

DYNAVAX TECHNOLOGIES CORP

Form S-3

November 16, 2007

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As filed with the Securities and Exchange Commission on November 16, 2007
Registration No. 333-

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

**FORM S-3
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933**

Dynavax Technologies Corporation
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

33-0728374
(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)

**Deborah A. Smeltzer
Vice President, Operations and Chief Financial Officer
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:
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Palo Alto, California 94306
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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.

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. o

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. o

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. o

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. o

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
Common Stock, \$0.001 par value per share	1,850,000	\$ 5.12	\$ 9,472,000	\$ 291

(1) Includes 1,300,000 shares of Common Stock issuable upon the exercise of warrants and an additional 550,000 shares of Common Stock that may be issued upon the redemption of those warrants following certain major transactions, and events of default and upon the occurrence of certain events. 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 November 14, 2007, as reported on the Nasdaq Global Market.

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.

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The information in this prospectus is not complete and may be changed. We 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 November 16, 2007

PRELIMINARY PROSPECTUS

1,850,000 Shares

DYNAVAX TECHNOLOGIES CORPORATION

Common Stock

This prospectus relates to the disposition from time to time of up to 1,850,000 shares of our Common Stock, which includes 1,300,000 shares of our Common Stock issuable upon the exercise of warrants and an additional 550,000 shares of our Common Stock that may be issued upon the redemption of those warrants following certain major transactions, events of default and upon the occurrence of certain events. We are not selling any Common Stock under this prospectus and will not receive any of the proceeds from the sale of shares by the selling stockholders.

The selling stockholders may sell the shares of Common Stock described in this prospectus in a number of different ways and at varying prices. We provide more information about how the selling stockholders may sell their shares of Common Stock in the section entitled **Plan of Distribution** on page 11. We will not be paying any underwriting discounts or commissions in this offering.

The Common Stock is traded on the Nasdaq Global Market under the symbol **DVAX**. On November 14, 2007, the reported closing price of the Common Stock was \$5.09 per share.

An investment in the shares offered hereby involves a high degrees 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 November [_____], 2007.

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ABOUT THIS PROSPECTUS

You should rely only on the information contained or incorporated by reference in this prospectus. We have not, and the selling stockholders have not, authorized anyone to provide you with information different from that contained in this prospectus. The selling stockholders are offering to sell, and seeking offers to buy, shares of 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.

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PROSPECTUS SUMMARY

Dynavax Technologies Corporation

Dynavax Technologies Corporation discovers, develops, and intends to commercialize innovative TLR9 agonist-based products to treat and prevent infectious diseases, allergies, cancer, and chronic inflammatory diseases using versatile, proprietary approaches that alter immune system responses in highly specific ways. Our TLR9 agonists are based on immunostimulatory sequences, or ISS, which are short DNA sequences that enhance the ability of the immune system to fight disease and control chronic inflammation.

Our product candidates include: HEPLISAV, a hepatitis B vaccine in Phase 3 partnered with Merck & Co. Inc.; TOLAMBA(TM), a ragweed allergy immunotherapy in Phase 2; a therapy for non-Hodgkin's lymphoma (NHL) in Phase 2 and for metastatic colorectal cancer in Phase 1; and a therapy for hepatitis B also in Phase 1. Our preclinical asthma and COPD program is partnered with AstraZeneca. The National Institutes of Health (NIH) partially funds our preclinical work on a vaccine for influenza. Symphony Dynamo, Inc. (SDI) funds our colorectal cancer trials and our preclinical hepatitis C therapeutic program, and the selling stockholders (as defined in the selling stockholders table on page 11) have committed funding for our allergy programs.

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 Technologies, HEPLISAV and TOLAMBA are registered trademarks of Dynavax Technologies Corporation. 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, or SEC. See [Where You Can Find More Information](#) and [Incorporation of Certain Documents by Reference](#).

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RISK FACTORS

Various statements in this Quarterly Report on Form 10-Q 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.

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 \$215.8 million as of September 30, 2007. 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 and are scheduled to terminate in 2009. 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 significant revenue. Clinical trials for certain of our 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 or raise additional capital on less favorable terms.

If we are unable to secure additional funding, we will have to reduce or discontinue operations.

We believe our existing capital resources will be adequate to satisfy our capital needs for at least the next twelve months. Because of the significant time and resources it will take to develop and commercialize our product candidates, we will require substantial additional capital resources in order to continue our operations, and any such funding may not allow us to continue operations as currently planned. We expect capital outlays and operating expenditures to increase over the next several years as we expand our operations, and any change in plans may increase these outlays and expenditures. We may be unable to obtain additional capital on acceptable terms, or at all and we may be required to delay, reduce the scope of, or eliminate some or all of our programs, or discontinue our operations.

