

DYNAVAX TECHNOLOGIES CORP

Form 424B3

October 04, 2006

Table of Contents

**Filed pursuant to Rule 424(b)(3)  
Registration No. 333-137608**

**Prospectus  
\$75,000,000  
Common Stock**

We may offer and sell from time to time shares of our common stock in one or more offerings in amounts, at prices and on the terms that we will determine at the time of offering, with an aggregate initial offering price of up to \$75,000,000. Each time we sell common stock, we will provide specific terms of the securities offered in a supplement to this prospectus. The prospectus supplement may also add, update or change information contained in this prospectus. You should read this prospectus and the applicable prospectus supplement carefully before you invest in any securities. This prospectus may not be used to consummate a sale of securities unless accompanied by the applicable prospectus supplement.

We will sell these securities directly to our stockholders or to purchasers or through agents on our behalf or through underwriters or dealers as designated from time to time. If any agents or underwriters are involved in the sale of any of these securities, the applicable prospectus supplement will provide the names of the agents or underwriters and any applicable fees, commissions or discounts.

Our common stock trades on the Nasdaq Global Market under the trading symbol DVAX. On September 22, 2006, the last reported sale price of our common stock was \$4.50 per share. We recommend that you obtain current market quotations for our common stock prior to making an investment decision.

**INVESTING IN OUR SECURITIES INVOLVES A HIGH DEGREE OF RISK. SEE THE SECTIONS ENTITLED RISK FACTORS IN OUR MOST RECENT ANNUAL REPORT ON FORM 10-K AND IN OUR MOST RECENT QUARTERLY REPORT ON FORM 10-Q, BOTH AS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION, AND BOTH OF WHICH ARE INCORPORATED HEREIN BY REFERENCE IN THEIR ENTIRETY.**

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is October 3, 2006.

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**Table of Contents**

	<b>Page</b>
<u>OVERVIEW</u>	1
<u>RISK FACTORS</u>	2
<u>CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS</u>	3
<u>USE OF PROCEEDS</u>	3
<u>PLAN OF DISTRIBUTION</u>	3
<u>LEGAL MATTERS</u>	4
<u>EXPERTS</u>	4
<u>WHERE YOU CAN FIND MORE INFORMATION ABOUT DYNAVAX AND THIS OFFERING</u>	4

This prospectus is part of a registration statement we filed with the Securities and Exchange Commission, or the SEC. You should rely only on the information we have provided or incorporated by reference in this prospectus or any prospectus supplement. We have not authorized anyone to provide you with information different from that contained in this prospectus. No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus. You must not rely on any unauthorized information or representation. This prospectus is an offer to sell only the securities offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. You should assume that the information in this prospectus or any prospectus supplement is accurate only as of the date on the front of the document and that any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus or any sale of a security.

**Table of Contents****OVERVIEW****Overview**

Dynavax Technologies Corporation (the Company) discovers, develops and intends to commercialize innovative products to treat and prevent allergies, infectious diseases, cancer and chronic inflammatory diseases using versatile, proprietary approaches that alter immune system responses in highly specific ways. Our clinical development programs are based on immunostimulatory sequences, or ISS, which are short DNA sequences designed to enhance the ability of the immune system to fight disease and control chronic inflammation. Our most advanced ISS-based clinical pipeline programs are a ragweed allergy immunotherapeutic and a hepatitis B vaccine.

Our clinical development pipeline currently includes: TOLAMBA, a ragweed allergy immunotherapeutic, for which a major safety and efficacy trial is currently underway, and that is in a supportive clinical trial in ragweed allergic children; HEPLISAV, a hepatitis B vaccine that is currently in a Phase 3 clinical trial; SUPERVAX, a hepatitis B vaccine; and a cancer therapy currently in a Phase 2 clinical trial and anticipated to enter clinical trials in solid tumors. We have preclinical programs in hepatitis B therapy and hepatitis C therapy that are funded by Symphony Dynamo, Inc. (SDI) and preclinical programs focused on chronic inflammation, antiviral therapies and improved, next-generation vaccines using ISS and other technologies. We also have a research collaboration and license agreement with AstraZeneca for the discovery and development of TLR-9 agonist based therapies for the treatment of asthma and chronic pulmonary disease, or COPD. The collaboration will utilize our proprietary second-generation TLR-9 agonist immunostimulatory sequences.

