, resulting in higher cost or delays in our product development efforts.

We and these third parties are required to comply with applicable current good manufacturing practice regulations and other international regulatory requirements. If one of these parties fails to maintain compliance with these regulations, the production of our product candidates could be interrupted, resulting in delays and additional costs. 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.

We have limited experience in manufacturing sufficient quantities of ISS for our clinical trials and rely on a single third party to produce the ISS we need for our clinical trials.

We have relied on a single supplier to produce our ISS for clinical trials. To date, we have manufactured only small quantities of ISS ourselves for research purposes. If we were unable to maintain or replace our existing source for ISS, we would have to establish internal ISS manufacturing capability which would result in increased capital and operating costs and delays in developing and commercializing our product

candidates. We or other third parties may not be able to produce 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 good manufacturing practices 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 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.

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 in a reasonable time frame, if at all.

Table of Contents

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.

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

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

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

- the indication for which the product is approved and its approved labeling;
- the presence of other competing approved therapies;
- the potential advantages of the product over existing and future treatment methods;
- the relative convenience and ease of administration of the product;
- the strength of our sales, marketing and distribution support;
- the price and cost-effectiveness of the product; and
- sufficient third-party reimbursement.

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

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. We also will need to enter into collaborative relationships to provide funding to support our 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, a change in business strategy, a change of control or other reasons;

our shortage of capital resources may impact a willingness on the part of potential companies to collaborate;

our contracts for collaborative arrangements are terminable for convenience 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 do not have day to day control over the activities of our partners and have limited control over their decisions;

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 and achieve market acceptance of products developed from our drug candidates;

Table of Contents

- 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 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 or licensing or financing arrangements could result in significant dilution of our share value.

Funding from collaboration partners and other parties may in the future involve issuance of our equity securities. Because we do not currently have any such arrangements, we cannot be certain how the terms under which such shares are issued will be determined or when such determinations will be made. The current market for financing or collaborative arrangements often involves the issuance of warrants as additional consideration in establishing the purchase price of the equity securities issued. Any such issuance could result in significant 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 diseases, asthma and inflammatory and autoimmune 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, 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. 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, 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. We currently have no key person insurance on any of our employees.

Because we are a relatively small biopharmaceutical company with limited resources, we may not be able to attract and retain qualified personnel.

Our success in developing marketable products and achieving a competitive position will depend, in part, on our ability to attract and retain qualified scientific and management personnel, particularly in areas requiring specific technical, scientific or medical expertise. There is intense competition for the services of these 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.

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

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

Table of Contents

To date, we have not filed for marketing approval for any of our product candidates outside the U.S. 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.

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 the term of 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 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 & Co., Inc. (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 U.S., they remain in force in the U.S. To the extent we are able to commercialize HEPLISAV in the U.S. 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 in the U.S., 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. (Pfizer), 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.

Table of Contents

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

Our success depends on our ability to:

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

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

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

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

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

other parties may design around technologies we have licensed, patented or developed.

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

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

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

We 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

Table of Contents

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.

The President of the United States recently signed into law the Health Care and Education Reconciliation Act of 2010. We are unable to predict what impact reform legislation will have on our business or future prospects and 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 and to manage our business accordingly.

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 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.

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.

Table of Contents

We may need to implement additional financial and accounting systems, procedures or controls as our business and organization changes and to comply with reporting requirements.

We are required to comply with the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the SEC. Compliance with