The success of our TLR9 product candidates depends on achieving successful clinical results and regulatory approval. Failure to obtain regulatory approvals could require us to discontinue operations.

None of our TLR9 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 United States, including the FDA, and by foreign regulatory agencies. Our success is primarily dependent on our ability to obtain regulatory approval for our most advanced TLR9 product candidates. Approval processes in the United States 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.

Many new drug candidates, including many drug candidates that have completed Phase 3 clinical trials, have shown promising results in early clinical trials and subsequently failed to establish sufficient safety and efficacy to obtain regulatory approval. Despite the time and money expended, regulatory approvals are uncertain. Failure to

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.

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

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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 or inadequate supply of the product candidate. In addition, our ability to conduct clinical trials for some of our product candidates is limited due to the seasonal nature. Even a small delay in a trial for any product candidate could require us to delay commencement of the trial until the target population is available for testing, which could result in a delay of an entire year.

Our registration and commercial timelines depend on results of the current and planned clinical trials and further discussions with the FDA. Any extension, suspension, 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;

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.

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 must pass a pre-approval inspection of manufacturing facilities by the FDA and foreign regulatory agencies before obtaining marketing approval and 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 candidates in clinical trials rely on a single lead ISS compound, 1018 ISS, 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.

Our most advanced product candidates in clinical trials are based on our 1018 ISS compound, and substantially all 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 or discontinue all of our clinical trials. In addition, as all of our clinical product candidates contain ISS, 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 third parties and our facility in Düsseldorf, Germany to supply materials necessary to manufacture our clinical product candidates for our clinical trials and for fulfilling our manufacturing obligations under our collaboration with Merck. 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 or breach of our obligations under our Merck collaboration.

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We rely on a number of third parties and our facility in Düsseldorf 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 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 FDA 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 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, which is part of our collaboration with Merck & Co., Inc. or Merck. We are obligated to manufacture, on behalf of Merck, HEPLISAV for clinical development and commercial quantities of hepatitis B surface antigen until such time as we can effect the appropriate technology transfer to Merck. Accordingly, we will have to allocate the entire capacity of our Düsseldorf facility to meet our obligations under the Merck collaboration. Moreover, in order to meet our commercial supply obligations to Merck, we expect to have to establish commercial-scale manufacturing capability for HEPLISAV, which will involve increased capital and operating costs and the assumption of risks associated with the construction, validation and operation of a new commercial manufacturing facility as well as the continued operation of our existing facility. There can be no assurance that we can successfully meet our supply obligations to Merck and maintain our internal product candidate timelines and, if we undertake the establishment of a new commercial manufacturing facility, that we can finance the capital costs and ongoing expenses that we would need to undertake until or if HEPLISAV achieves commercial success. There also can be no assurance that the cost of meeting our supply obligation to Merck will be covered by the negotiated supply price.

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 or terminated. Any extension, delay or termination of our clinical trials would delay 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 successfully commercialize them, our products may not gain market acceptance among physicians, patients, health care payors and the medical community. The FDA or other regulatory agencies could limit the labeling indication for which our product candidates may be marketed or could otherwise limit marketing efforts for our products. If we are unable to 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. We also intend to enter into collaborative relationships to provide

funding to support our research and development programs. The process of establishing collaborative relationships is difficult, time-consuming and involves significant uncertainty. Moreover, even if we do establish collaborative relationships, our collaborators 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. 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, we may have to delay or discontinue further development of

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one or more of our product candidates, undertake development and commercialization activities at our own expense or find alternative sources of capital.

In October 2007, we entered into a collaborative arrangement with Merck in which we and Merck will further develop and commercialize HEPLISAV. Pursuant to the terms of the collaboration, we are obligated to complete ongoing clinical studies, manufacture and supply on behalf of Merck, and conduct technology transfer with respect to our existing HEPLISAV development program. Although we will be reimbursed for specified development efforts and the delivery of clinical material to Merck in the further development and commercialization of HEPLISAV, Merck controls the development and commercialization plans for the product. There can be no assurance that we will successfully and timely fulfill our obligations under the collaboration, that Merck may not develop or market a potentially competitive product, or that HEPLISAV, even if successfully developed, can achieve commercial success sufficient for us to achieve all of the milestones and royalties contemplated under the collaborative arrangement.