**Recent Developments***TOLAMBA*

TOLAMBA (formerly, Amb a 1 ISS Conjugate or AIC) is a novel injectable product candidate to treat ragweed allergy. In early 2006, we announced results from a two-year Phase 2/3 clinical trial of TOLAMBA showing that patients treated with a single six-week course of TOLAMBA prior to the 2004 season experienced a statistically significant reduction in total nasal symptom scores and other efficacy endpoints compared to placebo-treated patients in the second year of the trial. The safety profile of TOLAMBA was favorable. Systemic side effects were indistinguishable from placebo and local injection site tenderness was minor and transient.

Following a discussion with the U.S. Food & Drug Administration (FDA) in the first quarter 2006, we decided to conduct an additional major safety and efficacy trial with the goal of determining whether a more intensive, single-course dosing regimen can elicit a greater treatment effect than prior regimens. In the second quarter of 2006, we initiated the Dynavax Allergic Rhinitis TOLAMBA Trial, or DARTT, and announced that enrollment in the DARTT exceeded expectations relative to the speed and number of study subjects. DARTT is a two-year, multi-center, well-controlled study in 738 ragweed allergic subjects, aged 18 to 55 years, randomized into three arms: prior dosing regimen, higher total dose regimen, and placebo. Subjects receive six injections over six weeks prior to the start of the 2006 ragweed season. Ragweed symptoms will be followed over the 2006 and 2007 ragweed seasons. The primary endpoint is reduction in total nasal symptom scores (TNSS) in the higher total dose arm compared to placebo during the second (2007) ragweed season. The trial design includes an interim analysis anticipated to be conducted in early 2007 following completion of the 2006 ragweed season. We anticipate that data from the DARTT interim analysis, if positive, combined with the safety and efficacy data from the recently completed two year Phase 2/3 trial, and from an ongoing trial in ragweed allergic children, could provide sufficient patient data for determining the potential timeline to registration.

*HEPLISAV*

HEPLISAV, our product candidate for hepatitis B prophylaxis, completed a Phase 2/3 trial conducted in Singapore in adults (40 years of age and older) who are more difficult to immunize with conventional vaccines. Results from the final analysis of this trial showed statistically significant superiority in protective antibody response and robustness of protective effect after three vaccinations when compared to GlaxoSmithKline's Engerix-B. We intend to focus our development activities and resources on maximizing the potential of HEPLISAV's demonstrated superiority over conventional hepatitis B vaccine in both the younger (under 40 years of age) and older adult populations, and its potential in the worldwide dialysis market.

The pivotal Phase 3 trial in the older, more difficult to immunize population in Asia and the U.S.-based Phase 1 trial in patients with end-stage renal disease (pre-hemodialysis) are ongoing. We are in the process of planning additional trials designed to support registration activities. In the second half of 2006, we plan to initiate pivotal Phase 3 safety and efficacy trials for HEPLISAV in the younger adult population in the U.S., Europe and Canada. Also in the second half of 2006, we anticipate initiating a Phase 2 trial in the dialysis population that would be conducted in Europe and/or Canada.

**Table of Contents***SUPERVAX*

In April 2006, we announced the acquisition of Rhein Biotech GmbH, which we refer to as Dynavax Europe. As a result, we acquired a hepatitis B vaccine product called SUPERVAX that has been tested in more than 600 subjects and has demonstrated safety and 99% seroprotection compared to conventional vaccine when administered on a convenient, 0, 1-month two-dose schedule. We intend to continue development of and registration activities for SUPERVAX as a two-dose vaccine for commercialization in developing countries.

*Symphony Dynamo, Inc.*

In April 2006, we entered into a series of related agreements with Symphony Capital Partners, LP to advance specific Dynavax ISS-based programs for cancer, hepatitis B therapy and hepatitis C therapy through certain stages of clinical development. Pursuant to the agreements, Symphony Dynamo, Inc. (SDI) has agreed to invest \$50.0 million to fund the clinical development of these programs and we have licensed to SDI our intellectual property rights related to these programs. SDI is a wholly-owned subsidiary of Symphony Dynamo Holdings LLC (Holdings), which provided \$20.0 million in funding to SDI at closing, and which is obligated to fund an additional \$30.0 million in one year following closing. We continue to be primarily responsible for the development of these programs.

Pursuant to the agreements, we issued to Holdings a five-year warrant to purchase 2,000,000 shares of Dynavax common stock at \$7.32 per share, representing a 25% premium over the recent 60-day trading range average of \$5.86 per share. The warrant exercise price is subject to reduction to \$5.86 per share under certain circumstances. The warrant may be exercised or surrendered for a cash payment upon consummation of an all cash merger or acquisition of Dynavax, the obligation for which would be settled by the surviving entity. In consideration for the warrant, Dynavax received an exclusive purchase option (Purchase Option) to acquire all of the programs through the purchase of all of the equity in Symphony Dynamo during the five-year term at specified prices. The Purchase Option exercise price is payable in cash or a combination of cash and shares of Dynavax common stock, at Dynavax's sole discretion. Dynavax also has an option to purchase either the hepatitis B or hepatitis C program (Program Option) during the first year of the agreement. The Program Option is exercisable at our sole discretion at a price which is payable in cash only and will be fully creditable against the exercise price for any subsequent exercise of the Purchase Option. If the Company does not exercise its exclusive right to purchase some or all of the programs licensed under the agreement, the intellectual property rights to the programs at the end of the development period will remain with SDI.

In cancer, we believe that the potent and multifaceted biological activities of ISS offer a number of distinct approaches to cancer therapy in a wide range of tumor types. We are evaluating the potential of ISS to enhance the effect of monoclonal antibodies in cancer therapies. We have conducted an open-label Phase I, dose-escalation trial of ISS in combination with Rituxan® (rituximab) in 20 patients with non-Hodgkin's lymphoma (NHL). Results of this study showed dose-dependent pharmacological activity without significant toxicity. A follow-up Phase 2 trial of ISS with Rituxan in NHL is currently underway in 30 patients with histologically confirmed CD20+, B-cell follicular NHL who have received at least one previous treatment regimen for lymphoma. The primary objective is to assess the proportion of patients who are alive and without disease progression one year after initiating Rituxan therapy. Mechanistic studies will be performed to characterize the enhancement of antitumor activity by ISS.

We anticipate that our cancer product candidate will advance into clinical trials in solid tumors in 2006, and our hepatitis B and hepatitis C therapeutic product candidates are currently planned to enter the clinic in 2007.

**Other Information**

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](http://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 Technologies is a registered trademark of Dynavax Technologies Corporation. Each of the other trademarks, trade names or service marks appearing in this prospectus belongs to its respective holder.

**RISK FACTORS**

You should carefully consider the specific risks set forth under the caption "Risk Factors" in the applicable prospectus supplement, under the caption "Risk Factors" under Item 2 of Part I of our Form 10-Q for the quarter ended

June 30, 2006, which is incorporated by reference in this prospectus, and any subsequent report that is incorporated by reference into this prospectus, before

**Table of Contents**

making an investment decision.

**CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS**

The statements in this prospectus and the documents incorporated by reference contain forward-looking statements 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, our future research and development, our preclinical and clinical product development efforts, the timing of the introduction of our products, the effect of GAAP accounting pronouncements, uncertainty regarding our future operating results and our profitability, anticipated sources of funds and all plans, objectives, expectations and intentions. These statements appear in a number of places and can be identified by the use of forward-looking terminology such as may, will, should, expect, plan, anticipate, believe, estimate, predict, future, intend, or certain or the negative of these terms or other comparable terminology, or by discussions of strategy.