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 treat or prevent infectious diseases, allergy, asthma and cancer, as well as those focusing more generally on the immune system. 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.

We depend on key employees in a competitive market for skilled personnel, and the loss of the services of any of our key employees would affect our ability to develop and commercialize our product candidates and achieve our objectives.

We are highly dependent on the principal members of our management, operations and scientific staff, including our Chief Executive Officer, Dr. Dino Dina. We experience intense competition for qualified personnel. Our future success also depends in part on the continued service of our executive management team, key scientific and management personnel and our ability to recruit, train and retain essential scientific personnel for our drug discovery and development programs, including those who will be responsible for overseeing our preclinical testing and clinical trials as well as for the establishment of collaborations with other companies. If we lose the services of any key personnel, our research and product development goals, including the identification and establishment of key collaborations, operations and marketing efforts could be delayed or curtailed.

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;

adverse tax consequences;

the fluctuation of conversion rates between foreign currencies and the U.S. dollar; and

regional and geopolitical risks.

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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 our licenses from the Regents of the University of California. 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 with the Regents of the University of California, or UC. Our dependence on these licenses subjects us to numerous risks, such as disputes regarding the creation or use of intellectual property by us and UC, or scientific collaborators. Additionally, our agreements with UC generally contain diligence or milestone-based termination provisions. Our failure to meet any obligations pursuant to these provisions could allow UC to terminate our agreements or convert exclusive to non-exclusive licenses. In addition, our license agreements with UC 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.

If third parties successfully assert that we have infringed their patents and proprietary rights or challenge the validity of 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 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.

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 United States, 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. In addition, 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. 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, Coley, has issued U.S. patent claims, as well as patent claims pending with the U.S. Patent and Trademark Office, or PTO, 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 Coley 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 the U.S. other than with respect to HEPLISAV. Such a license 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 United States 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

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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 might 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.

Our TLR9 allergy program, including the development of TOLAMBA, relies on debt funding that is accessible only on the achievement of specified development milestones. We may not be able to achieve the milestones in a timely manner and as a result may not receive or have access to sufficient funding to continue further development of TOLAMBA. Even if we achieve such milestones, we will be obligated to repay up to \$30 million in July 2010 and we may not have sufficient funds to pay such amounts upon maturity.

In July 2007, we entered into a funding arrangement with the selling stockholders to support our further development of our allergy product programs, including TOLAMBA. Our continued access to the funding is dependent upon our successful achievement of specified milestones in a timely manner. There can be no assurance that TOLAMBA will be entered into planned clinical studies or successfully achieve the planned end points, and failure to successfully further develop TOLAMBA according to our current clinical plans may result in the termination of further development efforts. Moreover, even if we achieve the planned clinical results, we will be required to issue an additional warrants to purchase up to 3,000,000 shares of our Common Stock and repay outstanding loans to the selling stockholders. We may be required to enter into a financing arrangement or license arrangement with one or more third parties, or some combination of these in order to repay the loan at maturity. There can be no assurance that any financing or licensing arrangement will be available or even if available, that the terms would be favorable to us and our stockholders.

We have licensed some of our development and commercialization rights to certain of our development programs in connection with our Symphony Dynamo funding arrangement and will not receive any future royalties or revenues with respect to this intellectual property unless we exercise an option to repurchase some

or all of the programs in the future. We may not obtain sufficient clinical data in order to determine whether we should exercise our option prior to the expiration of the development period, and even if we decide to exercise, we may not have the financial resources to exercise our option in a timely manner.

In April 2006, we granted an exclusive license to the intellectual property for certain ISS compounds for cancer, hepatitis B and hepatitis C therapeutics to Symphony Dynamo, Inc., or SDI, in consideration for a commitment from Symphony Capital Partners, LP and certain of its affiliates, or Symphony, and its co-investors to provide \$50 million of committed capital to advance these programs. As part of the arrangement, we received an option granting us the exclusive right, but not the obligation, to acquire certain or all of the programs at specified points in time at specified prices during the term of the five-year development period. The development programs under the arrangement are jointly managed by SDI and us, and there can be no assurance that we will agree on various decisions that will enable us to successfully develop the potential products, or even if we are in agreement on the development plans, that the development efforts will result in sufficient clinical data to make a fully informed decision with respect to the exercise of our option. If we do not exercise the purchase option prior to its expiration, then our rights in and with respect to the SDI programs will

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terminate and we will no longer have rights to any of the programs licensed to SDI under the arrangement. In April 2007, we exercised our option for the hepatitis B program. The exercise of this program option triggers a payment obligation of \$15 million to Symphony upon the expiration of the SDI collaboration in 2011 if the purchase option for all programs is not exercised.