Our actual results may differ materially from the results expressed or implied by these forward-looking statements because of the risk factors and other factors disclosed in this prospectus and documents incorporated by reference. The risk factors may not be all of the factors that could cause actual results to vary materially from the forward-looking statements. The forward-looking statements made or incorporated in this prospectus relate only to circumstances as of the date on which the statements are made. 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.

**USE OF PROCEEDS**

Unless otherwise provided in the applicable prospectus supplement, we intend to use the net proceeds from the sale of the common stock under this prospectus for general corporate purposes, including clinical trials, research and development expenses, general and administrative expenses, and potential acquisitions of companies, products and technologies that complement our business. We will set forth in the prospectus supplement our intended use for the net proceeds received from the sale of any securities. Pending the application of the net proceeds, we intend to invest the net proceeds generally in short-term, investment grade, interest bearing securities.

**PLAN OF DISTRIBUTION**

We may sell the securities from time to time pursuant to underwritten public offerings, negotiated transactions, block trades or a combination of these methods. We may sell the securities (1) through underwriters or dealers, (2) through agents and/or (3) directly to one or more purchasers. We may distribute the securities from time to time in one or more transactions:

at a fixed price or prices, which may be changed;

at market prices prevailing at the time of sale;

at prices related to such prevailing market prices; or

We may solicit directly offers to purchase the securities being offered by this prospectus. We may also designate agents to solicit offers to purchase the securities from time to time. We will name in a prospectus supplement any agent involved in the offer or sale of our securities.

If we utilize a dealer in the sale of the securities being offered by this prospectus, we will sell the securities to the dealer, as principal. The dealer may then resell the securities to the public at varying prices to be determined by the dealer at the time of resale.

If we utilize an underwriter in the sale of the securities being offered by this prospectus, we will execute an underwriting agreement with the underwriter at the time of sale and we will provide the name of any underwriter in the prospectus supplement that the underwriter will use to make resales of the securities to the public. In connection with the sale of the securities, we, or the purchasers of securities for whom the underwriter may act as agent, may compensate the underwriter in the form of underwriting discounts or commissions. The underwriter may sell the securities to or through dealers, and the underwriter may compensate those dealers in the form of discounts, concessions or commissions.



We will provide in the applicable prospectus supplement any compensation we pay to underwriters, dealers or agents in connection with the offering of the securities, and any discounts, concessions or commissions allowed by underwriters to participating dealers. Underwriters, dealers and agents participating in the distribution of the securities may be deemed to be underwriters within the meaning of the Securities Act of 1933, and any discounts and commissions received by them and any profit realized by them on

## **Table of Contents**

resale of the securities may be deemed to be underwriting discounts and commissions. We may enter into agreements to indemnify underwriters, dealers and agents against civil liabilities, including liabilities under the Securities Act, or to contribute to payments they may be required to make in respect thereof.

We may authorize underwriters, dealers or agents to solicit offers by certain purchasers to purchase the common stock from us at the public offering price set forth in the prospectus supplement. These purchases will be subject only to those conditions set forth in the prospectus supplement, and the prospectus supplement will set forth any commissions we pay for solicitation of these purchases.

To facilitate the offering of securities, certain persons participating in the offering may engage in transactions that stabilize, maintain or otherwise affect the price of the securities. This may include over-allotments or short sales of the securities, which involves the sale by persons participating in the offering of more securities than we sold to them. In these circumstances, these persons would cover such over-allotments or short positions by making purchases in the open market or by exercising their over-allotment option. In addition, these persons may stabilize or maintain the price of the securities by bidding for or purchasing securities in the open market or by imposing penalty bids, whereby selling concessions allowed to dealers participating in the offering may be reclaimed if securities sold by them are repurchased in connection with stabilization transactions. The effect of these transactions may be to stabilize or maintain the market price of the securities at a level above that which might otherwise prevail in the open market. These transactions may be discontinued at any time.

The underwriters, dealers and agents may engage in transactions with us, or perform services for us, in the ordinary course of business.

To the extent required, this prospectus may be amended or supplemented from time to time to describe a specific plan of distribution.

## **LEGAL MATTERS**

The validity of the securities being offered hereby will be passed upon by Cooley Godward LLP, Palo Alto, California.

## **EXPERTS**

The consolidated financial statements of Dynavax Technologies Corporation incorporated by reference in Dynavax Technologies Corporation's Annual Report (Form 10-K/A) for the year ended December 31, 2005, and Dynavax Technologies Corporation management's assessment of the effectiveness of internal control over financial reporting as of December 31, 2005 incorporated by reference therein, have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their reports thereon, incorporated by reference therein, and incorporated herein by reference. Such financial statements and management's assessment have been incorporated herein by reference in reliance upon such reports given on the authority of such firm as experts in accounting and auditing.

## **WHERE YOU CAN FIND MORE INFORMATION ABOUT DYNAVAX AND THIS OFFERING**

We are a reporting company and we file annual, quarterly and current reports, proxy statements and other information with the SEC. We have filed with the SEC a registration statement on Form S-3 under the Securities Act to register the shares of common stock offered by this prospectus. However, this prospectus does not contain all of the information contained in the registration statement and the exhibits and schedules to the registration statement. For further information with respect to us and the securities offered under this prospectus, we refer you to the registration statement and the exhibits and schedules filed as a part of the registration statement. You may read and copy the registration statement, as well as our reports, proxy statements and other information, at the SEC's public reference rooms at 450 Fifth Street, N.W., in Washington, DC. You can request copies of these documents by contacting the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for further information about the operation of the public reference rooms. Our SEC filings are also available at the SEC's website at [www.sec.gov](http://www.sec.gov). In addition, you can read and copy our SEC filings at the office of the National Association of Securities Dealers, Inc. at 1735 K Street, N.W., Washington, D.C. 20006.

The SEC allows us to incorporate by reference the information contained in documents that we file with them, which means that we can disclose important information to you by referring to those documents. The information incorporated by reference is considered to be part of this prospectus. Information in this prospectus modifies or

supersedes information incorporated by reference that we filed with the SEC prior to the date of this prospectus, and information that we file later with the SEC also will automatically update and supersede this information. We incorporate by reference the documents listed below, any filings we will make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended, after the date we filed the registration statement of which this prospectus is a part and before the effective date of the registration statement and any future filings we will make with the SEC under those sections.

We incorporate by reference the documents listed below and any documents that we file in the future with the SEC under

**Table of Contents**

Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934 after the date of this prospectus and before the completion of the offering (other than current reports furnished under Item 9 or Item 12 of Form 8-K):

1. Our Registration Statement on Form S-8 filed with the SEC on August 4, 2006;
2. Our Annual Report on Form 10-K for the year ended December 31, 2005, filed with the SEC on March 16, 2006, as amended by Amendment No. 1 filed on August 4, 2006;
3. Our Quarterly Reports on Form 10-Q for the period ended March 31, 2006, filed with the SEC on May 5, 2006 and for the period ended June 30, 2006, filed with the SEC on August 4, 2006;
4. Our Current Reports on Form 8-K filed with the SEC on April 24, 2006, April 27, 2006, May 1, 2006, July 28, 2006, August 18, 2006, August 31, 2006 and September 8, 2006;
5. Our Definitive Proxy Statement on Form 14A filed with the SEC on April 28, 2006;
6. The description of our common stock set forth in Registration Statement on Form S-3 (Registration No. 333-134688) filed with the SEC on June 2, 2006; and
7. The description of our common stock set forth in Registration Statement on Form S-1 (Registration No. 333-109965) filed with the SEC on February 5, 2004.

We will furnish without charge to you, on written or oral request, a copy of any or all of the documents incorporated by reference, including exhibits to these documents. You should direct any requests for documents to Deborah A. Smeltzer, Vice President, Operations and Chief Financial Officer, 2929 Seventh Street, Suite 100, Berkeley, CA 94710-2753, (510) 848-5100.