If we elect to exercise the purchase option, we will be required to make a substantial payment, which at our election may be paid partially in shares of our common stock. As a result, in order to exercise the option, we will be required to make a substantial payment of cash and possibly issue a substantial number of shares of our common stock. We do not currently have the resources to exercise the option and we may be required to enter into a financing arrangement or license arrangement with one or more third parties, or some combination of these in order to exercise the option, even if we paid a portion of the purchase price with our common stock. There can be no assurance that any financing or licensing arrangement will be available or even if available, that the terms would be favorable to us and our stockholders. In addition, the exercise of the purchase option will likely require us to record a significant charge to earnings and may adversely impact future operating results.

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 product liability insurance coverage in the amount of \$1 million for each occurrence for clinical trials with umbrella coverage of an additional \$4 million. 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. 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. 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 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.

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;

our ability to establish and maintain collaborations for the development and commercialization of our product candidates;

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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 enter into and maintain collaborations;

maintenance of our existing exclusive licensing agreements with the Regents of the University of California;

changes in government regulations, general economic conditions, industry announcements;

issuance of new or changed securities analysts' reports or recommendations;

actual or anticipated fluctuations in our quarterly financial and operating results; and

volume of trading in our common stock

One or more of these factors could cause a 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 is especially relevant for us because we have experienced greater than average stock price volatility, as have other biotechnology companies in recent years. We may in the future be the target of similar litigation. Securities litigation could result in substantial costs, and divert management's attention and resources, which could harm our business, operating results and financial conditions.

Anti-takeover provisions of our certificate of incorporation, bylaws and Delaware law 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.

In addition, we are 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 five years unless the holder's acquisition of our stock was approved in advance by our Board of Directors.

We will continue to implement additional financial and accounting systems, procedures or controls as we grow our business and organization and to satisfy new 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 Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, and other requirements may increase our costs and require additional management resources. We may need to continue to implement additional finance and accounting systems, procedures and controls as we grow our business and organization and to comply with new reporting requirements. Specifically, we have integrated the operations, technologies, products and personnel of Dynavax Europe into our operations and Dynavax Europe's operations will be required to be included in our assessment of internal controls over financial reporting under Section 404 by the end of 2007. There can

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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 auditors are unable to issue an unqualified attestation as to the effectiveness of our internal controls over financial reporting, 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.

INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the information that we incorporate by reference, contains various forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as anticipates, believes, continue estimates, expects, intends, may, plans, potential, predicts, should, will, or the negative or other comparable terminology. These forward-looking statements may also use different phrases. Discussions containing these forward-looking statements may be found, among other places, in Business and Management's Discussion and Analysis of Financial Condition and Results of Operations incorporated by reference from our most recent annual report on Form 10-K and in our most recent quarterly report on Form 10-Q subsequent to the filing of our most recent annual report on Form 10-K with the SEC, as well as any amendments thereto reflected in subsequent filings with the SEC. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. Forward-looking statements include, but are not limited to, statements about:

- our expectations with respect to the clinical development and timing of clinical development of our product candidates, our clinical trials and the regulatory approval process;

- the commercialization of our TOLAMBA and HEPLISAV products;

- our expectations with respect to our collaborations and programs funded by third parties;

- our expectations with regard to our ability to retain, obtain and protect necessary intellectual property to commercialize our products; and

- our expectations regarding our capital requirements, how long our current financial resources will last, and our needs for additional financing.

Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to differ materially from any future results, performance or achievements expressed or implied by such forward-looking statements. These risks include those risks discussed under the heading Risk Factors and elsewhere in this prospectus. Because the factors referred to above could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us or on our behalf, you should not place undue reliance on any forward-looking statements. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made, and, except as required by law, we undertake no obligation to publicly revise our forward-looking statements to reflect events or circumstances that arise after the date of this prospectus or the date of documents incorporated by reference in this prospectus that include forward-looking statements. You should read this prospectus and the documents that we reference and have filed as exhibits to the registration statement of which this prospectus is a part with the understanding that we cannot guarantee future results, levels of activity, performance

or achievements.

USE OF PROCEEDS

We will not receive any of the proceeds from the sale of shares of our Common Stock by the selling stockholders pursuant to this prospectus. A portion of the shares covered by this prospectus are issuable upon exercise of warrants to purchase our Common Stock. Upon any exercise of the warrants for cash, the selling stockholders would pay us the exercise price of the warrants. The cash exercise price of the warrants is \$5.75 per share of our Common Stock. Under certain conditions set forth in the warrants, the warrants are

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exercisable on a cashless basis. If the warrants are exercised on a cashless basis, we would not receive any cash payment from the selling stockholders upon any exercise of the warrants.

SELLING STOCKHOLDERS

On July 18, 2007, we entered into a loan agreement with the selling stockholders that provided for us to receive up to \$30,000,000 of loans over a three-year period, subject to our satisfaction of specific milestones and agreed to issue to those stockholders warrants to purchase up to 5,550,000 shares of our Common Stock at a premium to the then current trading price following the achievement of certain milestones. In connection with the execution of the agreement we issued warrants to the selling stockholders to purchase an aggregate of 1,250,000 shares of our Common Stock at \$5.13 per share and filed a registration statement on August 31, 2007. Upon completion of a milestone on October 18, 2007, we issued warrants to purchase an additional 1,300,000 shares of our Common Stock at a price of \$5.75 per share. We agreed to file a registration statement with respect to each issuance, of which this prospectus is a part, with the Securities and Exchange Commission to register the disposition of any Common Stock issued pursuant to the warrants and to use our best efforts to keep the registration statement effective until the earlier of (a) such time as all of the shares registered hereunder may be sold without restrictions under the Securities Act as determined in the reasonable opinion of counsel to the selling stockholders, and (b) such time as all such shares registered hereunder have been sold by the selling stockholders. Additional information on our transaction with the selling stockholders is contained in our current report on Form 8-K, filed with the SEC on July 24, 2007, incorporated by reference herein.

The following table sets forth:

the name of each of the selling stockholders;

the number of shares of our Common Stock owned by each such selling stockholder prior to this offering;

the number of shares of our Common Stock being offered pursuant to this prospectus;

the number of shares of our Common Stock owned upon completion of this offering; and

the percentage (if one percent or more) of Common Stock owned by each such selling stockholder after this offering.

This table is prepared based on information supplied to us by the selling stockholders and reflects holdings as of November 14, 2007. As used in this prospectus, the term *selling stockholder* includes each of the selling stockholders listed below, and any donees, pledges, transferees or other successors in interest selling shares received after the date of this prospectus from a selling stockholder as a gift, pledge, or other non-sale related transfer. The number of shares in the column *Shares of Common Stock Being Offered* plus 550,000 of the shares referred to in footnote (1) to the table represent all of the shares that selling stockholders may offer under this prospectus. The selling stockholder may sell some, all or none of its shares. We do not know how long the selling stockholders will hold the shares before selling them, and we currently have no agreements, arrangements or understandings with the selling stockholders regarding the sale of any of the shares.

Beneficial ownership is determined in accordance with Rule 13d-3(d) promulgated by the SEC under the Securities Exchange Act. As of November 14, 2007, 39,764,520 shares of our Common Stock were outstanding.

Name of Selling Stockholder(1)(2)	Shares of Common Stock Owned Prior to Offering(3)	Shares of Common Stock Being Offered(7)	Shares of Common Stock Owned After Offering(8)	% of Common Stock
Deerfield Special Situations Fund International Limited	1,134,926(4)	136,890	998,036(9)	2.5%
Deerfield Special Situations Fund, L.P.	589,904(5)	79,690	510,214(10)	1.3%

Deerfield Private Design Fund, L.P.	801,210(6)	408,460	392,750(6)	1.0%
Deerfield Private Design International, L.P.	1,323,960(6)	674,960	649,000(6)	1.6%

- (1) In addition to the shares of Common Stock listed, these selling stockholders may offer up to an aggregate of 1,080,000 shares of Common Stock that are issuable upon redemption of warrants following certain major transactions or events of default and upon the occurrence of certain events. The resale of an aggregate of 550,000 of these shares is being registered under the registration statement of which this prospectus is a part and the resale of the balance of these shares is registered under another registration statement.
- (2) James E. Flynn has the power to vote or dispose of the shares held by the selling stockholders.

- (3) Includes shares of Common Stock issuable upon exercise of warrants. For the purposes hereof, we assume the issuance of all such shares pursuant to a cash exercise.

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- (4) Includes 268,515 shares of Common Stock issuable upon the exercise of warrants held by the selling stockholder and 866,411 shares of Common Stock owned by the selling stockholder.

- (5) Includes 156,315 shares of Common Stock issuable upon the exercise of warrants held by the selling stockholder and 433,589 shares of Common Stock owned by the selling stockholder.

- (6) Represents shares of Common Stock issuable upon the exercise of warrants held by these selling stockholders

- (7) Represents shares of Common Stock issuable upon the exercise of warrants held by these selling stockholders. The disposition of these shares

is being registered under the registration statement of which this prospectus is a part and, for the purposes hereof, we assume the issuance of all such shares pursuant to a cash exercise.

(8) The resale of these shares is registered under another registration statement.

(9) Includes 131,625 shares of Common Stock issuable upon the exercise of warrants held by the selling stockholder and 866,411 shares of Common Stock owned by the selling stockholder.

(10) Includes 76,625 shares of Common Stock issuable upon the exercise of warrants held by the selling stockholder and 433,589 shares of Common Stock owned by the selling stockholder.

PLAN OF DISTRIBUTION

We are registering the shares of Common Stock issuable upon exercise of the warrants to permit the resale of these shares of Common Stock by the holders thereof from time to time after the date of this prospectus. We will not receive any of the proceeds from the sale by the selling stockholders of the shares of Common Stock. We will bear all fees and expenses incident to our obligation to register the shares of Common Stock.

The selling stockholders may sell all or a portion of the shares of Common Stock beneficially owned by them and offered hereby from time to time directly or through one or more underwriters, broker-dealers or agents. If the shares of Common Stock are sold through underwriters or broker-dealers, the selling stockholders will be responsible for underwriting discounts or commissions or agent's commissions. We will file a prospectus supplement if the selling stockholders engage one or more underwriters. The shares of Common Stock may be sold in one or more transactions at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale, or at negotiated prices. These sales may be executed in transactions, which may involve crosses or block transactions:

on any national securities exchange or quotation service on which the securities may be listed or quoted at the time of sale;

in the over-the-counter market;

in transactions otherwise than on these exchanges or systems or in the over-the-counter market;

through the writing of options, whether such options are listed on an options exchange or otherwise;

involving ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;

involving block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;

involving purchases by a broker-dealer as principal and resale by the broker-dealer for its account;

in an exchange distribution in accordance with the rules of the applicable exchange;

in privately negotiated transactions;

through the settlement of short sales;

where broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;

in a combination of any such methods of sale; and

through any other method permitted pursuant to applicable law.

The selling stockholders may also sell shares under Rule 144 under the Securities Act, if available, rather than under this prospectus, provided the sale meets the criteria and conforms to the requirements of such Rule.

If the selling stockholders effect such transactions by selling shares of Common Stock to or through underwriters, broker-dealers or agents, such underwriters, broker-dealers or agents may receive commissions in the form of discounts, concessions or commissions from the selling stockholders or commissions from purchasers of the shares of Common Stock for whom they may act as agent or to

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whom they may sell as principal (which discounts, concessions or commissions as to particular underwriters, broker-dealers or agents may be in excess of those customary in the types of transactions involved). In connection with sales of the shares of Common Stock or otherwise, the selling stockholders may enter into hedging transactions with broker-dealers, which may in turn engage in short sales of the shares of Common Stock in the course of hedging in positions they assume. The selling stockholders may also sell shares of Common Stock short and deliver shares of Common Stock covered by this prospectus to close out short positions. The selling stockholders may also loan or pledge shares of Common Stock to broker-dealers that in turn may sell such shares.

The selling stockholders may pledge or grant a security interest in some or all of the warrants or shares of Common Stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of Common Stock from time to time pursuant to this prospectus or any supplement to this prospectus under Rule 424 or other applicable provision of the Securities Act modifying and superseding, if necessary, the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus. The selling stockholders also may transfer and donate the shares of Common Stock in other circumstances in which case the transferees, donees, pledgees or other successors in interest will be the selling stockholders for purposes of this prospectus. We will file a prospectus supplement naming the new selling stockholders if the shares are transferred, donated or pledged.

The selling stockholders and any broker-dealer participating in the distribution of the shares of Common Stock may be deemed to be underwriters within the meaning of the Securities Act, and any commission paid, or any discounts or concessions allowed to, any such broker-dealer may be deemed to be underwriting commissions or discounts under the Securities Act. At the time a particular offering of the shares of Common Stock is made, a prospectus supplement, if required, may be distributed which will set forth the aggregate amount of shares of Common Stock being offered and the terms of the offering, including the name or names of any broker-dealers or agents, any discounts, commissions and other